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"Knowing is not enough; we must apply.
Willing is not enough; we must do"
—GOETHE

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EMERGING STRONGER FROM COVID-19: PRIORITIES FOR HEALTH SYSTEM TRANSFORMATION

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PREFACE

We know from Isaac Newton's third law that forces come in pairs: for every action, there is an equal and opposite reaction. But when it comes to human catastrophe, a post-acute human tendency often sets in to diffuse the reactive forces from what ought to be their primary directionality. Without a strong resolve to keep sharp focus on the most basic lessons learned about preparedness shortfalls, the stage is set, seamlessly and senselessly, for the tragedy of the next event. In 2001, terrorism on American soil drew collective attention to the gaps in national security that made our nation vulnerable to attack. In 2004, Hurricane Katrina made clear the need for infrastructure that is resilient to natural disaster. Both responses have led to focused change, albeit imperfect, in the nation's preparedness. On the other hand, the tragedy of mass murders, such as the 2014 shooting in Sandy Hook, have been followed by societal inaction, and left the nation unprotected from the full force of the occurrence of similar catastrophes.

To date, in mid-2022, the United States has lost more than a million people to the COVID-19 pandemic. We have been real-time witnesses to heroic front-line responses to the disease, death, inequity, and economic strife unleashed by the virus, but we have also been real-time witnesses to the consequences not only of poor preparedness to contend with newly emerging health threats, but especially to the consequences of structural failures of our health system. The nation's health system is poised at a critical junction point, with the opportunity to emerge stronger not merely in resistance to a novel infectious disease threat, but as a secure and sustained steward of the human condition over time.

For decades, the U.S. health system has fallen far short of its potential to produce individual and population health. In contrast to health care spending that exceeds that of any Organisation for Economic Co-operation and Development (OECD) nation, the U.S. experiences lower life expectancies, higher suicide rates, higher chronic disease burdens, higher obesity rates, and higher hospitalization rates from preventable causes than any of its peers. The inequities, lack of community

engagement, misaligned resources and incentives, untapped digital potential, and slow rate of evidence mobilization that belie these trends were also at the root of the nation's experience with COVID-19. To fully realize the health system effectiveness, efficiency, equity, and continuous learning that will translate to better and more holistic health and well-being, leaders from across the U.S. health system must take action to leverage both the learnings and the transformational opportunities that have accompanied the pandemic's devastation.

Cognizant of the potential near-term and long-term importance of understanding in detail the features, impacts, and responses within and between various health sectors during the pandemic, the National Academy of Medicine's (NAM's) Leadership Consortium, comprised of the leadership of organizations from all major health system sectors, has undertaken a sector-by-sector review of the U.S. health system. The papers contained within assess the weaknesses that existed prior to COVID-19, how each sector has responded to the pandemic, and the opportunities that exist for health system strengthening and transformation. The resulting sectoral impact assessments are presented here in *Emerging Stronger from COVID-19: Priorities for Health System Transformation*. Each assessment team has been led by members of the NAM Leadership Consortium. *Emerging Stronger* is comprised of nine chapters that summarize the findings, opportunities, and collaborative options for sectoral transformation, followed by a chapter on cross-sector priorities for change, including:

1. Patients, Families, and Communities
2. Clinicians and Professional Societies
3. Care Systems
4. Digital Health
5. Public Health
6. Health Care Payers
7. Health Product Manufacturers and Innovators
8. Biomedical Research
9. Quality, Safety, and Standards Organizations
10. Health System Transformation: Common Priorities Across Sectors

The summary insights, drawn from the shared perspectives of the sector authors, underscore three deeply rooted common features leading to the core problems within each sector:

1. Systemic fragmentation,
2. Perverse incentives, and
3. Structural inequities.

Accordingly, the authors note the importance of forceful collaborative engagement of transformational opportunities for stakeholders setting priorities for organizations in each of their sectors:

1. **Financing** that is linked, integrated, seamless, and focused on outcomes for people and populations;
2. **Digital** interoperability and shared data;
3. **Culture** and accountability focused on outcomes most important to people and their communities;
4. **Learning** that is real world, continuous, and timely; and
5. **Public health** integrity as an explicit responsibility of every organization.

Taken together, the assessments in *Emerging Stronger* provide a unique and comprehensive review of the U.S. health system's experience throughout the pandemic, as well as a roadmap toward a healthier future. It integrates the deep and growing knowledge base of the NAM with the expertise of leaders engaging the pandemic in real-time, offering both information and inspiration for aligned action on key opportunities. In this respect, we extend our deep appreciation to the members of the NAM Leadership Consortium, the project Steering Committee composed of the lead authors of each sector assessment, their collaborating colleagues from the field, the expert reviewers of each of the papers, and the superb NAM staff who coordinated and facilitated their work.

As Americans, innovation, improvement, and invention is our shared birthright. This publication underscores the imperative and the promise of applying the full strength of the nation for system-wide transformation as we apply the clarity of the lessons learned to create a health system that is effective, efficient, equitable—and continuously learning.

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ACRONYMS AND ABBREVIATIONS

AACN	American Association of Colleges of Nursing
AAMC	Association of American Medical Colleges
AAP	American Academy of Pediatrics
ACA	Affordable Care Act
ACCORD	Accelerating COVID-19 Research & Development platform
ACGME	Accreditation Council for Graduate Medical Education
ACLA	American Clinical Laboratory Association
ACO	accountable care organization
ACTIV	Accelerating COVID-19 Therapeutic Interventions and Vaccines
ADHD	attention deficit and hyperactivity disorder
AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
AI	artificial intelligence
AMA	American Medical Association
AMC	academic medical center
ANA	American Nurses Association
AO	accrediting organization
APA	American Psychological Association
API	application programming interface
APM	alternative payment model
ARPA-H	Advanced Research Projects Agency for Health
ASC	ambulatory surgical center
BARDA	Biomedical Advanced Research and Development Authority
BBC	British Broadcasting Company
BLS	Bureau of Labor Statistics
CAH	critical access hospital
CARES Act	Coronavirus Aid, Relief, and Economic Security Act

CBO	community-based organization
CCNE	Commission on Collegiate Nursing Education
CCO	coordinated care organization
CCPA	California Consumer Privacy Act
CDC	Centers for Disease Control and Prevention
CDM	PCORnet Common Data Model
CEAL	NIH Community Engagement Alliance
CHART	Community Health Access and Rural Transformation Model
CHW	community health worker
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare & Medicaid Services
CoP	condition of participation
COVID-19	coronavirus disease 2019
CoVPN	COVID-19 Prevention Network
CPT	Current Procedural Terminology
CRS	Congressional Research Service
CTL	Crisis Text Line
DOD	Department of Defense
DOJ	Department of Justice
DPA	U.S. Defense Production Act
DR2	NIH Disaster Research Response Program
ED	emergency department
EHR	electronic health record
EUA	emergency use authorization
FAIR	findable, accessible, interoperable, and reusable
FCC	Federal Communications Commission
FDA	U.S. Food and Drug Administration
FEMA	Federal Emergency Management Agency
FFS	fee-for-service
FHIR®	Fast Healthcare Interoperability Resources®
FTC	Federal Trade Commission
FY	fiscal year
GDPR	General Data Protection Regulation
GME	graduate medical education
GPO	group purchasing organization

HaH	Hospital at Home
HAI	hospital acquired infection
HCBS	home- and community-based services
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HITECH Act	Health Information Technology for Economic and Clinical Health Act
HIV	human immunodeficiency virus
HPMI	health product manufacturers and innovators
HRSA	Health Resources and Services Administration
ICU	intensive care unit
IDN	integrated delivery network
IDSA	Infectious Diseases Society of America
IHI	Institute for Healthcare Improvement
IMP	investigational medicinal product
IOM	Institute of Medicine
IoT	internet-of-things
IP	intellectual property
IT	information technology
JHU	Johns Hopkins University
KFF	Kaiser Family Foundation
LGBTQ+	lesbian, gay, bisexual, transgender, queer or questioning, and other gender identities and sexual orientations
LHS	learning health system
MIPS	Merit-based Incentive Payment System
ML	machine learning
MLR	medical loss ratio
N3C	National COVID Cohort Collaborative
NAM	National Academy of Medicine
NCHS	National Center for Health Statistics
NCQA	National Center for Quality Assurance
NGS	next generation sequencing
NHLBI	National Heart, Lung, and Blood Institute

NHSN	National Healthcare Safety Network
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NPI	nonpharmaceutical intervention
NQF	National Quality Forum
NRC	National Research Council
OASH	Office of the Assistant Secretary for Health
OASPE	Office of the Assistant Secretary for Planning and Evaluation
OCR	Office for Civil Rights
OHDSI	Observational Health Data Sciences and Informatics
OHRP	Office for Human Research Protections
OIG	Office of Inspector General
ONC	Office of the National Coordinator for Health Information Technology
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy
OWS	Operation Warp Speed
PA	physician assistant
PCORI	Patient-Centered Outcomes Research Institute
PCR	polymerase chain reaction
PHAB	Public Health Accreditation Board
PHR	personal health record
PHRASES	Public Health Reaching Across Sectors
PPE	personal protective equipment
PTSD	posttraumatic stress disorder
QIN-QIO	Quality Innovation Network-QIO
QIO	Quality Improvement Organization
QR	quick response
R&D	research and development
RADx	Rapid Acceleration of Diagnostics initiative
RN	registered nurse
RWD	real-world data
SAMHSA	Substance Abuse and Mental Health Services Administration
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SDoH	social determinants of health

SNAP	Supplemental Nutrition Assistance Program
SNF	skilled nursing facility
SNS	Strategic National Stockpile
UCSF	University of California, San Francisco
UK	United Kingdom
UPMC	University of Pittsburgh Medical Center
U.S.	United States
USCDI	United States Core Data for Interoperability
USNS	U.S. Navy Ship
VA	U.S. Department of Veterans Affairs
VAERS	Vaccine Adverse Event Reporting System
VTEU	Vaccine and Treatment Evaluation Unit
WHO	World Health Organization
WIC	Special Supplemental Nutrition Program for Women, Infants, and Children

1

PATIENTS, FAMILIES, AND COMMUNITIES COVID-19 IMPACT ASSESSMENT: LESSONS LEARNED AND COMPELLING NEEDS

Frederick Isasi, JD, MPH; Mary D. Naylor, PhD, RN; David Skorton, MD; David C. Grabowski, PhD; Sandra Hernández, MD; and Valerie Montgomery Rice, MD

INTRODUCTION

The health system exists to serve the most fundamental need of society: people's health and well-being. To do so effectively requires engaging people as a partnership proposition in all elements of health system structure and function. Patients, families, and communities represent a wide-ranging group of individuals and populations contending with a host of health conditions and engaging in the health system for prevention, screening, diagnosis, and treatment. Yet patients, families, and communities are not simply passive recipients of health services—they are also active partners in scientific research, collaborators for shared decision making in care and related matters, and advocates for the population health priorities salient to their communities. The 2017 National Academies of Sciences, Engineering, and Medicine (the National Academies) report *Communities in Action: Pathways to Health Equity* shared the significance of the role of communities in promoting health equity. The report concluded that community-driven solutions are necessary, as communities are in a unique position to drive priorities and actions tailored to their needs that address many of the determinants of health (NASEM, 2017). In addition, the enhanced engagement of patients, families, and communities has been encouraged as a strategy in health policy change, research, and care delivery to improve the quality of care and drive health equity (Simon et al., 2020). Orienting the different health system sectors around the experiences, needs, and considerations of patients, families, and communities is a necessary precondition to achieve the values of equity, efficiency, and effectiveness.

Unfortunately, the U.S. health system has long fallen short of those aspirations, as evidenced by the persistent increase in health expenditures without commensurate improvements in population health (Schoen and Solis-Roman, 2016). Indeed, life expectancy in America has declined in recent years, a stark contrast with trends in other high-income countries (Harper et al., 2021). Additionally, before the start of the COVID-19 pandemic, the United States grappled with other challenges, such as the misdiagnosis of patients and medical errors leading to thousands of preventable deaths each year (Anderson and Abrahamson, 2017; JHU, 2016). Rather than occupying the center of the health system, many patients, families, and communities have been relegated to the periphery, as evidenced by challenges in achieving population health. Furthermore, longstanding disparities in health status and health outcomes affect communities of color; low-income populations; people with disabilities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) communities; people with limited English proficiency; and older adults (Maani and Galea, 2020).

It is amid this period of declining health and growing inequality in America that the COVID-19 pandemic struck. The public health emergency—which remains ongoing at the time of this paper's publication—has negatively impacted the lives of virtually every patient, family, and community throughout the nation and the world. The virus has taken a tremendous toll on the health of these groups, with 45,655,635 cases, 3,223,806 hospitalizations, and 740,348 deaths in the United States as of October 27, 2021 (CDC, 2021a). Additionally, the added stressors from the pandemic's upending of everyday life (manifesting in worsening mental health outcomes for nearly every population) and disruption to other types of necessary health services (e.g., chronic disease management) have made it even more challenging for patients, families, and communities to pursue and achieve health and well-being (Blecker et al., 2021; Panchal et al., 2021; Ettman et al., 2020). Altogether, the cumulative health effects of COVID-19 precipitated a full-year decline in average life expectancy in the United States during 2020.

The pandemic has also erupted the existing fault lines of race and class in the health system. Morbidity and mortality attributed to COVID-19 have disproportionately affected populations in the United States along the axis of age, income, social determinants of health (e.g., geographic location, education), race, ethnicity, gender and sexual orientation, and immigration status (Garcia et al., 2021; Lopez et al., 2021; Oregon Health Authority, n.d.). For example, declines in life expectancy due to COVID-19 were significantly greater for Black (2.7 years) and Latinx (1.9 years) populations compared to Whites (0.8 years), with the gap between Black and White populations representing the largest disparity in over twenty years (CDC, 2021b). Further, the impact of the pandemic on populations with multiple and intersecting identities (e.g., low-income rural residents, low-income women of

color, low-income older adults of color) is probably more significant, as the groups are more likely to experience inequities and disparities.

Collectively, the devastating impact of and response to the COVID-19 pandemic underscores and illuminates the fragilities and inequities in health status and in the health system, as well as the disparities present in factors that significantly influence health and wellness (e.g., wealth, social determinants of health). However, the pandemic also presents leaders with an opportunity to implement comprehensive reforms to assure health and well-being for all by recentering the health system around patients, families, and communities and addressing the historical legacies and structural inadequacies across sectors contributing to the disparities in population health.

This discussion paper aims to provide a comprehensive review of the impact and implications of the COVID-19 pandemic on patients, families, and communities (see *Figure 1-1*). Importantly, this assessment seeks to offer the perspectives of sector leaders on the system's failures and opportunities for change, and elevate the stories and experiences of patients, families, and communities who have demonstrated remarkable resilience while bearing the myriad impacts of COVID-19. While this assessment will focus broadly on patients, families, and communities, it will substantively address the inequities that exist for marginalized populations, focusing on low-income populations, communities of color, and older adults and their family caregivers. This paper will highlight the interplay of patients and families, who comprise communities, and who are connected to the broader health system, as reflected in the socio-ecological model (Kilanowski, 2017). Identifying the progress and challenges faced by patients, families, and communities within the health system both prior to and during COVID-19 will allow for building on pandemic-era innovations and cross-sector collaborations to achieve meaningful improvements for all.

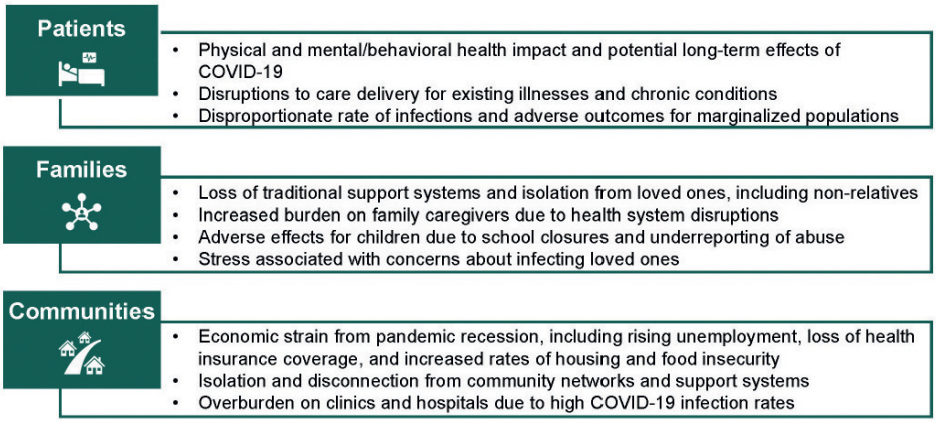

FIGURE 1-1 | Impact of the Pandemic on Patients, Families, and Communities

PRE-COVID-19 EXPERIENCE OF PATIENTS, FAMILIES, AND COMMUNITIES

Over the years, there has been more focus on approaches to increase patient- and family-engaged care, address the social determinants of health, and improve patient-centered outcomes research. Yet, despite evidence of the positive benefits arising from increased engagement, patients, families, and communities, these changes are far from widespread and have not resulted in major population health improvements. Further, patients, families, and communities still faced critical challenges prior to the pandemic including gaps in access to key services and public health infrastructure and the constraints and consequences of structural and institutional racism. This section presents the pre-pandemic progress and challenges for patients, families, and communities (see *Table 1-1*).

Key Successes for Patients, Families, and Communities Prior to the Pandemic

Increase in Patient- and Family-Engaged Care

Patient-centered care focuses on providing care that respects and responds to patient preferences, needs, and values, and ensures that clinical decisions are guided by patient values (IOM, 2003). In recent years, payers, providers, and policy makers have invested in several approaches to increase patient and family engagement in care delivery that include changing how care is delivered (e.g., development of Patient-Centered Medical Homes), paid for (e.g., moving away from fee-for-service to alternative payment models, developing value-based programs), and measured (e.g., development and use of patient-reported outcome measures) (CMS, 2020a; Carman et al., 2013). In addition, engagement across care settings has improved the salience of information sharing, supported the redesign of clinical facilities and care models, empowered patients to be represented on hospital and health system boards, and fostered changes to organizational culture (Carman et al., 2013). Despite challenges in implementing patient engagement approaches (e.g., lack of shared guidelines or education on best practices for engagement), a growing body of evidence highlights the benefits of patient- and family-engaged care, including improvements to patient safety, perceptions of quality, medication adherence, functional status and recovery, and rates of medical errors (Skufca, 2019; Graffigna et al., 2017; AHRQ, 2013).

TABLE 1-1 | Pre-Pandemic Experiences of Patients, Families, and Communities

Domain	Theme	Description
Progress Areas	Increase in Patient- and Family-Engaged Care	• Emphasis on patient-centered delivery models and patient-reported outcomes • Focus on care coordination and shared decision-making
	Focus on Social Determinants of Health	• New payment and delivery reforms to integrate health and social services • Creation of cross-sector partnerships to better meet community needs
	Improving Patient-Centered Research and Outcomes	• Advent of Patient-Centered Outcomes Research Institute • Increased uptake of community-partnered research practices
Challenge Areas	Underinvestment in Public Health Infrastructure	• Chronic underfunding of both preventive and emergency public health services • Variation in health department resources and capabilities • Lack of significant coordination between public health and health systems
	Access to Care	• Millions of Americans continue to be uninsured and underinsured • Uneven distribution of providers constrains patient access to health services
	Health Care Costs	• Persistent growth in health expenditures without commensurate gains in health outcomes • Patients are increasingly liable for a greater share of their health care costs
	Inequities and Structural Racism	• Longstanding disparities in population health for marginalized populations • Gaps in access, quality, and outcomes are the product of racist structures embedded within the health system

Focus on Social Determinants of Health and Addressing Social Needs

Substantial evidence illustrates how the social determinants of health, including education, transportation, housing, and access to food, influence patient- and population-level health outcomes. In recent years, payers and providers have sought to improve the health care system's capacity to address the patient-level social needs through partnerships and integrated delivery models (NASEM, 2017).

For example, payers are exploring federal demonstration models such as Accountable Health Communities to state initiatives to screen and refer for social needs through Medicaid managed care (Crook et al., 2021; Artiga and Hinton, 2018). Likewise, health department partnerships conceived and rolled out under the guidance of the Public Health 3.0 framework and care systems investments in social services, such as access to safe and affordable housing, illustrate cross-sector efforts to address the social determinants of health that impact patients, families, and communities (Horwitz et al., 2020; OASH, 2016). Certainly, much more work is needed among payers, health systems, and providers, alongside patients and community-based organizations, to understand how to capture information on social needs, identify resources available, and support use by patients.

Improving Patient-Centered Research and Outcomes

The voices of patients, families, and communities are integral to research to ensure that the benefits are accessible to all patients and inclusive of the outcomes that matter most to them (PCORI, 2021a). Models of community-partnered participatory research and patient-centered outcomes research—in which patients, families, and communities are treated as active partners and included in question selection, data ownership, and outcomes dissemination—represent authentic approaches to improving the equity and benefits of research (Jones and Wells, 2007). For example, the creation of the Patient-Centered Outcomes Research Institute (PCORI) seems to reflect a continued interest in and commitment to patient-centered comparative effectiveness research. Findings from PCORI-funded research projects on addressing disparities and improving health systems have been translated into practice to address various health and health care issues (PCORI, 2021b). Likewise, the Food & Drug Administration's (FDA's) patient-focused drug development program has supported the use of patient experience data to ensure regulatory decision making better captures patients' perspectives (Hunter et al., 2015).

Challenges Impacting Patients, Families, and Communities Prior to the Pandemic

Underinvestment in Public Health Infrastructure

Robust public health infrastructure at the local, state, tribal, and national levels is necessary to support disease prevention and health promotion. However, public health in the United States has traditionally operated separately and distinctly from other sectors and has long been chronically underfunded, with substantial declines in the share of national health expenditures dedicated to public health and its workforce over

the past twenty years. The result has been a persistent inability to focus on coordinated and effective preventive services addressing the health and well-being of communities and has led to an increasing emphasis on medical care and interventions (Pope, 2019; Himmelstein and Woolhandler, 2016). The chronic disinvestment in public health and significant heterogeneity in health department capacity across the country also affects preparedness for emergency situations. Indeed, funding for emergency preparedness has declined significantly despite multiple infectious disease outbreaks since the turn of the millennium (Murthy et al., 2017). Further, the underinvestment in public health has made it challenging to develop, build, and maintain effective and significant coordination between public health and health systems.

Inequitable Access to Quality Care

Patients, families, and communities across America have long encountered barriers to accessing necessary health services. First, 14.5 percent of Americans lacked access to health insurance before the pandemic, with affordability cited as the most common barrier to coverage (Cha and Cohen, 2020). Second, when Americans have health insurance, their coverage may not encompass the full scope of their health needs. For example, 23 percent of Medicare beneficiaries are underinsured (Schoen and Solis-Roman, 2016). Likewise, many Medicare beneficiaries lack coverage for long-term services and supports (Reaves and Musumeci, 2015). Third, beyond questions of insurance, many communities suffer from a dearth of providers, with over 80 million patients and families living in Health Professional Shortage Areas (KFF, 2020). A key area of need is behavioral/mental health (KFF, 2020). There is a lack of parity in service capacity and financial structures between behavioral/mental and physical health, which impacts systems serving patients, families, and communities (Schoch-Spana, 2020). Relatedly, there often are not enough providers from diverse backgrounds (Takeshita et al., 2020). Last, due to geographic variation, rural residents often have less coverage and do not receive recommended care when compared to urban populations (James et al., 2017). Rural residents make up an estimated 19 percent of the US population, and within these communities, 80 percent of the population are considered medically underserved (HRSA, 2017).

Increasing Health Care Costs

Even when patients and families can access care, the continually rising cost of care continues to be a deterrent for many communities. Indeed, premiums on average in 2020 exceeded $21,000 for families with employer-sponsored health insurance, while deductibles have risen at five times the rate of workers' earnings

over the past decade (KFF, 2021). High out-of-pocket costs for deductibles, coinsurance, and copayments can also deter patients from seeking necessary care, such as refilling prescriptions for medications and receiving needed medical treatments. Moreover, beneficiaries in Medicare's fee-for-service benefit program often have high out-of-pocket costs and/or no caps on out-of-pocket expenses, which increases their financial risk and the economic impact associated with receiving care for catastrophic illness. Additionally, "surprise billing," which describes significant out-of-pocket expenses for health services that were not apparent at the time of treatment, highlights how the cost of care can have long-lasting consequences on the health and well-being of families (Kliff and Sanger-Katz, 2020). Increasing health care costs have significant impacts on families' abilities to build, maintain, and transfer wealth, which further negatively influences the health and well-being of future generations.

Inequities and Structural Racism in Health and Health Care

The persistence of inequities in health and health care is not the result of a broken system but rather the product of a "carefully crafted system functioning exactly as intended with social policies rooted in racism" (Williams, 2020). Health inequities are fueled by social, environmental, and structural determinants of health that plague US society, including but not limited to generational and situational poverty; mass incarceration; police brutality; dysfunctional and uncoordinated educational, criminal, and health systems; inadequate transportation; poor housing conditions, capacity, and stability; poor nutrition and diet; and lack of health literacy (Dawes, 2020). Health inequities due to structural racism impact communities of color, including Indigenous, Black, Asian American and Pacific Islander, and Latinx populations and subpopulations.

The inequities that stem from structural and institutional racism affect both the health of communities and the experiences of patients and families with the health care system. Consider the case of residential segregation, a social policy with significant implications for the health of communities. In the 100 metropolitan areas in the United States, 68 percent of Black children and 58 percent of Latinx children live in neighborhoods with either low or very low social and economic opportunities compared to 27 percent of White children (Acevedo-Garcia et al., 2014). Wealth, a more comprehensive representation of collective economic resources than income, has increasingly been viewed as an indicator of individual and population health. Significantly, in 2016, the median wealth of White, Latinx, and Black families was $171,000, $20,600, and $17,100, respectively (Braveman et al., 2018).

Similarly, housing instability, food insecurity, and other social needs are all more prevalent among communities of color, which are negatively associated

with the health status of these populations. In addition, conditions such as obesity (47 percent for both Black patients and Latinx patients compared to 38 percent among White patients) and diabetes (19 percent for Black patients and 22 percent for Latinx patients compared to 13 percent among White patients) have greater incidence and prevalence among communities of color. These disparities in health status create the basis for disparities in health outcomes and life expectancy; for example, Black patients are twice as likely to die from cardiovascular disease as White patients, while cancer death rates are 19 percent higher for Black men than White men (CDC, 2019; DeSantis et al., 2019).

Yet despite long-standing documentation of the outcomes gap between communities of color and White patients, non-White patients continue to experience differential treatment in the U.S. health care system. Discrimination based on race or ethnicity is the most frequently reported type of discrimination by patients (Nong et al., 2020). As noted in the Institute of Medicine report, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, and other articles, Black patients are less likely to receive preventive care (e.g., cancer screenings), accurate diagnoses (e.g., pain assessments), consistent and efficient treatment (e.g., wait times for surgery, practice patterns for myocardial infarctions), and supportive services (e.g., end-of-life care), illustrating the pervasive nature and devastating consequences of structural racism in the health care system (Ornstein et al., 2020; Warren and Smalley, 2020; Eaglehouse et al., 2019; Hoffman et al., 2016; Bradley et al., 2004; IOM, 2003).

Importantly, the impact of each of the existing challenges listed above on patients, families, and communities is magnified when evaluated through the lens of structural and institutional racism. While public health infrastructure is atrophying across America, the gaps are particularly dire among communities of color, with Black, Indigenous, and Latinx populations more likely than White populations to contend with neighborhoods with toxic sites; substandard plumbing; polluted air, waters, and lands; and insufficient access to fresh and nutritious food items. Likewise, of the more than 33 million Americans who were uninsured in 2019, Black and Latinx adults were more likely than White adults to lack health care coverage (Cha and Cohen, 2020). Even in areas where progress has increased patient and family engagement, communities of color continue to be left behind. Many value-based care programs disadvantage patients with greater social needs. For example, physicians caring for patients with more social needs scored lower under the Merit-based Incentive Payment System, while accountable care organizations serving minority patients were associated with poorer performance on Medicare quality measures (Khullar et al., 2020; Lewis et al., 2017). Likewise, underrepresentation of communities of color is a long-standing problem for clinical research. For instance, mortality from cardiovascular

disease is twice as high for Black patients compared to White patients, yet Black patients account for only 4 percent of study participants in cardiovascular clinical trials (Khan et al., 2020; CDC, 2017).

It is critical to note that intersectionality, or how social identities such as race, ethnicity, class, gender, and age "intersect," has a profound effect on health and health outcomes. The above-referenced examples highlight disparities by race and ethnicity; however, when race and ethnicity are combined with other characteristics, they can often produce increased and exacerbated health inequities and worse health outcomes. For example, a January 2021 report found that among older adults, Black and Hispanic individuals are three and two times more likely than White individuals, respectively, to report that their care preferences were not considered, making them more likely to report lower satisfaction and decline medical care (Tavares et al., 2021). Additionally, compared to one in six low-income White women, one in five low-income Black women are uninsured (NCCARE360, 2020).

Consequently, while patients, families, and communities as a whole face discrete challenges, achieving the goal of enabling each member of US society to reach their full health potential requires grounding the challenges and opportunities for patients, families, and communities using the framework of health equity (NASEM, 2017). Only by redressing historical legacies and the ongoing perpetuation of structural and institutional racism will the health care system be truly centered on the needs, experiences, and considerations of patients, families, and communities.

PATIENTS, FAMILIES, AND COMMUNITIES EXPERIENCES DURING COVID-19

The COVID-19 pandemic has affected patients, families, and communities across America in myriad ways. However, the most fundamental consequences of the virus are health-related. With persistently high infection rates and the susceptibility of specific populations to severe illness, COVID-19 has become the leading cause of death in the United States (Amin et al., 2021; Woolf et al., 2021). However, the health effects of COVID-19 (e.g., risk of hospitalization) and the response of the health system to COVID-19 (e.g., access to testing and treatment) were not equally distributed across all Americans. Indeed, the health outcomes of patients and families during COVID-19 was determined by a combination of both health (e.g., chronic diseases) and social (e.g., class, race, ethnicity, living conditions) factors, with evidence clearly demonstrating the virus's disparate impact on communities of color, low-income populations, and older adults.

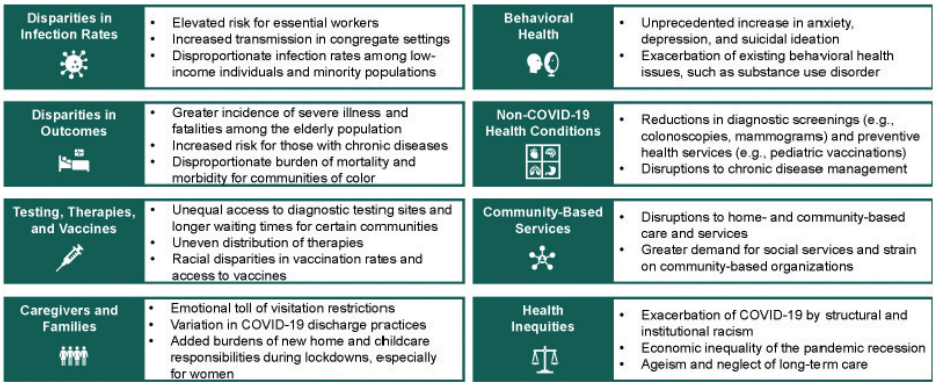

FIGURE 1-2 | Experiences of Patients, Families, and Communities During COVID-19

Yet while the United States is one of the countries that leads the world in COVID-19 cases and deaths, these stark numbers alone do not adequately reflect or demonstrate the significant and wide-ranging impact the pandemic has had on patients, families, and communities (JHU, 2021). COVID-19 has negatively affected multiple aspects of the lives of patients, families, and communities, including the severe economic consequences of the pandemic-related recession and the mental health toll from the disruption in relationships and social networks. To fully capture the experience of patients, families, and communities during COVID-19, this section will review the health consequences of the virus as well as the upstream and downstream effects on society. Key domains of focus include:

1. Disparities in COVID-19 infection rates
2. Disparities in COVID-19 morbidity and mortality
3. Disparities in COVID-19 testing, treatment, and vaccination
4. Impact of COVID-19 on caregivers and families
5. Impact of COVID-19 on behavioral health
6. Impact of COVID-19 on non-COVID-19 health conditions
7. Impact of COVID-19 on community-based services
8. Impact of COVID-19 on health and social equity (see *Figure 1-2*)

Disparities in COVID-19 Infection Rates

Over 45 million cases of infection have occurred in the United States as of October 27, 2021 (CDC, 2021c). Although COVID-19 has affected patients of all ages and backgrounds, adults between the ages of 18 and 64 have accounted

for nearly 75 percent of cases. While children were thought to be less susceptible to infection, over 11 percent of cases are attributed to pediatric patients, although the likelihood of escalation to severe illness still appears lower (CDC, 2021d). In addition, infections have disproportionately affected select populations, including communities of color and individuals living in congregate settings. For example, the rate of COVID-19 infections is higher for Black (1.1 times), Latinx (1.3 times), and Indigenous (1.9 times) patients as compared to White patients (CDC, 2021e). This section will review the contextual factors contributing to disparities in COVID-19 infection, including the increased risk for (1) "essential" workers (of whom a disproportionately large percentage are people of color) and (2) patients and families living in crowded conditions with limited ability to socially distance (Associated Press, 2020; HRSA, 2017).

Essential Employees Are More Likely to Be Exposed to COVID-19

Health care workers—clinicians, allied health professionals, and staff at health care facilities—are at substantial risk of exposure to COVID-19 due to their service on the front lines of the pandemic. However, their susceptibility to infection increased significantly due to prolonged shortages of personal protective equipment (PPE), with gaps particularly persisting for workers in nursing homes (McGarry et al., 2020). Over 3,600 US health care workers are reported to have died from COVID-19, with 67 percent of deaths affecting workers of color (Gould and Shierholz, 2020). In fact, being a health care worker at a nursing home was one of the most dangerous jobs in America during the early months of the pandemic (McGarry et al., 2020).

Workers in other industries deemed "essential" by the government have also been at high risk of exposure to COVID-19. Over 40 percent of these frontline employees identify as people of color, and less than one-fifth of Black or Latinx workers possessed the capacity to telework (compared to one-third of White workers) (Gould and Shierholz, 2020). These frontline occupations include jobs in direct care (i.e., day care providers, personal aides, and home health care), construction, hospitality, agriculture, and meatpacking (CEPR, 2020; Gould and Wilson, 2020). A member of that community illustrates the impact below (see *Box 1-1*).

Unlike health care, many industries requiring workers to report in person may not have provided adequate PPE and did not develop or use physical distancing protocols, increasing the risk of COVID-19 transmission among coworkers and customers. For example, tens of thousands of meatpacking workers have been infected with COVID-19, with 87 percent of cases affecting people of color (Wang et al., 2020). Likewise, direct care workers—who play a central role in providing home- and community-based services—have increased susceptibility to COVID-19 exposure due to their close contact with high-risk individuals.

BOX 1-1

Stories of Lived Experience: Impact of Being a Frontline Employee During COVID-19

"Our community – the majority work in the service industry, and they are out providing you their food, cleaning the hospitals, and doing the sanitation. So they are very, very high risk of getting infected with COVID."

—Sandra Rodriguez, Gulfton, Texas

A significant proportion of direct care workers in the United States are women (>80 percent), people of color (60 percent), immigrants (25 percent), and those over the age of 55 (23 percent) (PHI, 2020; Scales, 2020). Yet despite their substantial exposure and individual risk factors, most lack access to paid sick leave and were not included in the emergency provisions of the Families First Coronavirus Response Act, layering their health risks with added financial uncertainty (Long and Rae, 2020). Furthermore, workers in congregate living spaces, where there are high rates of COVID-19 transmission, were also likely to be infected. For example, nearly 4,000 cases were reported among prison staff in the spring of 2020 (Rabin, 2020a). Likewise, many nursing homes—which account for over one-third of COVID-19 deaths—rely on staffing models where many workers are simultaneously employed by and required to travel between multiple homes. Modeling studies suggest nearly half of nursing home cases are linked to staff networks, leaving workers—the majority of whom are women—in an impossible bind: risk contracting COVID-19 or risk termination (Chen et al., 2021; de Freytas-Tamura, 2020; Argentum, 2018).

Lastly, the challenges facing essential workers were magnified for immigrant and undocumented workers, who may be less likely to notify the Occupational Safety and Health Administration about workplace safety concerns for fear of deportation (NRC, 2003). They may also have concerns about being considered a "public charge," where until recently, receipt of public benefits would render them ineligible for legal permanent residence (Federal Register, 2019). This fear of being deemed a "public charge" has haunted individuals like Maria and Francisco Garcia, who have worked the produce fields of the Coachella Valley for over 25 years. Maria and Francisco are undocumented, and their daughter Mariana is a U.S. citizen. Recently, Maria and Francisco became eligible to apply to become Permanent Residents; however, with the rapid spread of COVID-19 in California's agricultural regions, they feared contracting the virus at work and jeopardizing their chance of becoming naturalized citizens if they seek medical care

(Bion, 2020). Additionally, undocumented individuals, including their U.S.-citizen spouses or children, are excluded from receiving direct cash relief provided by the federal government and may continue to work and increase the risk of exposure to COVID-19 to financially provide for their families (CARES Act, 2020).

Crowded Living Conditions Increase the Likelihood of Contracting COVID-19

Living conditions in which households or multiple individuals live together near one another are high-risk environments for the spread of infectious diseases. These conditions limit the capacity of individuals to distance themselves in the event one member of the household becomes sick. Location- and housing-based risk factors for COVID-19 disproportionately affect marginalized populations.

First, people of color are more likely than White populations to live in multigenerational households. This arrangement is especially true for immigrant communities, such as the Latinx population, where one in four live in multigenerational households (Cohn and Passel, 2018). The risk of infection is multiplied when considering the overrepresentation of essential workers in multigenerational housing, with such individuals reporting significant challenges with self-isolation during COVID-19 (Yu, 2020a; Cohn and Passel, 2018). For example, Rina Chavarria, a meatpacking worker in Los Angeles who contracted COVID-19 while at work, had to isolate herself in a makeshift bubble consisting of a lower bunk bed sealed off with clear vinyl plastic and tape for two weeks to avoid infecting her 12-year-old son, who has bronchial problems (see *Box 1-2*) (Yu, 2020b).

Second, people with low incomes living in poor housing conditions—as defined by cost, overcrowding, and inadequate facilities—are more likely to be infected. Analyses of over 3,000 counties in the United States found that a 5 percent increase in the number of households with poor conditions in a given county was associated with a 50 percent increase in the risk of COVID-19 incidence

BOX 1-2

Stories of Lived Experience: Impact of Isolating to Prevent Transmission to Family Members

"These were very sad weeks, behind plastic, without being able to hug or kiss them – this was the hardest part – away from your family, as if you have some kind of pestilence."

—Rina Chivarria, Los Angeles, California

(Ahmad et al., 2020). Relatedly, studies have also reported that a 0.1-point increase in a US county's Social Vulnerability Index—defined by the CDC to include factors such as poverty and housing conditions—was associated with a 14 percent increase in the incidence of COVID-19 infection (Karmakar et al., 2020). Communities of color are overrepresented in the population of individuals living in poor housing conditions. For example, the proportion of Latinx families living in crowded conditions is nine times higher than White families in California, a state where infections have disproportionately impacted Latinx communities (KFF, 2021; Wen and Sadeghi, 2020).

Third, congregate living facilities—including homeless shelters, correctional facilities, and nursing homes—became hotbeds for COVID-19 transmission. For example, testing at homeless shelters in major metropolitan areas in the spring of 2020 found resident infection rates to range between 17 percent and 66 percent in shelters with at least two confirmed cases, illustrating the ease of viral spread (Mosites et al., 2020). In jails and prisons—where justice-involved populations are disproportionately people of color—the known infection rate for COVID-19 is approximately 5.5 times higher than in the general population (Saloner et al., 2020). Furthermore, in nursing homes—which have been called "ground zero" for COVID-19 due to their high rates of infections and fatalities—severe outbreaks were more likely in facilities with higher shares of Black or Latinx residents (Barnett and Grabowski, 2020; Chidambaram et al., 2020).

Disparities in COVID-19 Morbidity and Mortality

The CDC estimates that about 20 to 30 percent of those with COVID-19 become acutely ill and require emergency department (ED) visits or hospitalizations, with approximately 5 to 15 percent of hospitalized patients requiring treatment in an intensive care unit (ICU) (Garg et al., 2020). Several factors contribute to the likelihood that an infected individual will progress to severe illness, including preexisting health conditions and age. Notably, the burden of severe illness and fatalities is disproportionately higher for older adults and populations of color. This section reviews the disparities in health outcomes for patients following COVID-19 infection.

Increased Risk for Individuals with Chronic Illnesses

Individuals with preexisting conditions (e.g., cardiovascular disease), poor health (e.g., obesity), and unhealthy behaviors (e.g., smoking) are all at elevated risk for severe COVID-19. Indeed, almost 90 percent of those hospitalized for COVID-19 also had two or more chronic conditions, while nearly 75 percent of COVID-19 deaths occurred in patients with at least one preexisting condition (Verdery et al., 2020).

For example, studies of Medicare beneficiaries found kidney disease, cardiovascular disease, and diabetes to be strongly associated with the likelihood of hospitalization due to COVID-19 (Chang et al., 2021). Thus, while preexisting conditions may be one factor associated with increased risk for morbidity and mortality due to COVID-19, they may not be the sole cause of disparities in health outcomes among Black and Latinx Americans compared to White Americans. It is important to note that other factors, such as lack of consistent providers, lack of high-quality care, and experiences with systemic racism, may have a greater influence on health outcomes for communities of color (Aslan et al., 2021).

Burden Among Older Adults

Age is a substantial risk factor for COVID-19, with CDC analyses of laboratory-confirmed COVID-19 cases indicating that nearly 75 percent of deaths were attributed to individuals over 65 (Wortham et al., 2020). Compared to 5- to 17-year-olds, older adults 65 to 74 years are 40 times more likely to be hospitalized and have a 1,300 times greater risk of death due to COVID-19; older adults 75 to 84 years are 65 times more likely to be hospitalized and have a 3,200 times greater risk of death (CDC, 2021f). Several factors contribute to the increased risk of severe illness and death among older adults. First, older adults with chronic illnesses and functional limitations have an increased need for supports and services for activities of daily living and are at increased risk of exposure to COVID-19 (The SCAN Foundation, 2018). Second, older adults are overrepresented in nursing homes (84 percent of residents), which account for over one-third of United States COVID-19 deaths (New York Times, 2021; Harris-Kojetin et al., 2019). Third, the prevalence of chronic illnesses is greater among older adults. However, the experience of seniors is not uniform. For example, older adults who are dually eligible for Medicare and Medicaid are hospitalized at four times the rate of Medicare beneficiaries, while hospitalization rates are higher for Black (fourfold) and Latinx (twofold) Medicare beneficiaries as compared to White patients (CMS, 2021; Godoy, 2020).

Disparate Impact for Communities of Color

Evidence to date overwhelmingly illustrates the disproportionate morbidity and mortality from COVID-19 on populations of color of all ages. Compared to White and Asian American and Pacific Islander patients, Indigenous, Black, and Latinx individuals are approximately three times more likely to be hospitalized and twice as likely to die from COVID-19 (CDC, 2021g). While Asian American and Pacific Islander patients have been underrepresented in some analyses, and

while race and ethnicity data may not capture the full diversity of this population, analyses of Epic health records suggest Asian American patients who test positive for COVID-19 were at greater risk for hospitalization (1.3 times) and death (1.2 times) than White patients (Rubin-Miller et al., 2020). The disparities in hospitalization rates between White patients and populations of color are even larger in adults under 65 (CDC, 2021e). Furthermore, recent studies indicate that children of color are five to eight times more likely to be hospitalized with COVID-19 than White children and more likely to develop a serious complication such as multisystem inflammatory syndrome (Rabin, 2020b).

Disparities in COVID-19 health outcomes reflect disparities in the underlying health status of marginalized populations in the United States. The prevalence of illnesses such as diabetes and cardiovascular disease—leading risk factors for severe illness from COVID-19—is greater at baseline for populations of color, contributing to their risk of poor outcomes from COVID-19 (Lopez et al., 2021). Marginalized populations also have less access to health care resources (e.g., insurance), and Black and Latinx individuals report poorer health literacy about COVID-19 (Alsan et al., 2020). Notably, studies suggest there is no difference in COVID-19 mortality when comparing hospitalized White patients to hospitalized Black patients (Yehia et al., 2020). Likewise, while one-third of COVID-19 patients admitted to the ICU are Black (even though Black individuals account for only 13 percent of the United States population), researchers did not find an association between race and death for COVID-19 patients receiving critical care (Gupta et al., 2020). However, this preliminary evidence should be contextualized to the historically unequal treatment and care quality provided to Black patients in the U.S. health care system, including for COVID-19, with early data and patient stories reflecting the disparate experience of Black patients seeking care for COVID-19 (Eligon and Burch, 2020).

Additionally, the drivers of outcome disparities for communities of color must be understood considering the broader gaps in access to necessary health care resources that these populations face. Indeed, Black patients have poorer access to primary care physicians, experience local hospital closures at higher rates than their White peers due to residential segregation, and are sent to lower-quality nursing homes. These factors, together, may contribute to worse outcomes during the pandemic (Gebeloff et al., 2020; Ko et al., 2014; Gaskin et al., 2012). Patients of color also experienced worse outcomes in congregate facilities—a function of the staffing and resource shortages at nursing homes serving marginalized populations (Mor et al., 2004). For example, COVID-19 outbreaks were more widespread at nursing homes with more patients of color, and nursing homes with a higher share of Black (1.6 times) and Latinx (1.3 times) residents were more likely to have COVID-19 deaths than those with low shares of patients of

color (Abrams et al., 2020; Chidambaram et al., 2020; Li et al., 2020). Likewise, COVID-19 death rates are twice as high in prisons compared to the general population, with people of color accounting for most incarcerated individuals in the United States (Schnepel, 2020).

Challenges for COVID-19 Recovery

The morbidity associated with COVID-19 extends beyond the time frame of testing positive for the virus. Early evidence suggests that survivors of COVID-19 are confronting unpredictable trajectories with complex and long-term physical, cognitive, and emotional health consequences (Ayoubkhani et al., 2021). Almost all patients who are hospitalized and discharged have health implications that extend at least a few weeks. Because of their development of acute respiratory distress syndrome, patients who were treated using mechanical ventilation are at risk for lung injury (U.S. Chamber of Commerce Foundation, 2020). Others have developed new complex problems, hypothesized to be due to hyperinflammation, affecting the heart, brain, kidneys, and lungs. In addition, those who have been hospitalized often experience "the post-viral syndrome" or "long-COVID" with persistent shortness of breath, fatigue, and, for some, cognitive deficits such as difficulty concentrating (Havervall et al., 2021; Carfi et al., 2020). Anecdotal reports reveal that some otherwise healthy adults, even those not hospitalized, also report unresolved symptoms that require long-term rehabilitation and emotional support (Velasquez-Manoff, 2021). Ongoing observational studies at the National Institutes of Health examine the long-term consequences of this disease, which may influence health care delivery in the future (NHLBI, 2020). Given the burden of disease and hospitalization rate for specific populations of color, the United States will likely also face disparities in the long-term impacts of the pandemic.

Disparities in COVID-19 Testing, Treatment, and Vaccination

Just as certain patients, families, and communities experience disparities in their risk of infection and likelihood of experiencing severe illness, marginalized populations have also faced inequities in access to diagnostic testing, contact tracing programs, and the resources available to self-quarantine (Shceiber et al., 2020; Steinhauer and Goodnough, 2020). Furthermore, even as the health care system developed new therapeutics and vaccines capable of significantly reducing morbidity and mortality, the uptake of new biomedical innovations was uneven due to gaps in access and low levels of trust among many patients, families, and communities. This section reviews the disparities in the COVID-19 response, which not only exacerbated the inequities in health outcomes for many populations but also hindered the safe reopening of communities, states, and the country.

Gaps in Testing and Tracing Capacity

Access to rapid and accurate diagnostic testing was a significant challenge during the pandemic. At the peak of the pandemic, less than half of all laboratory tests were completed within three days, and some patients reported waiting weeks to receive results—delays that rendered diagnostic testing useless for health care decision making and health department contact tracing (HHS, 2020a; Kretzschmar et al., 2020; Mervosh and Fernandez, 2020). Even as the availability of testing improved, inequities persisted due to the uneven distribution of resources (Shceiber et al., 2020; Steinhauer and Goodnough, 2020). Although people of color were more likely to test positive for COVID-19, experience severe illness, and require hospital-level care, data from electronic medical records indicate that these same populations received COVID-19 tests at only slightly higher levels than White patients (Rubin-Miller et al., 2020). Furthermore, even though testing rates were slightly higher in the aggregate for people of color, the experiences of communities varied significantly across the country. For example, a national analysis of nearly 8,000 testing sites during the summer of 2020 revealed wait times for diagnostic testing to be longer in communities of color than in predominantly White communities (Bronner, 2020; Kim et al., 2020b). These studies likely underestimate the true disparities in access, given that many laboratory records lacked demographic data (Servick, 2020). Further, the lack of demographic data, in general, represents a major inequity that has been exacerbated by and has yet to be addressed during the pandemic. The stories from patients below during the pandemic help highlight the challenges of navigating a fragmented system with little support and poor communication (see *Box 1-3* and *Box 1-4*).

BOX 1-3

Stories of Lived Experience: Challenges Faced by Elizabeth de Garcia and Her Family in Navigating the Health System During the COVID-19 Pandemic

Elizabeth de Garcia, who is from the predominantly Latinx community of Montgomery Village, Maryland, told the Washington Post that in order to get one of her brothers tested in April, they had to make two hospital trips and dozens of phone calls. De Garcia did not know of any free testing sites in her county. To her knowledge, the closest one was 27 miles, a two-hour bus ride from her apartment and inherently risky activity in itself during the peak of the pandemic.

SOURCE: Tan, 2020.

BOX 1-4

Stories of Lived Experience: Challenges Faced by Joe Merlino and His Family in Navigating the Health System During the COVID-19 Pandemic

Joe Merlino lived with his elderly mother and a roommate, an essential worker whose workplace did not require regular COVID-19 testing, despite knowing some employees had been infected. Unfortunately, Joe and his mother began to experience more severe COVID-19 symptoms a few days after initial symptoms they attributed to allergies. After Joe called at least 12 different testing hotlines and scoured three different websites to figure out where he could get a test, he still had to wait four days before getting tested and an additional five days to receive the results. Unfortunately, his mother had to be hospitalized due to her symptoms, and she died.

SOURCE: Families USA, 2020.

Stories like Joe's show that without access to accurate and timely testing and the supports—such as paid sick leave and provision of housing to support isolation for individuals who test positive—one case can lead to additional community spread, more infections, and even deaths (Families USA, 2020; Lazer et al., 2020). Indeed, even when populations could access testing, the effectiveness of contact tracing programs and supportive services for quarantine requirements were often lacking. Many of the populations at greatest risk for COVID-19 infection and severe illness (e.g., older adults, people of color) have limited access to phones, poorer access to technology such as broadband and smartphones, and challenges with health literacy, making them less likely to receive calls from contact tracers or be able to easily research support for quarantine outside the home (Barna, 2020; Paakkari and Okan, 2020; Perrin and Turner, 2019).

Gaps in Access to Therapeutics and Vaccines

While tremendous investment and coordination by biomedical researchers and health product manufacturers and innovators enabled the development and emergency use authorizations of multiple COVID-19 therapeutics and vaccines in record time during 2020, new medical countermeasures were unevenly distributed among patients, families, and communities. For example, the initial allocation of remdesivir, an antiviral treatment for COVID-19, did not follow a clear methodology, leading to access delays for different communities (Boodman and

Ross, 2020). Furthermore, while the United States vaccinated nearly thirteen million individuals during the first month of COVID-19 vaccine availability, the majority of vaccines went to White patients, with Black patients accounting for little over 5 percent of all vaccinations (Painter et al., 2021). Although immunization campaigns remain in progress at the time of this paper's publication, the persistent variation in access to medical products during the pandemic reflects how COVID-19 has perpetuated long-standing disparities in access to care.

Impact of COVID-19 on Caregivers and Families

As of 2020, there were 53 million family caregivers to an adult or child with special needs (AARP, 2020). An AARP research report found that the majority of caregivers are women (61 percent), with 61 percent being White, 17 percent being Latinx, 4 percent being Black, and 5 percent being Asian American and Pacific Islander (AARP, 2020). Due to earned income (approximately 36 percent of caregiver households earn less than $50,000) and caring for two or more adults (24 percent), caregivers often experience greater financial strain, have competing demands of work, and suffer from high levels of emotional stress (AARP, 2020). COVID-19 has further impacted, and even increased, the physical and emotional well-being of caregivers and families. These impacts range from the devastating restrictions for visitations in health care facilities to the evolving burdens of home and childcare responsibilities due to closures of schools and workplaces.

First, many family members have been unable to support loved ones isolated in hospitals and receiving treatment for COVID-19, since health care facilities have imposed restrictions on visitation to limit the spread of infection (Wakam et al., 2020). Further, for patients who succumb to COVID-19, caregivers and family members are not able to be there in person, with hospitals resorting to using tablet technologies and videoconferencing platforms to enable patients, families, and caregivers to say goodbye (Heyward and Wood, 2020). Bereaved families are the secondary victims of COVID-19, as they experience sadness, anguish, anger, guilt, and an increased trauma response due to the pandemic (Graham, 2020). Reports estimate that for every loss due to COVID-19, approximately nine people are bereaved (Verdery et al., 2020). Additionally, as of July 2021, approximately 1.5 children per 100,000 in the United States have lost a primary caregiver due to COVID-19 (Van Beusekom, 2021). The potential for long-term adverse stress reactions is enormous.

Second, the impact of such restrictions has been particularly stark for nursing home residents, who are generally older and for whom prolonged loneliness and isolation are associated with functional decline (Mezuk et al., 2019; Perissinotto et al., 2012). For example, during the spring of 2020, many nursing homes imposed significant restrictions on visitations, with the lack of contact with family and

limitations on social activities in the facilities negatively impacting the mental health of these patients. Indeed, some residents reportedly stopped eating and entered a state of despair because of social isolation, which a 2020 consensus study report from the National Academies indicates can severely impact health and well-being (Abbasi, 2020; NASEM, 2020). Although visitation policies were later modified, guidelines continued to vary, creating challenges for patients and families alike.

Third, in an attempt to minimize the spread of COVID-19, hospital restrictions were also applied to other non-COVID-19-related areas. For example, many hospitals limited visitors for labor and delivery units (Arora et al., 2020). Likewise, the pandemic disrupted many palliative care activities—for which caregiver and family involvement in end-of-life conversations can play an important role—adding to the emotional burden for patients and potentially dislocating them from their support systems (Abbott et al., 2020). Thus, while infection control policies were necessary to mitigate the risk of COVID-19 transmission, the downstream effects on caregivers and families had significant impacts.

Beyond visitation restrictions, families and caregivers faced additional challenges in supporting patients infected by COVID-19. For example, during the early months of the pandemic, local, state, and federal guidelines regarding whether patients recovered from COVID-19 and discharged from hospitals could be admitted to skilled nursing facilities varied and were frequently modified, creating confusion for patients, caregivers, and clinicians (AHA, 2020; CMS, 2020b; Graham, 2020). Many patients who otherwise would have been admitted to such facilities were subsequently sent home with substantially increased health care needs. Unfortunately, information needed to address these needs was often not communicated to primary or home care clinicians, due in part to the Centers for Medicare & Medicaid Services' (CMS') relaxation of discharge planning reporting requirements (CMS, 2020b). Early in the pandemic, caregivers' preparation for their responsibilities for patients suffering from the effects of this ravaging and unpredictable disease was conducted via phone, not in person. These added responsibilities without additional resources for caregivers came when many Americans were confronting other major stressors, including competing roles as parents and financial stress due to loss of jobs (Long et al., 2020).

In addition to caregiving responsibilities, the upending of daily life for over a year (e.g., closure of schools and workplaces) has added to the stress of families. Families have had to navigate compounding challenges ranging from economic uncertainty, potential health impacts to loved ones, and supporting children with remote learning. As a result, the use of childcare centers has declined by over 50 percent during the pandemic, with COVID-19 requiring 67 percent of working parents to modify their childcare arrangements (U.S. Chamber of Commerce Foundation, 2020). Parents have had to become homeschooling teachers and have

few childcare options while managing caregiving for aging relatives (Jones, 2020). Unfortunately, the increased burden of home and childcare responsibilities, as well as caring for relatives, has largely fallen on women. For example, one in ten women with children under the age of 18 years quit their jobs due to the pandemic, and approximately 30 percent of working mothers took time off work because of their children's school or lack of day care. Women who are Black, Latinx, or low-income were more likely to quit their jobs for reasons related to COVID-19 (KFF, 2021). In addition, during the prenatal and postnatal time frame, people who are pregnant experience more burden, stress, and anxiety due to COVID-19, greatly impacting their mental health (Moyer et al., 2020). Further, in general, women have reported higher rates of symptoms of anxiety or depression during the pandemic than men, raising concerns about the long-term implications for gender equality in American society (Panchal et al., 2021; Cohen and Hsu, 2020; Taub, 2020).

Impact of COVID-19 on Behavioral Health

As with other public health and financial crises, the COVID-19 pandemic has negatively affected behavioral health. The pandemic has exacerbated mental health distress and illness and substance misuse in people with existing conditions and facilitated the development of new conditions while increasing long-standing challenges in accessing best practice interventions.

Increased Mental Health Distress

Since the start of the COVID-19 pandemic, changes in daily life have been required by everyone in the United States. These changes have resulted in a notable increase in mental health distress, including anxiety, depression, and increased substance misuse. Certainly, these life changes have been more challenging for some. Reports of symptoms of anxiety or depression have quadrupled among adults between June 2019 and January 2021 (Panchal et al., 2021). Changes, such as physical distancing and stay-at-home orders, have made it more difficult for people to connect with others, resulting in increased social isolation and stress. The negative impact of social isolation, anxiety, and depression also include impaired executive function, accelerated cognitive decline, poor cardiovascular function, and impaired immunity (Novotney, 2019). The stress of remote learning has affected the behavioral health of adolescents, with new diagnoses of attention deficit hyperactivity disorder increasing by 67 percent in March 2020 (Novotney, 2020). Likewise, greater baseline stress has disrupted sleep patterns for some individuals, increasing the incidence of insomnia symptoms and prescriptions for anti-insomnia medication (Morin and Carrier, 2021; Express Scripts, 2020). Compared to 37 percent of men, 53 percent

of women report negative mental health outcomes related to the pandemic. Older adults have been particularly affected, as their increased susceptibility to COVID-19 necessitated continued distancing despite the resulting emotional distress.

Social isolation is also associated with an increase in the risk of premature cardiovascular disease mortality (Alcaraz et al., 2018). There are also concerns about increased rates of suicide, driven by the increased rates of depression and anxiety. Suicidal ideation has more than doubled for adults, including evidence of greater risk for marginalized populations (Wan, 2020). As the story below from Michael Bamarni, who lost a loved one to suicide, demonstrates the impact of these losses can be profound (see *Box 1-5*) (Bamarni, 2021).

Unsurprisingly, COVID-19 has also placed significant strain on families and communities. New stresses related to financial constraints with job losses, interruptions in usual health care, lack of childcare, lack of family supports, changes to education structures and online schooling, and concerns about child education and development for children with existing delays are present. Economic challenges have created additional stress for individuals and families who may struggle to cover basic necessities like food or housing (Woolf et al., 2021). As mentioned above, women have been significantly impacted by stress during the pandemic. Further, the stress is experienced in people of all ages. Children, especially school-aged youth, have also been negatively affected by family stress, lack of access to community anchor institutions such as schools, and the limitations on outdoor activities, interpersonal development, and peer-to-peer connectivity. Studies have shown children living in higher-risk areas for COVID-19 to be at greater risk for psychological distress during the pandemic (Qin et al., 2021; Golberstein et al., 2020; Xie et al., 2020). Distressingly, ED visits related to mental health have increased substantially for children (24 percent) and adolescents (31 percent) during the pandemic (Leeb et al., 2020). As the pandemic

BOX 1-5

Stories of Lived Experience: Impact of Suicide on Loved Ones

"As someone who has lost a loved one to suicide, I understand why it's such a taboo topic. There are layers of anger and guilt over their decision, but also sadness and confusion. Why did they do it? Why wasn't I enough? What am I going to do without them? Who am I without them? Am I really never going to see them again?"

—Michael Bamarni, a man who lost a loved one to suicide

SOURCE: Bamarni, 2021.

extends well into 2021, the prolonged disruption to school, social activities, and educational and developmental trajectories for children and young adults has raised concerns about the long-term mental health effects for this "lost generation" (Kwai and Peltier, 2021; Santora, 2020).

Lastly, while the pandemic has added to the stress of all Americans, the mental health impacts have been especially severe for low-income populations and communities of color. During the COVID-19 pandemic, low-income populations and households with job loss report higher mental illness rates than those who have not lost a job or who have not experienced income loss (53 percent versus 32 percent). In addition, Black and Latinx individuals have reported greater rates of anxiety or depressive symptoms. The mental health impact for essential workers—among whom people of color are overrepresented—has been particularly negative (e.g., nearly threefold increase in experiencing suicidal thoughts) (Panchal et al., 2021). The trends are particularly alarming considering that these populations already had worse access to mental health services than White populations before the pandemic (SAMHSA, 2020a).

Increased Risk of Abuse

Intimate partner violence and child abuse and neglect are also exacerbated by structural and interpersonal changes resulting from the pandemic. This includes increased rates of abuse and neglect and related increases in mental illness such as depression, post-traumatic stress disorder, and substance misuse (Mechanic et al., 2008). For example, female survivors of intimate partner violence were more than twice as likely to experience depression or anxiety (Chandan et al., 2020). In addition, victims of child abuse and neglect and other adverse childhood experiences are well documented to be at greater risk for mental illness, functional impairment, and onset of risky behaviors, especially in the absence of access to best practice interventions (Springer et al., 2003).

Consequently, the prolonged restrictions of the pandemic raised concerns about the potential consequences of intimate partner violence and child abuse (SAMHSA, 2020b; Usher et al., 2020). For example, domestic violence hotlines experienced greater traffic during lockdowns, and cases are suspected of having increased significantly during the initial quarantine period (Hsu and Henke, 2020; Taub, 2020). Likewise, advocates and experts are concerned about the potential increase in child abuse and neglect, as the pandemic has limited school- and community-based reporting, which are the primary means of risk detection (Abramson, 2020; Schmidt, 2020). For instance, child reporting agencies have highlighted a decrease in notifications ranging from 20 percent to 70 percent during the pandemic. At the same time, CDC data indicates that ED visits due to child abuse and neglect

declined by 53 percent in the spring of 2020, raising concerns about victims "suffering in silence" (Baron et al., 2020; Swedo et al., 2020).

Exacerbation of Behavioral Health Problems

In addition to increasing the incidence of anxiety and depression, the strain of COVID-19 has exacerbated existing behavioral health problems for many Americans and increased rates of substance misuse. More than 13 percent of adults reported "new or increased substance use" (Czeisler et al., 2020). Alcohol sales have increased more than 25 percent, with new applications for online ordering and delivery increasing the ease of access (Van Beusekom, 2021). Similarly, cigarette sales increased during COVID-19, outpacing tobacco companies' expectations (Maloney, 2020). In addition, opioid and stimulant use is on the rise across the country. A recent analysis of 500,000 urine drug tests showed an increase of 32 percent in use of nonprescribed fentanyl, 20 percent for methamphetamine, and 10 percent for cocaine from mid-March through May 2020. Collectively, over 81,000 Americans died from a drug overdose in 2020—a record for overdose deaths in a 12-month period (CDC, 2020a).

Lastly, the negative health outcomes arising from intersections between COVID-19 and behavioral health have only been magnified for communities of color. For example, while the prevalence of substance use disorder is similar between Black and White populations, hospitalization and fatality rates were approximately 1.5 times higher for Black COVID-19 patients with substance use disorder than White patients (Warren and Smalley, 2020). Likewise, Black and Latinx people with mental illness or substance use disorders are incarcerated or experience housing instability at higher rates than the population at large (SAMHSA, 2020c). Further, people with mental illness tend to be incarcerated rather than receive community-based interventions, and Black individuals in correctional care facilities are frequently less likely to be diagnosed and referred for behavioral health compared to White patients (Piscitello et al., 2020; Kaba et al., 2015; Poyaoan, 2013). Together, these trends highlight how structural and institutional racism both increase the risk of poor outcomes from COVID-19 (e.g., representation in high-risk settings) and the negative spillover effects for other dimensions of health (e.g., poor baseline diagnosis and treatment of mental illness) for communities of color.

Treatment Services for Behavioral Health

Despite the increasing rates of behavioral health concerns and conditions, access to treatment, services, and supports is in major shortage across the country, and the pandemic has further exacerbated this problem. Prior to the pandemic,

projections indicated shortages in behavioral health practitioners (e.g., psychiatrists, psychologists, substance abuse and behavioral disorder counselors, mental health and substance abuse social workers, mental health counselors) by 2025. The need for behavioral health among Americans due to the pandemic will significantly outpace the addition of providers to the workforce and access to evidence-based care around the country (KFF, 2021).

One positive development during the pandemic was the new CMS flexibilities for telehealth, which supported an unprecedented expansion in virtual care offerings, including for behavioral health services (CMS, 2020c; HHS, 2020b). Generally, telehealth options have been well received by people in need of behavioral health services and service providers. While telephonic and telehealth access is by no means a solution for the systemic shortage of behavioral health services and providers, virtual care platforms have been critical for extending access during the pandemic (Warren and Smalley, 2020). Access to telephonic services and telehealth must be balanced with the need for high-quality care. In addition, uptake of tele-mental health services has remained robust even after outpatient facilities reopened (Mehrotra et al., 2021).

Still, transitioning to virtual support can be problematic for some patients. Therefore, care should be taken to address challenges such as building provider-patient relationships, overcoming language barriers, having privacy at home or in multigenerational houses, and providing access to and capacity for using technology, especially for older adults. Additionally, while changes in telehealth are beneficial, not everyone has access to high-speed internet connections or technology to support video-enabled visits (e.g., nearly half of seniors lack a smartphone), requiring regulatory flexibilities to address major barriers and providers to get creative with telephonic supports (Pew Research Center, 2021). For example, in some cases, patients have had to use the Wi-Fi services at local McDonald's parking lots to dial in to support groups. Indeed, early evidence suggests different rates of telehealth uptake across socioeconomic groups and differences in receptivity to audio- versus video-enabled services for different populations (Darrat et al., 2021; Fischer et al., 2020).

Impact of COVID-19 on Non-COVID-19 Health Conditions

Since March 2020, the COVID-19 pandemic has caused disruptions in care continuity for patients, families, and communities. Preventive care, screening, and chronic disease management have been modified to prevent the spread of COVID-19, and the implications for the health of patients and families are undeniable. Further, there have been disruptions to home- and community-based care, which have largely impacted families, older adults, and communities.

Challenges to Receiving Preventive Care and Screening

The closure of many physicians' offices during the spring of 2020 led to a significant decline in delivering many preventive health services. For example, while primary care appointments could still take place virtually, research has found the content of outpatient telehealth visits differs from an in-person visit, with lower rates of blood pressure level assessments (50 percent decline) and cholesterol level assessments (37 percent decline) for telehealth visits (Alexander et al., 2020). Likewise, rates of diagnostic services such as colonoscopies (88 percent decline) and mammograms (77 percent decline) decreased substantially during the spring of 2020 and continued to remain well below pre-pandemic baselines into the fall of 2020 (Kliff, 2020). It must also be reiterated that virtual primary care appointments are only available to some, with patients of color disproportionately experiencing barriers to telehealth access and primary care physicians. Some delayed or deferred care may represent waste or low-value care (e.g., age-inappropriate screenings), and the COVID-19 pandemic may yield new insights about over-diagnosis and the appropriateness of different health services (Cooney, 2021; Kim et al., 2020a).

Delays for various types of health services during COVID-19 are cause for concern. For example, children have had less access to routine health care and life-saving vaccines typically delivered at well-child visits, raising concerns about their vulnerability to illness in the future (AAP, 2020; Santoli et al., 2020). A particular area of concern is measles, which had begun to make a resurgence in the United States before the pandemic (Paules et al., 2019).

Changes to Chronic Disease Management

Experts in the spring of 2020 warned that COVID-19 might be accompanied by a second, "hidden" pandemic due to disruptions in chronic disease management (Barnett, 2020). Over 60 percent of Americans have at least one chronic disease, with illnesses such as cardiovascular disease and cancer accounting for most of the country's morbidity and mortality burden (CDC, 2021h). However, the pandemic presented many challenges to effective chronic disease management. First, many physicians' offices were closed during the spring of 2020, making it difficult for some patients to present for treatment services in person (SAMHSA, 2020). Some patients were also hesitant to seek treatment in the early days of the pandemic for fear of contracting COVID-19. Others who sought help had trouble obtaining resources, as facilities limited services (e.g., to individuals who were at high risk of contracting COVID-19) or even closed for multiple reasons (e.g., public health compliance, lack of PPE to protect the workforce, workers getting sick and experiencing burnout, transitioning to telehealth options).

Further, patients who had previously relied on clinical trials found their access to cutting-edge treatments for various health conditions reduced because of COVID-19. For example, a review of a nationwide database of trials estimated that from January to May 2020, there were 42 percent fewer oncology trials actively recruiting compared to a year prior (Gongora et al., 2021). In a starker example, at the University of Pennsylvania's Abramson Cancer Center, nearly 90 percent of cancer clinical trials suspended enrollment in spring 2020. Those that continued last April and May had less than a third of their baseline enrollments, limiting cancer patients' access to vital resources.

Emerging evidence illustrates the scope of disruptions in care continuity. For example, hospitalization rates for many chronic illnesses have declined, including heart failure (nearly threefold) and chronic obstructive pulmonary diseases (nearly fourfold) (Blecker et al., 2021). While declines could represent a response to previous overuse, the decrease in hospital admissions for emergencies such as stroke (49 percent reduction) and heart attacks (39 percent reduction) highlight the negative impact of deferrals on patient health (Bhambhvani et al., 2021). Overall, 41 percent of adults report delaying medical care in the spring and summer of 2020, with COVID-19 playing a key role in many patients' decision making (Anderson et al., 2021). Distressingly, delays were more common for Black and Latinx patients than White patients—another example of how the pandemic is widening existing disparities in health outcomes (Czeisler et al., 2020).

Impact of COVID-19 on Community-Based Services

Beyond clinical needs, the pandemic has also significantly affected access to key community services, ranging from the needs of specific populations (e.g., older adults, the disabled) to the exacerbation of social needs and risks (e.g., food, housing).

Disruption to Home- and Community-Based Care

Direct care workers serve twenty million older adults and adults with disabilities who need assistance with activities of daily living (e.g., bathing, dressing) and other routine tasks (e.g., cooking, shopping) (Scales, 2020). Recipients of home- and community-based services are disproportionately older adults and people of color, have chronic illnesses complicated by functional deficits compared to their peers, and are at increased risk for severe illness and death if they contract COVID-19 (CDC, 2021h; Sonnega et al., 2017). Unfortunately, most communities have no system for distributing PPE to or routinely testing these essential workers. Some, fearing the effects of the virus for themselves and their families, stopped

working. Others, fearing losing their jobs and income, continue to put themselves and their clients at risk. Common themes emerging from qualitative interviews with a sample of such workers in New York City during the pandemic were feelings of being invisible despite their frontline responsibilities and anxiety over trade-offs they made related to their work and personal lives (Sterling et al., 2020).

Impact on Patients with Disabilities

One in four adults in the United States lives with a disability, which encompasses many kinds of conditions, including physical (e.g., mobility limitations, sensory impairment) and cognitive (e.g., memory difficulties) disabilities (CDC, 2020b). While it is important to acknowledge the heterogeneity in communities with differing abilities in terms of risk level and access to resources, patients with differing abilities, in general, have experienced challenges during COVID-19. In addition, some disabilities increase the likelihood that individuals will contract COVID-19 and experience severe illness. For example, the nursing home population—which COVID-19 has disproportionately impacted—has high rates of physical (e.g., 80 percent requiring support for assisted daily living tasks) and mental disabilities (e.g., 48 percent suffering from some kind of dementia), for which support may have been less accessible during the pandemic (CDC, 2020c; Health in Aging, 2020). Likewise, claims data analyses indicate that the risk of death from COVID-19 was nearly three times higher for patients with developmental disabilities and intellectual disabilities (e.g., Down syndrome) (FAIR Health, West Health Institute, and Makary, 2020). Yet despite their elevated risk, support has often been lacking. For instance, some states' guidelines for allocating ventilators—later amended after intervention from the Department of Health and Human Services—discriminated against individuals with disabilities (Piscitello et al., 2020). Similar variation exists for states' prioritization frameworks for the COVID-19 vaccine (JHU, 2020). The challenges are layered upon the pandemic-era disruption to daily routines and support systems on which people with disabilities may rely.

Elevated Social Needs and Strain on Social Services

The health care consequences and financial strain of the pandemic have exacerbated the social needs of many families and communities. For example, millions of families faced housing instability (with thousands reporting evictions despite the CDC's moratorium), while rates of food insecurity doubled during COVID-19 (Nova, 2020; Schanzenbach and Pitts, 2020). These needs were often magnified for people of color, with food insecurity rates nearly twice as high for Black and Latinx families compared to White households (Harvard T.H. Chan School of Public Health, 2020). Community-based organizations (CBOs) have played a key role in supporting the

needs of patients and families during the pandemic, from coordinating with public health departments around COVID-19-related health needs to pivoting operations to virtual- (e.g., benefits counseling) and home-based (e.g., meal delivery) platforms (NCCARE360, 2020). However, increased demand for social services coupled with the logistical obstacles of the pandemic have created challenges for CBOs. For one, while some programs (e.g., meal delivery) increased due to demand, others have declined (e.g., transportation support). Additionally, the majority of CBOs report losing revenue during COVID-19, and staff layoffs coupled with declining volunteer support have constrained CBO capacity (Commonwealth Fund, 2020).

Impact of COVID-19 on Health and Social Equity

While the sections above note the distressing breadth of the pandemic's impact on patients, families, and communities, they also illustrate how each stressor and consequence of COVID-19 for the sector as a whole has been magnified for marginalized populations (see *Table 1-2*). It is necessary to emphasize that the pandemic did not cause these disparities so much as magnify existing inequities embedded into the structure of American society and the health system. Specifically, during the pandemic, the effects of structural and institutional racism, economic disparities, the gender gap, ageism, and environmental disparities have been felt by patients, families, and communities. The alarming effects of these inequities point to the need for the identification of approaches to improve the health and well-being of all patients, families, and communities.

Inequities and Structural Racism Exacerbates Impact of COVID-19 on Many Patients, Families, and Communities

Early in this paper, the authors detailed the impacts of structural and institutional racism on the health of communities of color and discussed the disparities in contracting, testing, contact tracing, and morbidity and mortality associated with COVID-19. Since structural and institutional racism are intertwined in all facets of the policies and systems in the United States, the impact on housing, education, employment, health care, the justice system, and other areas is evident. When combined with COVID-19, structural and institutional racism has ultimately led to the increased spread, worse health outcomes, and compounded risk factors that make the virus more dangerous and deadly for communities of color. In addition, the policies and systems in place across the nation reinforce stereotypes, discrimination, and unequal distribution of resources and are even more grossly magnified because of COVID-19. For example, housing practices that have led to segregation and low-income neighborhoods are exacerbating the impact of COVID-19 on patients,

TABLE 1-2 | The Disparate Impact of COVID-19 on Communities of Color

COVID-19 Impact Area	Pre-Pandemic Disparities	Pandemic-Era Disparities
Risk of Infection	People of color were disproportionately affected by infectious diseases (e.g. HIV/AIDS) and respiratory illness (e.g. asthma)	• COVID-19 infection rates were significantly higher for communities of color
Risk of Severe Illness	The prevalence of chronic illnesses such as cardiovascular disease and diabetes was higher among communities of color	• The burden of morbidity and mortality from COVID-19 was higher among Black and Latinx patients
Population-Specific Needs	People of color were overrepresented in essential jobs, justice-involved populations, and homeless populations, and more likely to live in poorer-quality nursing homes	• Communities of color had higher rates of COVID-19 hospitalizations and fatalities in the subgroups of the elderly, nursing home residents, adults, and children
Access to Health Services	Communities of color are more likely to be uninsured and live in a primary care shortage area	• Communities of color lacked ready access to diagnostic testing and were vaccinated at slower rates compared to White partners
Mental and Behavioral Health	People of color have less access to mental health services than White patients	• Incidence of symptoms of anxiety or depressive disorder during COVID-19 were higher for people of color
Non-COVID-19 Care	Black and Latinx patients at increased risk of early incidence and progression of chronic diseases	• Black and Latinx patients were more likely to defer or delay non-COVID-19 care during the pandemic
Social Needs	Income and wealth building inequality, ageism, gender pay gaps, and environmental disparities were prevalent throughout different facets of American society	• The pandemic exacerbated economic (e.g. financial security) and social (e.g. housing, food) needs among marginalized populations.

families, and communities (Yu et al., 2021). Likewise, educational systems in low-resource neighborhoods may have experienced more challenges instituting remote learning. With fewer eligible children receiving free or reduced school meals, schools may have found it more challenging to provide lessons to children who may now be going hungry (Bonney et al., 2021; Dorn et al., 2020).

Further health care disparities prior to COVID-19 exist in large part due to bias and discrimination. During the pandemic, these same biases and discriminatory practices could influence whether patients of color are turned away from hospitals, admitted, and treated. This was the case with Dr. Susan Moore, who experienced

BOX 1-6

Stories of Lived Experience:
Health Care Disparities During COVID-19

"I was crushed. He made me feel like a drug addict. And he knew I was a physician. I don't take narcotics . . . I put forward and maintain that if I was White, I wouldn't have to go through that."

—Dr. Susan Moore, a Black doctor who died from COVID-19 and reported undertreatment for pain

SOURCE: Nirappil, 2020.

racial discrimination while undergoing treatment for COVID-19, despite being a physician herself (see *Box 1-6*) (Nirappil, 2020).

Race-based discrimination has also been especially severe for Asian Americans and Pacific Islanders, who have reported greater exposure to stigma in surveys conducted during the pandemic (Lee and Waters, 2021). Hate crimes against Asian Americans and Pacific Islanders have risen by nearly 150 percent during 2020, even as overall reporting of hate crimes declined (Chaffin, 2021). Patterns of bias, discrimination, and stigma during the pandemic reflect the structural racism embedded against Asian Americans and Pacific Islanders in various facets of American society, including the health system, where disparities have long been masked due to the monolithic treatment of the diverse communities that comprise this population (Gordon et al., 2019).

Ultimately, the United States has yet to see and understand the long-term effects of this pandemic on the already fragile health system and associated social determinants of health as it relates to communities of color. Further, the pandemic will likely magnify and exacerbate the challenges caused by structural and institutional racism in education, wealth, health, and other areas for people of color for years to come unless action is taken.

Economic Disparities Are Worsening

The pandemic and associated physical distancing protocols spurred a national economic collapse, resulting in unemployment rates reaching a peak of nearly 15 percent in April 2020—the highest level of job loss since the Great Depression—and continuing to be twice as high as pre-pandemic rates as of December 2020 (Falk et al., 2021; BLS, 2020). The vast majority of those who have become unemployed

are in low-wage service industries. This group remains vulnerable to the downstream impacts of the pandemic—lack of access to food, housing instability, and financial insecurity—that are likely long term (Families USA, 2020). Further, millions of laid-off workers became uninsured during the pandemic recession, precipitating a nearly 9 percent increase in Medicaid enrollment (more than six million new beneficiaries) (Corallo and Rudowitz, 2021; Weissfeld et al., 2020). Additionally, over 250,000 individuals signed up for coverage after several state-based marketplaces opened special enrollment periods in 2020 to enroll newly uninsured, and an estimated 9 million Americans are eligible to participate in the special spring 2021 enrollment period (Keith, 2021; Lucia et al., 2020). The gender gap in employment losses due to COVID-19 is staggering, with women's participation in the labor force now at the lowest rate in over thirty years (Ewing-Nelson, 2021). Compared to men, who lost 4.4 million jobs, women have lost 5.4 million jobs during the recession. Intersections between gender, race, ethnicity, and income have resulted in Black and Latinx women experiencing higher rates of unemployment, lower earnings, and lower rates of contributions to retirement plans than White women and even wider gaps compared to White men. While the long-term impacts of the pandemic recession are unknown, it is likely that widening disparities by race, ethnicity, gender, wealth, and income will have significant consequences for communities, states, and the nation.

IMPACT OF COVID-19 ON PATIENTS, FAMILIES, AND COMMUNITIES' RELATIONSHIP TO THE HEALTH SYSTEM

Many patients, families, and communities experienced a lack of trust in government and science during the pandemic due to historical legacies of injustice and the disparate impact of the aforementioned challenges during COVID-19. This section will examine how the pandemic affected patients, families, and communities' trust in science and medicine and their relationship to other sectors of the health system. Areas of focus include:

1. Public trust;
2. Evidence-based science communication; and
3. Cross-sector relationships (see *Figure 1-3*).

Public Trust

Americans' trust in key public institutions and leaders—including the government and health system—was already at a generational all-time low when COVID-19 struck (Pew Research Center, 2020). In addition, inconsistencies

FIGURE 1-3 | Impact of COVID-19 on Patients, Families, and Communities' Relationship to the Health System

in communication and an uneven pandemic response have negatively impacted patients, families, and communities' trust in the health system. Based on feelings and instinct, this mistrust takes on many forms, including general unease, hesitancy, or suspicion, and can hinder outbreak containment efforts, from adherence to public health restrictions to hesitancy surrounding vaccines.

Growing mistrust among patients, families, and communities during COVID-19 must also be understood in light of historical and persistent racism in the health system. The past role of the scientific enterprise in mistreating marginalized populations (e.g., Black Americans and the Tuskegee syphilis study) and the present-day injustices experienced by communities of color in their interactions with American medicine (e.g., racial disparities in access to and quality of care) are important context for understanding patterns of mistrust during COVID-19 (Jamison, 2020; Kiesel, 2017). For instance, some fear that efforts to disseminate vaccines early to Black or other communities of color may be a way to use this historically disenfranchised group as "unwitting test subjects" (Jamison, 2020). One conspiracy theory circulating in Spanish on social media suggests that local testing sites are reusing dirty test swabs to deliberately infect people (Scheier, 2020). While the spread of fear, misinformation, and confusion can cause mistrust to flourish, these examples illustrate that the seeds of mistrust were planted well before the start of the COVID-19 pandemic.

Beyond the impact of structural racism, other reasons for mistrust and fear include the influence of anti-science or anti-vaccination movements, the unprecedented dissemination of misinformation and disinformation on social media, and the politicization of expertise—all of which are further detailed in the subsequent subsection (Trogen et al., 2020; Roberts, 2019). Mistrust has only made it more difficult to provide patients, families, and communities with the best information and care at the right time and will continue to hinder efforts at preventing, diagnosing, and treating COVID-19. Ultimately, this mistrust will greatly negatively impact the health of patients, families, and communities for years to come.

BOX 1-7

Stories of Lived Experience: Communicating Science to the Public

"I think there are a lot of people who don't understand the scientific thought process well – being able to recognize the difference between current theories and established information . . . I think if people understood the process of establishing theories better, they'd be more supportive."

—John Hartwig, a professor of chemistry at the University of California, Berkeley

SOURCE: Krämer, 2019.

Evidence-Based Science Communication

As a novel pathogen, the evidence base for COVID-19 has rapidly evolved throughout the pandemic as leaders in research, clinician care, and policy making sought to understand the mechanisms of transmission, impact of infection, differential risk for sub-populations, and effectiveness of new medical countermeasures. While the extraordinary rate of scientific progress during the pandemic should be celebrated, leaders from all sectors encountered challenges with effectively communicating the dynamism of scientific research and data and its influence on practices and policies in an accessible manner for the public. This is exemplified by a statement from John Hartwig, a professor of chemistry at the University of California, Berkeley (see *Box 1-7*) (Krämer, 2019).

Challenges for communication were especially amplified for patients, families, and communities due to the politicization of expertise, with surveys revealing stark differences in perceptions of pandemic response and scientific understanding of COVID-19 along politically partisan lines (Rothwell and Desai, 2020). While differences in health literacy may affect people's ability to understand nuances about COVID-19 and information on vaccines, the politicization of information and expertise has had a clear impact on the actions of patients, families, and communities, as demonstrated by an anonymized patient story shared by the dean of Clinical Affairs at Baylor University (see *Box 1-8*) (McDeavitt, 2020).

While this patient at Baylor University ultimately recovered, he saw three members of his family become hospitalized for COVID-19, with one family member later passing away (McDeavitt, 2020). This story is sadly not unique in the United States during COVID-19. In a May 2020 survey, more than two-thirds of Americans reported worrying about the volume of fake news and false information being spread about the virus, with close to half commenting on the difficulties of finding

BOX 1-8

Stories of Lived Experience: Perceptions of the Pandemic Response

"'I thought it was all a big hoax – the government trying to take control of things.' He knew people in other parts of the country had the virus, but he did not personally know anyone who had it. He didn't even know anyone who knew anyone who had it. The response of media and civic leaders seemed overblown. 'It was a big nothing. Thankfully, it seemed now it was behind us. We were opening back up. We had beaten the virus.'"

—Central Texas resident, who became ill with COVID-19

SOURCE: McDeavitt, 2020.

reliable and trustworthy information about COVID-19. The updated January 2021 survey noted that less than one in four respondents have good information hygiene (e.g., verifying information, engaging with the news, not amplifying unvetted information). Misinformation has been amplified by social media with negative consequences for each stage of pandemic response, from a climate of fear around lockdowns to wearing masks to hesitancy surrounding vaccination campaigns, as Dr. Sandra Quinn explains below (see *Box 1-9*) (Bowman, 2020).

Cross-Sector Relationships

As illustrated by the other discussion papers in the *Emerging Stronger After COVID-19* series, each sector of the health system has encountered its own distinct challenges during COVID-19. However, these different challenges share

BOX 1-9

Stories of Lived Experience: Challenges with Communicating COVID-19 Messaging

"We have forces that undermine science, contradictory messages day in and day out that create skepticism and diminish trust in government."

—Dr. Sandra Quinn, professor and chair of the family science department at the University of Maryland

SOURCE: Bowman, 2020.

a common denominator: they all affect the health and well-being of patients, families, and communities. Consequently, it is worth highlighting select examples to illustrate the importance of centering the challenges and lessons of the pandemic through the lens of patients, families, and communities.

For example, a bright spot of the pandemic has been the remarkable advances in scientific research and product development for COVID-19. However, many of the populations most affected by COVID-19 (e.g., racial and ethnic minorities, older adults) were the least represented in key clinical trials (Chastain et al., 2020; Helfand et al., 2020). At the level of the public health system, the experiences of many patients, families, and communities during COVID-19 went unrecorded due to inadequate collection of demographic information, including patient-level data on race and ethnicity. For the patients who did become infected, access to care delivery was affected by biases built into clinical algorithms and gaps in access to primary and specialty services. For example, there were no ICU beds available in nearly half of the nation's lowest-income communities; yet only 3 percent of the highest-income communities had the same problem (Kanter et al., 2020). Challenges with delivery should be interpreted in the context of challenges with quality and safety, including the variation in nursing home environments for patients of color and the inadequate attention of measurement systems to social needs and environmental risks.

Collectively, these examples illustrate how the experience of patients, families, and communities during COVID-19 must be understood in the context of their relationships with other sectors—and how improving population health and health equity during the COVID-19 pandemic and beyond will require a fundamental recentering of each sector around the perspectives of patients, families, and communities.

RESILIENCE OF PATIENTS, FAMILIES, AND COMMUNITIES IN THE FACE OF ADVERSITY

Despite the many physical, psychological, and emotional challenges and hardships described in this paper, patients, families, and communities continuously reflect strength and emerge more resilient even as the pandemic persists. Patients, families, and communities have not only adapted but found ways to thrive despite the adversity, trauma, and tragedy experienced because of the pandemic. Studies demonstrate that psychological resilience for individuals during the pandemic is due to modifiable factors that are pivotal to coping, including going outside, exercising, planning day-to-day routines, and praying (Killgore et al., 2020;Vinkers et al., 2020). Certainly, individuals deemed as essential by the federal government have continued to work tirelessly to support others. Families have found ways to be close to each other despite physical distancing through using video-based programs

and applications to celebrate important moments. Communities have cultivated coping and resilience through supports for patients and families. One example is the resurgence of mutual aid groups who support neighbors with COVID-19 by providing food delivery and supplies, which has helped to address the immediate needs of individuals in their communities. These informal efforts and grassroots organizing have helped to overcome existing gaps in social networks in ways that government or large institutions have been unable to do (Poyaoan, 2013). Within communities, food banks and drives have been developed and scaled to address food insecurity. Collaborations such as those with NYC Health + Hospitals, the NYC Department of Health and Mental Hygiene, and other city agencies have created hoteling programs, where patients with COVID-19 can isolate and receive food and medical supplies while recovering (Help Now NYC, 2021).

Additionally, there are ongoing efforts to study and strengthen existing collaborations. For example, a safety-net health system in San Francisco leveraged partnerships to repurpose existing systems and ensure that the most marginalized are receiving all of the community services and resources for which they are eligible (Brewster et al., 2020). Likewise, partnerships between key stakeholders from the academic medical center, the state department of health, and the homeless shelter network in Arkansas developed a streamlined referral process and quarantine strategies for individuals who are homeless (Hadden et al., 2020). CBOs are recognizing the needs in their communities and banding together to address them, as the example below makes clear (see *Box 1-10*) (personal communication, 2020).

BOX 1-10

Stories of Lived Experience: Community Collaboration and Resilience in Support of Individuals During COVID-19

In April 2020, as the spread of COVID-19 was accelerating, five community-based nonprofits formed the Latinx COVID-19 Collaboration. They saw a clear need, as Latinx individuals comprise 15% of San Francisco's total population but make up almost 50% of the city's COVID-19 cases. The collaboration includes a broad range of providers, ranging from mental health and immigrant rights nonprofits to organizations serving children and seniors. The collaboration has focused on implementing a COVID-19 response that integrates community-level prevention education, testing, and contact tracing with access to health care and supportive services, particularly housing, cash support and food. To strengthen and sustain its efforts, the collaboration has developed partnerships with San Francisco's Department of Public Health, the Office of Economic and Workforce Development, and a variety of private philanthropies.

As the pandemic continues, and even after, and as leaders in the health system address the challenges, coping and resilience will be essential to overcoming the effects of the pandemic. The lessons learned by the exemplars above, and the many more that exist, represent the fortitude that exists among patients, families, and communities.

TRANSFORMATIVE POLICY, REGULATORY, AND LEGAL CHANGES FOR IMPROVEMENTS TO PATIENTS, FAMILIES, AND COMMUNITIES

The challenges faced by patients, families, and communities are multifaceted and wide ranging. Yet, there are opportunities to leverage the resilience displayed during the pandemic, the existing resources of the sector, and collaboration across the health system to improve the health and well-being of all people in the United States during and after the pandemic. Foundational to achieving system-wide transformation will be ensuring that America's post-pandemic health policy roadmap is centered around the needs, interests, health, and well-being of patients, families, and communities. This section outlines priorities for policy making, regulatory guidance, and legislation to transform the current health system into one that centers patients, families, and communities; supports the existing resiliency at the broader community level; and ensures efficacy, effectiveness, and equity. The key domains for transformation include:

1. Facilitating active, continued, and meaningful engagement with patients, families, and communities;
2. Building and restoring trust through improving communication, working with trusted sources, and translating scientific practices;
3. Prioritizing investment in solutions designed to advance health equity;
4. Realigning care approaches to meet the needs of patients, families, and communities; and
5. Examining critical intersections and implementing aligned solutions between patients, families, communities and other sectors.

Facilitate Active, Continued, and Meaningful Engagement with Patients, Families, and Communities

The core and foundational elements of the U.S. health system (e.g., financing and payment policies, care delivery practices, and decision making) were not developed or initially implemented in consultation or collaboration with patients,

families, and communities. While efforts to engage these groups have certainly improved, the COVID-19 pandemic has emphasized the challenges and needs of patients, families, and communities are not well understood. Achieving active, continued, and meaningful engagement can bring about substantive and powerful changes that improve the health of the community and its members. Meaningful engagement of patients, families, and communities requires mobilizing resources, shifting power structures, redistributing resources, influencing and changing original systems of thinking, and shaping relationships among partners. Meaningful engagement can be catalytic and serve as the foundation for changing policies, programs, and practices (CTSAC, 2011).

Meaningful engagement also requires that leaders across all sectors engage those who use and are impacted by health and health care services. In particular, partnerships and collaborations with patients, families, and communities should include those who are most often left out, those who are often not well represented or well treated, and those who often have solutions to the challenges impacting them (e.g., communities of color, low-income populations). These communities should not just be asked to provide input along the margins or "rubber stamp" decisions made by others but be actively and consistently involved in the codesign of the system and collaboratively engaged in such topics as payment reform, performance measurement, quality improvement, health and biomedical research, use of digital health, and data sharing. Engagement with patients, families, and communities creates trust, facilitates multidirectional learning and inclusivity, and builds on the inherent resilience and strength of communities leading to healthier people and transformed health systems. For example, some coordinated care organizations (CCOs) in Oregon have been working to meaningfully engage patients and families (Oregon Health Authority, n.d.). CCOs are local and exist through partnerships with care providers, community members, and health system stakeholders that take on risk and financial responsibility for providing person-centered care and improving patient outcomes (Oregon Health Authority, n.d.). While this model continues to improve and build on lessons learned, it intends to place the patient at the center and shift power within the existing system to ensure that partners are equally involved in redesigning the system.

Further, as trust between patients, families, and health care teams in hospitals and other health care settings needs to be rebuilt, accelerated implementation of evidence-based strategies to improve engagement and prevent unnecessary and stressful breakdowns in communication are critical. Lessons can be learned from the Transitional Care Model and applied to other settings during and post pandemic to improve patient education, medication management, patient and family engagement, follow-up care, and health care provider accountability and engagement.

BOX 1-11

Considerations for Facilitating Active, Continued, and Meaningful Community and Health Care Engagement with Patients and Families

- Orient transformation efforts across all sectors of the health system and ensure alignment with the community's focus on the experiences and needs of patients and families.
- Affirm commitment to and investment in programs for patient-centered research, measurement, and care delivery.
- Leverage incentives and regulatory guidance to improve the representation of patients, families, and communities in decision making and governance across the health system.

Additionally, fostering trust between patients, families, and digital health developers and users can ensure that care practices are aligned and meet the direct needs of patients, taking into account potential barriers. For example, as telehealth, artificial intelligence, and machine learning innovations are designed, implemented, and evaluated, full and equitable engagement of patients and families can enhance trust and potentially lead to improved patient outcomes.

Federal and state legislative bodies could also assist and play an active role in ensuring that all sectors engage critical participants.This could be done by requiring such participation when allocating funding, training, and assistance, enabling community members to collaborate on policy solutions and guidance for policy makers and other government agencies. Policy makers could also reaffirm their commitment to existing programs and initiatives across the health and health care sectors, such as quality and safety (e.g., patient-reported outcomes at CMS) and biomedical research (e.g., patient-focused drug development at the FDA). Further, lessons about how to effectively engage patients, families, and communities can be leveraged from methodologies used for community-based participatory research and patient-centered outcomes research, including approaches on multidirectional learning and use of financial incentives to recognize participation (see *Box 1-11*).

Building and Restoring Trust Through Improved Communication, Trusted Sources, and Translation of Scientific Practices

The COVID-19 pandemic has underscored the historical and contemporaneous drivers of a lack of trust among patients, families, and communities in the different sectors of the U.S. health system. Restoring trust is a prerequisite for the health

system to achieve meaningful improvements in the health and health outcomes of patients, families, and communities. Therefore, in addition to the priority action listed above of orienting health system transformation around the experiences of patients, families, and communities, policy makers and system leaders should also consider the following actions to overcome mistrust and distrust, especially among marginalized and under-resourced populations.

First, restoration of public trust can occur with leaders following crisis communication principles laid out by the CDC and endeavoring to separate political aims from science-based and health-related messages. A unified and agreed-upon strategy for communication and outreach into communities that lack trust can help to build back a sense of inclusion. Health sector leaders should recognize that communication cannot take a one-size-fits-all approach and that messages must be tailored and translated to various communities and populations. As such, leaders working with patients, families, and communities must examine and test effective strategies and messages to communicate various topics as society continues to learn from the lessons of the pandemic and as system-wide transformation is hopefully accelerated due to COVID-19. Particular attention should be paid to adaptations in these strategies and messages to address unique trust issues of communities who are most impacted by structural racism and inequities, bearing in mind the unique experiences and history of interaction with the health system in the community.

Second, sector leaders should be mindful of not just the information and messages being communicated but also who is communicating the information. Early in the pandemic, there was strong public demand for expert voices, as people wanted to hear from the most trusted sources of information: scientists (83 percent), doctors (82 percent), and national health officials (77 percent) (Edelman Trust Barometer, 2020). More information from scientists, doctors, and national health officials is needed, and it is important for these experts to also dedicate time and effort to educating the public on how the scientific process works: making observations, creating a hypothesis to explain them, and testing that hypothesis by making more observations. Science, and the policies informed by that science, must follow the path suggested by factual observations, and communication to the public that decisions and approaches may change as more observations are made is critical (Skorton and McKinney, 2020).

Third, further consideration of trusted sources of health and scientific information beyond scientists, doctors, and health officials should be considered. As of January 2021, the public's view of trusted sources shifted to still include scientists (69 percent), as well as people in the local community (62 percent) and employers (60 percent) (Edelman, 2021). Translated and tailored messages can also be reinforced with patients, families, and communities by those viewed as reliable, credible, trustworthy, knowledgeable, and having the interest of

BOX 1-12

Considerations for Building and Restoring Trust Through Improved Communication, Trusted Sources, and Translation of Scientific Practices

- Separate scientific and medical messaging from political aims and incorporate the CDC's best practices for crisis communication.
- Empower scientists, doctors, and public health officials and dedicate resources and training to improve communication to different segments of the public.
- Partner with community leaders beyond health professionals and invest in diversifying the pipeline of health leaders to improve communication with marginalized people and families.

the community in mind, such as religious leaders, community health workers (CHWs), and employers. For example, CHWs and the CBOs that often employ them, have played a critical role during the pandemic, serving as first responders and closing gaps in contact tracing, testing, and vaccination for communities of color (Rahman et al., 2021; Wells et al., 2021). Given the lack of diversity among the health and health care workforce, building a pipeline of professionals, such as CHWs and non-clinical patient navigators, throughout the health sector can further lead to effective communication and built trust (see *Box 1-12*).

Prioritizing Investment in Solutions Designed to Advance Health Equity

Addressing the systems of inequity exposed by COVID-19 requires that first and foremost, individuals, caregivers, and members of communities, especially people of color and of lower socioeconomic status, be empowered as active partners in the design, implementation, and evaluation of health equity policy solutions. Human-centered design principles can be used to achieve solutions to complex, multifaceted issues, such as those in health and health care, through co-design where being people-centered—focusing on the needs and abilities of people—is critical. Further, recognizing the influence of intersectionality requires the empowerment and active engagement of individuals and people with intersecting identities to develop solutions that address the root causes of inequities.

Second, leaders, including mayors, governors, congressional representatives, chief executive officers (of nongovernmental organizations, health systems, digital health development companies, and many others), must take actions within their sphere of influence to advance health equity. These and other leaders should

move beyond merely describing the factors that affect health and investigate the most effective way to measure health equity among patients and communities (Dover and Belon, 2019). To track the progress made, there is a need to develop robust measures and measurement systems that capture performance in advancing health equity (e.g., federal, state, and local systems that collect standardized, valid data about an individual's demographics, including race, ethnicity, health-related social needs, and community's social determinants, and also enable aggregate and stratified reporting of these data). A 2019 National Academies consensus study offers examples of how policy makers and system leaders can better leverage data and digital tools to integrate social care into health care delivery (NASEM, 2019). Likewise, 2016 guidance for academic medical centers on assessing outcomes and communicating the value of biomedical research for the sector could be expanded to prioritize a broader constellation of social, political, and economic levers central to measuring efforts to advance health equity (Guthrie et al., 2016). Approaches such as these would foster the resilience of the entire health system by ensuring greater access to real-time data for early action and could be accelerated by federal funding or mandates, although there is also a role for private funders.

Third, multisector partnerships with the leaders mentioned above and organizations should be developed and structured to prioritize equity. Not only should equity be characterized as an outcome or goal of the partnership, but it should be integrated into all aspects and components of the collaborative function and strategy, such as inputs, processes, activities, and outputs. For example, it is important that tools such as health impact assessments are refined and expanded to allow policy makers to understand, in advance, the effect of any proposed local, state, and federal policies on equity before these policies are implemented. It is also important to evaluate the impact of these policies on equity after implementation, so stakeholders can understand where they were effective, why they were effective, and which policies need to be adjusted.

Last, leaders across all sectors should work collaboratively to create solutions that address the root causes of inequity, including social determinants of health and the structural and institutional racism that is the underpinning of American society. While strategies associated with interventions at an individual level (e.g., addressing food security, transportation) enable some progress, addressing the root causes of inequities through federal- and state-level policies and legislation at a population level will have the greatest impact on advancing equity. Social and economic policies and legislation outside of health and health care for populations most affected by structural and institutional racism, such as those dedicated to increasing opportunities for wealth, education, and housing, can significantly impact health outcomes. A state and federal legislative focus on equity will ultimately improve health outcomes and reduce the need and use of health care (see *Box 1-13*).

BOX 1-13

Considerations for Prioritizing Investment in Solutions Designed to Advance Health Equity

- Empower patients and families as active partners in the design, implementation, and evaluation of organization and community health equity policy initiatives, particularly through human-centered design principles.
- Invest in robust digital tools and data systems for collecting and measuring health inequities and progress to advance equity.
- Develop and structure multisector partnerships around health equity.
- Engage with leaders outside the health system to develop strategies for addressing the root causes of inequity, including social, economic, and environmental drivers of health.

Realigning Care Approaches to Meet the Needs of Patients, Families, and Communities

The toll of the COVID-19 pandemic on behavioral health access and treatment, long-term care, community-based care, and social needs is evident. As society emerges from the pandemic, transforming and realigning how the health system approaches and meets the needs of patients, families, and communities is crucial.

First, care approaches must focus on prevention. Strategies and programs targeted to supporting community mental health (e.g., Mental Health First Aid, trained CHWs), reducing social isolation, addressing adverse childhood experiences, and providing care to people coping with the loss of loved ones should be expanded and accelerated into widespread use. These programs, which can prevent the long-term consequences of stress reactions due to the pandemic, when developed alongside patients, families, and communities, can provide the supports that are oriented to real, not perceived, needs. Further, new investments must be instituted to develop multipronged strategies targeted toward improving the accessibility and use of preventive screening (e.g., public service announcements coupled with direct outreach from trusted clinicians and CHWs). These investments should be focused on populations with low incomes and communities of color to avert the worsening health impacts that were exacerbated due to the pandemic.

Second, revamping home- and community-based services (HCBS) care is necessary to advance the lessons learned from the pandemic and translate them to post-pandemic activities that will benefit patients, families, and communities. The disproportionally high rates of COVID-19 infections and deaths among

older populations have further highlighted the need to invest in the organization, funding, and regulation of long-term care services to ensure that individuals receive needed services in the most appropriate setting. There is an opportunity to assess lessons learned from state use of Medicaid flexibilities to address the needs of HCBS during COVID-19 or other pandemics and explore what can be permanently implemented to support long-term services and supports (Anthony et al., 2021). Further, increased investment in HCBS would enable more long-term care recipients to remain in their homes. In addition, current innovations, such as increased flexibility in telehealth reimbursement, support this modality of service provision. Policies that require that a fixed share of Medicaid HCBS payments be directed to caregivers through wage floors and wage pass-throughs would help ensure better pay and improved benefits for Medicaid-financed caregivers. Additionally, regulators should shore up infrastructure for community services (e.g., senior centers, home-delivered meals, legal assistance) given the distressing experiences of many seniors during COVID-19 (e.g., food insecurity, loneliness) (Goger, 2020; Vahia et al., 2020).

Third, with the increased need for behavioral health services due to the impacts of the pandemic, providers need to be prepared to deliver more care at higher quality. Medical home models, such as Vermont's Integrated Health Services Model, can provide care that "is patient-centered, comprehensive, team-based, coordinated, accessible, and focused on quality and safety" (PCC, 2021). This model facilitates and provides full integration of care to address patients' behavioral and primary care health needs, all while building strong patient and provider relationships (PCC, 2021). Other opportunities include a shift to reimburse behavioral health providers more for the care provided, especially given the need to increase providers and access post pandemic; full implementation of mental health parity law; expanded flexibilities, such as tele-behavioral health; and new practices, such as expanded availability of take-home medications for opioid use disorder (SAMHSA, n.d.). As the pandemic has made clear, safety net behavioral health providers operate on thin margins and have struggled to stay afloat during COVID-19. Enhanced Federal Medical Assistance Percentages for behavioral health services, increased investment from private and public payers, and encouragement of up-front payments to these providers would improve access to care, expand the reach of the "Money Follows the Person" demonstration to people with behavioral health needs, increase access to community-based services, and reduce unnecessary use of institutional care (CMS, 2020a). Relatedly, regulators should align Medicaid with the policies of other health plans to support a crisis response continuum that is community-based and diverts from costly sites of care (e.g., acute care and corrections settings) as outlined in SAMHSA's National Guidelines for Behavioral Health Crisis Care (SAMHSA, 2020d).

Fourth, aligning with the needs of patients, families, and communities requires an examination of who should and can provide care. There is a need to increase the pipeline of providers from diverse backgrounds including by race, ethnicity, language capacity, age, sex, and gender identity to improve access, trust, and communication, and provide culturally appropriate care (Takeshita et al., 2020). Clinician investment and training should focus on building a workforce prepared to address the unique stressors of diverse subgroups such as women, people with low incomes, populations of color, and their intersecting identities, as well as developing infrastructure and metrics to assess the quality of services provided. In many cases, patients, families, and communities want to receive care from those who act as liaisons between them and the health system, such as CHWs and peer providers. Encouraging maximum use of Medicaid/insurer-supported peer providers and ensuring a career ladder for them that is similar to what is in place for CHWs would grow the workforce and allow for more diverse providers facilitating coordination that meets the needs of those seeking care.

Last, further addressing the needs of patients, families, and communities would require changes to clinical practice. Specifically, clinicians should be able to continue to practice across state lines, and the telehealth flexibilities recently afforded by CMS, which have helped reduce traditional barriers to care, should be institutionalized (see *Box 1-14*) (APA, 2020).

BOX 1-14

Considerations for Realigning Care Approaches to Meet and Engage the Health-Related Needs of People and Their Families, and Strengthen Community Capacity

- Support the expansion of prevention programs focused on both primary care and behavioral health.
- Increase investment in home- and community-based services, including supporting the ability of patients to age in place and increasing resources available to Medicaid-financed caregivers.
- Implement payment reforms to increase coverage and access for behavioral health services.
- Expand networks of community health workers and peer providers to improve care coordination.
- Enhance the health professions workforce through a greater focus on diversity, cultural sensitivity, and scope of practice.

Examining Critical Intersections and Implementing Aligned Solutions Between Patients, Families, and Communities and Other Sectors

Transforming the patients, families, and communities sector ultimately cannot occur without intersection and alignment with the other eight health and health care sectors, as identified by the *Emerging Stronger After COVID-19* paper series. As such, there must be coordinated efforts across all sectors to engage patients, families, and communities and build trust. While successful implementation of each of the priority actions highlighted above will require collaborations with the other sectors, it is necessary to call out the need for additional alignment with specific sectors, particularly in the context of pandemic response. Select examples of intersections with other sectors are discussed below.

First, public health approaches and collaborations must be a core and prioritized focus of the health system. Traditionally, public health has operated separately and distinctly from other sectors and has not been integrated into responses to social and medical challenges (e.g., homelessness). As the United States moves forward with addressing COVID-19 and preparing for future pandemics, public health authorities should develop emergency response plans in conjunction with patients, families, and communities and other sectors. This would allow for proactive consideration of key questions of access (e.g., testing), mitigation, and equity (e.g., distribution of vaccines). Furthermore, proactive partnerships with patients, families, and communities would equip state and local public health leaders to better communicate to the public and partner with grassroots leaders and influencers to design targeted campaigns to combat potential misinformation in a crisis. Lessons learned from developing emergency response plans should be leveraged to facilitate collaborations between public health and other sectors to confront other pressing health care needs faced by people in communities.

Second, the research sector and public health sector should collaborate to expand patient-centered research for emergencies. For example, it would be beneficial for sectors to dedicate funding for studying strategies for community-based, culturally appropriate contact tracing and financial support for isolation and quarantine of low-income individuals to guide the response to future infectious disease outbreaks. Additionally, it will be important to build on the infrastructure developed during COVID-19 and increase access to clinical trial networks for marginalized populations to ensure biomedical research and research through health product manufacturers and innovators reflect the communities bearing the greatest health burdens.

Third, leaders from care delivery organizations, health plans, and digital health need to work together to improve the collection and exchange of health care

data both at baseline and in emergencies. Partnerships with patients, families, and communities will be key, as data collection efforts are more likely to be successful and mitigate historical distrust of the health care system when they include community members and organizations with established relationships with local residents and leaders. As previously noted, valuing patients, families, and communities requires collecting data that fully captures their experience. Developing infrastructure to collect data elements such as race, gender, sexual orientation, ethnicity, primary language, age, and socioeconomic status is critical to engage and inform patients, families, and communities. Further, developing frameworks to support the equitable development, implementation, integration, and evaluation of artificial intelligence and machine learning can support health stakeholders in the real-time use of these data to improve health outcomes, minimizing the opportunities to widen the chasm of disparities.

Fourth, intersections between payers and patients, families, and communities are critical for supporting family caregivers. Specifically, programs such as Medicaid Cash and Counseling and policies such as tax credits and paid leave for family caregivers would improve the quality of life for caregivers and their families. Likewise, coverage reforms for long-term care and support services would increase access to HCBS (Pearson et al., 2019). Beyond caregivers, payers and regulators could also support patients by investing in the health care workforce in their local communities. For example, developing reimbursement strategies for CHWs could both strengthen baseline health promotion efforts and improve preparation for emergencies.

Last, efforts of alignment are needed among patients, families, communities, health payers, state and local public health, and care delivery to ensure that significant resources are available to communities to address COVID-19, as well as to protect and save lives after the pandemic recedes. Under current federal statutory authority, federal Medicaid support is established retrospectively based on poverty levels within a state (CRS, 2020). As a result, the percentage of federal financial support for the Medicaid program does not automatically increase as demands for services rapidly increase during profound health or economic crises, especially at a time when state revenues may be rapidly decreasing. Instead, Congress must act to increase the federal Medicaid percentage, putting the fate of this lifeline program in difficult and sometimes lengthy political processes. Congress could consider developing an automatic federal funding increase for the Medicaid program during health or economic crises, sometimes referred to as "countercyclical" Medicaid funding mechanism, similar to federal funding for unemployment insurance. When increases in federal support are triggered through this funding mechanism, the increases also could be tied to maintaining eligibility

BOX 1-15

Considerations for Examining Critical Intersections and Implementing Aligned Solutions Between Patients, Families, and Communities and Other Sectors

- **Public Health:** Partner with patients, families, and community organizations in developing plans for responding to public health emergencies and other public health challenges.
- **Research:** Improved representation of marginalized individuals and families in studies of public health interventions and development of medical countermeasures.
- **Digital Health:** Modernize infrastructure for collecting and exchanging data, including demographic and social elements relevant to patients, families, and communities.
- **Payers:** Expand coverage of home- and community-based services and implement payment reforms for community health workers.

and benefits in the program through a "Maintenance of Effort" requirement, thereby ensuring increased federal support results in protected and expanded access to Medicaid coverage (see *Box 1-15*).

PRIORITIES MOVING FORWARD

This paper presents a comprehensive review of the available evidence regarding the multidimensional challenges that patients, families, and communities are confronting during the COVID-19 pandemic. This assessment reflects that patients, families, and communities are further impacted by the multisectoral responses to the COVID-19 pandemic that, in some situations, have supported those affected and, in others, exacerbated the problems. The proposed priority actions in this paper are by no means a panacea to fix the U.S. health system but rather touch on key issues that have been put into stark light by the COVID-19 pandemic. The pandemic has made it clear that the American public health system is underfunded, health coverage is piecemeal, and marginalized groups experience a higher rate of illness than others while struggling to access needed care. There are necessary changes, both short- and long-term, that all sectors involved in the U.S. health system must make to improve the overall health and well-being of our nation and its people. Centering the needs of patients, families, and communities must be at the core of all proposed changes. Elected officials,

doctors and scientists, public health experts, the private and public sectors, communities, families, and each of us as individuals must work together at the national, state, and local levels on these actions. Together, all of us can build on the resiliency that exists within individuals, families, and communities; partner with health systems and those at the local, state, and national levels; and foster true enduring and meaningful transformational change. The suggestions above spotlight how to improve sector-wide performance from a systems and governing level. Stopping the pandemic is everyone's responsibility, and applying the necessary changes to accomplish that goal will result in the transformation of the health care system into one where science, digital tools, incentives, and culture are aligned for continuous improvement, innovation, and equity, with individuals and families active participants in all elements.

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CLINICIANS AND PROFESSIONAL SOCIETIES COVID-19 IMPACT ASSESSMENT: LESSONS LEARNED AND COMPELLING NEEDS

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INTRODUCTION

Clinicians—who consist of physicians, nurses, pharmacists, and other allied health professionals involved in direct caregiving—are the foundation of the health care delivery system. While more than 17 million individuals in the American health system are employed in a clinical capacity and are critical members of care delivery teams nationwide, this paper will primarily focus on the experience of nurses (over 4 million) and physicians (1 million), who represent two of the largest professional groups in the health care workforce, prior to and during the COVID-19 pandemic (AACN, 2019; Salberg and Martiniano, 2018).

Today, the professional responsibilities of clinicians encompass both the traditional domains of caregiving (e.g., diagnosis, treatment, symptom management) and an appropriately increased focus on supporting the unique social needs of their patients (e.g., addressing the social determinants of health by inquiring about and connecting patients with resources to increase food security, stable housing, and reliable transportation, among others). Yet even as the clinical purview is expanding and the complexity of patient care is increasing due to the growing burden of chronic diseases, clinical capacity remains unevenly distributed across the country, with more than 80 million Americans residing in a "Health Professional Shortage Area" (KFF, 2020). The professional demands on practicing clinicians have also been exacerbated by an ever-increasing bevy of administrative

requirements which contribute to record rates of burnout and declining mental health and well-being among clinicians (NASEM, 2019; Rotenstein et al., 2018).

These workforce trends frame the backdrop for many of the challenges facing clinicians during the COVID-19 pandemic. Physicians, nurses, and other allied health professionals represent the frontlines of the health care system, and have worked tirelessly to care for infected patients from the outset of the outbreak. Clinicians in COVID-19 epicenters had to rapidly develop best practices for treating patients infected with a novel pathogen, were frequently asked to care for patients with inadequate personal protective equipment (PPE), and in some cases were required to staff clinical settings that they had not worked or trained in for decades, or not at all. In tandem, public health measures to contain the outbreak disrupted non-COVID-19 care, requiring clinicians to quickly learn how to operate virtual platforms and adapt service delivery where possible to ensure the continuity of care.

Navigating this evolving workplace environment amidst a deadly, new, and infectious disease has taken its toll on clinicians, who faced the same COVID-19 stressors as other Americans—juggling child care, caring for loved ones who had fallen ill—in addition to the added anxieties of a higher risk of exposure to infection, the psychological burden from prolonged separation from their families due to self-isolation requirements, and the emotional anguish arising from caring for high volumes of acutely ill patients. Persistent PPE shortages left clinicians exposed to the virus when caring for infected patients, with nurses and physicians accounting for 49% of the more than 3,600 health care worker deaths attributed to COVID-19 as of April 2021 (NASEM, 2020; KHN, 2020). The extreme stress also led many clinicians to report symptoms of anxiety, depression, and posttraumatic stress disorder (PTSD), with burnout—defined as "a syndrome characterized by a high degree of emotional exhaustion and depersonalization (i.e., cynicism), and a low sense of personal accomplishment at work"—carrying tragic consequences, including suicide (NAM, 2021; Rossi et al., 2020).

The public and government have lauded the critical role of health care workers during the pandemic, with clinicians frequently referred to as "heroes" for their service during COVID-19. And while clinicians have been remarkably adaptive, innovative, and resilient during the pandemic, verbal salutes alone are insufficient to address the systemic workforce challenges exacerbated by COVID-19. Instead, tangible and long-term investments in training, operations, and financing are needed to shore up the clinical capacity needed to care for future generations. A special focus on mental health, particularly efforts to reduce burnout and promote workforce well-being, will be needed following the pandemic.

This discussion paper will examine the clinician experience to date during COVID-19, identifying the challenges and lessons from pandemic response

activities to inform a series of priority actions for revitalizing the sector's capacity to address population health challenges, care for clinicians themselves, and respond to future public health emergencies.

THE CLINICIAN RESPONSE TO COVID-19

Beyond the basic frontline COVID-19 diagnosis and treatment responsibilities in hospitals and office practices nationwide, clinicians have worked to rapidly gather and synthesize evidence to inform care for exposed and infected patients and adapt care processes for non-COVID-19 care. In addition to their primary responsibilities of providing patient care, clinicians also engaged in other activities including modifying training programs and participating in public education and advocacy. Key elements of the clinician response include:

1. Developing and updating clinical guidelines for COVID-19;
2. Adapting delivery systems to support both COVID-19 and non-COVID-19 care;
3. Adjusting education and training programs to the circumstances of the pandemic; and
4. Leveraging advocacy and activism to inform the public and spotlight health system challenges (see *Figure 2-1*).

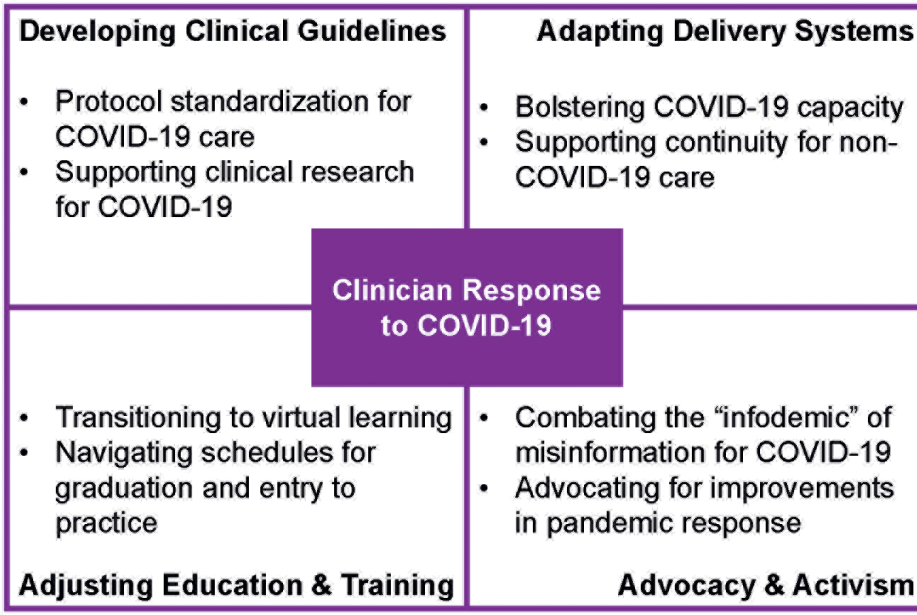

FIGURE 2-1 | The Clinician Response to COVID-19

Developing Clinician Guidelines for COVID-19

As a novel pathogen without a pre-defined evidence base, SARS-CoV-2 created an immediate challenge for health systems seeking to triage and treat the rapidly growing population of infected patients. However, it was challenging for clinicians to manage the sheer volume of new research—from the tens of thousands of preprints posted on servers such as medRxiv to peer-reviewed publications in academic journals—particularly considering the significant variation in methodological rigor and evidence quality. Consequently, to balance the urgency for new evidence with the need to uphold standards for quality, health systems and professional societies played an important role in both supporting COVID-19 studies and performing rapid and real-time syntheses of emerging evidence into guidelines to inform best practices for patient care.

Protocol Standardization

At the beginning of the pandemic, government agencies such as the National Institutes of Health (NIH) and global clinical partnerships such as the Surviving Sepsis Campaign worked quickly to extrapolate evidence from other viral infections into evidence-based guidelines for the management of COVID-19 (Poston et al., 2020). As new evidence emerged, professional societies within the U.S. worked to update guidelines and communicate the latest evidence to clinicians.

For example, the Infectious Diseases Society of America (IDSA) published initial treatment guidelines in April 2020, and has updated the document more than a dozen times since then to include the latest evidence from trials of potential therapeutic agents (IDSA, 2020). Likewise, rapid recommendations from the Surviving Sepsis Campaign—a collaboration between the Society of Critical Care Medicine and the European Society of Intensive Care Medicine—in March 2020 helped provide clarity about best practices for preventing infection transmission within health care facilities (e.g., the use of fitted respirators by health care workers, the use of negative pressure rooms for infected patients) (Surviving Sepsis Campaign, 2020). Furthermore, the American Association of Critical Care Nurses developed a number of procedure manuals to support trainings for COVID-19 (e.g., for intubation, for oral care practices), and in October 2020 launched an official micro-credential for COVID-19 Pulmonary and Ventilator Care with online verification to standardize and disseminate best practices across the health professions workforce (AACCN, 2020a; AACCN, 2020b). Initiatives such as these were critical for helping clinicians distinguish between the signal and noise in the growing literature on COVID-19, and ensure that patient care was informed by the latest standards.

Supporting Clinical Research

Clinicians played a key role in supporting the generation of new evidence in how to treat and combat COVID-19, from authoring case reports to collaborating with researchers to support clinical trials for potential therapies and vaccines. However, clinician support for COVID-19 research encountered a variety of challenges.

First, frontline clinicians' desire to do anything possible for acutely ill patients at risk for rapid deterioration often came into conflict with researchers' efforts to design and complete randomized clinical trials for COVID-19 therapies (Dominus, 2020). Second, conflicting results from clinical trials, evolving regulatory guidance, and the politicization of science during the pandemic contributed to "panic prescribing," or the off-label use of medications such as hydroxychloroquine for both COVID-19 prophylaxis and treatment (Gupta et al., 2020; Lynch et al., 2020). To provide guidance to frontline clinicians and help combat panic prescribing, the American Medical Association (AMA), American Pharmacists Association, and American Society of Health-System Pharmacists issued a joint statement on ordering, prescribing, or dispensing COVID-19 medications in April 2020 (AMA, 2020a). To help engage clinicians in COVID-19 research, the federal government developed programs such as the Clinical Trials Improvement activity in the Merit-based Incentive Payment System to encourage clinicians to report COVID-19 data to clinical trials or patient registries (CMS, 2020a).

Adapting Delivery Systems

With COVID-19 both increasing staffing demands at outbreak epicenters while disrupting care delivery for other diseases and elective procedures, health systems had to adapt care processes across all fronts to meet ongoing and emerging patient needs. Clinicians played a key role in supporting the adaptation of delivery systems, from flexible staffing for COVID-19 to the adoption of telehealth.

Bolstering COVID-19 Capacity

The surge in COVID-19 patients requiring intensive care soon outpaced the critical care capacity of even large academic medical centers. Although many health systems took steps to repurpose bed space and hospital units—so-called "surge capacity"—to meet patient needs, a key challenge was the shortage of clinicians with expertise in critical care (Spetz, 2020; Halpern et al., 2013). To fill gaps in care capacity, clinicians from service lines which had been halted by the pandemic were often redeployed and retrained when possible using specialized modules to support COVID-19 care (Keeley et al., 2020). For example, professional societies for medicine

(e.g., the American Thoracic Society, the Society for Critical Care Medicine) and nursing (e.g., the American Association of Critical Care Nurses) partnered together to develop online videos and courses on basic critical care management designed for non-critical care audiences. Additionally, with regulators providing temporary flexibilities for licensing and scope of practice, many clinicians volunteered to serve in COVID-19 hotspots to alleviate staffing shortages (AMA, 2020b). However, even as clinicians responded to the numerous calls to action, health systems struggled to procure the necessary PPE, creating persistent challenges for staff safety.

Supporting Care Continuity for Non-COVID-19 Care

The closure of many health care facilities and cancellation of in-person visits and elective procedures risked creating a second "hidden" pandemic through disruptions in chronic disease management (Barnett, 2020). With the Centers for Medicare and Medicaid Services (CMS) issuing temporary policies to support the expansion of telehealth and the Food and Drug Administration (FDA) providing regulatory flexibilities for the use of remote patient monitoring technologies, the locus of care delivery for non-COVID-19 services began shifting from traditional health care facilities to the home (CMS, 2020b; FDA, 2020). Clinicians and professional societies played an important role in supporting this transition, with providers and patients alike facing a rapid learning curve for telehealth.

While telehealth was an important stopgap, virtual care was not a perfect substitute. For example, early evidence comparing the use and content of virtual and in-person primary care visits found that telehealth visits were less likely to include assessments for chronic disease management (e.g., blood pressure measurement) (Alexander et al., 2020). Likewise, the transition to telehealth was more conducive for some specialties (e.g., behavioral health) as opposed to others (e.g., orthopedics) (Mehrotra et al., 2020). Additionally, clinicians encountered technical and operational challenges during the transition to telehealth, from poor integration of telehealth into electronic health records (EHRs) to the "digital divide" affecting the potential ability of marginalized populations to use telehealth (Jercich, 2020; Roberts and Mehrotra, 2020; Whaley et al., 2020). In addition to telehealth, clinicians—particularly those in community practice—also explored alternative avenues for patient outreach and engagement, ranging from pop-up clinics to house calls (Katersky and Kim, 2020).

Adjusting Education and Training Programs

Clinical education and training is embedded into the infrastructure of America's health system. Consequently, as major academic medical centers pivoted to shore up

capacity for COVID-19, health professions schools took steps to adjust education and training programs, from the suspension of in-person learning to the deployment of new pedagogical tools to reduce the impact of training disruptions for the next generation of clinicians.

Transitioning to Virtual Learning

In the spring of 2020, many institutions of higher education began transitioning to virtual learning following guidance from the Centers for Disease Control and Prevention (CDC) about recommended event cancellations and public health practices for slowing the transmission of COVID-19. In March 2020, national associations such as the Association of American Medical Colleges (AAMC) and the American Association of Colleges of Nursing (AACN) called on health professions schools to suspend or limit in-person clinical instruction by placing their clinical rotations on hold (AACN, 2020a; AAMC, 2020). While each academic institution had to make independent decisions, the recommendations from AAMC and AACN were widely driven by the persistent shortages of PPE across the health system and the collective effort to "flatten the curve" by reducing the potential to spread COVID-19.

The rapid transition to remote learning required innovation at all levels of clinical pedagogy. For example, health professions schools needed to develop contingency plans for how to offer online simulation-based education, particularly for students scheduled to graduate during 2020. The Academic Service Learning opportunities offered by the American Red Cross for prelicensure nursing students or registered nurses working on their bachelor's or post-graduate degrees are an example of one avenue for student engagement during the pandemic (American Red Cross, 2020). In addition to retrofitting established clinical curricula to virtual platforms, faculty were also focused on remaining up to date with the current local, state, and national guidelines to help prepare students for the uncertain and dynamic clinical environment they would be entering as new graduates. Reinforcements in public health, emergency preparedness, ethical decision-making, resilience and well-being strategies, and education on proper use of PPE became even more essential to prepare new providers entering the field.

Health professions schools did encounter several challenges during the transition to virtual learning, ranging from the variability in faculty comfort with remote learning platforms to gaps in access and support systems for students. Additionally, although schools sought to continue many non-hospital clinical experiences and create non-clinical volunteering opportunities for students, some students expressed concerns that cancellations of clinical rotations would negatively affect their career progression (Byrnes et al., 2020). To help navigate the uncertainties

of the pandemic, national associations and professional societies played a key role in providing guidance to educators and students and developing plans for the resumption of clinical instruction.

Graduation and Entry into Practice

Disruptions to in-person education created an atmosphere of confusion for clinical trainees during the early days of the pandemic, with health professions schools navigating the dual challenges of whether students scheduled to complete their training during 2020 would be able to graduate on time and what the appropriate role of health professions students should be in light of the frontline staffing needs in pandemic epicenters.

In the nursing profession, the Commission on Collegiate Nursing Education (CCNE) released guidance that recommended flexibility in the types of eligible experiences for students and the associated clinical hours as long as the outcomes were met (CCNE, 2020). While CCNE Guidelines for accreditation and the AACN Essentials, which guide nursing school curriculum, do not set clinical hour minimums for prelicensure baccalaureate programs, state boards of nursing vary in their requirements for in-person clinical rotations. This added a layer of complexity for students graduating during the pandemic. Exacerbating concern for an on-time graduation was the initial closure of in-person testing sites for the National Council Licensure Examination for Registered Nurses. Coordination by nursing leaders and professional societies enabled testing centers to reopen under limited capacity in line with the CDC guidelines.

As the pandemic wore on, additional guidance was released by AACN to help support schools of nursing reopen safely, taking into consideration campus risk, state alert levels, testing strategies, and clinical placement interactions, among other tactics (AACN, 2020b). Spring of 2020 captured a moment in time that was shrouded by confusion as the entire academic infrastructure navigated federal and state guidance and emerging best practices, and ultimately made decisions based on how best to protect the health and safety of students, faculty, and staff given their assessment of the overall environment. With graduations occurring in May and December of 2020, the task at hand focused on how to re-envision curricula so that students, already critical to the health care system, could be additive to the most pressing demand—vaccination. Health professions schools proved themselves to be active partners in the pandemic response by preparing students for public health efforts such as community education campaigns and contact tracing and moving up training on intramuscular injections (AACN, 2021).

In the medical school community, questions began to arise related to early graduation as medical students were being removed from their fourth-year clerkships.

Several medical schools, particularly those in COVID-19 epicenters, did allow students who expressed a desire to volunteer on the frontlines to graduate early (Orbey, 2020). However, early graduations were not seamless, as the transition from medical school to graduate medical education is complicated by a myriad number of issues including regulation of licensure and oversight of reimbursement. In April 2020, the Accreditation Council for Graduate Medical Education (ACGME) ultimately released a statement that recommended against the early graduation of allopathic and osteopathic medical students, noting challenges to residency if not appointed to an ACGME-accredited program and the ramifications to early appointments related to CMS reimbursement of direct and indirect graduate medical education (ACGME, 2020a). Recognizing the complexity of the situation for students and schools, the variation in medical center-specific staffing needs, and the physical and emotional pressures on trainees, the AMA also issued a series of recommended principles for medical students during COVID-19, including an emphasis that any early graduation initiatives should be voluntary and that such students should be designated as full providers with corresponding benefits to reduce physical risk and professional coercion (AMA, 2020c). ACGME also provided guidance for residents and fellows who may have been redeployed from their specialty area of training to fill staffing gaps in intensive care and meet other pandemic-specific patient needs.

Leveraging Advocacy and Activism

Clinicians have long been viewed as trusted voices of authority in American society. During the pandemic, clinicians often served as credible messengers to keep the public informed about public health best practices. Furthermore, clinician advocacy and activism, particularly on social media, played an important role in spotlighting challenges in the response to COVID-19, especially for issues such as PPE shortages and the impact of health inequities on COVID-19 outcomes. However, clinicians did experience challenges to their expertise and credibility due to the spread of misinformation and disinformation and the politicization of the pandemic (Satariano, 2020).

Combating Misinformation

Researchers and health officials at the World Health Organization (WHO) have documented the presence of an "infodemic" during COVID-19, from misleading statements by elected officials to the spread of misinformation and disinformation on social media (WHO, 2020). These trends were challenging within the clinician

community as well, with the sharing of insights about COVID-19 on social media blurring the line between individual anecdotes and empirical evidence.

Internally within the clinician community, social media platforms and professional societies began to take an active role in filtering emerging evidence and disseminating updates to guidelines. For example, a private Facebook group called "COVID-19 USA Physicians and Advanced Practice Providers"—which required individuals to verify their provider credentials in order to participate—had over 150,000 members as of fall 2020 and served as a useful forum for discussion and evidence sharing. Likewise, professional societies such as the AMA and the American Nurses Association (ANA) created dedicated webpages to serve as resource centers for clinicians, including guides on topics ranging from a code of medical and nursing ethics for the pandemic to best practices on infection control curated from the CDC, WHO, and other trusted organizations (AMA, 2020d; ANA, 2020a; Petri et al., 2020).

Externally, many clinicians became trusted messengers both in their communities and on social media. For example, Twitter, in an effort to reduce misleading misinformation, decided to verify (noted visually on Twitter as a blue check mark next to a person's username) health care professionals providing sound COVID-19 guidance so as to notify users and other health care professionals that the information was deemed reliable and that it was being provided by a person with the prerequisite expertise (Lunden, 2020). At all levels of government, clinicians frequently served an important role in communicating the latest evidence on COVID-19 to the public around testing, infection trends, and new medical products. These actions were important to emphasize public health best practices and evidence-based information, but in some cases carried personal (e.g., harassment on social media) and professional (e.g., potential penalties from employers) risks for clinicians (Carville et al., 2020; Roborgh and Fast, 2020).

Advocating for Pandemic Response

In addition to serving in an informational capacity, clinicians also organized at the national and grassroots levels to draw attention to the challenges of America's pandemic response. For example, a key area of focus was the persistent shortage of PPE in hospitals and health care facilities (Glasser, 2020). In response, health care workers organized on social media using the hashtag #GetUsPPE, launching a survey to identify PPE shortages across the country and partnering with professional societies to coordinate last-mile distribution of PPE at various health care sites (He et al., 2020).

Clinician advocacy placed particular emphasis on highlighting the disparate impact of COVID-19 on communities of color. National organizations, including

the AMA and ANA, played a leading role from the outset of the pandemic in advocating for improvements in the collection of race and ethnicity data to assess the impact of COVID-19 on marginalized populations (AMA, ANA, and APA, 2021). Additionally, following the tragic deaths of George Floyd, Breonna Taylor, and many other Black Americans during the pandemic, coupled with the disparate impact of COVID-19 on communities of color, clinicians organized to draw attention to the role of racism as a public health crisis. Statements from numerous professional societies affirmed the health consequences of structural racism and the necessity of embedding a focus on equity into clinical education and practice, and the Rainbow PUSH Coalition and National Medical Association collaborated to develop the COVID-19 Public Health Manifesto (AAN, 2020; AMA, 2020e; ANA, 2020b). Furthermore, amidst the growing number of reports of hate crimes against Asian Americans and Pacific Islanders during the pandemic, national organizations including the AMA and ANA spoke out to condemn xenophobia and racism, with the AMA highlighting the structural roots of present-day discrimination and the American Academy of Nursing issuing a statement identifying "Anti-Asian Discrimination as a Public Health Crisis" (AAN, 2021; AMA, 2020f; Smith, 2020).

Lastly, a key focus of clinician advocacy was addressing hesitancy surrounding the development and authorization of COVID-19 vaccines. For example, Black doctors in the National Medical Association formed a panel to review clinical trial data and organized listening sessions in collaboration with community leaders from organizations such as churches, fraternities, and sororities to address misinformation (Boodman, 2021). Similarly, Black nurses and doctors formed the Black Coalition Against COVID-19, which compiled resources and coordinated virtual town halls with key government officials to keep communities informed about the vaccine (Black Coalition Against COVID-19, n.d.). While these examples of advocacy illustrate the role of clinicians as "trusted messengers," they also highlight the elevated burden borne by minority clinicians during the pandemic, who have long been underrepresented across the health profession.

KEY CHALLENGES FOR THE CLINICIAN SECTOR DURING COVID-19

While clinicians have displayed remarkable resilience and innovation on the frontlines during the response to COVID-19, the pandemic has magnified many existing, systemic challenges across the sector. For example, the acute and prolonged stress of working under surge conditions has intensified the multiple, well-documented sources of chronic distress and "moral injury"

already endemic among health professionals today, challenging the long-term well-being and stability of the clinician workforce. Likewise, the upheaval to clinician education, practice, and finances during the pandemic has highlighted certain long-standing, structural inadequacies of clinician training, staffing, and financing. This section examines the systemic vulnerabilities in the clinician sector exposed and exacerbated by COVID-19, with a key focus on the following:

1. Clinician well-being and occupational distress;
2. Staffing and operations;
3. Disruptions to education and training; and
4. Financial and administrative impacts (see *Table 2-1*).

TABLE 2-1 | Key Challenges for the Clinician Sector

Challenge Area	Pre-Pandemic Trend	COVID-19 Experience
Clinician Well-Being and Occupational Distress	• Between 35% and 45% of clinicians reported occupational distress prior to the pandemic	• COVID-19 served as a massive acute stressor for clinicians, levying a significant physical, emotional, and moral toll on the workforce
Staffing and Operations	• Critical care clinicians were already in shortage prior to the pandemic • Digital systems were not optimally configured to support care coordination and rapid research initiatives	• Clinicians were retrained and redeployed to fill gaps in care capacity • Clinicians struggled to exchange data with public health departments and officials
Disruptions to Education and Training	• Communities of color were underrepresented in the clinician pipeline • Institutional racism and implicit biases were embedded in academic medicine	• The financial impact of the pandemic resulted in furloughs and hiring freezes • While all learners were affected by disruptions to clinical training, the disruptions disproportionately affected students from marginalized communities
Financial and Administrative Impacts	• Many clinicians were still reimbursed under inflexible payment arrangements • Temporary closures and reduced care volume created acute revenue shortfalls for clinicians and practices	• Care delays and cancellations created revenue shortfalls for clinicians under fee-for-service reimbursement systems • Many measurement and documentation requirements were untenable during the pandemic

Clinician Well-Being and Burnout

Pre-Pandemic Trends in Burnout and Degraded Well-Being

Over the past two decades, multiple complex factors have contributed to the growing challenge of occupational distress among health care professionals, which can manifest in a number of ways, including problems with work-life integration, fatigue and other physical symptoms, and moral distress and a loss of meaning in work (Van Mol et al., 2015). One of the most common manifestations of work-related distress is burnout (NASEM, 2019; West et al., 2018). National studies prior to the COVID-19 pandemic suggest that between 35% and 45% of clinicians have high levels of occupational burnout (Dyrbye et al., 2019a; Shanafelt et al., 2019; McHugh et al., 2011). Notably, nearly 20% of interprofessional clinicians reported they are considering leaving their jobs because of moral distress, which is the inability to translate moral choices into action, and is experienced by members of the clinical team in response to the ethical issues that threaten or violate their integrity (Epstein et al., 2019; Carse and Rushton, 2017; Dodek et al., 2016). These studies also suggest that burnout symptoms and challenges with work-life integration are more prevalent among clinicians compared to other sectors of the U.S. workforce (Dyrbye et al., 2020).

As reviewed in the National Academy of Medicine's (NAM) 2019 consensus study on clinician burnout, the causes of occupational distress are multifactorial and include excessive clinical demands, decreased control over work, inadequate time with patients, regulatory issues that create administrative burdens and lead to inefficiencies in care delivery, challenges integrating clinicians' personal and professional lives, unresolved ethical issues, suboptimal teamwork and unprofessional behavior by some team members, and inefficiencies created by suboptimal technologic tools and isolation from their patients (NASEM, 2019). Mounting evidence has documented how these stressors can cause adverse personal (e.g., broken relationships, depression, thoughts of suicide) and professional (e.g., absenteeism, presenteeism, increased risk of medical errors, decreased clinical productivity, increased risk for turnover) consequences in health care professionals (Shanafelt et al., 2020; Dyrbye et al., 2019b; Shanafelt et al., 2016; West et al., 2006). All of these consequences reduce the ability of delivery systems to achieve health care's quadruple aim of better care experiences and population health at a lower cost while fostering clinician well-being (Bodenheimer and Sinsky, 2014).

COVID-19 Stressors

The pandemic introduced new dimensions of chronic stressors to the clinician workforce, summarized in *Figure 2-2* (Shanafelt et al., 2020).

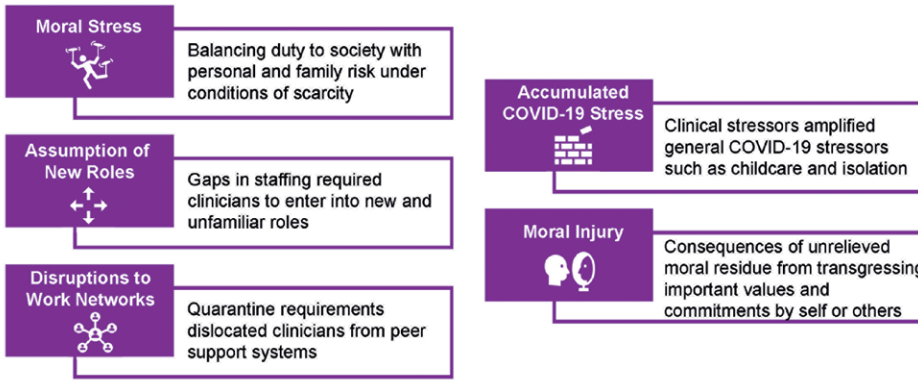

FIGURE 2-2 | COVID-19 Stressors for Clinicians

First, clinicians experienced moral stress in their attempt to balance their duty to society with personal health risks, particularly for older health care workers and those with health issues placing them at high risk for severe or fatal COVID-19 infection. Health care workers faced intensified concerns about the personal risk of becoming infected and the fear of being a vector of infection for their family members. The accumulated moral burden was often exacerbated by shortages of PPE, with many clinicians consequently considering quarantining themselves from their families despite their own needs for support and connection, further amplifying the experience of moral fatigue. Their moral stress was exacerbated by the introduction of novel ethical dilemmas created by models for allocating scarce resources, and intensified by new practice patterns and protocols, uncertainty or inconsistent decision-making, lack of health care worker protections, organizational structures for reporting concerns, and crisis management protocols that shifted decision making from individual clinicians to triage officers.

Second, clinicians answering the call to action on the frontlines were frequently deployed outside their typical area of practice, forcing them to acquire new skills and raising concerns that they were not providing optimal care or were causing harm to their patients. Most organizations also adopted strict visitation guidelines aimed at protecting the health of patients, families, and staff, which had the unintended consequence of creating moral distress for clinicians who assumed new roles to bridge the gaps left by family member absence and witnessed patients dying alone.

Third, disruptions to the workplace environment unmoored clinicians from their professional support networks during a time of crisis. For example, for the thousands of health care workers who did contract the virus, the resulting quarantine requirements created additional stress by separating clinicians from

their peer support systems at work and lead many health professionals to feel as though they were abandoning colleagues and patients in a time of need. Likewise, numerous clinicians went above and beyond their professional responsibilities only to be given notice of furloughs or layoffs when the crisis began to subside, disrupting team stability and cohesion at the precise time that health care workers were most reliant on support from one another. Social support, a key element of resilience, was also disrupted or dismantled.

Fourth, all of these occupation-specific challenges for clinicians were layered on top of the general social challenges of COVID-19 experienced by all Americans. Clinicians simultaneously had to navigate challenges such as childcare, family issues, and adjustments to shelter-in-place restrictions, all while lacking the ability to engage in many of the activities that health professionals traditionally relied on to recharge (e.g., recreation, social connection). Clinicians' prolonged exposure to critically ill and dying patients coupled with the systemic failures of organizations and the government resulted in unacknowledged and unprocessed grief for health care workers alongside the collective grief of the pandemic itself.

Fifth, COVID-19 exacerbated moral injury, which involves the betrayal of what one believes is "right," often in high stakes situations by those with legitimate authority or directly or indirectly by one's own actions or those of others (Shay, 2014). The preceding factors converged to create the conditions for what many clinicians experienced as an assault on their professional values and commitments (Rushton et al., 2021; Dean et al., 2020; Ulrich et al., 2020). Severe shortages of clinicians to treat the volume of patients with COVID-19, lack of governmental and organizational leadership and coordination, and systemic inequities that disproportionately impact people of color further eroded clinicians' ability to fulfill their core professional values (Rushton et al., 2021). As the pandemic progressed, clinicians were confronted with patients who refused to accept their COVID-19 diagnosis and accused clinicians of deceit or malintent, adding to their sense of defeat, discouragement, and fatigue. Instead of receiving the strength to keep going from their patients, clinicians experienced significant emotional distress when realizing that they had sacrificed their own well-being to provide care and treatment for the unrelenting number of people who contracted the virus—some because of lack of adherence to public health guidelines or lack of belief in the truth of COVID-19's existence. The moral residue of these unmet moral and ethical commitments has the potential to contribute even further to the physical and psychological burden of the pandemic.

Collectively, these challenges have resulted in massive acute stress and suffering for clinicians that is superimposed on the pre-existing occupational distress for the health profession. A number of studies have highlighted the increased rates of insomnia, anxiety, grief, depression, PTSD, and moral distress and injury among

clinicians caring for COVID-19 patients during the pandemic (Lai et al., 2020; Poston et al., 2020). Distressingly, the emerging evidence suggests that the risk of these conditions is greatest among clinicians who are women and who are nurses. These are also the individuals who typically bear the greatest burden of child and family caregiving, and as a consequence have experienced a dual burden of stress due to pandemic-induced disruptions to normal life (Lai et al., 2020).

The profound emotional, moral, and psychologic distress of clinicians during the pandemic, coupled with the erosion of trust in the health system due to failures of the COVID-19 response (e.g., shortages of PPE), the financial impact of the pandemic (e.g., pay cuts, furloughs, layoffs), and the misinformation spread by some elected officials (e.g., claims that clinicians were lying about or profiting from COVID-19), threaten the long-term well-being of the clinician workforce, and have systemic consequences for care delivery during and after the pandemic. COVID-19 is consequently a clarion call for the need to address clinician burnout, which long precedes the pandemic. Policymakers and health system leaders will need to take steps to develop holistic frameworks and multifaceted support systems that remodel delivery environments to promote clinician well-being (Dzau, 2021).

Staffing and Operations

While clinicians mobilized rapidly on the frontlines to support the response to COVID-19, the growing pains of redeploying clinicians from different sectors, the technical challenges of sharing data and coordinating across teams, and the targeted gaps in capacity across key clinical domains highlighted a number of challenges for staffing and operations.

Staffing and Clinical Capacity

Researchers have long drawn attention to the shortage of various health care workers and providers in the U.S. A key area of neglect has been in critical care capacity, with frequent shortages among both intensivists and registered nurses in the ICU and in step-down units due to the specialized training required to work in such environments and the high burnout rates reported by providers due to the harrowing experience of caring for acutely ill patients (Halpern et al., 2013; Cecile et al., 2006; Steichmiller, 2002). The consequence of these shortages was apparent during the COVID-19 pandemic, particularly given that between 12% and 33% of patients hospitalized with COVID-19 required ICU admission or mechanical ventilation (Goyal et al., 2020; Richardson et al., 2020; Wu and McGoogan, 2020).

While clinicians, as noted in the subsection on "Adapting Delivery Systems," took steps to fill capacity by cross-training from different specialties or traveling

to COVID-19 hotspots to volunteer at overwhelmed facilities, these temporary measures belie the systemic challenges facing the clinician workforce. From an operational perspective, pandemic-era innovations to centralize staffing and triage processes represent opportunities to improve the efficiency and flexibility of critical care both at baseline and during emergency situations. Additionally, evidence about the importance of collaborative clinical care during COVID-19 should encourage the adoption of integrated and multidisciplinary clinical teams across hospital service lines. From a capacity perspective, the sheer volume of staffing needs should be a call to action to invest in the pipeline of critical care clinicians and other specialties with long-standing staffing gaps.

Digital Infrastructure

Care delivery in the U.S. health system has long been fragmented, and a key challenge has been the lack of interoperability among data systems and EHRs. The importance of an interconnected and learning health system was evident during the COVID-19 pandemic, particularly due to the expansion of telehealth and remote patient monitoring. For example, challenges with electronic case reporting and differences in the type and quality of data collected within and across systems created challenges for clinicians caring for COVID-19 patients (e.g., delays in transmitting testing data affected decision-making for admissions and discharge). Likewise, variation in data systems and reporting capacity contributed to challenges for facile enrollment and follow-up for COVID-19 clinical trials. Furthermore, for non-COVID-19 care, gaps in the integration of telehealth and EHRs risked disrupting care continuity and care handoffs.

Clinicians did deploy technology throughout the pandemic to expand capacity, such as the development of virtual triage clinics and the creation of critical care command centers and tele-ICU teams (Keene et al., 2021). However, shifting the modality of care delivery does not resolve the underlying shortages in the clinician workforce that will require attention. In addition, sustainably integrating telehealth into care delivery moving forward will require policymakers and health system leaders to address systemic shortcomings in existing digital and technical infrastructure, with a particular focus on promoting interoperability and adopting uniform standards for data collection.

Disruptions to Education and Training

While health professions schools and academic medical centers pivoted quickly to remote learning platforms and professional societies introduced guidelines and flexibilities for current and graduating students, the overall disruption to clinical

education during the pandemic has created several challenges for the sector as a whole.

Impact on Training Programs

To preserve PPE, optimize staffing, and minimize infection risk, health professions schools had to adjust training programs, affecting the clinical education of health professions students.

First, many health professions schools paused clinical rotations for their students during the pandemic, interrupting an important period of clinical immersion for trainees (ACGME, 2020b). Second, at many academic medical centers, staffing shortages led to the redeployment of residents and fellows. For example, in one New York City hospital, pediatric residents were deployed to care for adult patients (Biala et al., 2020). While trainees rose to the occasion to meet the needs of patients, changes in clinical workflow posed challenges due to the rapid learning curve and have led to gaps in the clinical training of these trainees. Third, the training of physician- and nurse-scientists was disrupted as many research laboratories were either closed or repurposed for COVID-19-related activities (e.g., to serve as processing centers for COVID-19 diagnostics), and trainees were in many cases redeployed to fill clinical needs (Jumreornvong et al., 2020). Interruptions to the protected research time (for students) and laboratory start-up time (for early-career investigators and post-doctoral fellows) affected activities ranging from experiment completion to manuscript revisions to grant applications and renewals, all of which may carry consequences for future academic careers. Distressingly, the career costs of COVID-19's disruption of research activities appear to have disproportionately affected female scientists, as evidenced by the widened gender gap in publications during the pandemic, threatening to exacerbate long-standing inequities in academic nursing and medicine (Gewin, 2020; Spector and Overholser, 2020).

Financial Impacts

Health care systems and institutions of higher education across the country have suffered severe financial impacts due to COVID-19. To stabilize university finances, many schools took actions such as issuing hiring freezes, furloughing faculty and staff and introducing pay cuts, with these steps carrying short- and long-term implications for students and faculty.

First, from the perspective of faculty and newly minted clinicians interested in academic careers, many research programs at universities have been placed on hold during the pandemic as laboratory space and program resources were redirected to support pandemic activities. Many nurse- and physician-scientists

paused their primary research focus to engage with the COVID-19 research response (Pickler, 2020). Furthermore, hiring freezes may create challenges for the next generation of clinician-researchers in entering academic life.

Second, from the perspective of students, a year of remote learning during an economic crisis without a commensurate change in tuition rates has once again spotlighted the increasingly unaffordable nature of health professions education in the U.S. To ensure the sustainability of education for incoming and current students, guidelines for financial aid and student loan programs need to be amended to address flexibility in their requirements while at the same time offering relief. In the long term, policymakers and education leaders will need to renew conversations around increasing the affordability and sustainability of financing clinical educations, with a number of preexisting programs for loan and debt forgiveness coupled with innovations in pedagogy (e.g., efforts to shorten training) providing opportunities for further consideration (Pickler, 2020).

Disparities in Educational Access

Within the clinician workforce itself, students of color have been disproportionally impacted by COVID-19 as they attempt to cope with the disturbing effects of the pandemic in their communities. The emotional and mental strain of the pandemic compounds the existing challenges of institutional racism embedded in America's education and health structures, which long predates COVID-19 (Anderson, 2020). For students already enrolled in a health professions school, the transition to virtual learning was uneven due to resource inequities. For example, students who lacked access to high-speed internet or institutions which had lesser technical capabilities not only experienced disparities in didactic instruction (e.g., lectures, exams) but also in their ability to take part in remote versions of clinical training (e.g., scribing, telehealth visits, volunteer opportunities) (Jumreornvong et al., 2020).

In addition to increased awareness about inequities within clinical education during the pandemic, the disparate impact of COVID-19 on marginalized populations coupled with broader public discussion on racism and social justice during 2020 spotlighted many of the longstanding disparities in health professions education writ large. For example, nearly one-third of all Americans are either Black (13%) or Latinx (19%) (United States Census, n.d.). However, not a single medical specialty adequately reflects the racial and ethnic diversity of the broader U.S. population, despite evidence indicating improved health outcomes when patients are cared for by clinicians from a similar demographic background (Alsan et al., 2019; Deville et al., 2015). Likewise, the number of Black men matriculating to medical school remains largely unchanged over the past 30 years, even as the population of Black men in America grows, broadening this already existing disparity (Gallegos, 2016).

In baccalaureate nursing programs, only 11% of students are Black and 13% are Hispanic or Latinx (AACN, 2020c). While many health professions schools reaffirmed their commitment to addressing health disparities during the pandemic, the challenge for these institutions will be translating rhetoric into reality, including investments to diversify the clinician pipeline, policies to increase the affordability and accessibility of clinical education, and pedagogical interventions to introduce a meaningful focus on equity at all levels of clinical training (Yousif et al., 2020).

Financial and Administrative Impacts

Despite their centrality to the pandemic response, clinicians experienced a paradox of extreme financial instability. Delays in non-COVID-19 care and the cancellation of non-emergent procedures cut off key revenue streams for physicians and highlighted the instability of a fee-for-service reimbursement system. Furthermore, physicians and nurses alike struggled to comply with administrative requirements due to the stress and workload of the pandemic. While regulatory flexibilities (e.g., reimbursement for telehealth) and financial relief (e.g., from the Provider Relief Fund) did help to alleviate the immediate impact of the pandemic, the financial and administrative challenges of COVID-19 highlight deeper vulnerabilities for the clinician sector.

Disruptions to Clinician Reimbursement

The majority of clinicians, including physicians and Advanced Practice Registered Nurses, continue to be reimbursed through inflexible payment models that often fail to support the deployment of high-value services such as team-based efforts to proactively manage preventative and chronic disease care outside the office. Early in the pandemic, temporary practice closures, deferred patient visits, and sustained volume reductions to support social distancing requirements and conserve PPE precipitated extraordinary and sudden drops in fee-for-service based clinician revenue. The financial impact was magnified after factoring in the expenses incurred from responding to COVID-19, including the cost of procuring PPE (which due to shortages, often required practices to pay significant markups), performing frequent cleanings, upgrading ventilation systems, and redesigning office environments to minimize infection risk. Indeed, 81% of physicians continued to report lower revenue compared to pre-pandemic levels as of August 2020, with an average decline of 32% (AMA, 2020g).

However, federal relief funds appropriated through the Coronavirus Aid, Relief, and Economic Security (CARES) Act helped prevent insolvency, and health service volumes have rebounded to pre-pandemic utilization levels for some specialties

(Mehrotra et al., 2020). Despite considerable improvement and stabilization in fall 2020 compared to spring 2020, clinicians continue to express concerns about the uneven nature of the recovery, with national surveys during the fall of 2020 indicating that a significant number of nurses (32%) and primary care physicians (43%) believe that the financial recovery from COVID-19 for clinicians would take over a year (ANA, 2020c). The escalation of the pandemic during the winter of 2020 increased the strain on clinicians, with 91% of practices reporting a personnel shortage even as 62% of clinicians reported an increase in patient complexity. The prolonged nature of the pandemic has taken a toll, with over half of physicians reporting greater problems with payments in December 2020 as compared to the spring of 2020 (Primary Care Collaborative, 2021). While the situation continues to evolve and trends for utilization and reimbursement remain dynamic, it is clear that the disruption induced by COVID-19 and the uncertain timeline for resolving the public health emergency have generated substantial pressure on the clinician sector.

Temporary policies from public and private payers to reimburse telehealth at parity with in-person visits for the duration of the public health emergency have offered a financial lifeline for many physicians and nurses, while sustaining access to care for some patients. However, surveys of physicians indicate that the growth in telehealth visits early in the pandemic did not fully compensate for the decline in in-person visits, contributing to gaps in revenue (AMA, 2020g). Additionally, the transition to telehealth came at an operational cost (e.g., digitizing processes, procuring necessary hardware and software, aligning health record systems). Furthermore, while payers have reimbursed telehealth at parity, physicians have found it challenging to keep up to date with rapid changes in payment processes across different plans (Primary Care Collaborative, 2020).

A final challenge, related to the difficulties of billing, has been ensuring appropriate reimbursement for physicians providing COVID-19 care. Collaboration between the Current Procedural Terminology (CPT) Editorial Panel and the AMA and Specialty Society Relative Value Scale Update Committee helped create a new CPT code that appropriately quantifies the specific attributable costs for new infection control processes during the pandemic (AMA, 2020h). However, the time required to create and value the code and the delays in adoption by payers into their individual plan's coverage policies further added to the financial challenges of physicians.

Changes in Administrative Requirements

Many national incentive programs for clinicians rely on quality measure reporting and data submission for attribution and risk adjustment. However, COVID-19 exacerbated long-standing challenges for clinicians with quality measurement requirements, which can often be burdensome, somewhat unaligned between

payers, and provide only lagging feedback. Clinicians were further pressured during COVID-19 in fulfilling these administrative requirements (e.g., those required for Medicare's Merit-based Incentive Payment System, or MIPS). Such disruptions posed a setback for the larger quality improvement enterprise and limited policymakers' capacity to rapidly expand and target specific data collection for COVID-19.

The pandemic also illustrated how some administrative requirements in health care can constrain clinician decision-making and delay patient access to clinically appropriate care. A leading example of this is prior authorization, a well-intentioned tool for utilization management that has unfortunately created a significant administrative burden for clinicians, negatively affecting the timeliness and outcomes of care delivery, and increasingly shifting financial responsibility for necessary care onto patients (AMA, 2020h; AMA, 2020i; Gaines et al., 2020).

During the pandemic, many payers worked to streamline some administrative requirements to avoid care delays. For example, a number of payers temporarily paused some quality measurement programs or waived prior authorization requirements for certain types of COVID-19 and non-COVID-19 care (e.g., prescription medications, in-network facility transfers). Additionally, several other administrative requirements (e.g., documentation and signature requirements for various medical orders) were also temporarily waived to remove bottlenecks to care delivery and avoid adding to clinicians' already high rates of burnout during the pandemic (Sinsky and Linzer, 2020).

These policies are generally time-limited and are expected to expire at the conclusion of the public health emergency. However, some pandemic flexibilities may provide an opportunity to address pre-pandemic concerns around the burden of administrative requirements, such as the potential negative consequences of prior authorization on the timeliness of care delivery and the financial responsibility borne by patients. In the aftermath of the pandemic, it will be critical for payers and policymakers to resist a "return to normal," considering the significant body of evidence about the inefficiencies of existing administrative requirements and their association with clinician burnout. Consequently, clinicians should work to partner with leaders across other sectors to evaluate the experience from pandemic-era flexibilities to support the transformation of the quality measurement ecosystem and associated administrative processes.

PRIORITY ACTIONS AND POLICY CONSIDERATIONS

COVID-19 has illustrated the critical importance of a robust, healthy, and resilient clinician workforce to not only support the response to public health emergencies, but also meet urgent population health challenges such as the management of increasingly complex chronic diseases. To build on the innovations and adaptations

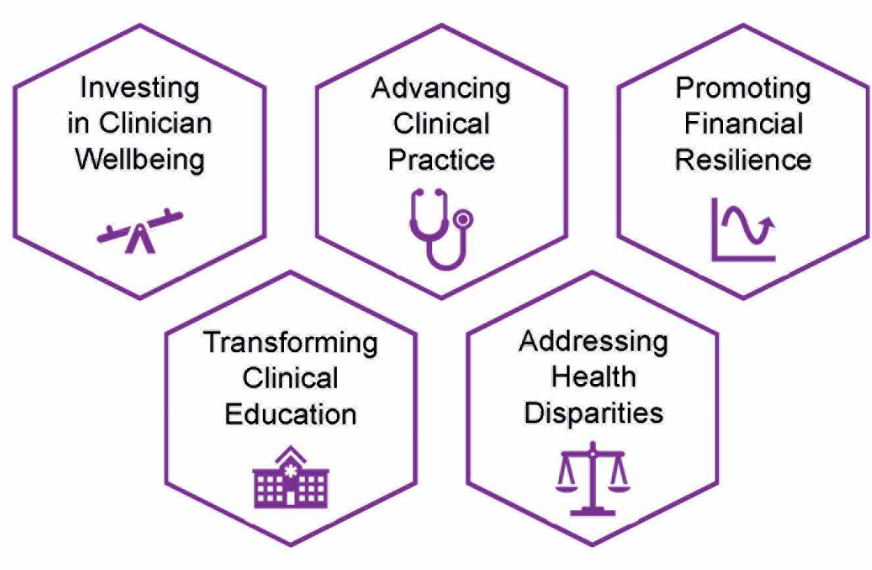

FIGURE 2-3 | Priority Areas for the Clinician Sector

of clinicians during COVID-19, regulators will need to implement policy and programmatic changes to improve the sector's overall preparedness and efficiency. In tandem, given the heavy toll levied by the pandemic on clinicians' morale and financial stability, it will be critical that policymakers and system leaders take steps to commit to long-term investments in workplace transformation and practice improvements to address systemic challenges facing the sector. This section outlines the priority actions and policy considerations for the clinician sector in the post-pandemic era, with key domains of focus including:

1. Investing in clinician well-being;
2. Advancing innovations in clinician practice;
3. Promoting financial resilience for clinicians;
4. Transforming education and training; and
5. Developing policies and programs to address health disparities (see *Figure 2-3*).

Investing in Clinician Well-Being

A holistic assessment of the clinician workforce during COVID-19 requires acknowledging the mental, physical, and moral toll of the pandemic as well as the commitment, tenacity, creativity, and perseverance of health professionals. Many clinicians met both the sheer, physical requirement of caring for volumes of patients that exceeded clinical capacity and the mental and emotional strain of

navigating system failures and profound and acute suffering with compassion and altruism. These examples of resilience and integrity should not be overlooked or taken for granted, and are a testament to the tremendous clinical leadership and clinician sacrifices undergirding America's pandemic response.

Yet in tandem, celebrations of clinician resilience must be accompanied with an examination of the well-documented and quantified emotional, psychological, moral, and physical burden experienced by clinicians during the pandemic. COVID-19 has helped to increase awareness about the challenges of burnout and other forms of distress, and the importance of clinician wellbeing at both the organizational as well as the societal level. Creating space for this conversation has led to sober yet realistic assessments of the current inadequacies of support systems for clinicians and the negative consequences on care quality and outcomes when clinicians are experiencing burnout, moral distress, and in more extreme circumstances, moral injury. Importantly, the pandemic has also generated an impetus for change, with an increasing number of organizations committing themselves to advancing the welfare of their clinical care teams. Notably, COVID-19 has helped empower clinicians to be their own advocates, with numerous examples of health care workers identifying creative solutions to the acute challenges of burnout and systems failures during the pandemic, ranging from addressing shortages of PPE to managing the complexity of staffing to developing new strategies for communication with patients and families. These efforts have affirmed the importance of grounding clinical work in relationships with patients and fostering workplace environments that are diverse and collaborative spaces for clinicians to thrive.

Building on this momentum and supporting the revitalization of the clinician workforce in the aftermath of COVID-19 will require addressing the long-standing drivers of chronic occupational distress and moral injury in the clinician workforce. The NAM's 2019 consensus study on clinician well-being provides an important starting point for policymakers and system leaders to begin to take action to proactively monitor clinicians for symptoms of occupational distress and develop robust support systems for clinicians experiencing emotional, psychological, and moral distress, with attention to reducing the stigma associated with seeking mental health care and associated services (NASEM, 2019). Some examples of tangible organizational, associational, and policy actions that leaders can take to address drivers of distress include developing a robust monitoring system with validated measurement tools for burnout and other forms of distress, realigning educational incentives to ensure that training programs foster professional well-being, and reducing burdensome administrative and documentation requirements.

Leaders themselves at all levels of the organization, from managers to executive team members, will also need training in the behaviors that promote well-being, and will need to apply frameworks for cultivating more inclusive and nurturing

cultures among all clinicians (Shanafelt et al., 2021; Shanfelt and Noseworthy, 2016). Modeling these behaviors by leadership is necessary to combat the high prevalence of stigma that clinicians report to be associated with seeking mental health resources. For example, a recent survey of nurses indicated that a lack of time and concerns around retribution, stigma, confidentiality, and licensing were among the leading deterrents to utilizing professional mental health support (ANA, 2020d). Leaders will also need to remain vigilant as many of the consequences of the pandemic on the health care workforce are still evolving, and the full impact of the pandemic will likely not be apparent for some time. To avoid further degradation of workforce well-being, policymakers and health systems need to act now and embrace a new paradigm of collaborative design with leaders and frontline clinicians to stem the tide of occupational distress, burnout, and moral suffering in health care.

Priority actions for investing in clinician well-being are summarized in *Box 2-1*.

BOX 2-1

Considerations for Investing in Clinician Well-Being

- Rebuild the trust that has been eroded during the pandemic by focusing on transparent communication and listening to and acting upon the concerns of frontline clinicians.
- Health care organizations should act on the recommendations in the NAM's 2019 report on clinician well-being. In particular, health care organizations should prioritize the mitigation of burnout and contributing factors (e.g., moral distress, problems with teamwork, inefficiency, work-life integration issues, isolation), develop a strategy, infrastructure, and leadership (e.g., Chief Wellness Officers) to address the issue, and measure progress on improving well-being.
- Strengthen protections for clinicians to report safety and ethical concerns without retribution or retaliation. Create provisions for risk compensation, disability insurance, and life insurance protections for health care workers.
- Train senior leadership, supervisors, and managers in the leadership behaviors that cultivate well-being, promote equity and inclusion. Leaders should also be trained to proactively recognize symptoms of emotional and moral distress, mental health issues and functional impairment in health care workers and understand how to guide referrals to institutional or community resources.
- Remove stigma and barriers to the use of mental health resources, including by providing sufficient insurance coverage for ongoing mental health services and access to mental health providers who are not employed by the health care organization and are trained in trauma informed care.

Advancing Innovations in Clinician Practice

COVID-19 has demonstrated the value of regulatory flexibilities (e.g., the temporary removal of licensing barriers to interstate practice) and organizational innovations (e.g., the development and uptake of crisis standards of care) for adapting clinical practice to meet patient needs. However, the pandemic has also illustrated the need for improvements in clinical capacity and infrastructure to break down siloes (e.g., between clinicians and researchers) and improve coordination (e.g., between clinicians and public health departments and officials) to foster preparedness for future public health emergencies.

In the aftermath of COVID-19, professional societies will need to review both the process and outputs of guideline development during the pandemic to identify best practices for developing and disseminating guidelines for clinical practice during crisis situations in which the evidence base is rapidly evolving. For example, academic journals played a key role in accelerating the review and publication of new materials by adopting open-access policies and receiving support from clinician researchers to expedite peer review. This in turn allowed for the rapid publication of and subsequent updates to clinical guidelines. A review of the clinical research experience during COVID-19 should also include a recognition of the fragmentation of many research efforts and the tensions that arose between clinical care and clinical research. Conversations and partnerships between health care organizations (e.g., Institutional Review Boards) and the research bodies (e.g., the NIH) to develop a dedicated infrastructure for large-scale platform trials, standards for data collection and exchange, and clear protocols would help improve coordination and ensure the sufficiency of study rigor (e.g., power, randomization). Beyond supporting research, bolstering clinical capacity for crises will require care organizations and professional societies to identify the potential skills and capacity gaps exposed by COVID-19 and work to accordingly update continuing education practices and support workforce development initiatives.

The pandemic has also illustrated the importance of digital tools and robust technological infrastructure for the future of clinical practice. Partnerships with policymakers will be key to ensuring that standards for the seamless exchange of data are implemented, guidelines for patient privacy are clarified, and resources to support the modernization of organizational competencies are available (particularly at the practice level, where the adoption of digital tools and telehealth has been uneven, especially among rural and safety net populations). Regulators will also need to collaborate with professional societies and clinicians to determine what lessons can be identified from COVID-19 flexibilities (e.g., around licensing) to maximize clinician capacity for the post-pandemic era.

BOX 2-2

Considerations for Advancing Innovations in Clinician Practice

- Advance frameworks that facilitate the ability of clinicians to be licensed in and care for patients in multiple states while following state licensure requirements.
- Implement effective recruitment and retention strategies to address workforce shortages in nursing and critical care.
- Encourage the use of system-wide standardized evidence-based protocols for critical care processes and encourage continuing education for clinicians related to key critical care functions.
- Within academic institutions, evaluate internal research review and oversight processes to reduce barriers and prioritize and accelerate needed research efforts during a crisis; for other trusted entities, publish evidence-based practice guidelines for clinicians rapidly and frequently during evolving public health emergencies.
- Invest in the infrastructure needed to achieve effective health data sharing, especially between health care organizations and public health departments and officials.

Central to these discussions will be balancing the need for appropriate oversight and credentialing with the recognition of pervasive capacity gaps in communities across America.

Priority actions for advancing innovations in clinical practice are summarized in *Box 2-2*.

Promoting Financial Resilience for Clinicians

With COVID-19 exposing the fragility of a volume-based reimbursement system, policymakers will need to implement payment reforms that drive improvements in quality, decrease spending, and promote financial resiliency for clinicians by transitioning to a more diverse set of payment models. Many examples of alternative payment models (APMs) have been trialed over the past decade, some of which may have been associated with modest cost savings pre-pandemic and improved financial positioning for clinicians during COVID-19. However, widespread adoption of such models has lagged. First, interested practices often lack the resources needed to invest in the tools and data systems needed to redesign care delivery. Second, the steep requirements for financial risk inherent in many APM models have posed barriers to participation.

Third, the risk adjustment for many APMs has been perceived to be inadequate, particularly given emerging evidence demonstrating the financial losses incurred by providers who treat patients with greater medical and social needs (AMA, 2017).

To strengthen the health care system and make practices more resilient to future public health emergencies, regulators should take steps to redesign payment models and provide the necessary support to clinicians to facilitate the transition away from volume-based reimbursement. Increasing the accessibility of pilot programs (e.g., Medicare's medical home models) for clinicians and fostering partnerships with payers may promote the adoption of new payment systems. Importantly, policymakers must also provide meaningful opportunities for clinicians to engage in the payment redesign process, particularly given the limited engagement by policymakers with existing advisory groups (e.g., the Physician-Focused Payment Model Technical Advisory Committee) (Micklos, 2018). Good faith, cross-sector collaborations—such as those formed during the pandemic—can help achieve consensus and spur the adoption of tangible reforms.

In addition to realigning financial incentives, policymakers, payers, and clinicians should work together to evaluate how COVID-19 flexibilities, where appropriate, could be iterated upon to reduce the administrative burden of clinicians. While quality measurement is critical to payment reform, measurement for the sake of measurement only adds to the administrative burden of clinicians. To improve and reinvent the quality measurement ecosystem for future pandemics, CMS and commercial payers should focus on streamlining measure sets to prioritize the most impactful metrics for patients and clinicians. Furthermore, transitioning to a selective approach for prior authorization, as proposed in a 2018 consensus statement issued by professional societies and industry associations, can help improve transparency, efficiency, and continuity of care beyond the pandemic (AMA, 2018).

As policymakers take steps to implement payment reforms, they must also recognize the fragile state of many practices following COVID-19. While the rapid allocation of federal relief funds helped temporarily stabilize many practices, assistance was fragmented, leaving out certain critical providers, and the duration of these measures remains inadequate to address ongoing revenue losses and increased expenses. In the short term, Congress and CMS could help accelerate providers' recovery from the financial impact of COVID-19 by extending pandemic-era policies for telehealth reimbursement, while using the lens of value-based payment to develop telehealth payment policies for the long term. With a growing body of evidence from the pandemic illustrating that many clinical conditions could be effectively managed using virtual care

BOX 2-3

Considerations for Promoting Financial Resilience for Clinicians

- Develop and implement innovative payment models that drive quality and value while building the resiliency and sustainability of clinical practices.
- Fund payment models that support high quality team-based care delivery and coordination in treatment planning and management.
- Build on COVID-19 reporting flexibilities to streamline future quality measurement and reduce the administrative burdens associated with prior authorization.
- Establish a standard approach for supporting patient access and continuity of health care during public health emergencies and natural disasters.
- Establish longer-term coverage and payment policies for telehealth services to promote continued availability of these services by medical practices post-COVID-19.

modalities, regulatory actions—including permanently lifting originating site requirements, and continuing coverage of certain telehealth modalities—will help support the continued use of these delivery innovations. In the long term, policymakers should build on the recent experiences with advanced payments, provider relief funding, and cost-sharing waivers to establish standard approaches to support patient access and continuity of medical care during future public health emergencies.

Priority actions for promoting financial resilience for clinicians are summarized in *Box 2-3*.

Transforming Education and Training

Pandemic-induced disruptions to and innovations in clinical education provide an important window for clinicians and professional societies to build upon existing momentum for reform to improve the affordability, accessibility, and equity of clinical education in the 21st century.

As a starting point, the broad inequities exposed by the COVID-19 pandemic illustrate the need for health professions schools to appropriately transform their curricula to prioritize attention to equity. In tandem, academic medicine and nursing will need to take a deliberate approach to rethinking pipeline recruitment, clinical training, hiring processes, and workforce organization to improve diversity across all axes of representation and create clinical environments that support

the development of historically underrepresented and marginalized populations (Coleman, 2020; Yousif et al., 2020). For example, the economic impact of the pandemic on both student and university finances should prompt a meaningful conversation about opportunities to improve the affordability of clinical education, and should merit consideration from policymakers to expand existing clinician pipeline programs, including the Health Career Opportunity Program and the National Health Service Corps (CMS, 2020c; Nolen, 2019; Heisler, 2018). Likewise, educators should incorporate lessons from COVID-19 to improve the equity of training and application processes, such as addressing the inequities created by the inconsistent availability of visiting clinical rotations in medical residency selection processes (Lucey and Johnston, 2020). To operationalize this systems-based approach to improving equity in clinical education, health professions schools will need to develop systems for measuring and assessing progress toward diversity, equity, and inclusion (Josiah Macy Jr. Foundation, 2020).

Efforts to transform clinical curricula should also incorporate evidence from COVID-19 on different pedagogical innovations. For example, educators may seek to update their curricula to include a new focus on crisis communication, critical appraisal of scientific evidence, and experiential opportunities to enhance "webside" manner for a new generation of clinicians who are digital natives (Chua et al., 2020). In the process, the trauma of COVID-19 should prompt educators to devote greater attention to issues of clinician well-being and ethical decision-making. The pandemic has also emphasized how clinical care is a "team sport," and that interprofessional education for physicians, nurses, and other allied health professionals is critical for the delivery of safe, empathetic, and high-quality patient care.

Furthermore, COVID-19 has illustrated the value of competency-based, time-variable education, which creates flexibility for learning without compromising rigor or the expected performance standards for students and trainees (Lucey and Johnston, 2020). Sustaining these innovations beyond the pandemic will require collaboration across health professions schools, professional societies, and policymakers. For example, scaling competency-based, time-variable education will not only necessitate investments in new education models, assessment tools, and faculty development programs, but also require academic institutions as well as licensing, certification, and regulatory bodies to shift their requirements from a time-based orientation (e.g., credit hours, program length) to an achievement-based orientation (e.g., mastery of required skills). Such partnerships will be critical for building on the momentum from COVID-19 to redirect the focus of clinical education away from process and towards outcomes.

Priority actions for transforming education and training are summarized in *Box 2-4*.

BOX 2-4

Considerations for Transforming Education and Training

- Address the drivers of inequities in resources and learner experiences in academic medicine and nursing, including structural racism.
- Address financial barriers to student access and progression in health professions education.
- Expand the prevalence of competency-based, time-variable education across health professions programs.
- Advance innovation in health professions education through technology and simulation for continuous learning.

Developing Policies and Programs to Address Health Disparities

The disparate impact of COVID-19 on marginalized populations is the result of long-standing disparities in population health in the U.S. for people made vulnerable by racism, socioeconomic disparities, geography, disability, and bias. Beyond the distressing gaps in access to affordable health care and the environmental challenges contributing to poorer health outcomes for marginalized populations, the pandemic has also demonstrated how inequities are embedded in various processes in health care (e.g., recruitment for clinical trials, guidelines for the allocation of medical products) (Chastain et al., 2020; Schmidt, 2020).

Addressing health disparities will require a systems approach inclusive of all sectors of the health system. But as direct providers of care to patients in need, clinicians will play an important role at combating inequities on the frontlines. At the level of care delivery, clinicians and professional societies will need to use the lens of equity to address implicit biases within clinical practice (e.g., the use of race when estimating kidney function) (Vyas et al., 2020; Eneanya et al., 2019). Clinicians will need to also review guidelines for public health emergencies to ensure that such protocols do not disadvantage certain groups.

Of course, meaningful progress to redress the disparities in American health care will require embedding equity and the ethos of justice in all aspects of clinical training, practice, and operations, rather than treating issues of representation and racial bias in isolation. Indeed, each of the priority actions listed above in *Box 2-1* through *Box 2-4* can and should be centered around the principles of equity,

BOX 2-5

Considerations for Addressing Health Disparities

- Develop fair, equitable, and transparent plans for resource allocation and access to testing, treatment, and nursing services. Plans should include adjustments for increasing access to people who are systematically disadvantaged, disabled, or otherwise vulnerable.
- All plans should be designed with a systematic inquiry into how racism might be at play in this decision or plan.
- Health care institutions and leaders should create ongoing methods of surveillance of the impact of their decisions and protocols on different types of professionals and staff and to proactively assess the unintended inequities or consequences that arise from them.
- Develop standardized protocols regarding participating in treatment decision-making or support by families, surrogates, and health care agents to patients during crisis situations that do not disadvantage certain groups or create barriers that disproportionately add burden to certain professions or roles.

whether it is a priority action to address clinician well-being (e.g., recognizing the association between racial bias and burnout) or a policy consideration for improving equity in clinician education (e.g., the chronic underrepresentation of communities of color in clinical practice) (Dyrbye et al., 2019c).

Priority actions for addressing health disparities are summarized in *Box 2-5*.

CONCLUSION

This discussion paper has sought to highlight the challenges and lessons for clinicians and professional societies during the COVID-19 pandemic. While this paper has focused primarily on the experience of physicians and nurses, which represent two of the largest segments of the health professions workforce, it is important to acknowledge the tremendous contributions of all health care workers, including a range of allied health professions who provide care in diverse clinical settings encompassing community clinics, long-term care facilities, and hospitals. The clinician sector has played a leading role during each stage of the response to COVID-19, from detecting and caring for the first infected patients at the beginning of the outbreak, to adapting care models to meet the needs of both COVID-19 and non-COVID-19 patients as the pandemic progressed,

to more recently supporting vaccination campaigns by administering shots and organizing to address vaccine hesitancy. Beyond care delivery, clinicians also worked to navigate uncertain clinical environments and an evolving evidence base to develop clinical guidelines for COVID-19. Furthermore, clinicians have served as trusted messengers and voices for change throughout the pandemic, organizing at the national and grassroots levels to highlight the role of structural racism in pandemic disparities and advocate for improving the equity of both the pandemic response and the health care system writ large.

Yet the diverse contributions of clinicians during the pandemic—layered on top of their first and foremost responsibility of delivering empathetic and effective patient care—have taken their toll. Emerging evidence unequivocally indicates the tremendous physical, mental, emotional, and moral burden imposed by a prolonged public health emergency on the clinician workforce. Pandemic-era stressors spanning dangers to clinicians' personal safety, to isolation from personal and professional support networks, to the persistent burden of working in understaffed and over-booked care delivery settings, to the role of structural racism in contributing to stark inequities in pandemic outcomes, have all exacerbated pre-pandemic trends of rising burnout, moral distress and deteriorating clinician well-being. COVID-19 has also exposed existing challenges for the clinician sector, from the instability of fee-for-service reimbursement to the gaps in clinical capacity for specific specialties (e.g., critical care) and populations (e.g., rural, safety net), to the inequities embedded into health professions training and clinical care. It has also illuminated the prevalence of moral injury associated with clinical care during the pandemic.

Although the pandemic remains ongoing at the time of this paper's publication, the experiences of clinicians to date offer valuable insights for policymakers as the country works to navigate the next phase of the pandemic and future emergency preparedness. For example, a key lesson from the pandemic is how building a robust health care system capable of meeting both population health needs and emergency situations is predicated on a sufficiently resourced clinician workforce. In this discussion paper, leaders from the clinician sector have sought to review the experience to date of clinicians and present the priority actions for guiding COVID-19 response and recovery. Considerations for policymakers include investing in clinician well-being, advancing innovations in clinician practice, promoting financial resilience for clinicians, transforming education and training, and developing policies and programs to address health disparities. A resilient health care system begins with a resilient health care workforce, and by addressing the systemic challenges exposed and exacerbated by the pandemic, policymakers can support and revitalize the clinician workforce to meet the health and care needs of patients and communities across America for COVID-19 and beyond.

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3

CARE SYSTEMS COVID-19 IMPACT ASSESSMENT: LESSONS LEARNED AND COMPELLING NEEDS

Jeffrey Balser, MD, PhD; Jaewon Ryu, MD, JD; Michelle Hood, MHA; Gary Kaplan, MD; Jonathan Perlin, MD, PhD; and Bruce Siegel, MD, MPH

INTRODUCTION AND SECTOR OVERVIEW

Health systems in the U.S. are constituted by a number of different care delivery units and a diverse workforce of clinicians and allied health professionals. This discussion paper will focus on the perspectives of America's more than 600 health systems—including both for-profit and not-for-profit systems and many of the nation's academic medical centers (AMCs), safety net facilities, critical access hospitals (CAHs), community hospitals, and rural hospitals—which collectively contain the majority of the nation's hospital beds, employ nearly half of the country's physicians, and provide health services ranging from basic primary care to complex surgical procedures (AHRQ, 2017). While this sector assessment will seek to broadly capture the experiences of care delivery organizations during the pandemic, and while many of the challenges and lessons identified in this discussion paper may apply to a range of delivery systems across the country, the review will not address the nuances of specific systems or provider types, such as the Veterans Health Administration (the largest delivery system in the U.S.), correctional care health systems, independent physician practices, and various types of community clinics and health centers. Many of the health systems encompassed in this sector assessment play a critical role in caring for vulnerable patients, serving predominantly low-income populations and shouldering a high burden of uncompensated care (Furukawa et al., 2019; AHRQ, 2018). Beyond clinical care, health systems also occupy a foundational role in their communities, from supporting scientific research to serving as the largest employer in many states across the country (Gooch, 2020). The landscape of U.S. health systems is summarized in *Figure 3-1*.

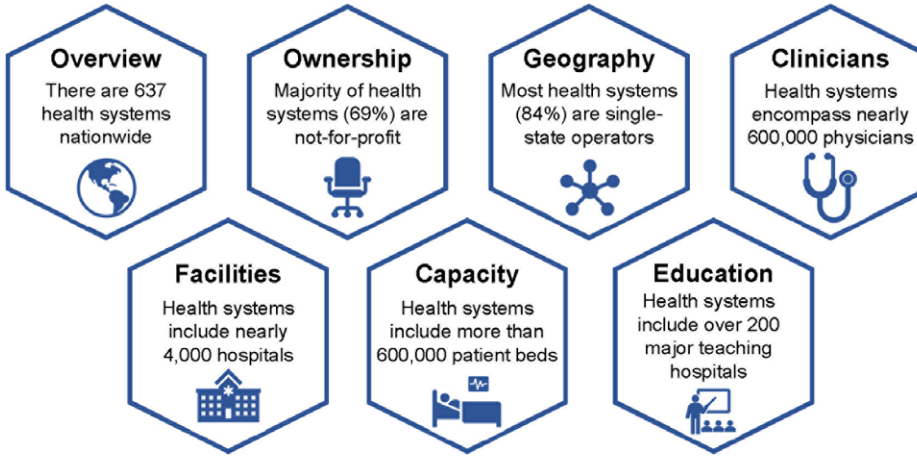

FIGURE 3-1 | Landscape of U.S. Health System

SOURCE: Figure includes data from Compendium of U.S. Health Systems, 2018. Content last reviewed March 2021. Agency for Healthcare Research and Quality, Rockville, MD. Available at: https://www.ahrq.gov/chsp/data-resources/compendium-2018.html.

In recent years, health systems in the U.S. have evolved in response to the growing complexity of patient needs, elevated market pressures, and a changing regulatory and payment environment. For example, as America's population ages and becomes more diverse, and the burden of chronic disease grows, health systems have increasingly invested in strategies to address complex population health challenges and created new care models that emphasize coordination, service integration, and the social determinants of health (SDoH) (Horwitz et al., 2020; AHA, 2019; The SCAN Foundation, 2018a; The SCAN Foundation, 2018b). As care delivery models have transformed, the market landscape for health systems has also shifted, with notable developments in vertical integration (e.g., payer-provider partnerships, provider group and nursing home acquisitions), horizontal consolidation (e.g., hospital mergers), and site-of-service migration (e.g., from inpatient facilities to outpatient settings or into the home) (Boston Consulting Group, 2020; Furukawa et al., 2020). These industry trends have occurred amidst a rapidly evolving regulatory environment, with health systems navigating a number of key policy issues including the effects of fiscal pressure on Medicare rates, changes to fee schedules, and new proposed rules for price transparency (Ehnes et al., 2020; Kliff, 2019).

These clinical, economic, and policy trends frame the environment for health systems prior to the COVID-19 pandemic. Since the beginning of the outbreak, health systems have (quite literally) operated at the frontlines, providing care to infected patients, taking steps to ensure the safety of providers and staff, and reconfiguring delivery systems to accommodate surges in service demand. As the

COVID-19 pandemic has progressed, health systems have also developed cross-cutting public health functions, from augmenting testing and contact tracing capacity for their communities to taking action to address the long-standing health inequities exposed by COVID-19. In most cases, health systems' pandemic response activities have entailed reducing or canceling non-emergent surgeries and minimizing non-COVID-19 inpatients. Freeing up bed space and staffing resources enabled hospitals to accommodate surges in infected patients, but also greatly reduced profitable service volume. Thus, the response to COVID-19 has carried a high price; disruptions to care delivery have deeply impacted health system finances, while adaptations for surge capacity have strained supply chains and taken a toll (mental, emotional, and physical) on the provider workforce.

This discussion paper seeks to describe the response and experience of hospitals and health systems within the U.S. health care system during COVID-19. At the time of this paper's publication, the pandemic remains ongoing and health systems' responsibilities and functions continue to evolve in response to public health needs—including most recently for COVID-19 vaccination campaigns. However, the core challenges for care delivery organizations during the pandemic—financial and operational disruption, supply chain and staffing strain, equity considerations, and cross-sector coordination—remain salient amidst an ever-shifting landscape, and offer a useful lens for navigating present uncertainties and future considerations. Consequently, in this paper, leaders from the care delivery sector will explore how pandemic-era challenges and innovations provide these health systems with an opportunity to transform care delivery to become more accessible, efficient, and equitable for all while fostering preparedness for future public health emergencies. (Recognizing the sector's heterogeneity and the diversity of delivery system experiences during the pandemic, the author group has supplemented the perspectives presented in this paper through interviews conducted by the Chartis Group with academic health system leaders from the following organizations: University of Pennsylvania, Brigham and Women's Hospital, Michigan Medicine, Yale New Haven Health System, Beth Israel Lahey, New York Presbyterian, Mt Sinai, University of Chicago, UT Southwestern, Vanderbilt University Medical Center, Emory, Washington University, West Virginia University Health System, and Thomas Jefferson.)

THE HEALTH SYSTEM RESPONSE TO COVID-19

Patient Care Functions

From the outset of the outbreak of COVID-19 in the U.S., health systems began mobilizing to shore up care delivery capacity for COVID-19 patients

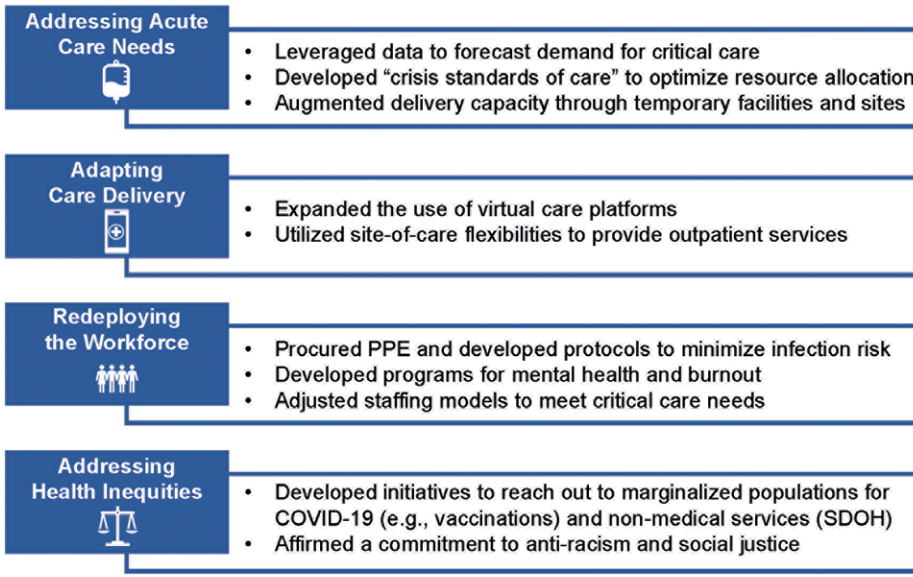

FIGURE 3-2 | Health System Functions During COVID-19

while developing contingencies to account for disruptions in non-COVID-19 care. Redesigning patient care during a pandemic required not only adapting delivery modalities (e.g., virtual platforms, site-of-care flexibilities), but also rethinking supply chains and staffing models to account for the stochasticity of infection rates. Key facets of health systems' pandemic response for patient care are presented below and summarized in *Figure 3-2*.

Addressing Acute Care Needs

With health systems possessing the majority of the nation's inpatient capacity, their first and foremost priority was ensuring that the health care facilities in their system had the capacity and resources needed to treat COVID-19 patients. Key strategies for managing inpatient surge capacity included the following.

First, a primary area of focus was anticipating demand for critical care. 63% of intensive care unit beds in U.S. hospitals were already occupied prior to the pandemic, leaving the health system with approximately 32,000 unoccupied intensive care unit beds at baseline (Tsai et al., 2020). With the virus spreading exponentially in hotspot areas but unevenly across the country, several health systems developed tools to predict needs based on published data, while others leveraged larger regional projections made possible by data initially compiled by the CDC's National Healthcare Safety Network (Moghadas et al., 2020; NHSN, 2020; Weissman et al., 2020). Health systems then worked with state and

local entities to share the latest data on bed availability and to triage the most appropriate and efficient use of all bed resources, including in skilled nursing facilities (SNFs), rehab, and long-term care centers.

Second, health systems developed new protocols to optimize limited resources and bed capacity. For example, experts proposed a series of "crisis standards of care," which offered a guide for allocating scarce resources (e.g., ventilators) and clarified trigger events for when health systems should consider activating such emergency protocols (Hick et al., 2020). Additionally, health systems developed new discharge protocols to facilitate care handoffs to home or to post-acute care facilities.

Third, health systems took steps to augment their overall delivery capacity. For example, systems leveraged regulatory flexibilities such as the "Hospital Without Walls" initiative to repurpose alternative sites for inpatient care (e.g., ambulatory surgery centers) (Podulka and Blum, 2020). Other systems leveraged telehealth, existing home health nursing programs, and relationships with third-party entities to implement the Centers for Medicare & Medicaid Services (CMS) Acute Hospital at Home (HaH) program—a care delivery paradigm that entails the provision of care in the patient's home, obviating the need for an inpatient admission and expediting discharge from inpatient facilities (Sitammagari et al., 2021; CMS, 2020a). Some systems have also leveraged temporary facilities to some extent, such as New York City's use of a tent hospital site in Central Park and the U.S. Navy Ship (USNS) Comfort. However, utilization of temporary facilities was challenging due to the complexity of transferring acutely ill patients.

Adapting Care Delivery Modalities and Locations

The pandemic significantly disrupted the delivery of non-COVID-19 care, with notable declines in emergency department visits, inpatient admissions, and outpatient visits. For example, studies have reported declines in emergency department volume to exceed 40% in some states between January 2020 and April 2020 (Jeffrey et al., 2020). Likewise, outpatient visits declined by nearly 60% between February 2020 and April 2020 (Mehrotra et al., 2020a). To meet patient needs, health systems leveraged new regulatory flexibilities to adapt care delivery to different modalities and sites of service.

First, health systems reported substantial growth in the use of virtual care platforms following announcements from public and private payers to temporarily expand coverage and reimburse telehealth at parity with in-person visits for the duration of the public health emergency. For example, leaders of the health systems interviewed for this discussion paper reported that telehealth utilization increased from negligible levels prior to COVID-19 to account for the majority of nonemergent patient interactions for the first quarter of 2020

(Koonin et al., 2020). While rates of virtual visits have declined as in-person care has resumed, rates of telehealth utilization still continue to substantially exceed pre-pandemic levels. As of October 2020, telehealth visits accounted for over 6% of all ambulatory care appointments in the U.S.—below the April 2020 peak of nearly 14%, but well above the pre-pandemic rate of 0.1% (Mehrotra et al., 2020b).

Second, health systems leveraged site-of-care flexibilities to ensure continuity of care and continue to meet patient needs within the constraints of shelter-in-place restrictions. For example, many systems shifted the delivery of outpatient services to home-based settings (e.g., wound care, chemotherapy) (Laughlin et al., 2020). While the long-term feasibility of these innovations will depend on the regulatory and payment environment, many patients noted the convenience and efficiency of home and virtual care, and surveys of health care leaders indicate that systems are exploring how these pandemic-era innovations could be better integrated into delivery models for continued use after the pandemic.

Redeploying the Workforce and Ensuring Staff Safety

A leading priority for health system leaders was ensuring the health and safety of staff throughout the pandemic. Health systems took several steps to protect their workforce while also reconfiguring clinical workflows to meet the needs of COVID-19 patients.

First, many health systems focused on ensuring staff safety by developing protocols for testing, tracing, and infection control, and procuring necessary personal protective equipment (PPE), with national shortages at the outset of the pandemic creating challenges for the protection of health care workers. For example, some health systems redesigned their workflows to minimize exposure and maximize safety. Key strategies included limiting clinician activities across sites, reducing the total number of physician and nursing staff at risk of exposure, and ensuring the availability of substitute team members and locations or facilities in the event of exposure.

Second, some health systems worked to develop support systems to alleviate the stress and strain of COVID-19 on their clinician workforce. Common strategies included centralizing mental health resources for providers, providing support for self-isolation requirements, and conducting proactive screenings for symptoms of anxiety, depression, and post-traumatic stress disorder in providers (NYC Health + Hospitals, 2020; UCSF, 2020). However, not all health systems—particularly those in rural communities and those serving safety net populations—possessed the same resources. Additionally, with the pandemic persisting for over a year, the accumulated stress of escalating waves of infection did take a toll on many health

professionals, with emerging evidence highlighting significant burnout in the clinician workforce (Matsuo et al., 2020).

Third, health systems that were able sought to adjust their staffing models to meet patient needs. For example, during COVID-19, some care areas faced staff shortages (e.g., Emergency Departments, Intensive Care Units), while others had underutilized staff due to the delay of scheduled, non-emergent procedures and outpatient services. With shortages ranging from respiratory therapists to physicians with critical care training, some health systems relied heavily on staffing firms and traveling providers to fill gaps during the early days of the pandemic. However, with the virus eventually affecting health systems across the country, hospitals later had little spare capacity, and the cost of *locum tenens* (substitute providers) increased substantially, adding to the financial strain of the pandemic (Capstone Headwaters, 2021). Other systems sought to rapidly cross-train health professionals to address surge staffing needs, developed specialized COVID-19 training for staff, and reassigned residents at AMCs from other inpatient service lines (e.g., obstetrics and gynecology, radiology, and surgery) to support COVID-19 care (Keeley et al., 2020). Yet while these measures highlight the adaptability of health systems during COVID-19, the prolonged nature of the pandemic and recurrence of staffing shortages well into the end of 2020 and beginning of 2021 created substantial pressures on hospitals across the country (Goldhill, 2020).

Addressing Health Disparities and Health Equity

COVID-19 magnified America's long-standing disparities in health care quality, access, and outcomes across racial and ethnic groups, socioeconomic strata, and geographies. In response, health systems worked to meet patients where they were and address non-medical needs. For example, several health systems created community outreach programs that sought to tailor public health resources to their community's context (e.g., development of Spanish language communication tools) and facilitate access to COVID-19 diagnosis and treatment (e.g., coordination for free testing sites) (AHA, 2020a). Partnerships with community organizations was key to outreach, with health systems frequently collaborating with the faith community to disseminate public health best practices, counter misinformation related to COVID-19 and vaccine mistrust, and organize drive-through testing sites (mHealth Fairview, 2020; Tupponce, 2020). To help address the environmental drivers of COVID-19's disparate impact, many health systems worked to screen their patients for non-medical but critical needs (e.g., food or housing insecurity), and accordingly collaborated with local medical (e.g., pharmacies) and non-medical (e.g., food banks, housing agencies) organizations to coordinate the provision of wraparound services.

Furthermore, in the wake of nationwide protests following the deaths of George Floyd, Breonna Taylor, and many other Black Americans, numerous health systems reaffirmed their commitment to combating health inequities, with many organizations beginning their work by launching task forces focused on anti-racism and social justice (McLean Hospital, 2020; Megerian, 2020; Michigan Medicine Headlines, 2020; VUMC Reporter, 2020). For example, a group of 39 of the nation's largest health systems pledged in September to take several steps to address health care disparities and structural racism in their organizations (Megerian, 2020; Paavola, 2020; VUMC Reporter, 2020). This group's pledge and statement was modeled after a June statement signed by 36 Chicago-area health systems (Paavola, 2020).

Public Health Functions

In addition to their primary functions for care delivery, health systems also played a critical role in the public health response, from supporting the development of medical countermeasures including diagnostics, therapeutics, and vaccines to scaling testing capacity and exchanging data to inform disease surveillance. Examples of cross-cutting public health functions are presented in *Figure 3-3*.

Testing and Tracing

Accurate and timely testing for COVID-19 was critical for health systems to effectively respond to the pandemic (OIG, 2020; HHS, 2020a). Many health systems were able to develop testing capacity through a combination of internal

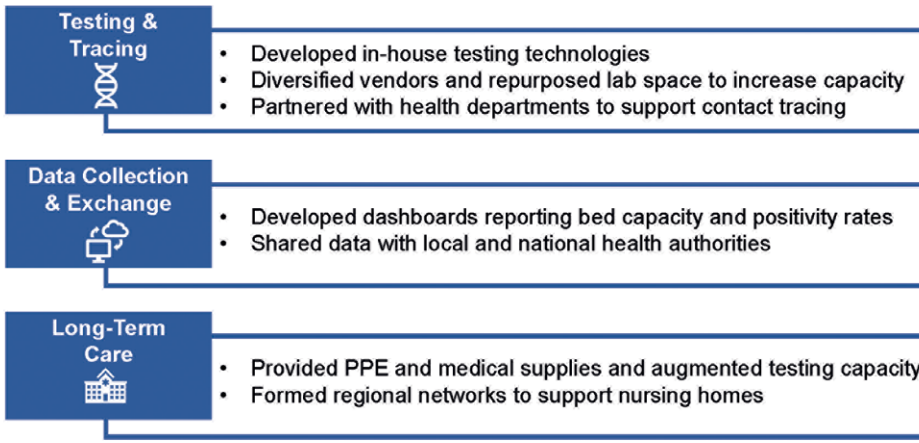

FIGURE 3-3 | Cross-Cutting Public Health Functions for COVID-19

resources and external vendors. However, a key challenge for system leaders was determining how to allocate or prioritize testing resources with different turnaround times for distinct operational (e.g., surveillance testing of staff) and care delivery (e.g., urgent scenarios) needs. Additionally, responses by systems may have varied according to their unique context, resources, and community needs, with some rural systems facing distinct challenges from integrated delivery systems in urban environments. Additionally, backlogs in test processing created bottlenecks for decision-making about patient care, which in turned slowed service allocation (e.g., whether a patient required a negative pressure room) and care transitions (e.g., discharge to post-acute care facilities) (Grabowski and Joynt Maddox, 2020).

Faced with an uncertain and rapidly evolving regulatory and scientific landscape, health systems took action to augment testing and tracing capacity. For one, hundreds of health systems developed their own diagnostic tests for SARS-CoV-2, with multiple health systems even receiving Emergency Use Authorizations from the Food and Drug Administration (FDA) for the molecular assays which they developed in-house (King, 2020; FDA, 2020a). In addition to developing their own tests, care delivery organizations leveraged their research laboratories to alert the FDA about issues with test performance (Pradhan, 2020).

As testing methods improved, care delivery organizations took steps to scale their testing capacity and support contact tracing efforts. Common strategies to mitigate the risk of supply shortages included diversifying laboratory supply vendors and opening new laboratory facilities to meet demand (Johnson, 2020). Many health systems also developed robust contact tracing programs for both their own staff and patients, with internal programs including the use of digital contact tracing tools and dedicated infection control teams (Brigham and Women's Hospital, 2020; Cohen, 2020). Health systems then used this expertise to support contact tracing at the community level, working to augment local health department capacity by offering to collect and process specimens and in some cases even providing training programs for newly hired contact tracers (Kennedy, 2020; Kurtzman, 2020). Notably, health systems often launched these initiatives without additional resources or funding, and often still faced regulatory and technical challenges for implementation.

Data Collection and Exchange

Due to their role in caring for COVID-19 patients and the in-house testing programs that many care delivery organizations developed, health systems possessed valuable data for COVID-19 to help inform both internal care planning as well as local disease surveillance. Indeed, several health systems developed their

own COVID-19 dashboards to keep the public informed. By aggregating data on disease surveillance with information on test positivity rates and bed capacity, health systems were able to help streamline provider and patient decision-making with respect to referrals and accordingly to manage supplies and surge capacity (Texas Medical Center, 2020).

Support for Long-Term Care

Nursing homes have been described as "ground zero" for COVID-19 in the U.S.—a trend that has persisted throughout the pandemic, with cases and fatalities peaking in December 2020 and January 2021 (The COVID Tracking Project, n.d.). Despite the vulnerability of nursing home residents, efforts to support long-term care facilities have been stymied by both existing systemic challenges (e.g., funding, staffing) and cross-cutting governance and regulation across levels of government (Barnett and Grabowski, 2020). In response, health systems have stepped up to support nursing homes during the pandemic, ranging from the sharing of infection control best practices and COVID-19 training materials to donations of PPE to facilities experiencing shortages and the provision of diagnostic capacity to reduce turnaround times for COVID-19 testing (Herman, 2020). As the pandemic progressed, several health systems were also formally contracted to develop regional collaboratives for coordinating testing, medical supplies, and rapid response team deployments for nursing homes experiencing rising caseloads (Lord, 2020).

KEY PANDEMIC-ERA CHALLENGES FOR HEALTH SYSTEMS

The harrowing experiences of health systems and health professionals in early pandemic epicenters illustrated the unprecedented challenges imposed on health systems from a care delivery perspective (Khullar, 2020). Yet as it became clear the outbreak had evaded early control and achieved national spread, the challenges for care delivery organizations began to evolve beyond patient care. The key challenges included:

1. Financial pressures from care delays, cancellations, and additional costs for pandemic response;
2. Supply chain strain for products ranging from PPE to essential medicines;
3. Workforce limitations and staffing shortages; and
4. The need to develop cross-cutting functions to support community needs (see *Table 3-1*).

TABLE 3-1 | Health System Challenges During COVID-19

Theme	Challenges	Example
Financial Impact	• Care delays and cancellations disrupted revenue streams and severely affected provider finances	• Financial losses for hospitals between March 2020 and June 2020 are estimated to exceed $200 billion
	• Providers incurred many pandemic-related costs (and paid premiums) to purchase supplies and restructure clinical workflows	• The cost of refilling essential medicines increased by 62% during April 2020
Supply Chain	• Health systems across the country reported persistent shortages of PPE, essential medicines, and medical devices	• Hospital demand for dexamethasone increased by 610% while fill rates declined to 54%
	• Outsourced manufacturing and depleted domestic reserves contributed to supply chain vulnerabilities	• Over 20% of nursing homes nationwide reported severe PPE shortages well into the summer of 2020
Workforce	• Pre-pandemic staffing shortages were an obstacle to the development of surge capacity for COVID-19	• Staff shortages for critical care led to increased demand among health systems for temporary clinicians
	• COVID-19 has exacerbated the existing challenges of burnout among health professionals	• Surveys of providers indicated elevated levels of stress and symptoms of anxiety, depression, and post-traumatic stress
System and Community-Wide Coordination	• Coordination within health systems and with other sectors was complicated by decentralized governance models	• Health department capacity varied widely across the country, requiring health systems in rural and underserved areas to take on additional responsibilities
	• Outdated technical infrastructure created challenges for data sharing	• Funding for the Hospital Preparedness Program was reduced by 46% between 2003 and 2020, limiting the resources available to hospitals to coordinate emergency response

Financial Impacts

Health systems encountered a paradox during COVID-19. Despite operating beyond their inpatient capacity during spikes in COVID-19, many health systems experienced substantial financial instability resulting from delayed or cancelled care that has persisted throughout the public health emergency. The sector incurred hundreds of billions of dollars in financial losses during the spring of 2020 (AHA, 2020b; Kaufman Hall, 2020a). Financial relief from the Coronavirus Aid, Relief,

and Economic Security (CARES) Act partially alleviated the impact, with federal appropriations limiting the overall decrease in the median hospital operating margin between 2019 and 2020 to a decrease of 1.2% (there would have been a decrease of nearly 5% without CARES funding) (Kaufman Hall, 2021). Notably, health systems with diversified revenue streams (e.g., health plan operations) and payment models (e.g., capitation) were able to partially offset some losses (Liss, 2021; Bannow, 2020). Nevertheless, the sector overall experienced significant financial impacts. Additionally, while health care has historically been considered "recession proof," the jobs recovery continues to lag, with net layoffs exceeding 110,000 jobs in U.S. hospitals alone as of September 2020 (BLS, 2020). The key drivers of the pandemic-induced financial impact include shifts in payer mix (e.g., expansion in self-pay and Medicaid patient segments due to the abrupt rise in unemployment), the lost revenue from delays and cancellations of scheduled, non-emergent procedures (a key revenue stream for care delivery systems), and the ancillary expenditures for pandemic preparedness and response. Together, these factors led to a 14% increase in expenses per discharge and a 6% decline in outpatient revenue during 2020, reflecting the financial difficulties for the sector as a whole (Kaufman Hall, 2021).

Care Delays and Cancellations

While American hospitals possess moderate excess capacity (average occupancy of 62% at baseline), the anticipated demand from COVID-19 suggested that hospitals would need to create additional inpatient capacity (Song and Ferris, 2018). To generate additional capacity, conserve supplies, and reduce the exposure risk for patients and staff, CMS recommended on March 18, 2020 that most elective surgeries and non-essential procedures be cancelled or delayed during the public health emergency (CMS, 2020b). Federal action was followed by executive orders from dozens of states and the District of Columbia (ACS, 2020). While well-intentioned and appropriate, these actions carried several challenges and financial consequences.

First, the meaning of "elective" was misinterpreted during the ensuing implementation of public health guidance. Although the defining characteristic of an "elective" procedure is that it is a scheduled operation, policymakers and the lay public conflated "elective" with "optional" (e.g., cosmetic surgery). While care deferrals and cancellations certainly freed up inpatient capacity, this imprecision in messaging may have delayed time-sensitive care (e.g., tumor biopsies, operable cancers, ischemic heart disease) and also created a backlog of millions of procedures (e.g., joint replacements, cataracts removal) which is forecasted to take months, if not years, to resolve (Berlin et al., 2020; Brindle et al., 2020).

Second, the cancellation or deferral of vast numbers of procedures and outpatient services had a profound effect on health systems' financial health. The volume-based payment system generally provides better reimbursement relative to cost for procedural than consultative services (Bai and Zare, 2020; Gondi and Chokshi, 2020; Khullar et al., 2020). Cancellations also generally affected hospitals' more profitable service lines (e.g., complex surgeries), with approximately 30% of inpatient revenue attributed to elective procedures (Khullar et al., 2020). Likewise, the 6% decline in outpatient revenue during 2020 negatively impacted the sector, as hospital revenue today is generally evenly distributed across both inpatient and outpatient service lines (Kaufman Hall, 2021; Khullar et al., 2020). Consequently, the volume declines which resulted from both governmental mandates and patient choices resulted in significant shortfalls in operating revenue, even at health systems where intensive care units were at capacity due to COVID-19, with rural hospitals and CAHs experiencing particularly severe impacts (Khullar et al., 2020).

Additional Pandemic-Related Expenditures

In addition to declining revenue streams due to service disruptions, care delivery organizations also incurred additional expenditures due to the resources and staffing costs associated with the pandemic response. Demand for many pandemic essentials (e.g., medication, PPE, labor) far outpaced supply, requiring many organizations to pay hefty premiums to replenish their stocks in anticipation of additional cases. For example, market research found key supplies (e.g., N95 respirators, nitryl gloves) in April 2020 to carry markups in excess of 1,000% of pre-COVID-19 pricing (SHOPP, 2020). Likewise, drug expenses per adjusted discharge increased by 62% during April 2020 for select critical care medicines which went into shortage (Kaufman Hall, 2020b). Beyond line-item costs, care delivery organizations also incurred additional expenses from the reconfiguration of facilities and staffing workflows for the pandemic response (Capstone Headwaters, 2021; Kaufman Hall, 2020b). Overall, non-labor expenses increased by 14% and supply expenses by 13% in 2020, illustrating the added costs from the COVID-19 response (Kaufman Hall, 2021).

While the $175 billion which Congress appropriated through the CARES Act offered health systems temporary financial relief, the long-term financial outlook for health systems remains unclear, particularly with the persistence of high COVID-19 caseloads and the uncertain time frame for the full return to pre-pandemic non-COVID-19 utilization levels. Additionally, the criteria and distribution system for financial relief required amendments, as the original methodology was anchored to historical levels of Medicare fee-for-service payments, creating inequities in allocation. This experience illustrates the need

for more transparent and targeted approaches that account for the unique context of different health systems (e.g., safety net institutions) (Socker et al., 2020).

Supply Chain

COVID-19 has exposed significant vulnerabilities in the global health care supply chain. These vulnerabilities preceded the pandemic, with the FDA documenting the periodic lapses of medical equipment, essential supplies, and pharmaceuticals. The drivers of supply chain vulnerability during COVID-19 include:

1. Baseline shortages of medical products;
2. The geographic consolidation of manufacturing; and
3. The lack of incentives for health systems to maintain excess capacity (see *Table 3-2*).

Baseline Shortages

Many medical products were already in shortage prior to COVID-19. For example, the FDA reported 51 new drug shortages during 2019, with agency intervention required to prevent another 154 new shortages over the course of the calendar year (FDA, 2020b). Yet while FDA documentation of supply chain

TABLE 3-2 | Drivers of Supply Chain Vulnerability

Theme	Challenges	Example
Baseline Shortages	• Health systems and the FDA had already documented many drug shortages prior to the pandemic, while lacking data on devices	• FDA reported 51 new drug shortages in 2019
	• SNS reserves were never fully replenished due to funding gaps	• Reserve PPE in the SNS was not replenished after H1N1
Geographic Consolidation	• Labor cost advantages contributed to the outsourcing of medical product manufacturing	• Majority of manufacturing facilities for active pharmaceutical ingredients and finished dosage forms are offshored
	• Race-to-the-bottom pricing deterred competition	• Most factories for PPE production are located in China
Misaligned Incentives	• Dominant industry paradigm was one of "just-in-time" production	• GPO and manufacturer pricing relationships contributed to capacity reductions
	• Health systems lacked financial incentives to stockpile medical supplies	

deficiencies is helpful, the agency's reports are a lagging indicator given that health systems experience difficulties in obtaining critical items well before the FDA publishes data on shortages. For example, surveys of hospital pharmacists found that 69% reported more than 50 shortages for their facility before the pandemic (Hantel et al., 2019).

Given these existing shortages, it is no wonder that the supply chains quickly collapsed under pandemic-induced demand. For example, after randomized controlled trials found dexamethasone, a common and inexpensive steroid, substantially reduced mortality among hospitalized COVID-19 patients, hospital demand in the U.S. increased by 610% while the fill rate declined to 54% (Silverman, 2020; The RECOVERY Collaborative Group, 2020). Such an outcome was not unforeseen, considering that dexamethasone has been in shortage since February 2019 (FDA Drug Shortages, 2020). The challenges are magnified for devices, as prior to the passage of the CARES Act the FDA did not possess the same mandate to proactively collect and report data regarding device shortages as it did for drugs (FDA, 2020c).

The U.S. does maintain reserves of essential medicines and key medical devices and equipment in the Strategic National Stockpile (SNS) for use during emergency situations. However, the SNS has long been underfunded and lacked appropriate procedures for efficient and coordinated distribution (Gerstein, 2020). For example, reserve PPE in the SNS was not replenished after the 2009 H1N1 pandemic (Reinhard and Brown, 2020). Likewise, the approximately 12,000 ventilators in the SNS at the beginning of the COVID-19 outbreak were considered insufficient to meet patient needs in March 2020. While the federal government and health systems did take steps to address these challenges, the presence of baseline shortages created significant barriers for effective emergency response from the outset of the pandemic.

Geographic Consolidation

The American health care system's heavy reliance on overseas manufacturers and its predilection toward maintaining lower inventory, which under normal circumstances enables cost savings and efficiencies, became critical weaknesses during a pandemic that fueled global demand for products. Indeed, the supply chains for the overwhelming majority of medical product classes today are offshored. For example, FDA officials in 2019 testimony to Congress noted that the majority of manufacturing facilities for active pharmaceutical ingredients (72%) and finished dosage form (53%) were located outside of the U.S. (Woodcock, 2019). Likewise, the majority of factories which manufacture PPE are located in China, which also acquired a significant portion of the global supply at the beginning of the pandemic (Bradsher and Alderman, 2020).

The concentration of manufacturing capacity offshore is the result of labor cost advantages on the part of international producers, which have both enabled such manufacturers to scale their operations and also rendered it challenging for producers from more costly geographies (e.g., the U.S.) to compete. The resulting narrowing of the number of suppliers renders the market more vulnerable to supply shocks and pricing instability (as was the case for COVID-19) and has also been tied to gaps in quality. For example, the FDA's interagency task force on drug shortages identified the leading causes of supply chain vulnerabilities to include a reliance on low-price clauses by group purchasing organizations (GPOs) during contract negotiations and immature quality management systems (e.g., incentives for compliance rather than continuous improvement) (FDA, 2019).

Misaligned Incentives

With rising cost pressures, health systems have gravitated over the last two decades towards more efficient strategies that lower supply chain costs while optimizing quality, such as just-in-time manufacturing, just-in-time distribution, and just-in-time delivery (Khorasani et al., 2020). The advent of GPOs during this same period of time led the distribution of medical supplies to become increasingly consolidated and efficient, but may have also reduced excess production capacity in the system.

While health system innovations (e.g., retrofitting medical devices to meet patient needs) and public-private partnerships (e.g., PPE donation drives, 3D print exchange curated by the National Institutes of Health) helped to address shortages, the overall challenges during COVID-19 illustrate the need to consider new strategies that allow for far greater medical supply surge capacity.

Workforce

An important focus for health systems was reconfiguring staffing workflows for pandemic response. This process not only highlighted existing challenges in the workforce (e.g., staffing shortages, limited flexibility of existing models) but also spotlighted the pervasive challenge of burnout among health professionals. Key workforce challenges are as follows.

Staffing Shortages

Increased demand for care during COVID-19 highlighted gaps in staffing supply for health systems in general and across select clinical domains (e.g., critical care) and care sites (e.g., post-acute care). Many of these shortages preceded the pandemic. For example, analyses performed by the U.S. Department

of Health and Human Services project multiple states to have deficits exceeding 10,000 nurses by 2030 (HHS, 2017). Such shortages—which are attributed to a number of factors including burnout-induced turnover and the dearth of nurse educators—undermine health systems' capacity for general inpatient care, leading care delivery organizations to increasingly rely on traveling clinicians to fill in gaps at baseline (Galewitz, 2015). Researchers have also reported an association between staffing shortages and poor health outcomes for inpatient care (Griffiths et al., 2018). High volumes of hospitalizations during COVID-19 illustrate the consequences of these preexisting workforce gaps, with health system demand for nurses regularly outpacing available local and national supply throughout the pandemic (McLernon, 2020).

The staffing shortages for general inpatient care are even more pronounced in specific specialties and care sites. For example, while a significant number of COVID-19 patients required admission to the Intensive Care Unit (ICU), only half of all acute care hospitals in the U.S. had any intensivists at all according to the Society for Critical Care Medicine, creating challenges for managing admission volume (SCCM, 2019). Capacity gaps became a persistent issue during COVID-19, with ICU occupancy approaching nearly 80% in January 2021—well above the pre-pandemic baseline of 63% (Kaufman Hall, 2021). While the growing use of advanced practice providers (e.g., nurse practitioners, physician assistants) has helped to fill staffing gaps, shortages have persisted in part due to the uneven distribution of labor across the country (Flynn, 2018). Indeed, while the number of registered nurses (RNs) primarily practicing in critical care settings has increased in recent years, current staffing levels continue to lag behind system needs (Smiley et al., 2018).

Many facilities have in turn become chronically understaffed, particularly in the post-acute care setting. For example, nursing homes have been understaffed for years, with CMS in 2018 issuing one-star ratings to nearly 1,400 facilities due to staffing shortages (approximately 9% of all nursing homes) (Rau, 2018; Spanko, 2018). The longstanding shortage of nursing home staff can be attributed to many factors, including inadequate salaries and poor working conditions (BLS, 2019). These capacity gaps, coupled with the increasing use of contract workers in the industry, created challenges during the pandemic due to the susceptibility of post-acute care facilities to COVID-19 outbreaks, with 21% of U.S. nursing homes reporting staff shortages during the summer of 2020 (McGarry et al., 2020).

Training and Flexibility

Staffing gaps are also overlaid with skill gaps, particularly in critical care. For example, baseline education programs for advanced practice providers offer little

exposure to critical care, and dedicated fellowship opportunities have limited seats and funding (SCCM, 2019). The pandemic has also highlighted the challenges that health systems face at efficiently retraining and redeploying staff in response to episodic demand. For example, many health systems relied on *locum tenens* to meet staffing needs during COVID-19. This response is an outgrowth of pre-pandemic patterns, in which the majority of health care facilities now routinely utilize temporary physicians and nurses, particularly in the acute care specialties. However, the need for temporary physicians tends to be concentrated with select specialties; for example, demand for *locum tenens* in emergency medicine and anesthesiology has tripled over the past decade (Staff Care, 2020). These trends illustrate the need for more flexible workflows and internal capacity for cross-training across specialties to meet health system needs, as well as the need to address chronic issues such as limited funding for health professions education and nationwide nursing shortages.

Workforce Well-Being

A significant area of focus for health systems prior to COVID-19 was addressing growing rates of burnout among health professionals. The National Academy of Medicine's 2019 report on the subject highlighted the multifactorial nature of burnout (e.g., documentation burden and administrative requirements) and the important role of health systems in developing a supportive workplace environment that fosters the health and well-being of their staff (NASEM, 2019). Emerging evidence illustrates the toll of COVID-19 on the physical, mental, and emotional health of health professionals. Distressingly, burnout has only exacerbated existing inequities within the health system. For example, women—who represent the majority of frontline health care workers—accounted for the majority of COVID-19 cases among health care workers, and also bore a disproportionate burden of added personal responsibilities during the pandemic (e.g., childcare, school closures) (CDC, 2020a). Health systems are increasingly evaluating systems-level solutions to support the health care workforce, including addressing long-standing issues around work-life integration and gender inequities in representation and personal responsibilities (Brubaker, 2020).

System and Community-Wide Coordination

COVID-19 required stakeholders from across multiple sectors to collaborate, share resources, and develop joint strategies for pandemic response. However, systems did not always have relationships with the relevant entities prior to the pandemic, which created challenges for communication. Furthermore, the

preexisting technical infrastructure in many facilities was often outdated and lacked the capacity for the facile exchange of data and information. Challenges encountered in system- and community-wide coordination are explored below.

Coordination Across Systems

Many health systems in America span multiple provider types, communities, regions, and even states. However, as reported in a spring 2020 survey of AMC leaders, facilities and organizations within these systems often continue to operate in a decentralized manner, which in many cases created challenges for communication, resource sharing, and protocol development. These challenges also manifested in coordination with other sectors. For example, the organization of public health in America varies significantly across the country, with some states employing a centralized model while others delegating most decision-making authority to local health agencies. Coordination with public health was further complicated by the heterogeneity in health department resources and capabilities in the U.S., as well as the lack of strong federal guidance and leadership (Haffajee and Mello, 2020).

Data Sharing

Health systems faced challenges receiving and sharing data with public agencies, with specific barriers associated with standardizing data elements (e.g., for demographic information) and integrating with electronic health records (CDC, 2020b; Holmgren et al., 2020). Health systems also experienced significant challenges with data reporting at the national level. The midsummer migration of hospital data reporting systems for COVID-19 created tremendous technical difficulties, imposed transition costs, and resulted in missing or erroneous data (Tahir and Roubein, 2020a). Following implementation, 15% of hospitals remained missing from the database, and many were only able to provide half of the requested information, further compromising the accuracy and reliability of national disease surveillance reports (Tahir and Roubein, 2020b). These technical hurdles created challenges for data sharing beyond disease surveillance; for example, health systems were limited in their ability to communicate timely information about bed capacity and supply stocks in order to efficiently coordinate referrals, plan health services, and allocate resources.

PRIORITY ACTIONS AND POLICY CONSIDERATIONS

The root causes of many of the challenges described in the prior section precede COVID-19. Consequently, health systems are analyzing the challenges

manifest in the pandemic as opportunities for improvement. In particular, systems are looking at new ways to address gaps in financing, infrastructure, and coordination to improve the sector's overall efficiency as well as enhance preparedness for future emergencies. Sustaining and scaling these best practices will require policy, regulatory, and in some cases legislative, changes. Of course, solutions are far from universal; the heterogeneity of the care delivery sector will require nuanced improvement initiatives that reflect the context of specific subsectors (e.g., rural hospitals, safety net hospitals). This section outlines several priority areas and policy considerations for sector-wide improvement. The key domains for transformation include:

1. Enhancing the financial resiliency of health systems;
2. Providing for surge capacity in the medical supply chain for care delivery organizations;
3. Investing in new workforce support and development programs and staffing models;
4. Improving health system flexibility and built-in capacity for inpatient care;
5. Building upon renewed commitments and taking concrete actions to address health inequities;
6. Addressing subsector-specific challenges for baseline operations and emergency preparedness; and
7. Fostering linkages between health systems, community-based providers and public health departments (see *Figure 3-4*).

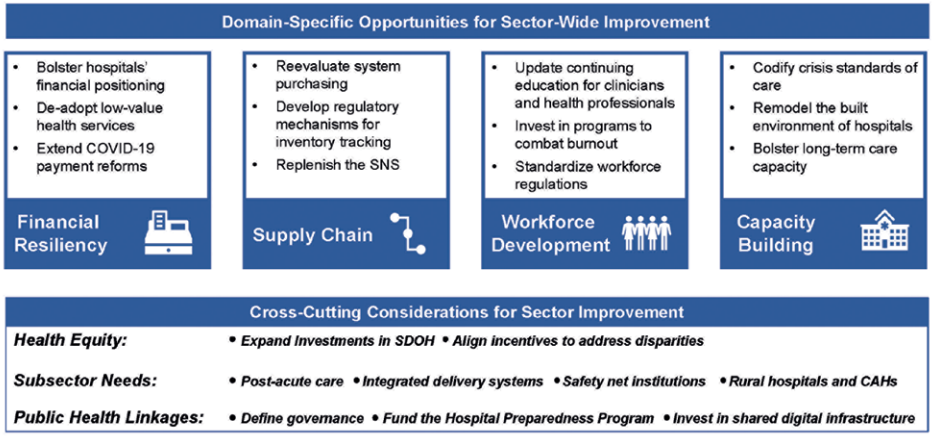

FIGURE 3-4 | Priority Actions for Sector Transformation and Emergency Preparedness

Enhancing Financial Resiliency

The pandemic exposed the precarious financial foundations of America's health systems. While federal relief dollars and reimbursement flexibilities helped to soften the pandemic's blow, the ongoing financial impact of COVID-19 (e.g., from increased operating costs, delayed or canceled care, growth in uncompensated care, and bad debt due to pandemic-induced loss of employer-sponsored insurance) should prompt exploration of opportunities to improve the sector's financial resiliency. At the operational level, health systems are likely to take steps to reinforce the resilience of their business model. For example, health systems may expand their efforts to diversify their revenue streams, including not only vertical businesses beyond direct provision of health services (e.g., supply chain collaboratives, laboratory companies) but greater collaboration with payers on risk-based arrangements. Likewise, with the concurrent decline in high-margin elective procedures and outpatient services severely affecting hospital credit ratings, systems moving forward may opt to reduce costs and capital investments to conserve cash, in some cases to avoid violating financial covenants.

At the policy level, health systems are uncertain whether the care models developed during the pandemic will be followed by the financial incentives and reimbursement infrastructure needed to truly become mainstays in care delivery. For example, telehealth and HaH programs have both existed for years and possess a rich body of evidence supporting their efficacy; however, they lacked uptake prior to the pandemic due to gaps in reimbursement driven by public and private payer concerns about 'supply induced demand,' which is now being examined through the lens of the pandemic (NCQA, 2020). COVID-19 caused most major payers to temporarily enhance payments, enabling health systems to deploy these innovations at unprecedented scale (e.g., reimbursing virtual visits at parity). However, most of these regulatory flexibilities will expire at the conclusion of the public health emergency. Although regulators and legislators have signaled a willingness to make flexibilities such as telehealth permanent, questions remain about potential thresholds on payment, metrics for quality, and guardrails for fraud and abuse (Ross, 2020; Wicklund, 2020). Policymakers will also need to address concerns about patient privacy and challenges for data governance. Similar considerations apply to other delivery innovations. For example, to sustain the expansion of and interest in HaH programs during the pandemic, regulators will need to develop new pathways for reimbursing home-based hospitalizations to account for the potential savings yielded from HaH models (NCHS, 2020; Nundy and Patel, 2020). Furthermore, with CMS flexibilities allowing hospitals to perform site relocations for outpatient services without incurring reductions

BOX 3-1

Considerations to Enhance the Financial Resiliency of Health Systems

- Take steps to diversify revenue streams and increase balance sheet strength to bolster financial positioning
- Leverage momentum from the pandemic to de-adopt low-value and wasteful services
- Extend reimbursement flexibilities for new delivery models and provide regulatory clarity for post-pandemic payment and operations

in reimbursement, regulators will need to provide clarity on the future of site-neutral payments and provide technical assistance and oversight for providers implementing home-based care solutions (Bekelman et al., 2020).

Beyond delivery models, the pandemic also provides health systems with an opportunity to address existing inefficiencies in health care financing. For example, deferred care can provide an opportunity to support the de-adoption of low-value and wasteful services (e.g., inappropriate screenings), building on programs such as the Choosing Wisely initiative of the American Board of Internal Medicine Foundation (Kim et al., 2020a; Powers et al., 2020; Rosenberg et al., 2015). Likewise, health systems could build on new partnerships with other sectors to address administrative inefficiencies around payment and care coordination.

Priority actions to enhance sector-wide financial resiliency for health systems are summarized in *Box 3-1*.

Strengthening National and Health System Supply Chains

COVID-19 focused care delivery organizations' attention on the limited surge capacity in the U.S. health care supply chain. From the elevated infection risk for staff due to the paucity of PPE, to persistent gaps in testing capacity due to supply shortages, to the dearth of medical supplies (e.g., swabs, syringes) and essential medicines, the pandemic has illustrated the need to reconceptualize health care supply chains as a critical national infrastructure.

At the organizational level, health systems may consider emergency supply options where just-in-time production is utilized, and the industry may reevaluate the contractual obligations of GPOs, with a particular focus on surge capacity guarantees (Devaiah et al., 2020). Health systems may seek to diversify

their vendors, develop new protocols for crisis situations, and enhance oversight of waste and inventory. Hospitals in particular may express increased interest in collaborative initiatives and regional resource-sharing programs, building on previous coalitions to address shortages of essential medicines (CivicaRx, 2020). Likewise, health systems may seek to build on regional models for disaster medical response to improve coordination of key medical supplies across local facilities during emergency situations (Mitchell et al., 2020).

At the national level, policies and practices that will enhance supply chain surge capacity include identifying the raw materials and manufactured products that are currently in short supply, as well as inventorying similar and substitutive materials that are currently not in shortage, and delineating the necessary inventory levels for both categories of items that are needed for health systems to function under both normal and crisis conditions. To support this endeavor, regulators could consider creating a low-burden mechanism for tracking essential materials (e.g., a National Drug Code identifier system for consumable medical supplies) that is paired with clear protocols for communication about inventory status across health systems, manufacturers, and regulators. As regulators and health systems work to map supply chains and forecast inventory, policymakers could also perform analyses of potential geographic bottlenecks to identify nodes in the supply chain which may be vulnerable to disruption (e.g., from political events, natural disasters). Policymakers will need to develop incentives to support product diversification, particularly for supply chains that are currently dominated by a single manufacturer. The Defense Production Act of 1950 should be readily leveraged to assess, replenish, and enhance the distribution of critical health care stockpiles (The White House, 2021). In parallel, preparations for future public health emergencies will require increased funding for the SNS, as well as updates to protocols for resource allocation during emergency situations and mechanisms for monitoring inventory turnover (e.g., from use in an emergency, or for when products become obsolete or expired). Lastly, at the state and federal level, anti-price gouging statutes can be extended to encompass health care supplies following emergency declarations.

Priority actions for strengthening medical supply chains for health systems are summarized in *Box 3-2*.

Investing in Workforce Development

The pandemic illustrates the advantages of staffing protocols and training that are responsive to episodic demand, as well as the benefits of support systems that promote health and well-being across the workforce.

BOX 3-2

Considerations to Strengthen Health System Supply Chains

- Reevaluate vendor selection and GPO contracts, and explore opportunities for regional collaboration
- Develop a regulatory mechanism for tracking and reporting inventory across systems and stakeholders
- Increase funding for the SNS and update protocols for resource allocation

From an operational perspective, COVID-19 has highlighted how flexible staffing and training approaches can better position health systems for the redeployment of staff. For example, to address staffing needs in critical care, cross-training of physicians, nurses, and other health professionals to work in critical settings was essential for filling capacity gaps. Health systems, with the support of accrediting bodies, could foster preparedness by supporting the development of systems of continuing medical education that incorporate annual updates for critical care (e.g., dedicated yearly rotations, simulation training). Likewise, health systems could streamline the future redeployment of staff by standardizing care processes as much as possible within health systems to reduce the risk of errors.

Beyond staffing models, health systems are reaffirming their commitment to supporting the health and well-being of health professionals given both the existing trends for burnout and the significant strain of the pandemic. Approaches to guide system leaders and policymakers are provided in the 2019 National Academy of Medicine consensus study on clinician well-being, as well as other sources (The Blue Ridge Academic Health Group, 2019). Bolstering support systems within health care organizations to support mental health and building on pandemic-era flexibilities to address sources of burnout (e.g., the documentation burden) could further improve the resilience of the health care workforce (NASEM, 2019). For example, greater attention to work-life balance—particularly in light of the disproportionate impact of the pandemic on female health care workers—could include strategies such as expansions to paid leave, temporary housing, emergency funds for unforeseen expenses, and improvements in the accessibility and affordability of childcare for health care workers.

Lastly, investing in workforce development will also require actions from regulators and professional societies. With COVID-19 illustrating the value of sharing staff across state lines during surge periods, rapid recruitment during future emergencies could be supported by improving the uniformity of guidelines

BOX 3-3

Considerations for Investing in Workforce Development

- Explore updates to continuing medical education and the creation of flexible staffing models
- Reaffirm a commitment to investing in workplace wellness, including new and preexisting strategies to reduce clinician burnout
- Evaluate opportunities to standardize health care workforce regulations for emergency situations

for scope of practice and developing a national database with information on training, certification, and other experience factors.

Priority actions for workforce development are summarized in *Box 3-3*.

Building Capacity for Patient Care

While health systems met the challenge of surge capacity through unprecedented collaboration and innovation, the COVID-19 experience reveals the importance of identifying new approaches to rapidly and sustainably expanding inpatient care capacity during public health emergencies. Given the role that appropriate rationing of critical care resources might have to play in these crisis settings, experts should also evaluate whether the crisis standards of care that were implemented during COVID-19, including the triggers for activation and the guidelines for specific situations (e.g., allocations of scare ventilator resources), were optimized or require improvements (Hick et al., 2020). Additionally, elevated awareness following the pandemic of the limited supply of health care resources at baseline—and the often unequal distribution of those resources across the population—may prompt a broader reflection on existing inequities and gaps in access to types of health services and products.

Health systems could evaluate the host of operational innovations used to manage episodic demand during COVID-19, with special consideration of those practices that are likely to be useful and sustainable for the future. At the facility level, infrastructure changes such as the development of select inpatient rooms as "universal rooms" capable of conversion for critical care needs, or the construction of entire units with negative pressure ventilation, can anticipate future surges in patients with infectious diseases. Inpatient capacity guidelines at state and local levels could facilitate the construction of public health surge capacity,

BOX 3-4

Considerations for Health System Capacity Building

- Evaluate and codify COVID-19 crisis standards for care for future emergencies
- Invest in remodeling the built environment of health care facilities to better support surge capacity

with considerations for public funding, building codes, and certificate-of-need guidance to support emergency capacity. Clinicians and hospitals could play a key role in identifying evidence-based practices to inform the development of these guidelines. Furthermore, state, local, and federal programs could be developed with incentives in support of construction that allows for surge capacity, such as private patient rooms that are sufficiently large for double occupancy, with additional oxygen lines and other capabilities, as well as cameras and videoconferencing technology installed in hallways and other locations outside of patient rooms to minimize the frequency of health professionals entering patients' rooms to reduce contamination and conserve PPE.

Priority actions for health system capacity building are summarized in *Box 3-4*.

Renewing Commitments to Health Equity

COVID-19 has laid bare the systemic disparities in health outcomes in the U.S. across race, ethnicity, and socioeconomic strata. Nationwide, investments for improving health require additional focus on SDoH to address the environmental drivers of health inequity in America (e.g., housing stability, food insecurity, economic stability, social and community context) (CDC, n.d.; Healthy People 2030, n.d.). Expanding on the kinds of multi-sectoral partnerships identified in the National Academies of Sciences, Engineering, and Medicine 2017 report on *Pathways to Health Equity* may provide a path forward for investments in the root causes of poor health (NASEM, 2017).

However, actualizing goals to addressing health disparities and structural racism will require sustainable financing systems that support equity-oriented activities. Consequently, payment systems that support delivery models with defined and measurable objectives for closing the outcomes gap for care quality and outcomes will be needed. Policymakers could explore creative mechanisms for pooling funds and investing in community needs, while regulators could advance their support for innovative models such as Accountable Health Communities and

BOX 3-5

Considerations for Renewing Commitments and Instituting Concrete Actions for Health Equity

- Expand investments and partnerships to address the social determinants of health
- Explore opportunities to align incentives to address disparities in care quality and outcomes

health insurance benefit designs that provide explicit support for SDoH (CMS, 2020c).

Lastly, while this subsection provides examples of specific equity-oriented actions, it should be noted that each of the priority actions highlighted in this paper can and should be approached through the lens of health equity—from the disproportionate financial impact of the pandemic on health systems serving marginalized populations to the unequal distribution of pandemic stressors among the health care workforce.

Priority actions for health system capacity building are summarized in *Box 3-5*.

Addressing Subsector-Specific Challenges

Care delivery in the U.S. is distributed across a complex matrix of providers and facilities, and each unit of care delivery experienced unique challenges during the COVID-19 pandemic. This section outlines the priority areas for specific health system subsectors.

Post-Acute Care

Post-acute care—which include care settings such as inpatient rehabilitation facilities, long-term care hospitals, and SNFs—has been a key area of focus during the pandemic.

First, post-acute care settings have accounted for a disproportionate number of U.S. COVID-19 deaths (Barnett and Grabowski, 2020; Miller, 2020a; New York Times, 2020). The challenges for health systems (e.g., financial impact, supply shortages, staffing gaps) have been magnified in this subsector. For example, 20% of SNFs continued to report severe PPE shortages throughout the summer months of 2020 (McGarry et al., 2020). Likewise, the decline in short-term Medicare admissions placed downward pressure on unit reimbursement

for nursing homes, severely impacting the finances of postacute care providers (Silver-Greenberg and Harris, 2020). Improving the financial stability of post-acute care to withstand this kind of public health emergency will require a broad set of strategies, ranging from coverage reform for long-term care, reimbursement alignment across payers, improved standards for supply and staff capacity, and training and infrastructure for infection control (Grabowski, 2020). For example, nursing home deaths and cases have been negligible in Hong Kong, which has required all facilities to maintain a one-month supply of PPE following the 2003 outbreak of Severe Acute Respiratory Syndrome (Khazan, 2020).

Second, COVID-19 has exposed the pre-pandemic gaps in post-acute care capacity, with the "long haul" effects of COVID-19 illustrating the importance of developing a more robust infrastructure for rehabilitative care. With average SNF occupancy rates exceeding 85% prior to the pandemic, the system had little spare capacity to accommodate COVID-19 survivors during the pandemic (Grabowski and Joynt Maddox, 2020). While health systems in recent years have worked to develop in-house rehabilitation capacity due to challenges with timely access to postacute care, such efforts were complicated during the pandemic by staffing gaps and PPE shortages. Shoring up post-acute care capacity for COVID-19 and beyond will require a range of compensation and workplace improvements to meet staffing needs, as well as new investments in alternatives to institutional post-acute care that leverage technology and home care solutions.

Integrated Delivery Systems

Integrated delivery systems, which are networks of health care facilities and programs that align incentives and resources, have played a critical role during the pandemic response, from serving as hubs for COVID-19 care to pioneering innovations in testing and infection control and continuing to deliver complex and necessary non-COVID-19 care (e.g., transplants, cancer care) (Enthoven, 2009). However, integrated delivery systems also faced notable challenges with regards to operations and financing.

First, for AMCs, the pandemic created unique challenges for medical student and resident education. Many AMCs transitioned preclinical instruction to virtual formats, suspended medical student clerkships and away rotations, offered pathways to early graduation to supplement frontline health care workers, and adopted a phased approach for managing resident involvement in COVID-19 care to optimize care planning and PPE conservation (Kim et al., 2020b; Murphy, 2020; Whelan et al., 2020). Pedagogical innovations during COVID-19, coupled with the transformation of care delivery during the pandemic, may foster long-term changes in medical education. Additionally, the staffing shortages exposed

by the pandemic, particularly in rural and underserved communities, may prompt reforms of education financing. For example, given nursing shortages during COVID-19, policymakers may consider building on the Graduate Nursing Education Demonstration project, which increased graduation rates of advanced practice RNs by 67% over a 6-year period (Jones-Schenk and Leavitt, 2020; CMS, 2019). Likewise, legislators are experiencing renewed calls for reforms to graduate medical education (GME) financing—which capped Medicare support for residency positions in 1997—as well as financing programs such as the National Health Service Corps (Heisler, 2018; IOM, 2014).

Second, the pandemic has illustrated the value of integrated leadership and centrally coordinated decision-making for integrated delivery systems, which occupy a growing geographic and economic footprint of the nation's health care system, but often are decentralized in their oversight and governance. To cover the cost of uncompensated care and myriad other subsidized services, from behavioral health services to teaching and research, nearly all health systems depend on specific high-margin service lines (Johnston, 2019). The pandemic may prompt integrated delivery systems and policymakers to consider financing reforms that address the uneven distribution of funding for the essential services provided by these institutions. Furthermore, the prominent role of integrated delivery systems in providing public health and scientific leadership during the pandemic (e.g., guideline creation, medical countermeasure development) may motivate greater collaboration with health departments and federal, state, and local officials to improve public health infrastructure (e.g., data infrastructure), combat care inequities (e.g., resource coordination), and enhance research and development capacity (e.g., clinical trial networks) (Shapiro and Rothman, 2020).

Safety Net Institutions

The role of safety net institutions—which are entities providing a significant level of care to the uninsured, Medicaid, and other vulnerable populations—is likely to increase as pandemic-induced layoffs affect health insurance coverage for millions of Americans (Stolberg, 2020; IOM, 2000). Such institutions already operate on narrow margins due to the instability of public financing and the financial burden of providing uncompensated care (Khullar and Chokshi, 2018; Felland et al., 2016).Yet the pandemic has also illustrated the critical importance of safety net institutions to drive innovation in care delivery, from coordinating with health departments to spearheading efforts during the pandemic to address patients' non-medical needs such as housing insecurity and support for self-isolation.

Increased support for safety net systems will be imperative as the health system recovers from COVID-19. Financial support geared towards addressing gaps in

health equity would help to address the full scope of needs for the marginalized populations which safety net systems serve (Elnahal, 2020). This support can be coupled to the broader adoption of population-based payment systems—which have been successfully trialed at several institutions—and could help improve the financial stability of safety net systems. Additionally, the "braiding and blending" of health and social funds could enhance interdependencies with the public health system (Butler et al., 2020; Stine et al., 2017).

Rural Hospitals and CAHs

Health care in rural America was already in crisis prior to the pandemic, with nearly 40% of all rural hospitals at risk of closure (Miller, 2020b). Challenges abound, such as the gaps in reimbursement due to poor reimbursement rates across public and private payers and low occupancy rates compared to other hospitals nationwide (Kacik, 2018). COVID-19 imposed additional pressures on these structural inadequacies, with already narrow (and often negative) rural margins further contracted under service cancellations, payment rates compromised by Medicaid cuts, and additional pandemic-related expenditures (e.g., for PPE) incurred without commensurate improvements in revenue (Diaz et al., 2020).

The aftermath of the pandemic will require substantive efforts in order to restore financial stability to rural hospitals. For example, CMS recently announced the Community Health Access and Rural Transformation (CHART) Model to support delivery transformation and financial stability in rural areas (CMS, 2020d). Other ongoing reforms, such as the HHS Rural Action Plan, provide promising opportunities to address longstanding disparities in health care access and outcomes (HHS, 2020a). Importantly, the vibrancy of rural hospitals requires fundamental infrastructure investments, such as expanded broadband to ensure rural providers benefit from the transition to telehealth. Payment reforms such as low-volume adjustments could help improve the financial stability of rural facilities, while building on GME pilots such as the Teaching Health Center program could help support workforce development in rural areas (AHA, 2020c; Barclift et al., 2016).

Priority areas for each subsector are summarized in *Box 3-6*.

Fostering Linkages with Public Health

The pandemic has illustrated the urgent need to develop greater functional integration between health systems and public health departments. Such linkages require governance structures, physical infrastructure, and dedicated funding. Additionally, policy guidance and support for cross-sector coordination is

BOX 3-6

Considerations for Addressing Subsector Specific Challenges

- **Post-Acute Care:** Develop surge capacity for supplies, improve market compensation and working conditions to bolster staffing, and explore opportunities for payment and coverage reforms for long-term care
- **Integrated Delivery Systems:** Explore reforms to reduce the reliance on cross-subsidization to support essential services, and continue partnerships developed during the pandemic with local and state health departments and governments
- **Safety Net Institutions:** Examine avenues for bolstering financial stability, and explore opportunities to "braid and blend" funding for health and social services
- **Rural Hospitals and CAHs:** Investigate care delivery demonstration models, and provide support for rural infrastructure investments in telehealth and workforce development

especially timely as health systems navigate how they can best leverage their delivery network and clinical infrastructure to support COVID-19 vaccination campaigns in their local and state jurisdictions.

First, clear governance structures demarcating the responsibilities for stakeholders from each sector are needed to streamline coordination for emergency situations. Health system and health department capabilities vary widely across the U.S., and many health departments are chronically underfunded. This heterogeneity in resources contributes to variability in emergency response, with health systems often developing add-on functions in regions with underdeveloped public health infrastructure. For example, in some states, health systems helped to coordinate the distribution of COVID-19 therapies such as remdesivir and were intimately involved in the development of the micro-plans for COVID-19 vaccine distribution. Likewise, some health systems played an active role in supporting testing, tracing, and disease surveillance. Actors across the system will need to work together to proactively define key functions and the attribution of responsibilities. Consequently, in the aftermath of the pandemic, health systems and health departments should coordinate to review models of successful partnerships during COVID-19, identify protocols for crisis situations (e.g., designation of dedicated emergency response centers), and define key elements for information sharing (e.g., bed capacity, medical supplies) (Liebman and Patel, 2020; NHRN, 2020; PA Media, 2020).

Second, robust linkages will require investments in shared infrastructure, particularly around technology and data systems. The challenges with data

integrity during COVID-19 have only reaffirmed the need for interoperability both across health systems and between care delivery organizations. The Office of the National Coordinator for Health IT could build on its 2020 interoperability rule to address regulatory issues regarding patient privacy and data interoperability and define standardized approaches for the collection and reporting of common data elements (e.g., demographic information) (Savage et al., 2020). Importantly, efforts to promote interoperability for health systems must also be paired with guidance and resources to modernize shared technical infrastructure for public health. For example, legislators could consider expanding the CDC's "Digital Bridge" program. Moreover, ongoing review of the performance of "meaningful use" requirements should include health system integration with public health services (CDC, 2019).

Third, expanded purviews and partnerships aimed at emergency preparedness will require appropriate resources. This includes the Hospital Preparedness Program, for which funding levels have declined from $515 million in 2003 to $276 million in 2020, and should include a review of the program's mandate and functions (HHS, 2020b; Watson et al., 2017). The Assistant Secretary for Preparedness and Response should also consider reviewing the performance of the Hospital Preparedness Program during COVID-19 and ensure the program is appropriately reformed and resourced to address both short-term (e.g., natural disasters) and sustained public health emergencies.

Priority areas for improving coordination between health systems and public health are summarized in *Box 3-7*.

BOX 3-7

Considerations for Fostering Linkages Between Health Systems and Public Health

- Collaboratively define protocols for crisis situations, including roles, responsibilities, and resources
- Ensure that interoperable digital infrastructure is made available to enable facile information sharing between health systems and public health entities
- Review and appropriately support emergency preparedness programs, such as the Hospital Preparedness Program, as well as programs of collaboration and information between health systems and public health entities
- Develop clear governance structures demarcating the responsibilities for health care and public health stakeholders both during and after emergencies

CONCLUSION

Health systems have been foundational to America's response to COVID-19, focused first and foremost on providing care to infected patients while navigating challenges ranging from capacity gaps to supply chain shortages. Yet the pandemic has also highlighted how the multifaceted role of health systems today includes functions beyond care delivery. For example, hospitals partnered with organizations across the health system to support public health functions ranging from testing, contact tracing, and more recently, vaccination, as well as working to address the non-medical needs and inequities exacerbated by the pandemic for marginalized populations.

While health systems have played a key role in the pandemic response, COVID-19 has significantly impacted multiple aspects of health system operations, ranging from tremendous financial uncertainty to inadequate resources to meet the needs of patients during persistent waves of outbreaks. Different care delivery organizations across the sector also had distinct experiences, from the unique pressures on post-acute care facilities to the cross-sector coordination led by integrated delivery systems. Many of the vulnerabilities exposed by the pandemic represent longstanding challenges for health systems, from shortages of key personnel (e.g., the critical care workforce) to the lack of centralized coordination for the medical product supply chain. Although health systems adapted throughout the pandemic to meet the needs of patients, from introducing innovative new delivery models such as virtual care platforms and Hospital at Home programs to rethinking staffing workflows and entering new cross-sector partnerships, the overall pandemic experience highlights opportunities for the sector to not only improve long-term preparedness for public health emergencies but also the effectiveness of baseline operations.

This discussion paper has sought to capture the experiences of hospitals and health systems during the COVID-19 pandemic and identify opportunities to leverage the lessons of COVID-19 to support performance improvements to the sector more broadly. Although the public health emergency remains ongoing, this review of the experience and evidence to date is applicable for both navigating the next phase for the pandemic and identifying priority actions for upcoming policy reforms. Key policy considerations include enhancing financial resiliency, creating surge capacity in the medical supply chain, investing in new workforce support and development programs and staffing models, improving flexibility and built-in capacity for inpatient care, building upon renewed commitments to address health inequities, addressing subsector-specific challenges, and fostering linkages between health systems and other sectors such as public health. Regulators and system leaders can leverage these lessons to guide the recovery from COVID-19 and the response to future public health emergencies, strengthening the health system's capacity to address the population health challenges of the 21st century.

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4

DIGITAL HEALTH COVID-19 IMPACT ASSESSMENT: LESSONS LEARNED AND COMPELLING NEEDS

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Over the last decade, some of the digital technologies that have profoundly transformed industries from banking to media have, at last, arrived in health care. A medical records system that only 20 years ago consisted mainly of handwritten notes stored in patient charts is today almost entirely digital. Radiological images are acquired, stored, and viewed digitally. Prescriptions are transmitted and reimbursed electronically. Hospital bedside devices for monitoring patient status, and even the location of equipment such as hospital beds, are tracked electronically. In more advanced systems, distributed sensors monitor not only equipment but also the vital signs, weight, heart rhythm, and movement of patients. And, in what may prove to be the most transformational development of all, the promise of artificial intelligence (AI) is now revealing itself in enhancing the detection of diseases and reducing errors by intelligently assisting the interpretation of blood tests, electrocardiograms, images from radiology, pathology, ophthalmology, and beyond.

The medical impact of these technologies is also being felt outside the hospital, as affordable consumer technologies encourage a growing number of patients to exercise more (through activity-tracking smartwatches and Internet-connected home exercise machines), eat better (via nutrient-counting apps and self-improvement apps), and choose among a wide array of customized health care options (through the use of websites to obtain reviews of providers, fill prescriptions, and more). Telemedicine offers the opportunity to obtain care

BOX 4-1

Definition of Digital Health

"Digital health technologies encompass a broad range of tools, including "mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine. Digital health technologies use computing platforms, connectivity, software, and sensors for health care and related uses."

SOURCE: U.S. FDA, n.d. *What Is Digital Health?* Available at: https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health (accessed January 10, 2022).

without the disruption of traveling to and from a doctor's office, and AI-powered chatbots are providing consumers with convenient 24/7 access to health care expertise.

Indeed, digital health technologies (see *Box 4-1*) are starting to approach the promise of health care delivery that is no longer sporadically provided, confined to the four walls of a hospital, and built around the convenience of the physician. Instead, they are allowing for a people-centered, collaborative approach to continuous health and wellness. The evolving digital foundation of a person-centered health care system is making it possible to envision a system that is more holistic, centers on the needs of the patient and their support structure, and embraces a longitudinal view of health, wellness, and social equity, in contrast to the mostly fragmented, reactive health care system that currently exists.

COVID-19 arrived in the context of such promise and demonstration of opportunity—the first global pandemic of the digital age. There have been many shining examples of how digital health solutions have helped in critical ways during the pandemic. Perhaps the most noticeable acceleration, both in the United States and other parts of the world, has been in the rapid adoption of telemedicine, but there have also been less visible digitally-dependent advances that are just as important across all sectors of health care, public health, and medical research. In many ways, the response to COVID-19 sparked years of advances in mere months.

However, the pandemic also revealed important limitations to digital health technologies and exposed significant challenges and equity concerns. One of the most significant lessons learned in the U.S. is that digital health's ability to help address the pandemic is dependent on a coherent and accessible data infrastructure. Despite the digitization of information made possible by the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act, various critical health care data sources are simply not yet ready to be put to

use (HHS, 2009). This can be crippling in key situations, because data fuel digital technologies that ultimately support people—both those who require care and those entrusted with delivering it.

SYNOPSIS OF THE CRISIS, THROUGH A DIGITAL LENS

In the early days of the rise of COVID-19 in the U.S., the health care industry, as well as local and federal leaders, sought answers to many critical questions, including the following:

- Who are the most vulnerable people, and where is the infection spreading?
- How many COVID-19 patients does each health system serve, and what is the system's capacity for treating them?
- What capacity does each health system have for testing, and who should get tested and when?
- How can the health care community best triage patients who may be highly infectious?
- Does each health system have an adequate supply of personal protective equipment (PPE), intensive care units (ICUs), and ventilators—and most importantly, do they have the appropriately trained and adequately rested staff that are required to deliver care and monitor complex equipment?
- Should care be redirected to designated institutions, and should some of America's major referral systems be allowed to continue providing routine medical care, designating specific facilities for the pandemic, while others manage care for those who cannot afford to miss or go untreated for pre-existing chronic conditions?
- For each COVID-19 patient, what are the key data elements of treatment and outcome, and what does a population-scale analysis of these data elements tell us about best practices?
- For COVID-19 patients with comorbidities or already on a course of medication, what does population-scale analysis of these treatments and outcomes tell us about risks and treatment effectiveness with near real-time data?
- What are the best treatment protocols for people with COVID-19 and other diseases, especially when the pandemic has interrupted usual capabilities for in-person evaluation and care?
- How can clinical researchers conduct clinical trials and keep study participants safe when they cannot conduct in-person visits or evaluate treatment effects?

The U.S. health care community looked to the interconnected system of devices, digital platforms, and data to help address these questions, since surely the

answers lurked within the petabytes of digital data being generated daily by the health care system. At first glance, the task seemed simple enough: these digital data only needed to be extracted, integrated, and disseminated in useful forms with the use of a wide range of digital tools such as telemedicine, biosensors, easy-to-use digital apps, machine learning, and AI. Although these tools are relatively commonplace in many industries, the health care industry has struggled to leverage them (Glaser, 2019). Despite notable strides in digital interoperability, health care interoperability still requires a significant architectural mobilization of largely ad hoc collaborations and new system deployments.

Telemedicine proved to be an example of successful digital impact. More generally, however, society's lived experience with emerging technologies was often far short of expectations (Kelly, 2019a). The answers to the pressing questions listed above fell far outside the normal operational capabilities of health systems, and in crisis-response situations they often eluded stakeholders for critical periods of time, highlighting the tremendous gap between existing raw data and urgently needed aggregation and insights. Technology may provide the tools, but solutions require the capacity for successful implementation, turning the promise into real-world practice, especially for the most vulnerable patients and communities. Even the implementation of telemedicine, widely lauded as a success within the pandemic, was not distributed equally and resulted in variable access to care for seniors, as well as Black and Hispanic patients and rural communities separated by the widening digital divide (Gilson et al., 2020).

As a result, during the initial stage of the pandemic in the U.S., decision-makers were essentially flying blind. Electronic health record (EHR) systems were mired in a sea of codes, few of which pertained to COVID-19, due to its novelty (Glaser, 2020). These systems were not connected to enterprise resource planning systems, and thus lacked the ability to correlate relevant patient encounters with human resources and physical capacity. The utilization of testing, PPE, beds, and ventilators varied within and across each and every health system (and often varied even across departments within a single hospital or clinic) (Weiner, 2019). Public health departments in charge of implementing rules, policies, public guidance, and contact tracing operations each operated within their own data silos—often taking the form of piles of spreadsheets—and were almost always unconnected and non-interoperable with any other health care information technology (IT) system (Hern, 2020; Llupia et al., 2020). In too many cases, the only effective communication of data between health care delivery systems and public health agencies was through a fax machine (Kliff and Sanger Katz, 2020).

Scores of medical researchers diverted their attention to patient treatment and compassionate application of experimental treatments, often discovering critical, life-saving insights while providing this care. However, the sharing of these

insights through effective digital channels was initially done in ad hoc ways (often through social media) and well outside the traditional channels used for medical research. These structured and unstructured data, the biomedical communities' ideas and experiences, and newly developed digital tools were trapped in the urgency of crisis response. Applying even rudimentary machine learning or AI tools in ways that would inform or persuade other clinicians or regulators was well beyond reach, in part because these tools required voluminous, ready-to-use data (Peiffer-Smadja et al., 2020).

Legions of technologists rushed to address these crises in access, connectivity, and interoperability, and achieved some great successes through heroic and unprecedented collaborations, some involving thousands of health care and technology experts and their organizations. However, in the process, these efforts often resulted in the creation of yet more data silos and more digital platforms that not only struggled to interoperate with the rest of the health care ecosystem, but also contributed more staggering, ineluctable complexity. Ongoing challenges in vaccine distribution and monitoring are the most current and urgent example of the existing limitations of data visibility, fluidity, transparency, and access.

One is reminded of the poem by Samuel Taylor Coleridge, *The Rime of the Ancient Mariner*. It contains the famous verse, "Water, water, everywhere, nor any drop to drink" (Coleridge, 1834). Despite nearly complete digitization of health care data, and an abundance of tools available for data analysis, machine learning, AI, and visualization, the health care community expended far more effort than should have been necessary to quench its thirst for high-quality, actionable data upon which these technologies, patients, and caregivers foundationally depended. Data were needed not only from health systems, but also from all other relevant sources—personal, social, infrastructural, biological, population-wide, and more.

How did the U.S. find itself in this situation, despite possessing unimaginably powerful digital capabilities? Imagine for a moment that we are setting out to build a house. We, of course, would need good tools, an adequate supply of lumber, and an understanding of the architecture of the house we are trying to build. However, if we lacked the components required to support the process of construction—skilled tradespeople, heavy equipment, building inspectors, and other infrastructure—it would be impossible to connect the tools and lumber to the architecture and realize a completed house. Furthermore, without a modularity that is both intentionally designed and defined, as we see in industry standards and building codes, the orchestration of architectural components such as electrical systems, plumbing, roofing, and heating would be wildly complex and unwieldy.

Even more important, innovators who make technological advances in those component systems would find it hard to survive in the marketplace because they

would not have standard places to "plug in" their new ideas at industrial scale. Indeed, such innovators, out of desperation, would likely find themselves forced to stray into other domains, as well as make moves to protect themselves from new competitors in order to stay viable. In such a scenario, home construction would likely be a low-productivity, artisanal activity—much like early automobile production.

This is exactly the situation that is occurring in today's health care data ecosystem. In digital health, it is not enough to have the AI tools and the data (that is, the "digital lumber"). Addressing the nation's deficiencies will require an overall system architecture, with modular components that allow innovation to flourish, and an infrastructure to support that architecture all the way from design to coordinated implementation, safe deployment, managed evolution, and continuous feedback. To extend the metaphor, health data must advance from its current artisanal state and achieve industrialization.

These concepts of *data architecture, modularity,* and *infrastructure* are foundational needs in medicine and health care, just as they have been shown to be in areas such as global telecommunications, supply chains, and more. Achieving digital transformation in these areas requires not only technological advances, but also new organizational structures involving key public-private partnerships. The goal in this paper, then, is to present lessons learned from COVID-19 that may inform any plans made for meaningful progress along these lines. This discussion paper examines how the current digital health infrastructure and applications have both supported and hindered management of the COVID-19 pandemic, using the insights to extract lessons learned and develop a set of requirements and conditions for future progress. In parallel, and informed by this work, the National Academy of Medicine's Leadership Consortium: Collaboration for a Value and Science-Driven Health System is developing a comprehensive framework for advancing progress in digital health. While this paper focuses on the COVID-19 experience, its development has been coordinated with that broader proposal, particularly as it relates to the concept of a learning health system (LHS). As such, what is presented in this paper can be viewed as a practical living example—a "use case"—of the key desired current and anticipated features of the LHS model.

The first challenge President Joseph Biden directed the Office of Science and Technology Policy (OSTP) to address in 2021 was, "What can we learn from the pandemic about what is possible—or what ought to be possible—to address the widest range of needs related to our public health?" (Biden, 2021). The specific needs highlighted by President Biden—including the need to "dramatically improve our ability to rapidly address [biological] threats," the need to "dramatically speed our ability to develop and conduct clinical trials of therapies for other types of diseases like cancer," and the need to "enable the rapid sharing, with patient

consent, of health information to build a smarter and more effective health care system"— are central issues that were also independently highlighted during the development of this paper (Biden, 2021). Critically, this paper is foundationally rooted in the vital equity imperative captured by another challenge issued by President Biden: "How can we guarantee that the fruits of science and technology are fully shared across America and among all Americans?" (Biden, 2021).

DIGITAL HEALTH: ACCOMPLISHMENTS AND OPPORTUNITIES ACROSS THE HEALTH SYSTEM SECTORS

This paper is one of nine sectoral assessments that, together, provide a coordinated analysis of the health care system's response to the COVID-19 pandemic (NAM, 2021). Across all of these sectoral assessments (the *Emerging Stronger After COVID-19* series), the achievements and challenges of digital technologies are remarkably prominent. Put together, they reveal important accomplishments, as well as opportunities for improvements, in the ways that digital data technologies can and should be harnessed for crisis response and better resilience for managing day-to-day patient care functions in the future.

Table 4-1 summarizes the elements of digital health as they appear in the other sectoral assessments. The elements can be grouped under the following themes:

- Telehealth became real, practical, and essential during the COVID-19 response.
- Data proved critical for care coordination, forecasting, and quality improvement, but data collection was a time-consuming and sometimes a chaotic burden on clinicians and administrators.
- Data interoperability and scaling proved to be more aspirational than reality in health care delivery and public health assessments.
- Effective public-private partnerships proved essential in crisis response.
- The digital divide was occasionally bridged but continued to contribute to and often exacerbated health inequities.
- Digital tools, including AI, became key to advancing knowledge and coping with information overload.

Common across all the papers in the *Emerging Stronger After COVID-19* series is the recognition that to achieve the goal of a learning health care system built around and foundationally focused on sustaining the health of individuals and enabling the care of patients, there must be relevant, fluid data flowing within an agile yet robust infrastructure (NAM, 2021). All tasks of digital health care, including "generat[ing] new health-related knowledge, monitor[ing] its application, predict[ing] response, and guid[ing] courses of action," depend on

TABLE 4-1 | Digital Health Challenges and Opportunities Revealed in the Eight Other Sector Papers

	Digital Health Challenges and Opportunities					
Sectors	**Telehealth**	**Data for Coordination, Forecasting, and Quality**	**Data Interoperability**	**Effective Public-Private Partnerships**	**Health Inequities**	**AI Tools to Address Information Overload**
Health Product Manufacturers	Remote monitoring of clinical trials was leveraged	Design of COVID-19 clinical trials was critically dependent on up-to-date pandemic information		R&D alliances enabled sharing, in digital form, pre-clinical and clinical protocols, plus predictive models, without jeopardizing IP or competitiveness (e.g. COVID-19 vaccine development)		
Clinicians and Professional Societies	A variety of virtual mental health services emerged	Care continuity between EHRs and telehealth systems was addressed; further, certification and accreditation, typically conducted in-person, shifted to a mostly virtual mode	Interoperability was critical for emergency preparedness; outdated infrastructure affected credibility through data backlogs, glitches, and lost test results		Social and behavioral risk data emerged as a key to improve services; the lack of cultural training for providers impeded equitable access	Clinicians found it hard to manage the volume of pre-prints with relevant clinical information; there was a lack of remote learning for continuing medical education and moderated social media groups to share timely and relevant information

Payers		Risk of fraud/abuse potential in virtual care was reduced through digital analytics; opportunities remain to improve cost benchmarks for value-based payment arrangements and alternative payment models	The lack of standardized data elements affected uniform payments	Most payers had limited to no access to race and socioeconomic data
Care Delivery Organizations	Virtual and bot-based triage clinics emerged; tele-ICU expanded	The support for demand forecasting and planning emerged as a digital need	Data interoperability was lacking between care delivery organizations	Supply chain issues for PPE and testing predominantly impacted home health care workers
Quality and Safety		The administrative burden of quality measurement and reporting became overwhelming	The lack of standardized data elements affected the usefulness of reporting (e.g. race and ethnicity)	

continued

TABLE 4-1 | Continued

	Digital Health Challenges and Opportunities					
Sectors	**Telehealth**	**Data for Coordination, Forecasting, and Quality**	**Data Interoperability**	**Effective Public-Private Partnerships**	**Health Inequities**	**AI Tools to Address Information Overload**
Patients, Families, and Communities	Expanded telehealth to support "all"		Digital means to address patient privacy concerns emerged as a critical need		The deepening digital divide became more pronounced: Access to essential technology and reliable internet created inequities; inequities also arose from a lack of language translation and other communication challenges due to sensory deficits of patients	
Public Health		Challenges encountered with electronic case reporting and disparities in the quality of data collected were addressed	Outdated infrastructure impeded facile exchange of information; no scalable way to keep track of millions of cases	The lack of deeper data on communities beyond county/ZIP code information impeded planning and forecasting		

Research	Virtual clinical trial monitoring emerged in practice	Variation in data systems and reporting capacity contributed to challenges for facile enrollment and follow-up for COVID-19 clinical trials	Innovative analytics, evidence accelerators, and disaster response research programs emerged; current research networks were repurposed to address the pandemic (e.g. PCORI)

SOURCE: All sector papers outlined in the table can be found at nam.edu/TransformingHealth.

data—data quality, data analysis, and the patient-centered implementation of results (NAM, 2021). When the data infrastructure is limited, the capabilities of technology and the effectiveness of the health care system as a whole are severely constrained. Data can and should be an effective mechanism to align learning and health care delivery with the requirements of individual patients, provided that their perspectives and needs are intentionally incorporated.

LESSONS LEARNED DURING THE COVID-19 RESPONSE

The limitations revealed by the digital health field's encounter with COVID-19 highlights a recurrent lesson in the history of technology development: The discovery of a new technology does not lead immediately to its gainful application (Shaywitz, 2019). Characteristically, the initial emergence of a powerful new technology, or series of technologies, requires a long period of subsequent, generally iterative, innovation, often by early adopters who begin to understand how to harness the potential of the technology and drive its reduction to practice (Interaction Design Foundation, 2020). Famously, when the electric generator initially replaced steam power, factory owners swapped out one power source for another, realizing only minimal gains in productivity. It was not until new innovators fundamentally restructured the workflow of factories, coupling technology innovation with business model innovation, that the large productivity gains enabled by electricity were achieved (Harford, 2017). Harnessing the power of advanced information technologies such as AI will require an equally fundamental restructuring codified in numerous innovations.

One way of evaluating the COVID-19 experience is to understand that the pandemic brought a unique group of latent use cases to the forefront in health care delivery and health policy. These use cases quickly overwhelmed the capacity of current technology. While the pandemic made these shortcomings visible in a very public fashion, the challenges of similar use cases have been described frequently over the last decade in the medical and gray literature. A national technology review should be conducted to understand the ways in which the current system failed and to consider ways to address the gaps that hold back our ability to use technology to fully achieve health care that is effective, efficient, equitable, enhances the patient experience, and saves lives.

Historically, health care solutions have evolved functionally, along disciplinary lines. The public health, clinician, payer, life science, and patient-advocacy communities (and the many sub-communities within these categories) have understandably focused on solving the problems they each view as most relevant. This has resulted in an assortment of often very different solutions in which patients and communities have not always been the focus. Many of these

solutions, however, involved common data elements that were not aligned across organizations or disciplines. The grand challenge of responding to the pandemic and making digital health more robust is developing "yes, and" approaches and solutions that remain highly responsive to critical local needs, contribute to broader data needs beyond those related to the COVID-19 pandemic to serve patients and communities, and to enable improved analysis and upgrades in the quality and equity of care.

Achieving these goals is a tall order and one that is likely to be addressed most effectively by iterative experimentation, rather than a fixed prescription or defined recipe. It requires a constant focus on the needs of the individuals whose health must be maintained, and, when required, restored. Yet this pursuit must be guided by key learnings and transcendent principles learned from challenges with COVID-19 as well as the important, if limited, successes achieved.

Over the next several subsections, this paper contemplates digital health lessons learned during the response to COVID-19, integrating and expanding upon key themes surfaced in other papers in the *Emerging Stronger After COVID-19* series (NAM, 2021). This is followed by a discussion on observations for the future and a final section on key priorities to inform a vision for a better future.

Data Without Architecture Leads to Data Siloes

As has been witnessed throughout all sectors of medicine and health care delivery, the COVID-19 pandemic created a critical and urgent demand for data to answer the questions posed in the opening section of this paper. This demand, in turn, elicited a determined response by technologists and technology companies to create and deploy systems to make that data available. Hundreds, and perhaps thousands, of new data systems were created and deployed with incredible speed to allow hospitals and health systems to forecast COVID-19 capacity and utilization, improve connectivity between health care delivery and public health operations, create evidence and share best practices for treating a novel disease, and more (Joyner et al., 2021; Blumenthal et al., 2020; Sun et al., 2020). While perhaps less visible to the general public than the rapid rise of available telemedicine services, the deployment of these data systems was no less impressive and no less important to the response to the pandemic. These data system deployments successfully harnessed the technological progress of the past 50 years.

Although these elements of response were incredibly important and undoubtedly saved lives, the systems fell far short of what was and is actually needed as a foundation for coordinated national response and patient empowerment. In the middle of the pandemic, with speed being of the essence, the lack of coordination

around a common architecture meant that nearly all of these new data systems struggled to interoperate with each other. This happened either intentionally by design or, more often, because the task of interoperability was left to a nebulous day in the future in the name of haste. While enabling interoperability in any single component system might, in most cases, require relatively modest engineering effort, when multiplied by the thousands of data systems across counties, states, and nations, any aspiration towards a unified data asset became infeasible in practice. The tremendous scientific and technical advances in machine readability that power global supply chains, massive retail markets, internet search, social media, and more are a stark contrast to the creation of yet more inaccessible data silos in health care.

The lack of available data and digital interoperability was particularly acute when seeking to understand the number and trends of COVID-19 patient encounters, the capacity of the health system to treat those patients, and developments in the utilization of that capacity. In an effort to provide more visibility, the U.S. Centers for Disease Control and Prevention (CDC) published new data modules to standardize the reporting of encounter, capacity, and utilization data elements (CDC, 2021a). In March 2020, then Vice President Michael Pence issued a request to all health care delivery organizations in the U.S. to report such data on a daily basis (CMS, 2020a). While this step was tremendously helpful, it was disappointing to see the nation reduced to asking every over-stressed hospital and clinic to take on the additional burden of gathering data manually, filling out a spreadsheet, and emailing it in every day—a method that would hardly be tolerated in any modern manufacturing, supply chain, e-commerce, or logistics system.

The fundamental lesson is that without coordination around a comprehensive data architecture, as exists in other industries, all of the digital tools and data assets of the past two or more decades are decidedly less useful than expected. ***As the U.S. looks to the future, it will need to embrace the importance of data architecture for any coordinated national or international response to health crises, and find effective ways to define such an architecture and then create the infrastructure to put it into action.***

Right-Sizing Health Care Regulation Can Improve Patient Care in a Hurry

Improving and optimizing health care delivery requires the development and uptake of innovations, such as digital health solutions, especially telemedicine, which clearly enabled health care delivery during the pandemic. One of the enormous challenges of innovation in health care is the lack of opportunity to test innovative solutions in the clinical environment. From the perspective

of innovation theory, innovation occurs most often in unregulated spaces (Christensen, 1997). While there were many factors that contributed to the nation's rapid uptake of telemedicine in response to the pandemic, both in terms of technology innovations and policy prescriptions, a key moment was the public statement by the U.S. Department of Health and Human Services (HHS) Office of Civil Rights (OCR) that it would use its discretion with regard to enforcing Health Insurance Portability and Accountability Act (HIPAA) provisions during the public health crisis. Overnight, a debate that had raged for over two decades about virtual medical visits was resolved with a massive migration of clinical care to digital platforms and, consequently, no widespread reports of data or privacy breaches (Perrin et al., 2020). Indeed, it is possible that proactive policies that extend this type of posture in enforcement discretion may help speed innovation in other areas of health care as well (Keesara et al., 2020).

The key lesson from the COVID-19 response is that such "right-sizing" of regulation can be extremely important and productive. For example, HIPAA was implemented in the 1990s to protect individuals from misuse of their data by specific third-party covered entities such as health care providers or insurers in a world where consumers had no access to their data and no insight into how their data were being used. While the privacy of health information remains a concern today, individuals also need to be able to share their health information with trusted people, organizations, and digital applications of their choosing that are not currently covered under HIPAA. Meanwhile, consumer privacy laws have been rapidly evolving, including the General Data Privacy Regulation (GDPR) in Europe and the California Consumer Privacy Act (CCPA), which serve to protect information that is shared by consumers and patients with third parties (CCPA, 2018; GDPR, n.d.). The general consumer data privacy approach ensures that there is a consistent set of standards across the market, rather than a patchwork of different data privacy standards based on the use of the data or categorization of the service. Such modern standards could focus on questions like: Who owns the data? How can and will consumers use data? What will be the impact of data on each individual's, and the nation's, overall health and well-being? What are the key measures of success?

The expansion of telemedicine was also facilitated in part by changes in clinical licensing requirements and assurance of payment. Medical licensure occurs at the state level, but in the midst of a crisis, state-based licensure regimes were relaxed to allow movement of essential clinical staff across state lines. National or inter-state cross licensure could facilitate access to digital services (especially for those in rural areas), removing one barrier to interstate provision of care. At the same time, the migration to telemedicine was accelerated by the implementation of site-neutral payment policies ensuring equal reimbursement for virtual and

in-person visits. Once the pandemic recedes, business models predicated on facility fees for visits may find it financially challenging to provide virtual services.

Current Health Care Data Systems Are Inadequate for Longitudinal Patient Care and Data Needs

A variety of technology-related challenges in health care delivery were highlighted during the pandemic. The first major challenge was related to connectivity—the ability to gather and aggregate data about individual patients over time. For example, a typical use case might be to discharge a patient with a documented COVID-19 infection from a hospital to a rehabilitation facility with a requirement for supplemental oxygen. Now, consider the need to monitor the patient throughout. The hospital has an EHR that includes the clinical data related to the hospital stay. The rehabilitation facility has a separate record system related to the stay in that facility. The patient might have an oxygen sensor that provides data that is recorded on their cell phone (if at all). There is no system today that aggregates data from these three sources.

Although this is a simple use case, this type of scenario illustrates how a health care system's capacity became stressed and how the ways in which patients accessed health care resources became less conventional as the pandemic progressed. Failures often occurred because the technology architecture focused on the needs of the individual providers, not the needs of the patient. An alternative architecture, such as a personal health record (PHR), would in principle enable a more patient-centered ability to capture and share data, and thereby provide significant clinical value. A PHR architecture puts patients at the center of health care information, including control over the access to those data. As a means of organizing health care information, a PHR does not have to require the patient's direct interaction but can be viewed as a "canvas"—an "organizing principle" for health data—that enables patients to aggregate and share data for their own health benefit. As highlighted in a situation such as COVID-19, where patients may be obtaining health care from a diverse set of providers and via a diverse set of delivery means (such as telehealth), the "portability" of a PHR should, in principle, benefit all stakeholders in a patient's care and safety.

PHR architectures have been proposed to the HHS Office of the National Coordinator for Health Information Technology (ONC) several times, but have never been adopted due to privacy concerns or concerns about data overload (Liu et al., 2011; Witry et al., 2010). Nevertheless, a growing number of health care systems around the world today are seeking ways to adopt this approach. However, the fundamental lesson is that in order to evaluate a system architecture, it is important to prioritize the specific use cases for the technology, as well as

the consumer's need and willingness to engage with it. This statement may seem simple, but clarifying that *the primary use case of health information technology is patient care from the patient perspective* helps to advance the deployment of technology that may better optimize the delivery of preventive services, primary care services, and chronic care that is safe and effective (Schulman and Richman, 2019).

There are, of course, many important secondary use cases for technology as well, and they are readily apparent in improving health care quality, research, and public health. Yet these secondary use cases too often receive priority in policy discussions. These use cases are essential, even crucial, for a high performing health care system, but they have to be developed in ways that do not overshadow the primary use case of providing patient care from the patient perspective. To take one common example, there are often use cases that depend on a wireless networking environment, with high-speed data and video services available for patients. Unfortunately, access to high-speed broadband services today is limited in many high-needs environments in the U.S., creating a digital divide and disadvantaging crucial populations of people from receiving care. With a patient-centered approach, this infrastructure challenge immediately illuminates a key factor in health care disparities and digital technology today.

A second challenge in today's health care data systems pertains to productivity. Many physicians became overwhelmed with clinical duties in the midst of the pandemic but did not experience even temporary relief from burdensome documentation requirements. Challenges with electronic health records, including the user interface, length of notes, and administrative tasks—which the majority of clinicians are required to use for patient documentation—are all well documented (Holmgren et al., 2020; Downing et al., 2018; Ratwani et al., 2018; Tseng et al., 2018). From a clinician perspective, EHR systems are not optimized for patient throughput and have limited flexibility to respond to volume by adjusting data entry requirements. Further, most EHR systems have few tools to help clinicians locate and prioritize the essential information for each clinical encounter. This is not the case in other major industries that rely on digital documentation. For example, airplanes generate tremendous amounts of data, but pilots are not tasked with sorting through them. Pilots are provided with heads-up displays that share only the information required for immediate decision-making.

While the burden of clinical documentation and the lack of adequate user interfaces are hardly a new lesson learned during the COVID-19 response, the pandemic did highlight that an overstressed health care system was unable to cope with the need to collect even more data and, more important, effectively focus on the key data elements most pertinent for crisis response. Clearly, a major effort must be made to reduce this burden and thereby create greater capacity for smart data collection in times of greatest need.

A third challenge is the distinction between *data* and *services* in the technology environment. High-fidelity clinical data provide a record of clinical conditions, treatment, and response over time. This was the primary description of data in the paper record environment. However, many conceptualizations of the EHR were aimed at reducing the burden of paper record storage by creating electronic files. This solved the storage and transmission issue but did not lead to a transformation of care. Today, the value is in how data are used. Rather than simply being stored as a record, data have become the resource driving our most advanced digital technologies. Services are the benefits we receive from the data. In the broader economy, data are used to power technology such as machine learning (ML) in the pursuit of optimization of attributes of digital services for consumers. Services range from digital tools providing insights to complete experiences such as online banking, digital shopping, and streaming video entertainment.

The transformation from data to services can be illustrated by some of the shifts that have occurred in libraries. Libraries used to house vast collections of documents, which served as the data for researchers. A revolution in data storage occurred when new technologies allowed for paper records to be transferred to microfiche, dramatically reducing storage costs for the library, and in the process making more data accessible by making it easier to store more documents. Nonetheless, the retrieval process remained the same: Researchers went to the library to access the data. There were no new services created by this advance in data storage that improved research access or productivity. A second, more significant, revolution occurred when we moved from microfiche records to machine-readable digital records. People could now use the data to power new digital services such as online search and retrieval for documents. Research projects that once required weeks or months of sitting at microfiche readers to review documents and curate reference lists can now be completed online, from any location with internet access, in minutes or days. Even more important, the patterns of use across individuals can be collected and used to inform even more productive and intelligent use of the data. The leap in productivity came from the digital services which allowed better access and curation of data for the user (PubMed and online access) (Collins, 2019).

Similarly, medical knowledge was previously contained in voluminous textbooks, laboriously curated and updated every few years with "new editions," which contained the latest synthesis of the medical literature. This resource was only available in the medical library, far away from the provision of patient care. Now, the data from these textbooks have been transformed to a continuously updated service called Up-To-Date which is available everywhere—from home, in the ward, in the clinic, and on clinicians' phones (UpToDate, n.d.). This digital service has been so transformative that the medical certification process—which used to require mastery of the content

of medical textbooks—is now focused on the application of knowledge by including the Up-To-Date service as a tool on medical board recertification exams.

Data are of limited value when they are static, or when they are irretrievable in machine-readable and "clean" condition. Yet in health care, the value of data is limited by design, regulation, and practice. The core of provider-based EHR systems was developed using decades-old architectures (and a half-century-old computer language), all developed long before the ability to apply ML to the data. These EHR systems were built as data repositories as their original use case. In essence, "data" is not an action word in health care.

Further, there is little conceptual or business linkage between data and services. Again, consider a simple use case of helping a patient to manage their diabetes at home. After a decade of intensive research, clinicians now have closed-loop pumps and sensor systems that can assist Type I diabetes with daily glucose monitoring efforts. However, the majority of diabetes patients have Type II and use smart glucose meters to collect data that are uploaded to free-standing smartphone apps but do not integrate with clinical records or clinical decision support tools and hence are invisible to the care team. Obviously, these data need to be made available to the care team readily or else the utility of collecting them is very limited in improving overall health. The clear lesson here is the need for high-quality clinical data to support high-quality clinical services for patients.

Technological, Geographical, Social, and Political Barriers Impede Critical Public Health Response

As described in detail in the "Public Health COVID-19 Impact Assessment: Lessons Learned and Compelling Needs" discussion paper (and summarized in *Table 4-1*), COVID-19 presented the U.S. health care and public health communities with pressing and critical questions about the magnitude and management of the COVID-19 pandemic that were only partially addressed (DeSalvo et al., 2021).

The successful use of data included U.S. visibility into nationwide case counts of COVID-19, laboratory testing results, data on special subpopulations, and, more recently, on vaccinations (CDC, 2021b). Monitoring national public health progress became a routine pastime, with most major news outlets summarizing epidemiology data in near real time. Progress was also made on timely data about hospitalization rates, including ICU care, and non-traditional public health data such as human mobility patterns that would help understand and monitor the pandemic. The adoption and adaptation of existing health information technology and data infrastructures were critical to collecting and analyzing these public health data. Newer technologies such as application programming interfaces (APIs) and cloud-native applications facilitated progress.

While technology has enabled progress, there remain clear geographical, socioeconomic, legal, and political barriers to collecting, organizing, integrating, analyzing, and then disseminating local, regional, and national data owned by various groups and subject to state and local jurisdictional policies and regulations. The major lessons learned in this pandemic are magnified versions of prior lessons such as the lack of visibility on nationwide public health data and the lack of truly interoperable health information technology systems in health care settings. Even when data are available and exchanged between health care providers and the public health sector, there are gaps in the completeness, timeliness, and granularity of the data available for monitoring the pandemic.

For example, while the U.S. was able to create data systems that summarized laboratory testing information to manage the pandemic, the datasets were not complete enough to incorporate SARS-CoV-2 test performance into calculations of disease prevalence. Since SARS-CoV-2 test sensitivity and specificity varies widely and because differing tests were used by different laboratories in different locales, two contiguous counties in the same state could appear to have the same disease prevalence while, in reality, disease prevalence may have been different due to testing patterns and testing performance. Similarly, information about affected patients was frequently missing (e.g., race/ethnicity, comorbidities, likelihood of exposure) as was information on rates of asymptomatic COVID-19 positive patients. These gaps were critical because pandemic management approaches (e.g., recommendations for shelter-in-place) were based on observed disease prevalence, change over time, and a subpopulation's risk of exposure to the disease. The key observation is that better data integration across a variety of data types and data sources is critical for public health decision-making and timely and equitable action.

Innovative technology solutions can also advance public health and population-based management of the pandemic. One byproduct of the pandemic is that data visualization has become a widely accepted public health practice. Graphical data analysis techniques allow anyone to easily understand and respond to the pandemic, from sophisticated epidemiologists to individual Americans trying to figure out how to plan their day (JHU, 2021a). Software has also advanced traditional public health activities like monitoring vaccine performance over time. As a part of COVID-19 vaccine monitoring, the CDC has advanced a program called "v-safe" (CDC, 2021c). Vaccinated individuals use a Quick Response (QR) code or other registration strategy to sign up for a national monitoring database intended to document post-vaccination symptoms and identify potential safety concerns. The technology platform is secure and private, and provides a mechanism to drill into new potential safety signals of concern and to follow up. An enhancement to the Vaccine Adverse Event Reporting System (VAERS) could be the ability to link

incidence reports with public health immunization records to verify that the person reporting the side effect actually received a vaccine.

Digital platforms have also been used for case investigation and contact tracing. These systems allow for notification and monitoring of persons exposed or infected with SARS-CoV-2 (CDC, 2019). Digital tools provide for symptom monitoring and clinical and public health referral of persons who may need additional support for testing, isolation, and quarantine. While data visualization and person-focused software to facilitate participation in monitoring appear to be basic tools, they are truly innovative when incorporated into public health tasks. The key lesson learned here is that incorporating appropriate technology innovations into public health is a critical task for the nation's safety, security, and overall health.

Modernized, integrated, real-time public health data systems at every level of government will revolutionize the nation's response to health threats. There is a clear need for a national public health data ecosystem that functions well in the inter-pandemic phase and can then seamlessly adapt and scale for a future pandemic or other public health emergency (Sittig and Singh, 2020). Preserving the privacy and confidentiality of individuals while collecting and disseminating public health data remains a foundational principle. Modernization would ideally reduce the burden of health care providers in reporting conditions to local public health officials and of public health reporting to the federal government (CDC, 2021d). To fully realize this, standards and approaches to reporting a minimal set of public health data need to be universally adopted and enforced.

Realizing this vision requires sustained investment and guidance to state, local, tribal, and territorial health departments, the creation of advanced tools and capabilities at all levels, and the realization of best-in-class innovation with research, the private sector, and public health partners. Investments to date have laid the groundwork and spurred real progress, but much work remains to be done. In addition, there is a critical need to build and support a public health workforce that is skilled in informatics and data science to establish and maintain the ecosystem. This can be accomplished by reskilling, upskilling, recruiting, and retaining a data science workforce with the skills required to meet 21st century health threats. Finally, developing equitable governance while preserving privacy will require consensus building and cross-sector partnerships.

Operations Infrastructure, Such as Supply Chains, Are Critical and Data-Dependent

Health care's digital infrastructure was critical to all aspects of managing the health of the population during the pandemic, including optimizing a wide range

of day-to-day operations, such as ensuring food availability in grocery stores or determining whether university students could attend classes in person. Like other aspects of managing the pandemic, a critical feature of the pandemic response was the need for readily analyzable data to inform and refine the operations of hospitals, universities, businesses, and other organizations. The early days of the pandemic offered dramatic examples of challenges, including deficiencies in supply chains in a range of industries, including hospitals. Physician executives were compelled to step out of their normal roles to help optimize supply chains for PPE and ventilators. The initial scramble for supplies was characterized by confusion but also remarkable improvisation such as in the activation of presidential emergency use authorizations and whiskey manufacturing plants repurposing their operations to make hand sanitizers with 80% alcohol (Distillery Trail, 2020). Because many health care systems did not stockpile inventory, they were left vulnerable due to shortages when the need surged. For example, early in the pandemic, two-thirds of health care workers in the U.S. did not have enough masks, and about 70% of workers had to wear the same mask for more than one day, putting them at even greater risk of COVID-19 infection (Lagu et al., 2020).

From lessons learned in managing supply chains during the COVID-19 pandemic, the U.S. health care system has an opportunity to optimize approaches to sourcing, inventory management, analytics and technology to better understand vulnerabilities and to address them. A flexible, resilient and pandemic-ready supply chain would include the following features:

- Sharing of accurate, timely, and real-time data between providers and suppliers to improve transparency in inventory tracking across individual health systems and allow for the equitable, trustworthy distribution of hospital supplies.
- Expanding investments in safety stockpiles that would reduce reliance on just-in-time orders and provide a sense of probabilities on supply availability.
- Using predictive modeling AI that incorporates information on individual part manufacturing and sourcing from current and potential suppliers.
- Improving supply-chain analytics by integrating data with user workflows for efficient data mining by product, geography, and timeline.
- Adopting internet-of-things (IoT) connectivity and digitization that will allow hospitals to better track products throughout the supply chain and assess vulnerability (e.g. single-sourced supplies, financially fragile suppliers) from shipping all the way to the point of care.
- Connectedness to and visibility by government actors responsible for making allowances and shifts in response to critical demands (e.g., the U.S. Food and Drug Administration's ability to provide emergency authorization for new manufacturers).

Supply-chain optimization can affect the quality of care through multiple factors, including by saving time for key personnel, allowing physicians to spend more time with the right patients, reducing the time spent looking for supplies, and allowing for better recall management to reduce patient safety risks. This case example has broad applicability across a range of daily operations, from better management of regional hospitals and ICU beds to ensuring a safe national food supply.

COVID-19 Spurred Progress and Exposed Key Gaps in Access to Digital Therapeutics

The pandemic highlighted the immense opportunities to leverage digital capabilities in service of improved health. Simple-to-use but sophisticated software applications that can run on personal computer devices, such as Somryst, an FDA-cleared prescription application for the management of chronic insomnia in adults, offered digital solutions directly to many patients who needed them (Jarorski et al., 2021; Kuhn et al., 2017; Ritterband et al., 2017). Shelter-in-place and quarantine rules, which limited a patient's interface with the health care system, amplified the demand for care and increased the likelihood that patients and clinicians would gain experience with digital tools. As mentioned previously, relaxed regulations with regard to telehealth played a critical role in expanding access. Remote digital sensors such as heart rate monitors and pulse oximetry were well-utilized during the pandemic, offering the opportunity for more equitable home-based care monitoring. AI-powered conversational chatbots were deployed by the CDC and thousands of hospitals and clinics to enable patients to self-assess their potential COVID-19 symptoms. The use of digital therapeutics—software applications intended to deliver therapeutic relief—also expanded, especially for mental health interventions, where the FDA provided emergency use authorization of relevant digital therapeutics without review.

COVID-19 also highlighted the large unmet gaps in digital solutions for mental health. Pre-COVID-19, about 51 million U.S. adults (20% of the population) lived with a mental illness, and almost two-thirds of lost workdays in the U.S. were caused by mental illness (NIMH, n.d.). While most mental illnesses are treatable, nearly half of all people with mental illnesses do not receive any services; suicide was the tenth leading cause of death in individuals before COVID-19 (CDC, n.d.). The reasons for this care gap are multi-fold, ranging from stigma, lack of access, shortage of therapists, inadequate funding, and lack of parity between care for physical and mental health conditions. While the full impact of pandemic mitigation strategies on mental health may not be known for some time, early studies indicate an uptick in mental health disorders due to

the pandemic (Taquet et al., 2020). For example, surveys conducted by Kaiser Family Foundation in January 2021 indicate that four in ten U.S. adults during the pandemic experienced symptoms of anxiety or depressive disorder—an increase from pre-pandemic levels of one in ten adults (Panchal et al., 2021). Furthermore, accumulating evidence suggests the problems have been amplified for youth, marginalized communities, and people of color (Fegert et al., 2020; Moreno et al., 2020; Singh et al., 2020).

The collision between the profound mental health needs revealed and intensified by the pandemic and the profusion of digital health tools not only highlights the promise of digital health tools to help address mental health needs, but also reveals important limitations in these tools. Digital tools for mental health can be divided into two broad categories: (1) lower-risk triaging and health care delivery digital tools such as telemedicine (via apps) and crisis counseling (via text messaging), and (2) digital diagnostics and therapeutics intended to diagnose or treat mental illness.

Triaging and health care delivery tools were able to be utilized almost immediately after the onset of COVID-19, and offered a vital point of immediate medical and personal connection. For instance, the Crisis Text Line (CTL), which provides free, 24/7 counseling to people experiencing a mental health crisis via text messaging, reports that more than half of its users (65%) had not spoken to anyone else before contacting CTL (Crisis Text Line, 2021). At the same time, the scaling of this category of tools has been hampered by issues related to privacy, cross-state licensing, bandwidth, and limited reimbursement.

Digital therapeutics also offered the possibility of immediate assistance to many suffering from mental health challenges during the pandemic, and there were quite a few from which to choose. Pre-pandemic, there were more than 10,000 apps claiming to help with stress, depression, anxiety, and insomnia. However, nearly all these apps operated as "wellness apps," in that they were not subject to FDA oversight if they did not make overt medical claims. Remarkably, over the past decade, only three mental health digital therapeutics (for the treatment of insomnia, substance abuse, and attention deficit hyperactivity disorder) have sought and executed the studies to gain formal FDA clearance (FDA, 2020a; Pear Therapeutics, 2020; Pear Therapeutics, 2017). Therefore, it is difficult to evaluate scientifically the efficacy of the vast majority of apps that claim to help with mental illness. For example, a study of 73 apps addressing a range of mental well-being issues found that many indirectly claimed effectiveness through scientific phrasing, but only two provided direct evidence from a trial (Larsen et al., 2019).

Wellness and FDA-cleared apps are generally not integrated with clinician EHR systems, which presents another challenge in organizing and centralizing

patient data. Cognizant of the mental health impacts of the pandemic, the FDA waived the requirement that mental health-focused apps and digital therapeutics (such as symptom checking and triaging apps, and low risk therapy or counselling apps for anxiety, depression, or sleep) must submit a 510(k) premarket notification before distribution to the public (FDA, 2020b). A large number of mental health symptom checker and triaging apps took advantage of this opportunity, broadening the market of available apps. A mental health digital therapeutic (to treat ADHD symptoms), which was in the process of a de novo submission, was also able to come to market much sooner under this provision (FDA, 2020a). Several other companies with digital therapeutics in the pipeline are also actively looking to take advantage of this temporary relaxation (FDA, 2020b). Last but not least, pandemic-related shifts to contactless clinical trials have spurred the use of digital tools (e.g., wearables) to monitor psychiatric symptoms as well as the use of digital therapeutics to augment pharmacotherapy.

Given the widespread adoption of consumer-oriented digital tools during the rise of COVID-19, a key lesson learned is the importance of evaluating the performance of digital tools to better understand where they contributed the most and what factors correlated with success. Equally important is the critical evaluation of which patients were not well served by digital approaches, and what might be done to remedy these deficiencies. The availability of large real-world datasets would better harmonize effectiveness standards between the FDA and payers (e.g., the U.S. Centers for Medicare & Medicaid Services (CMS)). It will also be valuable to consider how the data gathered by these digital approaches might be best leveraged to advance public health, while protecting patient privacy and data rights. Such insights will hopefully also inform continued post-pandemic authorization of these devices as well as the establishment of new regulatory pathways.

Access to reliable digital tools and effective and well-integrated apps offer the potential to radically change how patients cope with mental health challenges—not only during pandemics but also in their daily lives in inter-pandemic times. The successes seen during the pandemic highlight these possibilities and raise the question of whether some pandemic-related exceptions should be made routine. A thorough "after-action" report is also critical to ensure that patients with mental health challenges and their providers can make informed, discerning care choices; to enable regulators to refine and optimize review and approval protocols; and to enable innovators to build on what is proven to work to develop even more effective approaches for the future. Scaling such solutions is important for the mental health space as well as the health care system writ large.

Advancements in Clinical Evidence Generation Were Essential But Rudimentary

COVID-19 generated an urgent need for medical science to understand and respond to the novel SARS-CoV-2 virus. Emerging digital technologies were pressed into service across the range of evidence-generation activities, including not only preclinical discovery and traditional clinical trials, but also extending to real-world data obtained from the observation and instrumentation of clinical treatments. The success of these approaches varied, highlighting their exceptional potential. The rapid sequencing of the SARS-CoV-2 virus genome and near-instantaneous global sharing of these data comes to mind, as well as the remaining work of leveraging and disseminating data from EHRs around the manifestation of COVID-19 symptoms and progression of the disease.

Preclinical Discovery

The ability of the international science community to share information about SARS-CoV-2 so quickly represents a prominent example of digitally enabled biomedical progress. The combination of next-generation sequencing (NGS) capabilities and powerful open-source data-sharing platforms such as NextStrain enabled scientists to characterize the molecular structure of the virus and rapidly share it with colleagues around the world. This shared understanding provided critical insights into how the virus was spreading and how it was evolving over time, while also enabling researchers to identify potential viral vulnerabilities. In addition to genetic sequencing data, researchers also used open platforms to share information related to the characterization of the immune system response to the virus, the chemical structures of potential antiviral compounds, 3-D structural data for models of SARS-CoV-2 proteins, transcriptional data, and histopathological images from infected tissue.

The conspicuous success of data generation and sharing in the preclinical area, like other examples of digital success, reflects in large measure the work done and progress achieved prior to the pandemic. Stemming from learnings tracing back at least to the human genome project two decades ago, these scientific communities now have deep experience sharing data, both technically and culturally, and have established standards and tacit conventions that facilitate this process (NIH, 2020; AHA, 2019; CDC, 2014). Critically, these efforts are enabled by features of the datasets themselves—on balance, these data tend to be highly structured, consistent, reliable and complete; generated by instruments; and ready for analysis. Analysis of clinical data, in contrast, must contend with the idiosyncrasies of health care delivery and the management of patient privacy, presenting additional thorny challenges. Ultimately, a key lesson for the future is

the importance of aligning and integrating these varied data sources in ways that build on the progress already achieved by the research community.

Bioinformatics

There is no question that genomics is a "big data" science, involving millions, possibly billions, of genomics, proteomics, metabolomics, and other -omics and related phenotypic data datasets, and continuing on an exponential growth trajectory. Bioinformatics brings crucial context to these data through tools such as machine learning algorithms and predictive analytics that can help understand the research and clinical data from a gene-centric approach to a multi-scale systems-level approach. For example, sequencing the SARS-CoV-2 genome and its bioinformatic analysis was the essential first step towards developing a vaccine against COVID-19 and provides a roadmap for tracking the emergence and spread of variants of the virus. However, to unleash the opportunities in bioinformatics requires coordinated community efforts.

Clinical Trials

The pandemic created profoundly disruptive threats to clinical trial efforts unrelated to the virus, as well as studies seeking to better understand and manage COVID-19. The successful execution of so many clinical studies under such difficult circumstances owes much to both the availability of emerging digital technologies and the inspirational resilience and adaptability of researchers, regulators and, especially, patients. As with preclinical research, most of the required technologies were already in place, at least provisionally; the needs created by the public health emergency merely served to accelerate implementation and adoption of these approaches in clinical trials.

Modern digital dashboards for clinical trials proved especially helpful in quickly understanding and effectively responding to the intensified needs created by the global health emergency (Duran et al., 2020; Mijuk, 2018). A particularly important application of digital technology was in remote patient evaluation, an effort promoted by guidance issued by the FDA in March 2020 (FDA, 2021). This effort encouraged trial sponsors to consider virtual assessments such as telemedicine visits as a means of ensuring subject safety. Remote monitoring was also enabled through the use of at-home sensors (such as pulse oximetry devices). Prior to the pandemic, the potential to use such remote devices had been highlighted in previous FDA guidance, but adoption was limited as many sponsors worried that the advantages did not outweigh the potential regulatory risks and potential inequities (Vyas et al., 2020). Remote approaches also helped sponsors monitor individual study sites when travel was prohibitively difficult.

The ability of the clinical research enterprise to continue during the pandemic reflects the pre-pandemic transition to a digital infrastructure within industry, regulatory bodies, clinical research organizations, academia, and health care organizations. At the same time, the environment of crisis response means that a full grasp of the key lessons learned is likely not yet apparent. Thus, a thorough post-pandemic review will be essential to evaluate the novel digital approaches used in clinical studies and to examine in a systematic and disciplined manner the impact on patient safety and the integrity of study data.

Real World Data

Data collected from the routine care of patients—termed "real world data" (RWD)—were of critical importance for advancing understanding of COVID-19, including not only diagnosis and treatment, but also the design and conduct of clinical trials. The digitization of health care over the last decade offered the promise of RWD that could be made available in near-real time from both the EHR and from insurance claims data (or "administrative data.") Other potential sources of RWD included biosensor information (e.g., accelerometer data in a watch), biological information (e.g., SARS-CoV-2 genomic information), socioeconomic data (e.g., personal or neighborhood resources), social media summaries (e.g., discussions on Reddit or Twitter), and immune profiles in response to infection. One critical realization during the pandemic was the need for reliable RWD sources to describe an evolving clinical scenario in near-real-time—writing the novel as the story unfolded.

Over the past decade, the medical research and business communities have had high expectations for RWD. Some of these are realized today and others are more future-looking. For COVID-19, RWD were used to refine clinical research studies, including choice of population, endpoints, and sample size, as well as assumptions involving the anticipated mortality by age, comorbidity, and disease severity—all factors that could otherwise be especially challenging to estimate in the earliest phases of a new disease (Wierzbra et al., 2020). RWD were also used to complete longitudinal study datasets, as demonstrated in the RECOVERY trial and as contemplated for studies in the iSpy platform trial network (RECOVERY, 2021; HDR UK, 2020; Plump and Reese, 2020; QLHP, 2019).

A critical question for any dataset used in clinical research is whether it is sufficiently reliable to meet the evidentiary task, and RWD is no exception. In recent years, intensive effort has been devoted to developing standardized approaches for documenting dataset characteristics and how these can be matched to a clinical research task (Brown et al., 2020; Franklin et al., 2020). The pandemic showed just how important this foundational work is in assessing the completeness, variable reliability, and provenance of data for the crisis response (Miksad and Abernethy, 2018).

The pandemic also highlighted important challenges in the use of RWD. An initial hurdle in the early days of the pandemic was learning how to work with RWD datasets, understanding their reliability, and developing common definitions for key parameters describing severity of disease, such as whether a patient was receiving supplemental oxygen. It was also important to contextualize data within the changing contours of the pandemic over time. For instance, the mortality rate of hospitalized patients in New York City decreased dramatically between spring and late summer 2020. The mismatch between the urgent need for RWD and its limited availability also led to some acknowledged setbacks. Two papers published in leading medical journals were subsequently withdrawn after the improbably robust RWD dataset upon which these articles were based was called into question (Piller and Servick, 2020). Greater familiarity with RWD might have identified this conspicuous red flag prior to publication.

The COVID-19 Evidence Accelerator was established by the Reagan-Udall Foundation in collaboration with Friends of Cancer Research to catalyze the effective sharing of RWD methods and insights using a public-private partnership model (COVID-19 Evidence Accelerator, 2020). The Evidence Accelerator was initially set up to help address a pre-specified set of questions around the natural history of the pandemic. The goal was to bring together data holders, analytic teams, technology innovators, government bodies, and others to solve problems, and the forum provided a legal space for cross-organization information sharing and problem solving. Perhaps not surprisingly, consortia that already had developed and implemented standardized models were able to adapt to the pandemic with particular speed; examples include Observational Health Data Sciences and Informatics (OHDSI), the U.S. Department of Veterans Affairs (VA), and University of California Health (Deardorff, 2021; OHDSI, 2021; VA, 2021). Many datasets required curation but were otherwise quickly adapted to help answer questions related to the pandemic. Additional work was required by data aggregators, who had collected large volumes of data that required further aggregation and analysis in order to make sense of the information.

A key determinative factor in driving value from RWD appeared to be data empathy—a deep familiarity with the clinical context of the data and experience in using it in a health care context (Shaywitz, 2021a). One particularly important lesson has been the renewed awareness of the gap between raw clinical data and derivable insight, along with the recognition that achieving such actionable understanding typically requires more than a technology fix—it needs insight into the nuances of both the clinical data available and the research question to be addressed. Extracting value from RWD, the health care community has learned, requires meaningful collaboration between clinical experts (who understand the often very local clinical context), statisticians (who recognize the evidentiary requirements for medical research), and

data scientists fluent in large data sets and the techniques, including data curation and AI, for organizing and understanding them (Shaywitz, 2020).

Digital Future of Evidence Generation

Digital technologies played a critical role in accelerating global understanding of the virus and the urgent development and critical evaluation of a range of potential countermeasures. The successes, from the global sharing of viral sequence data to the ability to conduct robust clinical trials during unprecedented circumstances, highlight the transformative potential of digital technologies, as well as the value in establishing both tools and culture in service of these technologies in advance of a Public Health Emergency. Critical lessons learned include the importance of:

- Incentivizing data sharing across the landscape from basic biological discoveries (e.g., SARS-CoV-2 viral sequence) to longitudinal clinical data (e.g., use of EHR data to complete long-term follow up of a person on a research study).
- Incentivizing data interoperability (e.g., the ability to merge variables across datasets from various sources) as well as documentation and improvements in data quality.
- Considering all evidence generation tasks as important, from basic description of the pandemic to determining treatment effectiveness.
- Leveraging digital technologies to more efficiently conduct evidence generation tasks more efficiently (e.g., telemedicine for remote monitoring or RWD for longitudinal follow up of patients enrolled in clinical trials).
- Matching the evidence generation task to the dataset and analytic approach.
- Conducting a post-pandemic "after action report" to carefully evaluate the benefits and risks of clinical research innovations deployed during the pandemic (e.g., remote patient evaluation using telehealth solutions) and to develop approaches to allow meaningful innovations to persist.
- Ensuring that all required types of expertise participate in evidence generation tasks, including clinicians.
- Leveraging public-private partnerships to advance solutions to quickly develop the science and explore innovations related to digital solutions for evidence generation tasks.

Harnessing AI and Other New Capabilities Depend on a Coherent Data Infrastructure

The advances of the past decade in AI—particularly ML and data science—have captured the attention of the field. Today, AI is infused into nearly all aspects of life,

including the smart diagnostics that predict when automobiles and home appliances are about to break down, the analytics that facilitate connections to relevant social circles and retailers, intelligent decision supports that help power global supply chains and ensure that foods and medicines get to where they are needed, and much more (Google Cloud, 2020; Tancev, 2020; Rice, 2019). Over the next five years, scientists expect AI systems to provide practical capabilities that may transform our understanding and abilities in human language, biology, climate modeling, social systems, and more, unleashing new waves of scientific and technological advancement (DeepMind, 2020; Wheeling, 2020; GPT3 Examples, n.d.).

While it can be hard at times to separate hype from reality, our nation is indeed living through a fundamental transformation, fueled by the ever-increasing ability of AI to absorb massive quantities of data—generated through a combination of human thought and activity, increasingly ubiquitous sensors, and simulations of progressively higher fidelity—and then to distill that data into knowledge that has practical significance for societies, communities, organizations, and individuals. This is a transformation that the authors of this paper want and believe society will demand in medicine and health care delivery.

From the perspective of data and AI, the COVID-19 pandemic has presented many opportunities to put this transformative vision into action. Examples of positive impact have together shown a bright future for AI. These examples include the widespread impact of intelligent chatbots, progress toward the accelerated discovery and development of therapeutics, and life-saving decision support systems based on intelligent forecasting (Brothers, 2020; Lyons, 2020; Magrabi et al., 2019).

At the same time, the COVID-19 experience brought into clearer view how challenging it can be to access the benefits what are still relatively new capabilities in data and AI. A consistently underappreciated aspect of digital systems is that the act of acquiring, aggregating, and normalizing data, while potentially an arduous task in and of itself, is only the first step in creating and deploying an intelligent system that can operate at enterprise-grade quality and scale. Other steps include establishing:

1. ML training infrastructure to process data,
2. Application infrastructure for deployment and user engagement,
3. Feedback infrastructure to monitor for faults and enable continuous improvement,
4. Ethics and compliance infrastructure to ensure fairness and accountability, and
5. DevOps infrastructure to manage and evolve the overall system.

Further, there is an overarching challenge of scale. AI requires massive amounts of data, but any single institution might have relatively limited data for any specific problem. Hence, the management of data sharing agreements, usage rights, and

chains of custody are themselves significant infrastructure needs. In other words, there is a significant infrastructure foundation necessary for any operational data and AI system. Data repositories such as the NCATS National COVID Cohort Collaborative Data Enclave established to address the COVID-19 pandemic could offer a rich trove of data and effective model for cooperatively exchanging data (NCATS, n.d.).

As AI has emerged from laboratories into operational deployments, various forms of AI lifecycle concepts codify the continuously evolving nature of these systems (see *Figure 4-1*).

AI and data are the tools and raw materials needed to power analysis, but the full operational lifecycle of any intelligent system depends on a comprehensive and coherent infrastructure. A similar lesson of lifecycle management applies to other emerging capabilities in information technology. For example, cryptographically secure distributed ledgers (e.g., blockchain technology) offers the capability to protect transactions while relieving participating parties from the need to work out a myriad of multilateral contractual arrangements. This has direct implications for decentralized patient identity systems (to enable, for example, secure vaccine credentials), supply chain management, and reimbursements for patient-owned data. As with AI, such capabilities are dependent on systems that are built on architectures that support the end-to-end requirements of all key stakeholders.

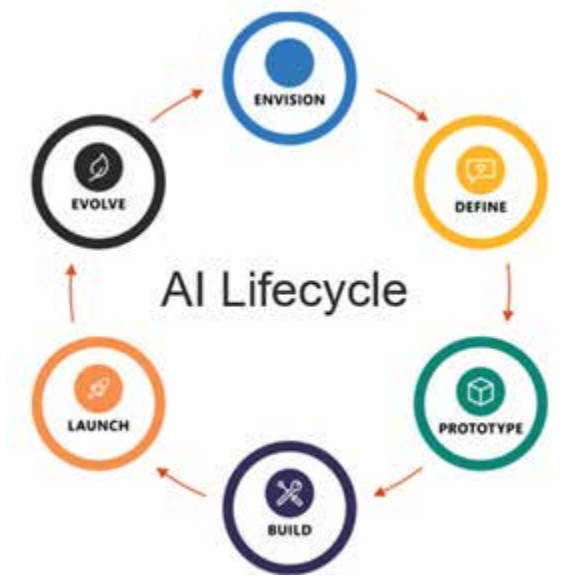

FIGURE 4-1 | Lifecycle for Continuous Management and Refinement of AI Models
SOURCE: Microsoft, Inc.

As the health care community thinks about the future, infrastructure preparedness requires an early understanding of not only the overall data and AI architecture, but also how bias is introduced and perpetuated by an AI system. Fortunately, a great deal of tooling is now available, with more emerging all the time, to help standardize aspects of this lifecycle's components. These include modern data standards, open API frameworks, DevOps platforms for AI development teams, and cloud-based computing infrastructure that is robust enough and specifically tuned to power all the above (FHIR, n.d.; SMART Health IT, 2020; Baroni, 2018). At the same time, there is a need for guidelines, standards, mechanisms, and governing structures to ensure that equity is ingrained throughout the AI lifecycle.

PRIORITIES FOR THE FUTURE OF DIGITAL HEALTH

The learned lessons from the COVID-19 experience help envision a better future and help prepare for a set of practical next steps. The COVID-19 experience has showed, more vividly than ever, the overwhelming need for readily analyzable and aggregated health care data, supported by systems to make sense of it, implement findings, and improve the work over time. Both the U.S. health care system's successes and failures in pandemic response have provided greater clarity on what our nation will need to focus on for future public health crises.

Insights gleaned from hard experience are pertinent not only to pandemic response. They are also relevant to the future of digital health broadly, and in particular they reinforce key elements of the concept of an LHS. The lessons learned during COVID-19 provide insights that update the LHS concept—insights relevant to person-centered care, business incentives, and cybersecurity.

Unleashing the Potential of a Learning Health System

Since the 2000s, the Institute of Medicine (now the National Academy of Medicine, or NAM) has advanced the vision of an LHS, "in which science, informatics, incentives, and culture are aligned for continuous improvement, innovation, and equity with best practices and discovery seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience" (NAM, n.d.). While the pandemic exposed health care's fault lines, its enormity and the resulting pace of scientific innovation brought the potential and need for an LHS into sharper focus.

In short order, the health care system had to define the illness, identify those who needed treatment, design and advance medical interventions, manage a complex health care system, and refine its approach based on evolving data.

Different types of data were put to work for specific goals (e.g., EHR data to define the likelihood of needing mechanical ventilation and to manage ICU beds; viral genomic sequences to inform vaccine development). These parallel streams of data were also combined, informing more refined actions including better optimization of health care delivery and personalization of care. Other digital tools, including data management capabilities, analytic and visualization solutions, telemedicine, and clinical decision support systems, enabled implementation of the pandemic response strategy. Even newer capabilities such as social media tools allowed efficient transmission of clinical observations among clinicians (e.g., observations about COVID-19 venous and arterial thrombotic complications via Twitter).

A key observation during the pandemic was the need for and value of accessible, interoperable, and readily analyzable data to support the response to COVID-19. This need is central to the functioning of the health system beyond the pandemic. Early features of an LHS became evident with the nascent data streams available in 2020, at once highlighting the power of the LHS vision and urgently motivating its concrete realization for the benefit of health care delivery, therapeutic innovation, and public health. Improved health care data sources would allow optimization of health care delivery through continuous data analysis, review, adaptation, and reevaluation. Individual health care systems or hospitals could quickly learn from each other. As a practical example, early in the pandemic, clinicians questioned the appropriate timing of oxygen delivery and mechanical ventilation, and whether ventilated patients recovered more quickly when in a prone position. Given the thousands of patients being diagnosed and treated across the U.S. and worldwide, more systematic learning could have been achieved if there were relevant, readily combined datasets.

The development and precise delivery of novel therapeutic approaches, both pharmacological and non-pharmacological, would also most likely be accelerated through the effective combination of biological and clinical data. Already, scientists are seeking to identify the best ways to manage patient illness based on the knowledge of the SARS-CoV-2 genome and its various clinical manifestations, building on the success of integrative initiatives such as the All of Us program in the U.S. and the United Kingdom (UK) Biobank (NIH, 2021; UK Biobank, 2021).

There is an especially striking need to extend LHS principles to public health, built on a foundation of accessible data with continuous learning enabled through real-time analysis, implementation, and refinement, which would directly inform the management of the pandemic. The UK's identification in late 2020 of a new SARS-CoV-2 variant with markedly increased transmissibility, B.1.1.7, highlights the value of such comprehensive data integration: the UK's critical insight was

explicitly enabled by the routine genetic sequencing of virus samples, combined with public health data on transmission rates (ECDC, 2021).

The U.S. has implemented a number of critical policy steps to build on LHS capabilities in line with the NAM vision outlined in 2006, such as the 2009 HITECH Act and the 2016 21st Century Cures Act (FDA, 2020c; HHS, 2017; IOM, 2007). Delivering on the vision will also require thoughtful leadership, increased focus on the nation's fundamental data infrastructure, and a more inclusive perspective that regards technologists not as technicians, tool makers, or service providers, but rather as essential partners who must be at the table to successfully design and implement an LHS.

Business Solutions Are Needed

In examining the failures of health information technology in the COVID-19 crisis, one observation is that the gaps in the system are significant, despite a decade of public investment in technology to support health care delivery. Many evaluations, including this paper, highlight the lack of an overarching data architecture to support the use cases for technology that developed during the pandemic. But in most settings, data architectures are designed to support business use cases that are core to the financial or business success of the organization. Thus, the failure of the data architecture is a symptom of a more general lack of an integrating business rationale for data fluidity in health care, a gap that profoundly influences stakeholder dynamics (Shaywitz, 2021b).

Despite a decade or more of discussion about interoperability, there has been limited discussion of what business solutions would be required to drive the market forward to true data availability. These business solution discussions have two diverging challenges. The first is that many of the core aims for patients are not supported by, or indeed conflict with, the fee-for-service business model of today's health care delivery. Practically, for many health care systems, the lack of technology interoperability is a key business proposition that helps to maintain patients in the system. The second challenge is that at the business level, most health care systems are struggling with limited EHR design flexibility, as well as maintenance and operational issues that reduce interest and capacity to consider the further complexity required to accommodate a common data architecture.

The data availability and quality challenges encountered during the pandemic were predominantly encountered in the health care delivery and public health spaces. These challenges stand in contrast to clinical evidence generation for new COVID-19 treatments or vaccines or biological discovery sciences, where there was much greater data availability. When the business imperative to generate high quality data was aligned with the commercial success of a medical product,

investments were made in standardized data collection (although in non-interoperable data silos). Meanwhile, the expectation that high-quality and readily analyzable data would be a "free" by-product of health care delivery is misaligned with reality—both because the business incentives in health care delivery do not reinforce data interoperability and, even when data are interoperable, the costs of data curation and cleaning are not factored into the system.

In other areas of the economy faced with similar data silo challenges, like banking, the rationale for change became a public-private partnership with the Federal Reserve to reduce transaction costs by standardizing data elements (The World Bank, 2019). The opportunity to reduce costs became the business rationale to drive standardization across firms and environments. In this case, the Federal Reserve served as a catalyst for this change, helping to address the activation energy needed to drive to the new transaction model. Such an overarching business catalyst and business solution are lacking in the health care system (Weinstein et al., 2021).

Business solutions could address real economic challenges faced by health care systems. For example, there are hundreds of different health care systems deploying hundreds of technologists, each performing required maintenance on their EHR systems. Could a different data architecture reduce these hidden costs, which currently amount to billions of dollars annually? (CMS, 2020b). Similarly, since 1996, there have been efforts to reduce transaction costs at a federal level, yet overall, billing and other transaction costs remain high (relative to other health care systems globally), contributing to the high cost of health care in the U.S. (ASPE, 1998; Tikkanen and Abrams, 2020; Tollen et al., 2020).

Solving the data architecture challenges identified in this report requires the development of business models focused on novel use cases to spur the investment and effort that will be required; these business cases should help focus national leadership on an actionable path forward for the public and private sector. The need for active coordination becomes apparent as a means to ensure that use cases are supported by core business models to the data architecture and that they are added in a coordinated fashion that does not create further non-interoperable data silos.

Cybersecurity Must Be High on the Agenda

As 2020 came to a close, the U.S. was hit by a large-scale cyberattack, likely conducted by a nation-state (Sanger, 2021). First discovered as a "supply chain attack" perpetrated through SolarWinds software patches, it has become clear that this event involved much more than just SolarWinds software and affected U.S. private industry and government systems, including HHS—a critical aspect of our nation's response to the pandemic (Perlroth, 2021).

At a time when digital health solutions are becoming an integral part of health and its management, this cyberattack demonstrates our vulnerabilities. While the SolarWinds attack was most likely perpetrated for espionage and nation-state activities, more mundane criminal and predatory behaviors have also been witnessed during the pandemic. For example, ransomware has been found in the cold storage units needed to maintain COVID-19 vaccines at appropriate temperatures, COVID-19 vaccines are being sold on the dark web, and the European Medicines Agency was hacked and commercial vaccine-related regulatory documents were stolen (BBC News, 2020; O'Murchu, 2020; Seals, 2020). In fact, sustained cyber assault has been witnessed across the entire vaccine clinical development and supply chain, both by criminal and potentially nation-state actors (Barrett, 2020; Sanger and LaFraniere, 2020).

The cybersecurity risks in digital health were well-known prior to the pandemic. Medical devices such as pacemakers are vulnerable to cyberattack (Peterson, 2013). Ransomware attacks on hospitals are all too commonplace; in October 2020, the FBI warned of increasing attempts (Bajak, 2020). Medical device manufacturers have a responsibility to design their products to limit cybersecurity risk and monitor them accordingly. Health care delivery organizations should also be attentive to network security and the responsibility of individuals using the systems to ward against phishing and other schemes. Regulations such as HHS's cybersecurity guidances and safety communications are intended to thwart cybersecurity breaches (FDA, 2020d; HHS, 2020). Yet, as the U.S. moves toward an IoT model, the threat amplifies.

One concern that warrants attention is that of adversarial data manipulation; for example, data arising from funduscopic examinations, chest X-rays, and of dermatological exams (Finlayson et al., 2018). The national response to COVID-19 depends on the ability to describe the evolving public health emergency, address it, and monitor actions—all of which depend on data. Medical misinformation may be malicious and is easily amplified via social media. Bad actors can erode or scramble a public health response by injecting incorrect data into systems ("data poisoning"). For example, misleading information about changes in the pandemic can lead to public health recommendations that worsen the pandemic (e.g., when the data erroneously suggest that the pandemic is under control) or cause public mistrust (e.g., when the data erroneously suggest that public health interventions are not working as intended). Malicious data manipulation could impair clinical trial results about vaccine efficacy (e.g., leading to delayed uptake of effective vaccines) or erroneously suggest safety challenges with vaccines, thereby slowing uptake and/or sending researchers on unnecessary hunts to understand safety signals. Adversarial ML algorithms are a practical byproduct of adversarial data manipulation. These sorts of adversarial threats are likely to grow as the use of data and the dependence upon algorithms intensifies.

Cybersecurity must be much more than an afterthought or an add-on; it is integral to the public health response to a crisis like COVID-19 and to the development of digital health capabilities. Cybersecurity leadership (e.g., the role of a Chief Information Security Officer) should be incorporated into digital health planning and implementation, and cybersecurity training for all health care employees should be intensified and frequently refreshed. Cyber vulnerabilities must be identified and proactively addressed.

The FDA's partnership with the "white hat" hacking community, initiated in 2018, and MITRE's *Medical Device Cybersecurity Regional Incident Preparedness and Response Playbook*, represent promising approaches (Kelly, 2019b; MITRE, 2018). Finally, the discovery of the SolarWinds supply chain attack may necessitate the rebuilding of government and other IT systems, which could represent an important opportunity to advance the nation's information architecture (Williams, 2020). The success of cybersecurity countermeasures will require leadership, vision and collaboration, including public-private partnerships.

Digital Health Training Is More Important Than Ever

Ongoing training is critical to ensure that the individuals accessing digital systems and associated data are qualified to make optimal use of them. Future generations must be ready to adapt to the evolving challenges and opportunities in health care and life sciences. They must also adopt appropriate digital health tools to support communities with new discoveries and knowledge and new business processes and business models, with the ultimate goal of improving clinical and economic outcomes. To reach a broad audience, such training in digital technologies can be delivered through public-private partnerships, including—but not limited to—degree-granting programs, micro-certifications, and massive open online courses. These programs can be structured around emerging roles—from efforts geared to understanding higher-level applications of digital technology in the clinical enterprise or health care system to more focused development of technical skills and methods. Learning objectives for these programs should be specific to their overall goals and audience, and can include consideration of broad knowledge of new and emerging digital technologies applied to health care and life sciences. Objectives can also consider methods and approaches on the use of informatics in the discovery and management of new knowledge relating to health, drug development, and understanding diseases. Ideally, all programs should be motivated by efforts to improve human health and enable health care professionals to acquire cross sectional training and experience in ethics, business, and policy to apply biomedical data, information, and knowledge effectively for scientific inquiry, problem solving, and decision-making.

Ensuring All Individuals Get the Care That They Need

Perhaps the most important and enduring observation reinforced by COVID-19 is that fulfilling the promise of emerging technology does not depend on the intrinsic capabilities of technology itself, but rather on people—the people who develop technology, of course, but also those who implement it and, most importantly, those who are served by it.

For many individuals, technology was a form of self-empowerment in supporting personal health management and prevention, such as using COVID-19 trackers to inform shelter-in-place decisions or meditation apps to manage anxiety. Digital technologies influenced all aspects of health management for the U.S. population as a whole. Nonetheless, some fundamental aspects of person-centered care bear remembering:

- As innovations are adopted, the most vulnerable people are often excluded from early access or application. For example, access to telemedicine requires both access to a computer or mobile device and to broadband, which means that access to telemedicine disproportionately benefited more affluent people, especially among individuals younger than 65 years and without comorbidities (Singh, 2020). Policymakers need to bear in mind the consequences of structural racism and digital redlining as they craft solutions for the future.
- Bias in underlying data can lead to erroneous conclusions and widen health disparities. This was evident during the pandemic when early digital descriptions of the pandemic missed patterns showing that Black Americans were at highest risk of contracting and dying of COVID-19, thereby squandering the chance for early targeted interventions for this population (The Economist, 2020; Maybank, 2020).
- Bias and conflict of interest in AI models have the potential to amplify discrimination. The risk that bias in the underlying data will bias the results of the AI model is well documented. In COVID-19, unrecognized low blood oxygen levels were three times more frequent in Black patients than white patients; however, the risk models predicting risk of severe disease may underestimate the impact for Black patients. Attempts to adjust or equalize these models can in and of themselves lead to furthering discriminatory decision-making (The Economist, 2020; Maybank, 2020; Racial Bias in Pulse Oximetry Measurement, 2020).
- Vaccine prioritization has proven to be more challenging than expected during the COVID-19 pandemic, with the initial rollout of the vaccine in early 2021 based on a first-come, first-serve model within the planned phases/tiers (Kates et al., 2021). To make vaccine distribution work for all Americans, a vaccine prioritization scheme should be based on the CDC's identified medical risks, but should also

take into account demographic risks (race, ethnicity, location). The framework put forth by the National Academies of Sciences, Engineering, and Medicine offers a model (NASEM, 2020). A robust priority scoring system would incorporate data provided by patients when they register to receive the vaccine, matched data from their EHRs, as well as guidelines from the CDC to ensure an equitable distribution that builds and strengthens herd immunity against COVID-19.

- User-centered design of software applications and interfaces is critical. If the people the software is serving cannot figure out how to use an application, then all good intentions are wasted. For example, many of the first recipients of the vaccine were 65 years and older and experienced difficulty attempting to register for a vaccine. If technical challenges persisted, or if many in this demographic group had not found another way to sign up for a vaccine, then more members of this vulnerable group would have gone unvaccinated (Andrews, 2021; Weil et al., 2021).
- The level of trust that people and communities place in new technologies varies widely. During COVID-19, in particular, health care decision-makers were often guilty of overlooking the role of grassroots community leaders in the important elements of awareness, activation, and engagement of people to work together in pandemic response. One step toward building trust is by having technologists work with community leaders.
- Finally, the health care workforce deserves special mention. Burnout among clinicians, and especially nurses, has been pervasive in the pandemic (MHA, 2020). Digital health tools, especially EHRs, can exacerbate burnout. Telemedicine removes the human contact with patients that may in itself be therapeutic to exhausted clinicians (Physician's Weekly, 2018). Even so, digital tools have the potential to help reduce burnout—such as clinical triage algorithms, remote digital monitoring devices, and voice-to-text capabilities to support clinical documentation—although many of these approaches are in their very early stages (Miliard, 2019).

The future development of digital health solutions should be planned in ways to keep this core "customer" at the forefront. Further, technology solutions should not be developed or assessed in isolation—they must co-evolve with the people that the solution is intended to impact.

THE PATH FORWARD: STEWARDING A SEAMLESS DIGITAL HEALTH INFRASTRUCTURE

American consumers today live in a world of digital services that offer choice, value, and convenience, and yet health care stubbornly remains one of the few

remaining sectors of the economy not designed for the consumer. This has devastating consequences for both individuals and populations, as illustrated by the documented health care disparities of the pandemic. The COVID-19 pandemic highlighted the latent ability for digital innovation throughout the health care system, with successes such as the rapid adoption of telemedicine. However, as this paper has shown, these isolated successes occurred in the context of a health data architecture that was absent or, at best, largely dysfunctional. The result is that relevant information that was needed to understand and respond to the pandemic failed to be delivered effectively and consistently.

While advanced digital technology exists in pockets throughout the health care system, the component systems are largely (and unnecessarily) disconnected and lack the incentives for connectivity and relevant interfaces. Referring back to the home-building analogy discussed in the introduction, it is as though there are no framing standards, thus requiring expensive customization to get doors and windows to fit; there is no common set of modular architectural components, thus requiring complex plans (and even legal agreements) to be negotiated between plumbers, electricians, and roofers, even though their work hardly relates to each other; and lastly, there is no infrastructure to support independent inspection, rendering the safety and performance of the house unknowable. This lack of a coherent data architecture, modularity, and infrastructure has proved a persistently unsurmounted barrier to the United States' transition to a functional digital health care system. This has constrained progress toward the fulfillment of what may be called health care's Quadruple Aim: better health, higher quality, lower cost, and more engaged people. Innovation is needed to achieve these four goals.

In scale, the challenge described here is equivalent to some of the largest public challenges ever addressed, yet it is one that, in technical terms, ought to be within grasp through a new approach to the U.S. national digital infrastructure for the health care system—one not dissimilar to the need for an interstate highway system, a common financial system, or our modern flight control system. All of these efforts were well-served by public-private partnerships, with benefits that fostered ingenuity and innovation and greatly expanded economic activity for the country at large. The federal government plays a foundational role in enabling such solutions.

Solutions of this magnitude depend on basic paradigm changes—from a model based on organic and spontaneous evolution that occurs naturally with changes in technology to one that recognizes that unencumbered organizational inertia and incentives are basic deterrents to nurturing the common good. For this change to occur, advantage must be taken of certain aspects of the forces in play. For example, much of the raw material for continuous learning is already at hand. The rapid digitization of health care (98% of clinical health records are digital, compared

to less than 15% in 2005) and the rapid advances in enabling digital technologies outside of health care have created many of the critical building blocks for a functional health data ecosystem. This represents not only a massive change in the technological foundation of health care, but is also conspicuous proof that the health care system itself can undergo comprehensive evolution. There is a need to align around basic governing rules and an approach to modularity so that consistent components can "plug in," work efficiently, and bring unique elements to the overall design. A modular approach fosters competition around components, enabling improved quality, reduced costs, and the ability to connect and optimize relevant modules to address distinct human as well as biological challenges in different domains, including public health.

That alignment process requires coordinative and regulatory initiative from a governing locus with the reach to advance a modular architecture that is adaptable for scale, location, and function in achieving, wherever applied, optimal health system effectiveness, efficiency, equity, and continuous learning. This assumes consistent orientation to the following aspects:

- Focusing on creating the conditions for innovation and establishing the relevant ground rules—not dictating or excessively specifying what the "right" solutions should be;
- Ensuring a commitment to public trust, equality, and health;
- Facilitating vital private-public partnerships; and
- Embracing and strategically facilitating incremental innovation, recognizing that solutions will emerge gradually.

Given this pivotal opportunity, the federal government should catalyze innovation centered around the principles of modular design. Imagine the implementation of a newly empowered initiative aimed at digital health innovation, bold in ambition and aligned with President Biden's first challenge to his science advisor of what can we learn from the pandemic about what is possible – or what ought to be possible – to address the widest range of needs related to our public health, but flexible, humble, and pragmatic in approach (View from Arch Street, 2021).

Leadership for the National Health Data Architecture

The primary mandate of this sector assessment is to identify shortfalls in health system function and operations and characterize them in a fashion that prompts clarity on the solutions required to eliminate those shortfalls. Organizational approaches through the creation of a new entity or entities—for example, the creation of a new governmental office for digital health integration as an

independent or White House level function—are essentially political questions that lie outside the scope of the review. The more fundamental questions relate not to an entity itself but to the capabilities, functions, and authorities that might be ascribed to a new or existing entity.

While the U.S. has many of the individual critical elements required for building and advancing an LHS, these components are rarely orchestrated in concert and cannot easily contribute to or build upon each other. Learning is much more haphazard than it should be. Success demands a system that leverages what is currently known about the current digital infrastructure and up-levels it for the future. Facilitative capacity can be substantial when invested with dynamic leadership and core expertise in areas such as health data architecture, AI/enterprise technology architecture, health care delivery, and cybersecurity.

The broad vision for the Office of the National Coordinator for Health Information Technology (ONC) at its outset implicitly embraced the notion of an expansive program of activities that engages agencies and offices across government and throughout the private sector—e.g., CMS, FDA, CDC, NIH, OCR, and the Office for Human Research Protections (OHRP). In principle, it can launch driver projects and new programs, as well as coordinate with and influence other governmental units such as the VA, the Federal Communications Commission (FCC), and the Federal Trade Commission (FTC), as appropriate; conduct public and private IT policies and initiatives, including prototypes and demonstrations for issues transcending individual agencies; and ensure transparent monitoring and reporting on progress.

Operational arrangements would take advantage of both the policy leverage of the White House and the domain expertise of HHS. Positioned to implement the strategic intent of the LHS with tactical and pragmatic approaches, the ONC was envisioned to regularly convene public-private partnerships and mobilize resources to support focused initiatives and address critical roadblocks or opportunities. The question is whether and how the necessary support might be mobilized.

Enhancing Government Agency Capacity and Decisions

Especially important is the ability to advance cross-agency and cross-sector programs and projects that create new capabilities and demonstrate what is possible. These efforts will be informed by the foundational expectation that solutions will be comprised of modular components—many of which will be connected by APIs, data pipelines, and the like. The role of the ONC or a related cross-government authority would neither be to mandate nor designate a single approach, but rather to nurture a diverse portfolio of modules and interstitial connectors. The goal should be to advance an overall national digital infrastructure and data architecture that promotes continuous innovation, interoperability, and improved data quality and safety.

Continuous dashboarding (e.g., Johns Hopkins COVID Tracking used to track COVID-19) represents a discrete use case, applicable to many health care areas such as other diseases, medical supply chain management, hospital bed availability, and vaccination programs (JHU, 2021b). Results from such dashboarding can be stratified and tailored for region and task. A review of challenges in accessing data and data quality concerns will inform new areas for intervention. A focus on health equity and underserved populations will ensure that critical data elements like race and ethnicity are incorporated in datasets and help to inform critical policy decisions. Making results publicly available will enhance transparency, reproducibility, and trust. Public access should also stimulate new businesses and follow-on innovation. Initiation could be expedited by leveraging the Biomedical Advanced Research and Development Authority (BARDA).

One important tool of an expanded capacity could be convening high-level public-private task forces, working groups, and actions to advance health and the core elements of an LHS. Examples of task force topics could include:

1. options and strategies for computing architecture, data architecture, and data interoperability;
2. elements of a national public health crisis pre-warning system;
3. the issues and options around a national "data trust" for public health;
4. how to operationalize and advance telemedicine and virtual care;
5. approaches to incentivize digital medicine solutions;
6. strategies for using digital capacity to create new evidence and appropriately update clinical care while ensuring data quality and protection; and
7. system-wide cybersecurity.

Achieving the Vision: A Challenging But Important Journey

The COVID-19 pandemic had disastrous consequences for the U.S. and the world, and digital health was a prominent but insufficient part of the national response. The visible rise of telemedicine was a great success story, but addressing the pandemic requires much more support and remediation of the digital health infrastructure. Digital tools helped the nation make sense of available data and put analytic results to work. Now, however, the inadequacies of digital infrastructure, cultural barriers, out-of-date policies, and misaligned incentives must be addressed. The technological progress of the past two decades and the many successes apparent in the COVID-19 response demonstrate that interoperable health data are essential and that developing the appropriate architectural framework to support fluid data, while being a major undertaking, is achievable.

It will require a multi-pronged approach to build a federal response to the digital health challenge that has sufficient leverage to catalyze the adoption of relevant data standards and architectures. There are living examples where this has been achieved before—for example, the Federal Reserve was created and has provided a practical architecture into which innovators and the banking industry have been able to "plug in." Secure data architecture, parsimonious common data standards, business incentives, and regulatory enforcement together contribute to an infrastructure for a secure financial system. While health care has complexities that do not exist in banking—including the fact that health care data are far more complex than currency data—the existence of a well-functioning Federal Reserve system is a vivid reminder that well-formulated public-private approaches can drive progress.

The task, then, is to lay the groundwork and create the conditions for change of the magnitude required. Success will require advancing a digital infrastructure and a data architecture that promotes modularity, interoperability and innovation; acknowledging that a "one-size-fits-all" approach is unlikely except in clearly identified circumstances; and orchestrating and acting through federal and public-private entities.

The solution requires a focus on fundamental elements woven into the fabric of American health care, including technical infrastructure, data architecture, and modularity. Many of the building blocks are already in place. Now, the country needs to build on this foundation, focusing on incremental progress while prioritizing public need, trust, equality, and innovation. This is the digital infrastructure capacity required for the journey to health and health care that is effective, efficient, equitable, and adds value for every American.

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5

PUBLIC HEALTH COVID-19 IMPACT ASSESSMENT: LESSONS LEARNED AND COMPELLING NEEDS

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INTRODUCTION

Gains in life expectancy and quality of life over the course of American history can be attributed to forward-looking investments in public health infrastructure (CDC, 1999). For example, the creation of municipal public health authorities in the 19th century supported improvements in sanitation and reduced the mortality burden from infectious diseases such as typhoid and cholera. Likewise, strategies to promote healthier environments and improve access to clinical services have improved the prevention and management of chronic diseases such as cardiovascular disease and cancer. In addressing each population health challenge, the public health sector has played a multifaceted role, from surveilling the causes and consequences of disease (e.g., the National Notifiable Diseases Surveillance System), to convening stakeholders across sectors to develop coordinated solutions (e.g., historical collaborations with housing authorities), to informing policymakers and the public about best practices (e.g., resources to promote tobacco cessation) (CDC, 2020a; CDC, 2019a; Krieger and Higgins, 2002).

These interdisciplinary functions are more important than ever due to the complexity and scope of population health challenges in the modern era. For the first time in generations, life expectancy in the United States (U.S.) has begun to decline, with primary drivers including increasing rates of drug overdoses and the growing burden of chronic diseases (Woolf and Schoomaker, 2019). In parallel, evidence continues to accumulate about the disparities in health outcomes

across racial groups and socioeconomic strata, emphasizing the need for health interventions that address both the medical (e.g., health behaviors, environmental influences) and non-medical (e.g., housing, transportation) drivers of poorer health (Zimmerman and Anderson, 2019; Chetty et al., 2016).

Yet as the need for robust public health infrastructure has grown, federal investment in public health capabilities has declined, with health departments operating for decades under persistent and widening resource gaps. Chronically inadequate funding, workforce shortages, and outdated infrastructure limit the sector's capacity to address existing population health needs and its flexibility to respond to emergency situations (ASTHO, 2020). COVID-19 has newly exposed and further exacerbated these long-standing challenges, while also illuminating the pervasive racial and socioeconomic inequities in health care access, quality, and outcomes in the U.S. While health departments have been foundational to the nation's response to the pandemic (e.g., guidance development, testing and tracing) the sector has experienced numerous challenges with causes both old (e.g., gaps in information technology) and new (e.g., politicization and mistrust of public health leaders and guidance). From the subversion of public health's mandate to the malignment of public health officials to the neglect of public health capabilities, the pandemic has illustrated the need for structural reforms to restore the public health sector's foundational role in American communities.

This discussion paper seeks to examine the public health sector's experience during COVID-19, exploring how legacy systems and policies shaped the sector's capacity to respond, highlighting health departments' key contributions and challenges during the pandemic, and identifying priority areas and policy considerations to enable the sector to be better prepared to meet population health needs in the 21st century.

THE PRE-PANDEMIC STATE OF PUBLIC HEALTH

In America, the functions of public health are inextricably tied to the varied forms of health department governance and operations. While health departments have faced numerous challenges during COVID-19, the roots of these problems—institutional siloes, rigid funding streams, ambiguities over authority, and neglected infrastructure and workforce development—long predate the pandemic. Consequently, understanding the barriers to and lessons from the pandemic's response requires first establishing the public health ecosystem leading into the pandemic. This section outlines the structural and political context for the sector, with a focus on public health's (1) mandate and governance and (2) functions and funding.

Mandate and Governance

The Institute of Medicine's (IOM) 1988 report on *The Future of Public Health* defined the mission of public health in the U.S. to be "the fulfillment of society's interest in assuring the conditions in which people can be healthy" (IOM, 1988). To convert this aspiration into action, the nation has developed a complex system of governance comprised of a diverse set of local, state, territorial, tribal, and federal agencies and authorities, all of whom collaborate to advance the public's health (CDC, 2020b; PHNIC, 2018). While a comprehensive and inclusive approach to public health governance is needed for the post-pandemic era, the authors represented in this paper will primarily focus on the experiences and perspectives of local and state health departments during COVID-19.

The governance of public health in America is local in origin, with municipal health boards pioneering advances in sanitation and cities and states developing laboratory capacity to support outbreak control. National initiatives for specific public health needs (e.g., tuberculosis control, HIV/AIDS) and the emerging interdependencies between the public sector's health, medical, and social service programs (e.g., partnerships between health departments and state Medicaid programs) increased the federal government's involvement in public health. However, while federal financing mechanisms (e.g., block grants) generally emphasize state responsibility, a national policy environment that prioritizes cost containment limits state health departments' capacity to respond to emerging public health needs (IOM, 1988).

Today, the organization of functions, delivery of services, and availability of resources for public health in the U.S. varies tremendously due to the country's size and the heterogeneity of community needs and demographics. The day-to-day governance and administration of public health is distributed across the 59 recognized state and territorial health departments and an estimated 2,500 local health agencies nationwide (NACCHO, 2019; ASTHO, 2016). While this decentralized model can offer advantages by emphasizing local context, health departments are hindered by the uneven distribution of purviews and foundational public health capabilities. From an operational perspective, state-local governance structures for public health can generally be described by four models: centralized, decentralized (or home rule), mixed, and shared (see *Figure 5-1*) (ASTHO, 2012). For example, Rhode Island can be considered a "centralized" model as it operates as a unified local and state health agency, while Massachusetts can be described as a "decentralized" model, with decision-making authority largely retained by 351 local health agencies across the state (OLRH, 2020; ASTHO, 2012). From a resource perspective, funding for public health

FIGURE 5-1 | Models of Public Health Governance
SOURCE: Adapted from https://astho.org/Research/Data-and-Analysis/State-and-Local-Governance-Classification-Tree/, with permission.

varies widely across the country. For example, state per capita spending on public health ranged from $7 in Missouri to $140 in New Mexico in 2019 (SHADAC, 2020).

In parallel with local public health efforts are the national initiatives led by the federal government. These include support for baseline public health functions, facilitation of pre-decisional and deliberative planning processes (including local and state health agencies) to prepare for public health threats, creation of countrywide health priorities (e.g., the Healthy People 2030 goals), support for cross-state collaborations, and resource allocation for public health and health care programs.

While there are many models of governance in public health, it is clear that the system as currently configured—with its origins from a different time with different population health challenges—is not optimally designed to meet the needs of America's communities in the 21st century. Health departments should of course be tailored to the needs of their local constituents. However, while agencies may vary in their form, they should not vary in their basic functions. Significant variation in how health departments make decisions (described above) and what resources are available to them to deliver services to their communities (described below) have contributed to heterogeneous outcomes prior to and during the pandemic.

Policymakers and public health leaders have developed various tools to achieve alignment on the public health mandate and public health governance, from accreditation programs to frameworks outlining the minimum services and capabilities for all health departments (PHAB, 2020). Yet these efforts have struggled to achieve scale; for example, nearly one-third of state health departments and the majority of local health departments have opted out of a national, voluntary accreditation program, in part due to the cost and staffing needs required to complete the accreditation process (CDC, 2020c; Yeager et al., 2016). Consequently, initiatives to promote unified standards without commensurate attention to the chronic funding gaps responsible for variation in foundational

public health capabilities run the risk of adding to health departments' reporting burden without resolving their underlying needs. The next section on "Functions and Funding" outlines how such systemic resource shortages for American public health, in tandem with the governance challenges described in this section, created the preconditions for pandemic-era challenges.

Functions and Funding

The functions of public health in America are described by the frameworks for "Essential" and "Foundational" public health services. The "Essential" public health services, which were developed in 1994 and updated in 2020, outline the key domains and areas of focus for the public health mission (e.g., investigating health hazards and their root causes), with a focus on equity centering the design and delivery of each service. In 2012, the IOM recommended that experts characterize the skills, capabilities, and services that health departments need to operationalize the goals of the "Essential" public health services framework (IOM, 2012). To this end, the Public Health Leadership Forum developed the framework of the "Foundational" public health services, which details the capabilities (e.g., emergency preparedness and response) and program areas (e.g., chronic disease and injury prevention) which all health departments should possess in addition to services tailored to the unique needs of the community which they serve (CDC, 2020b; PHNIC, 2018). *Figure 5-2* presents these two frameworks, which together provide health departments with a guide for what their responsibilities

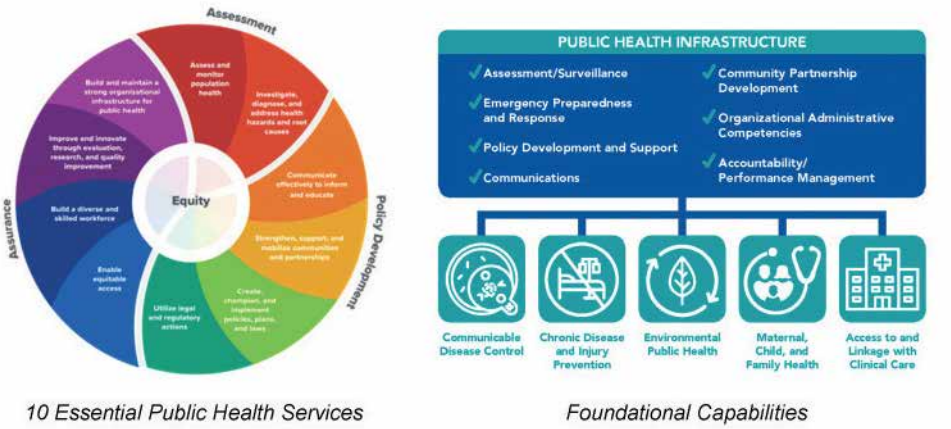

FIGURE 5-2 | Frameworks for Essential Services and Foundational Capabilities in Public Health
SOURCE: https://www.cdc.gov/publichealthgateway/publichealthservices/essentialhealthservices.html *(left)* and Public Health National Center for Innovations. Foundational public health services in action. PHNCI. https://phnci.org/national-frameworks/fphs. Published November 2018. *(right)*. Reprinted with permission.

are ("Essential" services) and how they can operationalize those responsibilities for their communities ("Foundational" services).

However, local execution of these programs and functions is often limited by constraints imposed by both federal agencies and state and local jurisdictions. First, funding levels have historically been inadequate to support the delivery of the Essential public health services, let alone prepare for emergency situations. Second, many funding streams for public health are "categorical", or restricted to specific priority areas (e.g., HIV, tobacco control), which leaves little flexibility for spending to support core foundational capabilities or to support surge needs in times of crisis (Leider et al., 2018a). Other funding streams are operated as block grants, but as noted in the IOM's 2012 report, *For the Public's Health*, such models in practice have been vulnerable to funding cuts (e.g., funding for the Preventive Health and Health Services block grant decreased by 35% from 1995 to 2012) (IOM, 2012).

Overall funding for foundational capabilities has run dry in the face of long-standing neglect and deprioritization by both local and national leaders, with the expenditures of public health agencies decreasing by approximately 10% (between 2010 and 2018) and the share of health care spending attributable to public health declining by nearly 17% (between 2002 and 2014) (ASTHO, 2020; Himmelstein and Woolhandler, 2016). Indeed, rather than valuing prevention, the American system has become increasingly biased in favor of reaction, with per capita spending on public health services equivalent to 1-3% of per capita expenditures on medical care (Himmelstein and Woolhandler, 2016). Chronically deprived of resources, the capabilities of health departments have begun to atrophy over several key domains (see *Figure 5-3*).

First, the public health workforce is understaffed and unequipped to meet the needs of local communities. Over the past decade, local health departments have eliminated over 56,000 jobs, while state health agencies have lost over

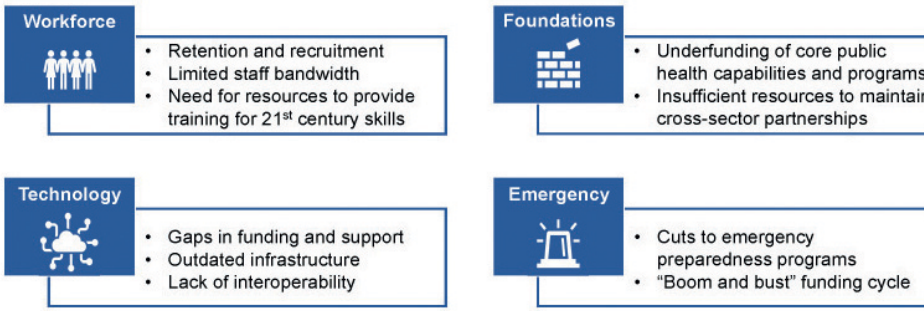

FIGURE 5-3 | Pre-Pandemic Challenge Areas for the Public Health Sector

10,000 jobs—a distressing trend considering how population health challenges have grown and multiple public health emergencies (e.g., the opioid epidemic, the Ebola and Zika outbreaks) have occurred over the same time period (ASTHO, 2020; NAACHO, 2018). The workforce that remains does not adequately reflect the population served and lacks formal public health training, with a significant proportion of health department staff on the cusp of either leaving the profession or retiring (Bogaert et al., 2019a; Bogaert et al., 2019b; NAACHO, 2020). These dire trends may not reflect the full scope of workforce needs, as there is no centralized monitoring system for public health, with the sector relying on periodic point estimates conducted by third-party organizations to gauge capacity. Local and state department leaders consequently have limited ability to appropriately benchmark their capacity and articulate community-specific needs. Furthermore, challenges with recruitment and retention—attributed primarily to low pay and the paucity of opportunities for career advancement, with a particular dearth of diversity in leadership positions—raise pressing concerns about the sector's future workforce capacity (Erwin et al., 2019; Leider et al., 2018b). Yet the workforce challenges are not simply a pipeline problem. Preparing the public health sector for tomorrow requires a workforce that is meaningfully different from years past, both in terms of the diversity of skills that health officials possess (e.g., need for new data science skills, digital capabilities, cultural and linguistic competencies) and the relationships health officials foster with other sectors (e.g., the health care system, the lay public). While regional Public Health Training Centers have helped fill gaps in health department capacity, and the development of new undergraduate and graduate education programs for public health have expanded the cohort of new public health professionals and trainees, additional resources and a national mandate for interdisciplinary training programs are necessary to address 21st-century public health challenges.

Second is the increasingly outdated nature of department capabilities, particularly for information technology (IT) infrastructure. Data exchange between public health and health systems remains fragmented, with few departments participating in the CDC's program to develop digital bridges due to lack of funding and capacity within health departments (CDC, 2020d; Miri and O'Neill, 2020). While the Council of State and Territorial Epidemiologists has developed a roadmap for creating a "data superhighway" for public health, such initiatives to date have lacked the necessary funding and policy support to become reality (CSTE, 2019).

Third is support for baseline preventive activities. Many core public health programs have been consistently underfunded (e.g., providing immunizations, diabetes prevention, lead control), with past funding cuts creating the preconditions for present-day population health challenges. For example, inflation-adjusted

funding for the prevention of sexually transmitted diseases declined by 40% between 2003 and 2018 even as disease prevalence increased over the same time period (e.g., rates of syphilis and gonorrhea approaching 30-year highs) (National Coalition of STD Directors, 2018; CDC, 2019b). These gaps in foundational capabilities are magnified during times of crisis, which often require staff to perform "double duty" without a commensurate increase in resources. In many cases, insufficient resources have also hindered health departments' capacity to maintain necessary cross-sector partnerships and linkages (e.g., with the social care sector, with private industry) which are needed to augment health department capacity and support locally tailored solutions.

Fourth is emergency preparedness. The turn of the millennium has witnessed the emergence of multiple pathogens with pandemic potential, including H1N1, SARS, Ebola, and Zika. Yet rather than renewing a commitment to real-time surveillance and surge capacity, funding for the Public Health Emergency Preparedness program declined by $265 million between 2002 and 2020 (Trust for America's Health, 2020; Murthy et al., 2017). While states and territories, as well as a few large local jurisdictions, received increased federal support during previous emergencies, such funding was time-limited and expired at the conclusion of the crisis. This "boom and bust" cycle of public health funding hinders preparedness for future emergencies, as the capacity developed in response to outbreaks is quickly eroded unless sustainable support structures are established. For example, emergency funding during the Zika outbreak equipped health departments to address long-neglected issues such as mosquito control and laboratory testing (Tavernise, 2016). The CDC also bolstered local health department capacity by assigning field staffers to outbreak hotspots (CDC, 2020e). However, funding expired after 2017, leading many outbreak control efforts to be rolled back or discontinued (CDC, 2020f).

Together, these challenges help to frame the environment in which the public health sector was operating prior to the pandemic. The next section describes how health departments navigated these existing challenges during their response to COVID-19.

STATE AND LOCAL PUBLIC HEALTH RESPONSE TO COVID-19

While health departments provided key functions (e.g., data reporting, testing clinics, contact tracing) during the pandemic, the challenges they encountered (e.g., barriers to exchanging information, operational siloes, lack of disaggregated data, and insufficient capacity and training) are indicative of fundamental design flaws and a lack of investment in America's public health system. Additionally, the sector's overall

response to COVID-19 has been uneven due to inconsistencies in national guidance, the staggered spread of the virus across the country, and differences in state and local health department capacity and authority. This section characterizes health department functions and challenges during the pandemic using the lens of the "Foundational" public health capabilities.

Health Department Functions

"Foundational" capabilities supporting the public health response to COVID-19 included the following domains:

1. Emergency preparedness and response (e.g., data collection and reporting);
2. Assessment and surveillance (e.g., testing and tracing capacity);
3. Communications (e.g., educating policymakers and the public);
4. Policy development and support (e.g., implementation and enforcement); and
5. Community partnership development (e.g., to address non-medical needs) (see *Table 5-1*).

Emergency Preparedness and Response

Health departments were the first line of response when the outbreak began, working to control the spread in communities across the country and putting into action their own emergency operations and response plans. These activities included, among other things, developing mechanisms to track and report data on the virus and leveraging their capabilities as Laboratory Response Network reference laboratories to support the development of COVID-19 diagnostics. As the outbreak expanded, the emergency response shifted, with public health playing a key role in the whole-of-government approach.

First, health departments began coordinating with local, state, and federal officials to support emergency planning across a given area. For example, the Northwest Healthcare Response Network was activated in Washington after the first cases were reported in Seattle (Mitchell et al., 2020). Likewise, in Louisiana, the Department of Health and the State Health Officer led briefings with lawmakers and consulted with local emergency managers, enabling the Governor to issue an emergency declaration to activate necessary resources (State of Louisiana, 2020).

Second, with the outbreak rapidly evolving, many health departments worked to set up dashboards on their websites to display the latest data on cases, hospitalizations, and deaths. Given the outdated technical infrastructure of many health departments—where the use of fax machines continues to be common—many officials sought to partner with the private sector (Kliff and

TABLE 5-1 | Role of Foundational Capabilities for Public Health During the COVID-19 Response

Foundational Capability	Key Challenges	Response Example
Emergency Preparedness and Response	Health departments activated emergency protocols, developed public-facing reporting mechanisms, and supported advancements in testing technology and capacity	• Louisiana collaborated with health insurers to develop the state's "COVID-19 Outbreak Tracker" • Seattle and King County (Washington) developed the Seattle Coronavirus Assessment Network
Assessment and Surveillance	Health departments had to organize testing and tracing capacity, requiring substantial coordination and workforce development	• Hamilton County (Tennessee) partnered with faith organizations to increase access to testing, while California funded the development of sites in communities of color • Massachusetts created a dedicated caller ID for its contact tracing team to increase response rates
Communications	Health departments had to both combat misinformation while updating the community on evolving trends and disseminating the latest data	• Multiple states, including Colorado, Florida, and Ohio created a dedicated COVID-19 call center with 24/7 operations • North Carolina launched the "3 Ws" campaign to communicate public health best practices
Policy Development and Support	Health departments had to clarify the scope of their mandate and authority and develop strategies for implementing and enforcing infection control policies	• Many cities, including Charlotte, Kansas City, and San Francisco used civil or criminal penalties for enforcement • Many cities and states conflicted over mask policies, school closures, and social distancing requirements for retail establishments such as restaurants
Community Partnership Development	Health departments had to coordinate across sectors and often perform out-of-scope functions (e.g., procurement)	• Washington established a Regional COVID Coordinating Center to organize medical care • Fairfax (Virginia) developed a Medical Isolation Program

Sanger-Katz, 2020). For example, Louisiana's health department collaborated with Blue Cross Blue Shield to develop a COVID-19 Outbreak Tracker, while in Washington, the state health department partnered with Microsoft to develop a data dashboard (BCBSL, 2020; Washington State Department of Health, 2020). Similarly, the health department and state officials in Michigan forged partnerships with academia to develop data dashboards and to make model-based projections to aid decision-making (Office of Governor Gretchen Whitmer, 2020).

Third, health departments supported diagnostic development and the expansion of testing capacity. State and local public health laboratories played a key role in identifying flaws with the CDC's diagnostic test during February 2020 (Boburg et al., 2020). As the number of COVID-19 cases began to rapidly grow, the federal government provided new flexibilities to state public health laboratories and commercial laboratories to expand the nation's testing capacity (FDA, 2020a). In response, health departments (e.g., Wadsworth Center at the New York State Department of Health) supported the development of new tests, coordinated testing infrastructure (e.g., 16 sites led by the Georgia Department of Health), and formed public-private partnerships to support disease surveillance (e.g., the Seattle Coronavirus Assessment Network) (SCAN, 2020; Miller, 2020; FDA, 2020b).

Assessment and Surveillance

Testing and tracing is a core public health capability maintained by departments for both common infectious diseases (e.g., sexually transmitted infections) and epidemics (e.g., Middle East Respiratory Syndrome). However, COVID-19 has carried significant challenges (e.g., the potential for asymptomatic transmission and "super-spreader" events), and the scale and speed of the outbreak rapidly outpaced the resources of health departments, leading experts to call for a substantial expansion in assessment and surveillance capabilities (Watson et al., 2020).

For testing, many innovations were not equally accessible to all populations, even though people of color were both more likely to test positive for COVID-19 and to experience severe outcomes from the disease (Rubin-Miller et al., 2020). For example, many of the retail testing sites established by the federal government were not accessible to communities of color (Coleman, 2020). Public health officials attempted to address inequities in access where possible, despite often lacking authority and resources. In California, the state funded nearly 100 community testing sites located in communities of color (Kim et al., 2020). Other health departments sought to meet communities where they were to increase access to testing. For example, Hamilton County in Tennessee partnered with the faith community

in Chattanooga to set up free COVID-19 testing sites at predominantly Black churches (WTCV, 2020). Yet despite these efforts, barriers persisted throughout the pandemic due to resource inequities and gaps in federal support for local health departments.

For tracing, health departments hired tens of thousands of new contact tracers during the summer of 2020 (Simmons-Duffin, 2020). Yet contact tracing efforts struggled, with rates of contact identification and interviews by health departments in the U.S. falling well below those of other countries (Dalton, 2020). Health departments have taken different strategies to improve response rates. For example, with many contact tracing calls either blocked or left unanswered due to the lack of caller identification, the Massachusetts Health Department worked with telecommunications providers to set up a standard "MA COVID Team" tag for each phone number (Bebinger, 2020). Contact tracing efforts focused on specific, vulnerable populations have also been promising, such as Boston's biweekly screening program at homeless shelters (O'Connell, 2020; Baggett et al., 2020).

However, efforts continued to fall short of expectations due to several challenges. First, state and local health departments lacked the resources they needed to hire and train contact tracers, with funding delayed by legislative gridlock over COVID-19 relief bills. Second, in the rush to scale, many departments relied on "quick fix" solutions for scaling disease investigation capacity (e.g., reliance on call centers) at the expense of recruiting local individuals who possessed tacit knowledge of their communities, limiting the effectiveness of tracing (Esmonde, 2020). Third, high rates of infection and prolonged delays in testing in many regions of the country outpaced the rate at which tracing could be performed (Steinhauer and Goodnough, 2020). Fourth, contact tracing in communities of color—which have been disproportionately affected by COVID-19—was particularly challenging due to low levels of trust generated from historical legacies of injustice.

Communications

To "inform, educate, and empower" is one of the ten essential services of public health departments in the U.S. (CDC, 2020b). This function has been of paramount importance during the COVID-19 pandemic, which has been accompanied by a "pandemic of misinformation" (UN News, 2020). Competing policy narratives, the undermining of public health leaders by elected officials, and the dissemination of pseudoscience and conspiracy theories through social media have left Americans understandably confused and ill-informed (Rogers, 2020). Patterns of misinformation and disinformation have distressingly emerged along partisan lines, contributing to the politicization of public health (Hamel et al., 2020; Tyson, 2020). Furthermore, distrust of the health care system has

grown among communities of color—who have historically experienced systemic injustices in American health care—due to gaps in the federal response to COVID-19 (Gramlich and Funk, 2020; Washington, 2020).

Local and state health departments have taken a number of steps to keep their local communities informed during the pandemic. For example, numerous state health departments such as those in Colorado, Florida, Minnesota, Ohio, Oklahoma, and many more established dedicated COVID-19 Call Centers to triage incoming questions (Sullivan, 2020). In North Carolina, the state's Department of Health and Human Services launched a "Know Your 3 W's" campaign—wear a mask, wait 6 feet apart, and wash your hands—early in the pandemic, and has used consistent messaging on the part of public officials during daily news conferences to encourage uptake (NCDHHS COVID-19 Response, 2020). In Seattle and King County, the Department of Health expanded its social media team to increase its digital operations and translated COVID-19 materials into over 30 languages to improve their accessibility (ELGL, 2020; King County, 2020). Health departments also sought to tailor communications campaigns around the goals of health equity. For example, the Black Arizona COVID-19 Task Force organized frequent virtual sessions and electronic communications with organizations and health care providers serving Black communities (AMA, 2020a).

Policy Development and Support

The federal government's delayed response, misleading statements about the virus's severity, and abandonment of the established pandemic playbook fragmented the emergency response across the U.S. (Haffajee and Mello; 2020; Karlawish, 2020). Lacking a unified national strategy and facing conflicting guidance about infection control (e.g., travel restrictions, mask policies), local and state health departments were left to develop and enforce public health guidance on their own. This in turn led to fragmented responses and raised questions about the scope of health department mandates and authorities.

For example, lacking federal guidance, local and state officials led the way in implementing shelter-in-place policies, beginning with counties in California's Bay Area (Aragon et al., 2021; County of Santa Clara Public Health Department, 2020). As the outbreak progressed, counties and cities began to take different strategies for enforcing public health restrictions. For example, some cities such as Kansas City indicated that violations of stay-at-home orders would be subject to civil penalties (e.g., suspension of business operations), while other areas such as Mecklenburg County in North Carolina levied criminal penalties (e.g., misdemeanor) (Lucas, 2020; Mecklenburg County, 2020).

However, public health and law enforcement often collaborated to emphasize that penalties were intended as a last resort. For example, in San Francisco—where non-compliant individuals could be fined or incarcerated—officials emphasized that they were "not interested in using a criminal justice approach for a public health challenge" (Dineen and Cassidy, 2020). Yet when policies were enforced, communities of color were often penalized at a disproportionate rate. For example, 61% of violations of shelter-in-place orders in Hamilton County in Ohio were attributed to Black individuals, even though only 27% of the county's population is Black (Kaplan and Hardy, 2020). The racially skewed application of enforcement policies, coupled with the broader conversations on police brutality following the deaths of George Floyd and Breonna Taylor that occurred in the midst of the pandemic, may deepen historical distrust of the health system within communities of color.

The development and implementation of public health guidance also raised important questions about the scope of health department mandates and federal authorities. An illustrative example is the use of face coverings, which evidence from natural experiments of mask mandates in the U.S. indicate helped avert a substantial number of COVID-19 cases and deaths (Lyu and Wehby, 2020). The CDC initially recommended against the use of face coverings for COVID-19 before reversing its stance in April 2020; even following that recommendation, the federal government did not provide consistent guidance to promote mask use (CDC, 2020g; CDC, 2020h; Haslett and Flaherty, 2020). State preemption also created challenges for local implementation; for example, in Texas, the Governor issued a ban on penalties for face coverings after Harris County implemented a mask mandate, while in Nebraska, the Douglas County Health Department withdrew its policy after the state's Attorney General challenged the city's authority for enforcement (Beauvis et al., 2020; Kaplan, 2020; Williams, 2020). Additionally, the delegation of authority from federal to state to local government also cascaded tension and distrust of health departments, taking a toll on public health officials and politicizing the policy development process.

Community Partnership Development

The pandemic not only cast a spotlight on America's underinvestment in public health infrastructure at the local, state, and national level, it also highlighted the systemic gaps in population health (Maani and Galea, 2020a; Maani and Galea, 2020b). Consequently, many health departments went beyond their routine responsibilities to meet their community's health and social needs during the pandemic.

For some health departments, this included collaborating with actors across the health care system to coordinate health services and care planning (e.g., isolation

procedures, surgery cancellations). For example, the health department of Seattle and King County helped create the Western Washington Regional COVID Coordination Center, which monitored outbreaks in long-term care facilities and coordinated referrals according to hospital capacity (Mitchell et al., 2020). With shortages of medical supplies hindering the pandemic response in many areas, and federal coordination for procurement and distribution lacking, local and state health departments played an active role in coordinating with health systems and the Strategic National Stockpile for materials such as personal protective equipment, medications, and test kits.

Another key challenge for health departments was supporting the ability of vulnerable patients who tested positive to safely self-isolate. Compared to white Americans, people of color are more likely to work jobs that cannot be performed remotely, live in households that are multigenerational, and live in densely populated areas (BLS, 2020; Cohn and Passel, 2020; Oppel et al., 2020). In response, the Fairfax County Department of Health in Virginia collaborated with the county's Office to Prevent and End Homelessness and used stimulus funding from the Coronavirus Aid, Relief, and Economic Security (CARES) Act to develop a Medical Isolation Program that repurposed hotel rooms for non-congregate sheltering (County of Fairfax, Virginia, 2020).

Beyond direct infection control, health departments have also adapted to meet other health and social needs of their population. In many counties, local health departments act as both a service coordinator (e.g., for social services) and provider (e.g., for primary and preventive care services), and due to shelter-in-place restrictions, had to adapt their operations to virtual modalities. For example, one regional health department in Kentucky transitioned to virtual visits for its Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) clinics, and was able to increase participation rates by 14% (Dearinger, 2020).

Health Department Challenges

Although health departments were critical to the pandemic response, their efforts were too often limited by factors ranging from ambiguity about decision-making authorities to operational fragmentation and outdated technical infrastructure (see *Figure 5-4*).

Clarifying Roles and Lines of Authority

Effective local public health governance in the U.S has always benefited from strong federal leadership. However, during the COVID-19 pandemic, the federal government largely delegated its responsibilities to governors, with significant

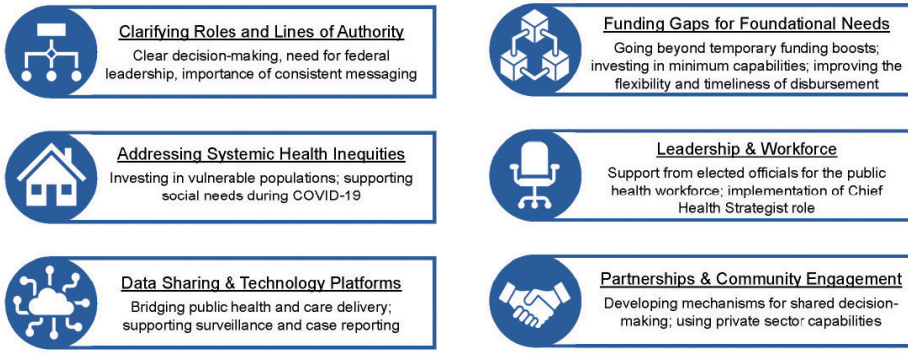

FIGURE 5-4 | Key Challenges for Local and State Health Departments During COVID-19

consequences for local and state health departments. This created several challenges.

First, the deviation from established federal protocols for public health emergencies and conflicting messages from senior leaders contributed to an atmosphere of confusion and fragmented the response across states. For example, states, and in some cases local jurisdictions, were left to make individual decisions about shelter-in-place orders during March 2020 without federal guidance. Given the variation in local and state health department governance models (see *Figure 5-1*), the lack of unified decision-making—which has persisted throughout the pandemic—has contributed to variation in the public health sector responses.

Second, local and state health departments struggled to procure supplies and navigate regulations. The federal government changed the rules for the Strategic National Stockpile—originally intended to "supplement state and local supplies during public health emergencies"—in the middle of the pandemic without advance notice, shifting the onus for procurement to states (Forgey, 2020). The "bidding war" that resulted between states for personal protective equipment and ventilators created uncertainty for health systems and expanded the scope of health department responsibilities at a time when public health officials were already overburdened (Subramanian, 2020). Additionally, some health departments were unfamiliar with many federal regulatory processes, such as emergency use authorizations for COVID-19 diagnostics, and the fragmented approach to test development and reagent procurement generated tremendous pressure on local and state departments.

Third, mixed messaging and shifting public health guidance—particularly around mechanisms of transmission (e.g., aerosols) and protocols for school reopenings—often became a barrier to effective local decision-making due to the presence of contradictory risk messages and misinformation campaigns. These challenges also manifested differently for local and state health departments.

For example, nursing homes are regulated across multiple levels of government, occasionally leading to conflict and confusion, as was the case in Indiana where the state and county issued different orders on policies for patient transfers (Flynn, 2020). Likewise, oversight of school reopenings varied significantly. In California, the variability of local responses to school reopenings has led some district leaders to advocate for the state to implement more uniform standards (Fensterwald, 2020). Future emergency responses would be substantially improved by clarifying lines of authority in an emergency and improving the consistency of messaging.

Funding Gaps for Foundational Needs

It is well-known and consistently documented that although the scope of public health responsibility has increased in recent years, the broadened purview has not been accompanied by a commensurate increase in resources, with health departments consistently remaining underfunded (ASTHO, 2020; NACCHO, 2019; NACCHO, 2020b). Previous committees convened by the IOM have repeatedly called for a paradigm shift in public funding (IOM, 1988; IOM, 2003; IOM, 2012). To help guide the identification and allocation of resources for population health, the Public Health Leadership Forum developed the Foundational Public Health Services framework, which aligns with Public Health Accreditation Board's (PHAB) Standards & Measures (Resnick et al., 2017; PHNCI, 2020; PHNCI, 2016). The severity of existing resource gaps will substantially increase due to the pandemic's potentially long-lasting effects on population health (e.g., mental health) and the damage it has made to progress on other public health priorities (e.g., the opioid crisis) (Galea et al., 2020; Haley and Saitz, 2020). While infectious disease outbreaks—including COVID-19—typically prompt the allocation of supplemental funding, such funds are time-limited, restricted to the outbreak at hand, and generally have not been followed with the long-term commitments needed to strengthen the foundational capabilities of public health departments (Murthy et al., 2017; HHS, 2020a).

Addressing Systemic Health Inequities

COVID-19 magnified America's underlying racial and socioeconomic inequities in population health (Maani and Galea, 2020a; Maani and Galea, 2020b). The disparities are especially stark for Black, Latinx, American Indian/Alaska Native, and Native Hawaiian and Pacific Islander populations who have experienced substantially higher rates of COVID-19 infection, hospitalization, and mortality compared to White Americans (CDC, 2020i; CDC, 2020j; Chang et al., 2020; Rubin-Miller et al., 2020; Torralba, 2020). In addition, the Asian American population—for which COVID-19 data are frequently underreported

and often not disaggregated—has experienced an alarming rise in discrimination and xenophobia (Hong, 2020;Yan et al., 2020).

To address these disparities, many health departments developed cross-cutting functions to address non-medical needs, and states such as Illinois, Louisiana, and Michigan created COVID-19 Health Equity Task Forces to explicitly address the pandemic's disparate impact (GovDelivery, 2020; Illinois Department of Health, 2020; Office of the Governor, 2020). With committed leadership, authentic partnership with communities, dedicated funding, accountability, and multi-sector engagement, these task forces' recommendations and actions have demonstrated progress on addressing disparities in COVID-19. For example, Chicago's Racial Equity Rapid Response team implemented an informational campaign that increased COVID-19 testing rates by 13%, performed preventative outreach calls to 68,000 patients, and secured $3.1 million in COVID-19 relief funding, which was used to address community needs such as rental assistance (AMA, 2020b). Likewise, the city health department and regional health commission in St. Louis partnered to launch PrepareSTL, which coordinated the distribution of personal protective equipment to underserved communities (e.g., at public housing complexes) and supported the expansion of testing capacity at Federally Qualified Health Centers (PrepareSTL, 2020). However, despite these promising examples, the paucity of resources dedicated to addressing health inequities and the social determinants of health limited the sector's overall capacity for response.

A notable challenge from the outset of the pandemic was the delay in capturing the magnitude of disparities (HHS, 2020b). While the challenges of collecting and exchanging demographic data precede COVID-19, the lack of data on race and ethnicity during the pandemic was especially problematic as it delayed the prioritization and allocation of resources to hard-hit communities. As data accumulated, it became evident that COVID-19 disproportionately affected populations who were the least likely to have access to basic public health resources. For example, the incidence of COVID-19 was 3.5 times higher among American Indian/Alaska Native populations—likely an underestimate given the lack of specificity in demographic data—yet American Indian/Alaska Native populations were often the least likely to access COVID-19 diagnostics or necessary inpatient care, in addition to basic public health resources such as running water (Close the Water Gap, 2020; Hatcher et al., 2020; NIHB, 2020; Schulz, 2020; Wade, 2020). It was also well-documented that vulnerable populations who live in congregate settings (e.g., individuals in homeless shelters, justice-involved populations) were particularly susceptible to COVID-19 outbreaks, yet health departments were largely unequipped to perform the necessary surveillance testing and provide resources for rehousing and self-isolation (Kuehn, 2020; Saloner et al., 2020).

The inequities exposed by COVID-19 are not new. The question is whether the pandemic will provide a sufficient impetus for elected officials to reverse the ongoing decay of public health infrastructure through meaningful, long-term investments in system capacity with dedicated resources and attention for addressing health inequities and the social determinants of health (Galea and Abdalla, 2020).

There are multiple avenues for change, such as improving public health's analytic capacity to elucidate the root causes of disparities. Furthermore, the Chief Health Strategist model of Public Health 3.0—in which public health leaders "work with all relevant partners so that they can drive initiatives including those that explicitly address 'upstream' social determinants of health"—represents a promising approach to breaking down historical siloes between public health and social care to foster meaningful change (OASH, 2016). For such interdisciplinary models to succeed, policymakers must address funding and resource gaps to restore health departments' foundational capabilities and make such cross-sector partnerships viable and sustainable.

Leadership and Workforce

Effective crisis management for public health requires clear communication from designated leaders who are empowered to make decisions. Many local and state public health officials have been celebrated during the pandemic for their poise and focus on the facts and evidence. However, as COVID-19 has continued, public health guidance and directives—which are designed using the latest evidence and contextualized to local communities—have become increasingly politicized. Public health officials have become a casualty of the polarized climate, with nearly 200 confirmed firings, resignations, or retirements as of December 2020 (Barry-Jester et al., 2020). Social media has played a prominent role in the harassment of public health officials, who have received death threats and been subjected to organized protests at their personal residences (Munz, 2020). Distressingly, some elected officials themselves have encouraged and even participated in these attacks, which not only undermine the pandemic response, but also build on growing public distrust of non-partisan, scientific institutions (Mello et al., 2020).

The challenges extend to the public health workforce as well, which has expanded substantially during the pandemic. The majority of hires have been for temporary contact tracing positions, requiring departments to dedicate resources to short-term training without filling the long-term need for a workforce with dedicated public health training and the requisite technical, cultural, and linguistic competencies. Contact tracers hired for COVID-19 have also experienced challenges, with reports of harassment on social media (Stone, 2020). Independently, several departments

have had to cross-train existing staff to meet demand for contact tracing, which can leave little spare capacity to address other core public health duties (IDSA, 2020). Elected leaders need to affirm their support for data-driven decision-making and the non-partisan nature of health departments to ensure their credibility, and must provide sufficient resources to ensure that public health functions are sustainable.

Data Sharing and Technology Platforms

A significant limiting factor for public health departments during COVID-19 has been the use of obsolete technology platforms. Additionally, there continues to be resistance on the part of hospitals to sharing key data that could be relevant during infectious disease outbreaks (e.g., admission, discharge, and transfer data) (Monica, 2020). Furthermore, even when hospitals or laboratories have been amenable to sharing data for COVID-19, they have only been required to report to the federal Department of Health and Human Services (HHS), and not to local health departments, potentially delaying local decision-making (Maxmen, 2020).

Technological limitations also mask the disparate impact of the COVID-19 pandemic on people of color, as noted in the preceding subsection on "Addressing Systemic Health Inequities" (Bassett et al., 2020). Analyses of state and local health departments suggest that more than a third of cases lacked race and ethnicity data due to both incomplete forms from clinical labs and health care sites and outdated digital infrastructure for health departments. Several states continued to report no ethnicity data at all as of September 2020 (Krieger et al., 2020). While individual health departments have sought to close the information gap, such as the New York City Department of Health and Mental Hygiene's publication of neighborhood-level COVID-19 maps as early as April 2020, the consistent gaps in public health surveillance and lack of technical uniformity have exacerbated the inequities of the pandemic (New York City, 2020; Krieger et al., 2020).

The use of outdated infrastructure, coupled with the lack of integration of new diagnostic technologies (e.g., point of care, home-based) with health departments or the health care system, has also slowed the pandemic response and affected the credibility of health officials. For example, a backlog of over 300,000 test results occurred in California in part due to data glitches (Shafer, 2020). Likewise, in Texas, more than 1 million test results were lost over the summer of 2020 (Goldberg, 2020). These data integrity challenges affected the ability of local officials to make decisions about reopenings, demonstrating the need for interoperable platforms for public health and reaffirming the urgency of ongoing collaborations to create a "data superhighway" for public health (CSTE, 2019). Importantly, these deficiencies are not due to a lack of will among local and state health departments, but to a dearth of resources to support building such systems.

Partnerships and Community Engagement

With the COVID-19 pandemic disrupting aspects of everyday life ranging from education to business operations to health care delivery, effective emergency response requires a broad set of community partnerships. Effective engagement strategies require health departments to convene diverse stakeholder groups, coordinate across historical siloes, and overcome cultural differences and the limited availability of funds.

For example, research indicates that the public health sector has long faced challenges with communicating across sectors (Castrucci et al., 2020). While nearly all local health departments engage in cross-sector partnerships (e.g., with K-12 schools), most engagement is surface level (e.g., information exchange), with notable gaps in collaboration with the media (NACCHO, 2019). Additionally, formal collaborations with other health care, community-based, and government partners have declined since 2008, and had not recovered to pre-recession levels prior to the pandemic. Gaps in communication posed challenges for combating misinformation and achieving compliance with COVID-19 restrictions. Partnerships provided a vehicle to support community engagement and secure buy-in. For example, "Challenge Seattle" brought together the Seattle and King County Health Department and business leaders from local companies (e.g., Amazon, Microsoft, and Starbucks) to create a forum for the co-development of best practices (e.g., workplace safety guidelines) and shared decision making about data reporting and reopening timelines (Challenge Seattle, 2020). However, the depth of engagement and cooperation varied across the country and was often hindered when elected officials contradicted public health guidance. For example, states such as Florida and Texas proceeded with lifting restrictions despite failing to meet both local and national criteria for reopening. The experience illustrates the value of tools such as the Public Health Reaching Across Sectors (PHRASES) project to help proactively develop relationships and partnerships for public health (PHRASES, 2020).

Moving forward, the challenge for health departments will be developing avenues to sustain these partnerships outside of crisis settings, while also determining which infrastructure and programmatic needs would be best met through internal capacity development as opposed to external collaboration.

PRIORITY ACTIONS AND POLICY CONSIDERATIONS

Generations of reports from the IOM have stressed the critical importance of public health infrastructure to population health and the need to address longstanding issues ranging from funding shortages to institutional siloes (IOM,

1988; IOM, 2003; IOM, 2012). COVID-19 has reaffirmed this call to action, demonstrating the centrality of robust public health systems to the health and wellbeing of society. As the U.S. prepares for the post-pandemic era, it will be imperative for policymakers to not only develop mechanisms to improve preparedness for future public health emergencies, but also to address the chronic neglect of foundational public health capabilities in communities across the country. This section outlines the priority actions and policy considerations for the public health sector, with a focus on:

1. Transforming public health funding;
2. Affirming the mandate for public health;
3. Promoting structural alignment across the public health sector;
4. Investing in leadership and workforce development;
5. Modernizing data and IT capabilities; and
6. Supporting partnerships and community engagement.

Transforming Public Health Funding

While public health has faced many challenges during COVID-19—including outdated infrastructure, a beleaguered workforce, and inequities in access and outcomes—the lasting lesson for policymakers must be a recognition that these structural shortcomings were not caused by the pandemic, but rather already endemic for the sector after decades of chronic neglect and underinvestment in public health. Each of the policy considerations in this section highlights an existing pressure point in the system and a series of priority actions for relieving strain on the sector and preparing public health to meet future challenges. Yet meaningful change within each domain will only be possible if policymakers address the generational gaps in resources for public health, and guide future investments with an explicit focus on health equity.

The funding problem has two dimensions. First, the scale of public health funding has long been inadequate to address the full scope of population health needs, with a particular dearth of targeted resources to address health inequities and the social determinants of health. Second, the organization of public health funding is far too restrictive and lacks the ability to rapidly reallocate funds to address emerging needs and crisis situations. These issues predate the pandemic and are pervasive at each level of the public health system, with COVID-19 providing a stark reminder of the human cost of disinvestments in public health.

Moving forward, policymakers should consider taking several steps to close the funding gaps in public health. For one, leaders at all levels of government—local, state, federal, tribal, and territorial—could consider implementing the

recommendations from the IOM's 2012 report to provide funding for a minimum package of public health services (e.g., maternal and child health promotion, mental health and substance abuse), and construct a system for monitoring spending and outcomes to optimize future resource allocations (IOM, 2012). The Public Health Infrastructure Fund represents a model for how policymakers can organize investments in the foundational capabilities of health departments (DeSalvo et al., 2019). Additionally, to better equip health departments to meet their local community needs and have the capacity to adapt during emergency situations, policymakers should consider implementing the recommendations from Public Health 3.0 to develop funding sources that are flexible in nature, as opposed to the current paradigm which emphasizes categorical funding (OASH, 2016).

Most importantly, funding must be dedicated to the explicit purpose of addressing racial and socioeconomic inequities in health. While so-called "braiding and budgeting" strategies have been promising (e.g., "Children's Cabinet" in Maryland), and new population-based payment models can help orient financing towards the social determinants of health (e.g., the California Accountable Communities for Health), truly moving the needle for disparities will require dedicated funding to sustain the many pandemic-era health equity initiatives beyond COVID-19 (Butler et al., 2020; OASH, 2016). Priority areas to transform public health funding are summarized in *Box 5-1*.

BOX 5-1

Considerations for Transforming Public Health Funding

- Allow for more flexibility in routine and emergency program funding streams to enable jurisdictions at all levels to directly meet the needs for public health surge capacity during times of crisis, in response to evolving epidemiological challenges, or to address the specific needs of vulnerable populations
- Establish adequate, reliable, flexible and sustainable funding mechanisms to support the foundational capabilities of public health via federal, state, and local mechanisms benchmarked to the populations and communities which a given department serves
- Invest in the upstream drivers of health, including the social determinants of health, to create more resilient communities with systems to support the full scope of health needs
- Create adequate, reliable, and sustainable funding sources to support jurisdictions at all levels to participate in established public health accreditation and/or quality improvement processes

Affirming the Mandate for Public Health

Closing the funding gap for public health must be accompanied by a focused effort to resolve ambiguities in the scope of jurisdictional authority, which contribute to the uneven nature of public health protection across the nation. In the aftermath of COVID-19, it will be imperative for state and local public health agencies to take the steps needed to achieve accountability to performance standards advanced by established national public health accreditation entities or equivalent state and local quality improvement bodies. Recognizing that public health in the 21st century requires the capacity to manage chronic diseases, address the social determinants of health, advance health equity, and maintain preparedness for global health threats, it will be imperative that the mandate for public health agencies include "Foundational" capabilities such as risk communication and laboratory services for rapid disease detection (PHNIC, 2018). To promote accountability, policymakers will need to ensure that any mandate for performance is sufficiently resourced and that health departments receive the necessary support and funding to perform reviews, conduct reporting, and achieve compliance—a key limiting factor for existing accreditation processes.

To enable state and local health departments to execute their public health mandate, policymakers will need to address inconsistencies in statutory authorities and responsibilities across jurisdictional boundaries. For example, the CDC's Public Health Law Program could consider leading a concerted effort to identify model statutory language that could be implemented to foster consistency in authorities (CDC, 2018). Such steps would improve the public's understanding of expected protections and provide clarity for funding, communications, and resource allocation, particularly during emergency situations. For example, if preparedness is the purview of all local health departments, then funding for such essential services should be directed to local public health agencies rather than to other local authorities. Proactively clarifying the scope of authorities will help to foster shared accountability with core governmental partners while also supporting stronger, clearer linkages across sectors.

Finally, any policy actions to affirm the mandate for public health must be inclusive of all types of agencies, including tribal and territorial health departments, which continue to be inadequately resourced and lack the necessary technical support and political standing needed to promote the health of their communities. While the unique challenges and specific considerations for these departments are beyond the scope of this paper, which is focused on local and state health agencies, it is necessary to acknowledge the historical legacies of systemic neglect and call for improved coordination with and dedicated attention to the needs of these entities.

BOX 5-2

Considerations for Affirming the Mandate for Public Health

- Harmonize statutory authorities across jurisdictions
- Allocate resources to fund a mandate for accountability across all jurisdictions for performance via established national public health accreditation entities or equivalent state and local quality improvement bodies within five years
- Require better coordination with and support for tribal governments and territorial health departments

Priority actions to affirm and clarify the mandate for the public health sector following COVID-19 are summarized in *Box 5-2*.

Promoting Structural Alignment Across the Public Health Sector

To operationalize their public health mandate, local and state departments need to be capable of delivering a standard set of evidence-based services to their communities. This remit is captured in the existing framework for "Essential" public health services that was updated in 2020 (CDC, 2020b). But as COVID-19 has shown, translating rhetoric into reality requires defined competencies and dedicated resources. The Public Health National Center for Innovations' framework for "Foundational" public health services outlines the capabilities which health departments need to develop to deliver on their mission (PHNIC, 2018). Additionally, the PHAB accreditation process can help to objectively assess a given department's capacity to deliver the 10 essential services (CDC, 2020c).

The challenge will be how to promote structural alignment to ensure that every local, state, tribal, and territorial public health department is equipped with the same basic tools. To be clear, promoting a convergence towards common functionality and standardized competencies does not mean that all departments must look and act exactly alike. The demographic and geographic diversity of America's communities inherently requires health departments to tailor their work to the unique needs of their local population. Rather, a standard set of guiding principles allows departments to collectively streamline their work from the outset, and also promotes excellence as a norm to improve quality and foster accountability across the nation. These steps would enhance the ability of health departments to meet the needs of their local communities and pursue innovation through cross-sector partnerships.

Health departments possess multiple avenues to promote structural alignment to advance the health of their communities. One approach is to develop formal collaboratives in which departments work to coordinate services across jurisdictions and sectors. For example, Allegheny Health Department in Pennsylvania launched "Live Well Allegheny", which aims to coordinate activities for chronic disease prevention (e.g., increasing access to healthy food, promoting partnerships for physical activity) across the 130 municipalities within the county (Allegheny County Health Department, 2019). Likewise, a number of health departments in Massachusetts have engaged in cross-jurisdictional sharing of public health services (e.g., the Central Massachusetts Regional Public Health Alliance, Berkshire Public Health Alliance), with the state's Office of Local and Regional Health providing technical assistance to local officials interested in developing new partnerships (OLRH, 2021).

Another model is to pursue functional regionalization, in which health departments collaborate on select initiatives to maximize efficiency. This model can help health departments achieve economies of scale for targeted public health campaigns. For example, Health Kansas City—a public-private partnership to create a culture of health—launched the Tobacco 21 | KC initiative, a regionally coordinated effort for a specific public health goal (promoting smoking cessation) in over a dozen municipalities (OASH, 2016). Another use case of functional regionalization is enhancing the purchasing power and service sharing across health departments to support emergency preparedness. For example, the Western Washington Regional COVID-19 Coordination Center helped triage patients according to facility capacity and monitor inventory for personal protective equipment (Mitchell et al., 2020). Likewise, in West Virginia, health departments worked together to coordinate between local pharmacies and long-term care facilities, enabling the state to be an early leader for COVID-19 vaccinations (Mervosh, 2021).

While the optimal model for a given health department will likely depend on the specific context and needs of the local community which they serve, these examples illustrate how strategic partnerships—coupled with sustainable funding—can better position health departments to deliver on their fundamental mission and address the increasingly complex health problems of the 21st century.

Opportunities to promote structural alignment are summarized in *Box 5-3*.

Investing in Leadership and Workforce Development

Public health workers and leaders have operated under unprecedented strain during the COVID-19 pandemic. The burden on staff was not only due to the scale and scope of the crisis, but also because of negative public sentiment

BOX 5-3

Considerations for Promoting Structural Alignment Across the Public Health Sector

- Align the structure and function of health departments to ensure all residents are protected by agencies possessing the foundational capabilities needed to perform the 10 Essential Public Health Services
- Define the ideal size and structure for health departments at the local level to have optimal performance, and reduce redundancy by addressing overlapping jurisdictions
- Transition toward models of shared services across jurisdictions and/or regionalization to improve effectiveness and efficiency

and active interference from elected officials. Given the existing challenges for the public health workforce, which range from the lack of diversity to gaps in recruitment, persistence of uncompetitive salaries, and limited opportunities for professional growth and advancement, systemic reforms to leadership and workforce development are needed to equip health departments with the human capital needed to deliver the public health mission in the 21st century (Sellers and Bork, 2020; De Beaumont Foundation, 2019).

The kind of leadership called for during the pandemic—interdisciplinary expertise, capacity to collaborate across sectors, ability to communicate with policymakers and the public—is characteristic of the model of the Chief Health Strategist proposed in the Public Health 3.0 report (DeSalvo et al., 2017). The Chief Health Strategist role, as envisioned, would draw from cross-cutting and diverse partnerships to build collective impact, leverage new sources of data to extract novel insights, and bolster the pipeline for the public health workforce through connections with non-governmental sectors like private business and academia. Chief Health Strategists will also need to possess the necessary savvy and policy relationships to support robust collaboration with local and state government and clear communication with the lay public to dispel myths and perceived tradeoff s associated with public health actions during public health emergencies. These are vital skillsets for navigating crisis situations.

Several pioneering communities across the country had already begun to experiment with this evolving model of enhanced leadership prior to the pandemic. For example, the Baltimore health department's work to address challenges ranging from the opioid crisis to racial inequities illustrated the value

of having public health officials who possess the capacity to mobilize community action to address upstream social determinants that have traditionally been beyond the reach of public health agencies (DeSalvo, 2017). Likewise, the Boston Public Health Commission has used the Chief Health Strategist model to form collaborations with community organizations, government agencies, and private sector entities across the city. For instance, with the city facing rising income inequality, the department's Chief Health Strategists have led initiatives to form new strategic partnerships related to housing and anti-displacement and inclusive economic growth (Boston Public Health Commission, 2019).

Fostering these collaborations is not just an attempt to energize current employees—it is critical to the sustainability of public health as a field. The public health workforce must be significantly expanded and transformed simply to meet its daily needs, let alone build reserves for the next public health crisis. Given that low pay is a leading factor undermining retention, the process of workforce development should begin with providing reasonable salaries to recruit and retain public health talent (Robin et al., 2019). Diversifying public health skillsets will require broadening departmental recruitment. For example, partnerships with academic institutions can help to hone education programs and skillsets for future employment through service learning and internships. Likewise, engaging the business community through business schools, short-term fellowships, and career exchange programs can provide avenues to support leadership development and foster expertise in finance and operations. Furthermore, as the COVID-19 experience has demonstrated, effective public health requires a workforce with capabilities in IT and data, to enable departments to appropriately respond to emerging health concerns and develop the capacity for online engagement with the public. Lastly, with the pandemic highlighting America's longstanding health disparities and the importance of tailoring solutions to the local context, recruitment efforts should prioritize drawing from the communities which health departments serve, with a special emphasis on developing pathways to the profession for individuals from all backgrounds and axes of representation.

Priority actions and policy considerations to support workforce development for public health are summarized in *Box 5-4*.

Modernizing Data and IT Capabilities

As outlined in the earlier section on the "State and Local Public Health Response to COVID-19", outdated technological infrastructure slowed the public health response on many occasions, from exchanging laboratory results with health systems to maintaining real-time dashboards for public information. While public-private partnerships enabled departments to fill technical gaps,

BOX 5-4

Considerations for Investing in Leadership and Workforce Development

- Adopt the Chief Health Strategist model for health department leadership
- Support the retention and recruitment of diverse public health professionals and leaders who are representative of the community they serve, with updated mechanisms to ensure appropriate compensation and recognition
- Develop programs and resources to support the ongoing professional development of the incumbent and pipeline workforce to meet the population health needs of the 21st century

the COVID-19 experience illustrated the overdue need to invest in health departments' data and IT capabilities.

In its ideal form, a 21st-century health department should not only possess the capacity to provide baseline data that is timely and locally relevant, but also be able to scale such efforts in times of crisis. This will require internal expertise as well as ongoing collaborations with academia and the private sector to enable real-time and geographically granular data (e.g., sub-county, neighborhood) to be shared, linked, and synthesized quickly to inform action. For example, the maps developed by the Coronavirus Resource Center at Johns Hopkins University are used globally as a reference point for tracking infection trends. A key area of focus will be ensuring the interoperability of data systems within the public health sector and across the health care system writ large to improve the efficiency of communication and execution. Investments in technical capabilities can also support health departments in their efforts to better identify disparities in health and address the upstream drivers of these disparities. In particular, developing and collecting standardized data elements for race, ethnicity, income, and other key demographic factors (e.g., ZIP Code) is critical to both diagnose and address inequities, as modeled by California's "vulnerability index" for COVID-19 (Blue Shield of California, 2020).

Box 5-5 highlights the policy considerations that would help to enhance the data and IT capabilities of public health agencies moving forward.

Supporting Partnerships and Community Engagement

The breadth of functions covered by public health requires partnerships with those outside the sector in the best of times, let alone emergency situations. In the aftermath of COVID-19, local and state public health officials need to

BOX 5-5

Considerations for Modernizing Data and IT Capabilities

- Build a 21st century digital infrastructure for public health at the local, state, and federal levels
- Establish national standards to enhance public health IT system interoperability
- Modernize surveillance approaches to include novel signals from data sources such as social media, electronic health records, and crowdsourcing
- Set national standards to ensure that health data is routinely disaggregated by race, ethnicity, and other key sociodemographic characteristics to the community level (as appropriate to ensure anonymity) to identify disproportionate health impacts and outcomes

build on the cross-sector relationships they have developed during the pandemic and develop sustainable avenues for coordination to address long-term health inequities and population health needs.

Partnership opportunities may manifest differently across each level of public health. For example, local health departments may benefit from partnerships with multiple sectors, particularly with community-based organizations. Collaborating on community needs assessments provides an opportunity for local health departments to partner with other entities to identify shared challenges and goals for a specific population and geography. Importantly, local collaborations can create a foundation of trust to promote coordination both in foundational areas and during crisis situations. Likewise, state health departments may benefit from forging strategic partnerships at a slightly larger scale, such as coordinating preparedness efforts with local and national governments, academic medical centers, regional hospital associations, and private industry.

This focus on strategic coalition-building across all dimensions of public health will not only reinforce the Chief Health Strategist model for public health leadership, but also address long-standing capacity gaps within the sector. For example, health departments should build on the PHRASES project from the de Beaumont Foundation to improve public health communication, as research shows that effective public health communication requires tailoring language to the unique context of different stakeholders (e.g., in business, in education) (Castrucci et al., 2020). Likewise, building on collaborations with academia—which has exponentially increased offerings for public health training programs and provided pandemic support functions including technology development, testing and tracing centers, and vaccine distribution

models—can offer added capacity for addressing complex population health challenges. The Academic Health Department model may provide a framework for future collaboration (Erwin et al., 2019). Additionally, developing mechanisms for outreach, mutual trust, and respect across community sectors can help streamline communication during emergency situations, when the real-time evolution of data can create an environment of misinformation and affect the credibility of health officials.

Beyond supporting communication and outreach, partnerships can also help augment the capacity of health departments to deliver on their public health mission. This requires establishing coordinating structures and identifying leadership organizations. In some cases, public health agencies may take the lead as backbone organizations, while in others, health departments may serve as a convener, with other partners leading the way for ground-level implementation. Under such models, established community entities can play crucial roles as sources of trusted information, helping to disseminate credible guidance and information for the population. Health systems and other care delivery organizations are natural partners in this regard given their role as community pillars and the shift to population health mandates and financing arrangements, as evidenced by the ongoing demonstrations for Accountable Health Communities. Such partnerships will be vital as the public health sector collaborates across government, health systems, and community organizations to scale initiatives to address health inequities.

Policy considerations for supporting partnership development and community engagement are presented in *Box 5-6*.

BOX 5-6

Considerations for Supporting Partnerships and Community Engagement

- Establish and maintain regional and/or state-level backbone entities that can be leveraged during crises for shared action
- Cultivate relationships with non-traditional partners including employers, the business sector, and technology
- Identify a new backbone national entity that can support collaboration to achieve unified policy recommendations from all the core components of the public health sector
- Enhance trust and credibility through improved risk communication with public health authorities

CONCLUSION

COVID-19 provides a stark reminder of the tremendous social value of robust public health systems and the harrowing consequences for populations when those capabilities are allowed to atrophy through neglect and underinvestment. The public health sector has been critical to America's pandemic response, from leading testing and tracing efforts to monitoring infection rates to coordinating vaccination campaigns to support outbreak control. Through the crisis, health departments have led in spite of the obstacles posed by insufficient resources, inadequate infrastructure, and institutional siloes—challenges which long predate the pandemic. Consequently, enhancing the sector's preparedness for future public health emergencies will require first addressing the structural inadequacies in how American public health is funded and governed, with a dedicated focus on remediating the pervasive and preexisting health inequities which have caused disproportionate outcomes during COVID-19.

In this discussion paper, leaders from the public health sector have sought to share their experiences to date from the pandemic response and propose a series of priority actions for policymakers to consider as the nation charts a roadmap for the post-pandemic era. These include closing funding gaps for foundational capabilities, affirming the mandate for public health, promoting structural alignment, investing in workforce development, modernizing data capabilities, and supporting cross-sector partnerships. Such actions are necessary to ensure that the tragedies of the present become a turning point for the future—a future where the United States is capable of protecting and promoting the health of all people in all communities against the population health challenges of the 21st century.

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None to disclose.

6

HEALTH CARE PAYERS COVID-19 IMPACT ASSESSMENT: LESSONS LEARNED AND COMPELLING NEEDS

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INTRODUCTION AND SECTOR OVERVIEW

In contrast with other high-income countries, health care insurance and payment in the United States is highly fragmented. America's multi-payer system spans an array of entities, including publicly financed programs (e.g., Medicare, Medicaid) and commercial insurers and health plans. *Figure 6–1* provides an overview of the different types of payers and populations in the U.S. (KFF, 2019a). This paper will focus on the perspective of payers covering Medicare, Medicaid, and adults with fully insured employer health plans, which together encompass the majority of Americans.

These payers aim to serve several functions in the U.S. health care system, including offering protection against the financial impact of unexpected health events, providing patients with access to a broad set of health services delivered by a network of health care professionals, coordinating those services, and using measurement and incentives to increase the affordability and quality of care delivery (Dey and Bach, 2019). Yet the common functions of payers can take many different forms with regards to operational arrangements (e.g., stand-alone plans versus joint ventures with delivery organizations), benefit design (e.g., covered services, cost distribution), and payment methodologies (e.g., volume- versus population-based payments). A key area of change for payers over the past decade has been the advent of so-called "value-based care," in which payers in both the

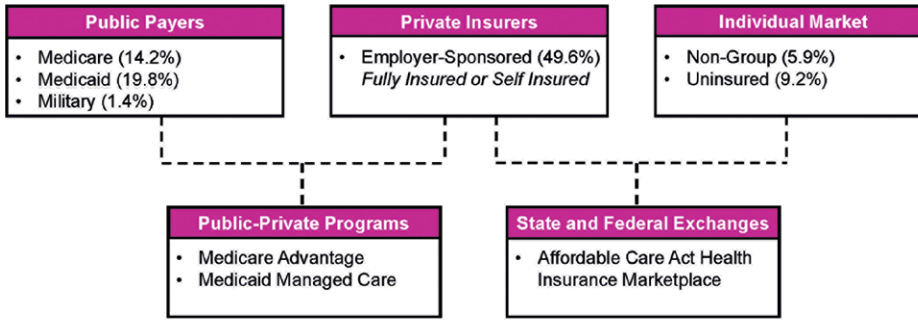

FIGURE 6-1 | Overview of America's Multi-Payer Landscape

public and private sector have sought to transition away from fee-for-service (FFS) arrangements to alternative payment models (APMs) that link reimbursement to the quality and outcomes of care delivery (Thomas et al., 2019).

It is amidst this period of renovation to the architecture of the U.S. health care system that COVID-19 struck. The public health emergency—which remains ongoing at the time of this paper's publication—has had tremendous consequences for the health of American society and the financial stability of the American health care system. During the spring of 2020, payers took steps based on regulatory requirements and recommendations to expand access to health services for both COVID-19 and non-COVID-19 health conditions (e.g., waiving administrative requirements, reimbursing telehealth). Many payers also independently deployed financial support and capital to stabilize providers, and leveraged their technological capabilities and community relationships to support outbreak response, from coordinating non-medical services to supporting immunization campaigns.

However, payers' pandemic response capabilities and their obligations to regulators, employers, providers, and patients evolved as high caseloads persisted and the downstream consequences of COVID-19 began to manifest. For example, trends in medical spending and utilization shifted as outbreaks escalated over the course of 2020. Payers initially experienced cost reductions due to care delays, but then experienced a subsequent increase in operating expenses due to the growing volume of COVID-19 patients and the resumption of deferred health services. Likewise, as insurance is an industry premised on forecasting and risk assessment, the fundamentally unpredictable nature of a pandemic created significant challenges for payer operations in 2021 (e.g., pricing, enrollment).

In this paper, leaders from the payer sector seek to describe the experience of health insurers during COVID-19 and identify the key challenges and opportunities learned from the pandemic and beyond. It is important to acknowledge that as an ongoing public health emergency, empirical evidence on health care costs and payment policies for COVID-19 remains nascent at this time, and data on the specific

actions of payers may vary according to differences in health insurance products, local market needs, and regulatory requirements. Nevertheless, one year into the pandemic, it is evident that the unprecedented disruption to the health care system as a result of COVID-19 provides a unique opportunity for payers to improve the efficiency and equity of health care financing in America. Consequently, the goal of this paper is to provide a preliminary review of payers' experiences during COVID-19 to date and to highlight the key lessons for how payers and regulators can navigate the uncertainties of COVID-19 and leverage the newfound momentum for health care reform, with a particular focus on improving affordability and accessibility.

THE PAYER RESPONSE TO COVID-19

The COVID-19 pandemic imposed a sudden and significant shock to America's fragmented health care system. While the volatility of COVID-19 did create challenges for payers (e.g., actuarial forecasting), the unprecedented reduction in health care spending resulted in improved financial performance for many health insurers during 2020. Many payers leveraged their resources and role to support patients, providers, and other stakeholders as the health care system evolved at unprecedented speed. For example, insurers facilitated the management and delivery of both COVID-19-related and non-pandemic health services across multiple care delivery partners. Likewise, health plans worked to aggregate and coordinate the new federal and state mandates, rules, waivers, and guidance regarding traditional health services (e.g., prescriptions, benefits) and COVID-19-related care (e.g., testing, treatment). Furthermore, payers collaborated with providers and developed partnerships with other sectors (e.g., public health, community-based organizations) to support the implementation of new flexibilities, communicate key changes, and help patients, the public, and employers to navigate the rapidly shifting delivery environment.

This section of the paper seeks to capture the primary areas of focus for the payer sector's response to the pandemic. While evidence on the scale and effects of payer actions is difficult to quantify at this stage, given that COVID-19 remains an evolving public health emergency at the time of this paper's publication, and it is challenging to generalize given the fragmented nature of America's multi-payer environment, the authors seek to offer salient examples from their vantage point. The key aspects of payers' COVID-19 response include:

1. Providing rapid and relevant information to key stakeholders;
2. Ensuring patients retained access to health services despite disruptions to in-person delivery;
3. Addressing the non-medical needs of patients, particularly in light of the pandemic's disparate impact on high-risk populations;

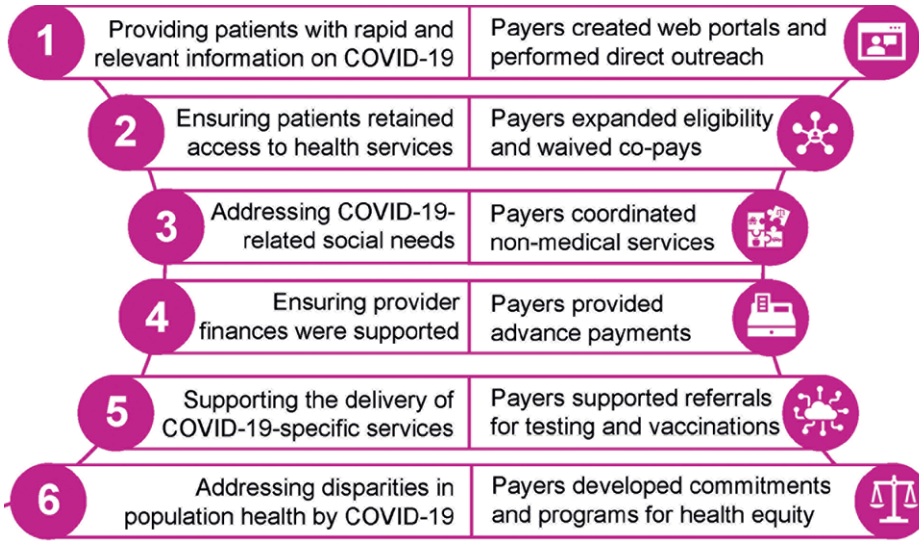

FIGURE 6-2 | Payer Responses to COVID-19 Challenges

4. Ensuring providers received adequate financial support amidst sudden revenue reductions and shifts toward virtual care;
5. Supporting the delivery of pandemic-specific services, including COVID-19 testing, treatments, and vaccinations, and the distribution of personal protective equipment (PPE); and
6. Providing resource commitments and program support to address health inequities (see *Figure 6-2*).

Adapting to the Pandemic: Role-Shifting, Partnerships, and Program Development

Providing Patients with Rapid and Relevant Information

Amidst an uncertain informational landscape, payers worked to synthesize evidence and provide outreach and education to help patients stay safe during the pandemic (Reynolds, 2020). Within the public sector, the Centers for Medicare and Medicaid Services (CMS) posted regular updates to frequently asked questions for beneficiaries, and issued proactive guidance to Medicare Advantage Organizations, Part D Sponsors, and Medicare-Medicaid Plans about the flexibilities (e.g., changes to benefits, waivers to cost-sharing) available to health plans covering Medicare beneficiaries during the public health emergency (CMS, 2020a). Within the private sector, some insurers established patient-facing

web portals to compile real-time information regarding coverage options for special enrollment, which often differed across individual, employer, Medicaid, and Medicare insurance markets (Blue Shield California, 2020a).

Health plans also leveraged their customer service teams to disseminate and answer coverage-specific questions from patients and employers using multiple modalities. For example, some payers deployed their patient services representatives to provide patients with the latest information on applicable government mandates. Other payers organized virtual town halls, with a particular focus on outreach to high-risk patients (e.g., the elderly) (UPMC, 2020). Payers' outreach efforts also extended beyond informational resources into direct clinical assistance. Examples include supporting virtual clinical assessments and facilitating connections with providers. Some plans even deployed care managers to hard-hit network hospitals to assist with post-acute care coordination.

Retaining Access to Health Services

In addition to complying with federally mandated coverage requirements for many components of COVID-19 diagnosis and treatment, payers also sought to reduce financial barriers to coverage for non-COVID-19 care for the duration of the public health emergency (AHIP, 2020a; Keith, 2020). In the public sector, CMS required Medicare Advantage organizations to waive certain referral requirements and cost-sharing policies, all without 30-day notification periods, to enable beneficiaries to access necessary care. Likewise, some state Medicaid programs expanded eligibility and benefits for long-term services and supports for seniors and patients with disabilities (Musunemci et al., 2020). For employer-sponsored insurance, many plans eliminated late fees, extended eligibility allowances for furloughed employees, and offered premium deferral mechanisms to balance employers' concerns of fiscal sustainability with the need to provide short-term relief to maintain members' coverage (CareFirst, 2020; KFF, 2019b). However, waivers for coverage and cost-sharing did not extend to out-of-network billing for both COVID-19 and non- COVID-19 health services. Additionally, the uptake of these policies varied across self-insured entities, which account for the majority of covered workers and are beyond the scope of this paper.

A key area of focus for payers across the sector was mitigating potential disruptions to patient access to prescription drugs (e.g., due to shortages or shelter-in-place restrictions) (Faust, 2020). CMS issued guidance to Part D sponsors, including reimbursement for out-of-network pharmacies and permissions for home delivery and prior authorizations (CMS, 2020b). Within the private sector, many insurers (e.g., all 36 Blue Cross Blue Shield Association companies) temporarily waived early refill limits on 30-day maintenance medication prescriptions and extended prior authorizations on 90-day medication supplies (BCBSA, 2020; CVS Health, 2020).

Addressing COVID-19-Related Social Needs

COVID-19 exposed and exacerbated many long-standing health inequities in the U.S., with the pandemic disproportionately affecting racial and ethnic minorities and socioeconomically disadvantaged populations. Payers took multiple actions to respond to these inequities.

First, at the policy level, CMS issued guidance that the agency would exercise enforcement discretion for mid-year benefit enhancements by Medicare Advantage organizations, including benefits addressing social needs (e.g., meal delivery, transportation services) (CMS, 2020a). While data on mid-year changes is still emerging, the number of Medicare Advantage plans offering Special Supplemental Benefits for the Chronically Ill more than tripled between 2020 and 2021 (PR Newswire, 2021). The majority of states also implemented new initiatives to address the social determinants of health through their Medicaid programs, with some programs occurring in conjunction with insurers (Gifford et al., 2020). For example, Pennsylvania implemented new requirements for Medicaid Managed Care Organizations to partner with community-based organizations, with implications for reimbursement.

Second, some commercial payers took independent action to address inequities, with select examples from the sector summarized in *Table 6-1* (AHIP, 2020a). For example, some payers developed a coordination function to match high-need patients with relevant community organizations (AHIP, 2020b). A few plans worked to augment financially strapped public assistance programs, such as direct outreach efforts and enrollment assistance for Supplemental Nutrition Assistance Program (SNAP) benefits and financial support for community organizations working on rapid rehousing solutions for the homeless population. Other payers sought to address the challenge of food insecurity by coordinating the home delivery of medically

TABLE 6-1 | Payer Support for the Social Determinants of Health

Member Needs	Example of Payer Response
Service Coordination	• Several payers, including Anthem and Cigna, partnered with Aunt Bertha, a platform that identifies social services in the member's local area
Food Insecurity	• Some payers, including Humana and AmeriHealth Cartas, delivered meals to members' homes • Anthem performed direct outreach to help eligible members enroll in SNAP
Transportation Barriers	• Bright Health covered non-emergency medical transportation for its members
Mental Health Services	• Several payers, including Aetna and Anthem, waived cost-sharing for counseling and other mental health services • Many payers developed population-specific resources, such as Blue Shield CA's BlueSky Initiative and Humana's partnership with Papa

tailored meals and groceries during the pandemic, with a focus on reaching both high-risk and COVID-19 positive patients. Additionally, plans worked to address the mental health burden of the pandemic by funding support programs (e.g., Crisis Text Line, domestic violence prevention programs) and coordinating virtual services for social connection in specific populations (e.g., older adults experiencing loneliness) (AHIP, 2020a). While these actions represent select examples of payer engagement, it is important to note that there are limited data on the scope and impact of payer actions for health equity during the pandemic. Data collection and evaluation is needed to assess the benefits and challenges of different pandemic-era pilots, and effectuating systemic change will require translating philanthropic investments into structural changes in benefit design and payment policy, for which uptake to date has been slow (Meyers et al., 2020).

Financial Support for Health Care Providers

Clinicians and health care organizations faced unprecedented financial challenges in spring 2020 amidst a sharp decline in visits that were paid on a FFS basis, as individuals complied with safer-at-home and physical distancing protocols, delaying visits to their health care providers (Roehr, 2020). The Paycheck Protection Program and other federal initiatives did provide substantial resources to hospitals and other providers to help ameliorate the resulting losses. However, with grants from the Provider Relief Fund favoring larger health systems and Medicare's Advanced Payments program providing limited support to safety-net providers, many smaller, independent practices—which at baseline lack the levels of capital reserves possessed by hospitals and provider groups—continued to face severe cash shortages (Cubanski et al., 2020; PCC, 2020a; Rosenbaum and Handley, 2020).

Given the delays and flux in federal relief efforts, commercial payers were well-positioned to offer support to clinicians to meet payroll, operating expenses, and ongoing patient needs—particularly considering that the decline in health care spending and utilization during COVID-19 had translated into improvements in insurers' financial performance in terms of commercial payers' gross margins and medical loss ratios (Dafny and McWilliams, 2020; McDermott et al., 2020b). To this end, health plans adopted an array of alternative financing strategies to infuse short-term capital into the care delivery system. For example, some plans coordinated direct financial support for providers and hospitals through financing guarantees, advance payments, and opportunities to restructure contracts from FFS arrangements to value-based contracts (e.g., risk-sharing capitated payments) (Blue Shield California, 2020b). For providers already operating under value-based contracts, some plans worked to provide up-front payments of quality bonuses or expected savings. In addition to providing infusions of cash (the amounts of

which varied between payers and due to lack of data cannot be comprehensively reported), many plans committed to eliminating utilization management protocols or prior authorization in markets experiencing challenges with inpatient, intensive care, or post-acute care capacity. Furthermore, some plans developed payment models that offered participating providers guaranteed revenue in exchange for a commitment to enter a value-based payment arrangement at a future date (BCBSA, 2020).

Addressing COVID-19-Specific Delivery System Needs

Payers have worked to support the distribution of medical supplies and services throughout the pandemic, beginning with testing and tracing efforts. For testing, some plans have directly invested in diagnostic development and supported supply procurement, such as funding the development of alternative reagents and medical supplies for collecting patient samples (e.g., polyester swabs and saline transport) (UnitedHealthGroup, 2020a). For tracing, several plans have leveraged their technical capabilities to advance public health surveillance and create infrastructure to guide re-openings, including developing data exchanges with local health departments to assist with epidemiological mapping and to support testing and contact tracing functions (BCBSL, 2020). Second, some payers have contributed resources and logistical expertise to support the planning and distribution of medical supplies, such as PPE (BCBSSC, 2020; MI Blues Perspectives, 2020). Third, some payers have collaborated with the biopharmaceutical industry to support data sharing and evidence generation for the development of COVID-19 medical countermeasures, such as partnering to increase access to monoclonal antibodies and using claims data to identify high-risk populations for enrollment in COVID-19 vaccine trials (Minemyer, 2020; UnitedHealthGroup, 2020b). Fourth, following the authorization of the first COVID-19 vaccines, some payers have played an active role in supporting immunization campaigns in their local markets, including helping to coordinate distribution and using claims data to support post-market safety surveillance (Gutierrez and Myers, 2021).

Addressing Systemic Health Inequities

COVID-19 both exposed and exacerbated existing disparities in health outcomes, particularly along racial and ethnic lines. Consequently, several payers took action to address the pandemic's disparate impact. Some plans made resource and financial commitments during the pandemic to support the communities that were bearing a disproportionate burden of COVID-19 infections. Payer actions

to address patients' medical needs (e.g., by increasing access to health services for chronic disease management), social needs (e.g., coordinating supportive housing, meals), and COVID-19-specific needs (e.g., PPE distribution, testing) sought to address the environmental challenges contributing to health disparities where possible.

However, payers also recognized that meaningfully addressing health disparities and structural racism will require long-term, systemic action. Consequently, many plans adopted commitments to equity intended to extend beyond the pandemic, with some payers already beginning to initiate partnerships with providers oriented around health equity (e.g., Blue Cross Blue Shield of Illinois' Health Equity Hospital Quality Incentive Pilot Program) (BCBSI, 2020).

Regulatory Tailwinds: Federal Actions and Payer Responses

Transformative Flexibilities for Payment and Care Delivery

Unprecedented regulatory flexibilities and guidance from the U.S. Department of Health and Human Services (HHS) and CMS coupled with statutory mandates and resources from COVID-19 relief legislation generated momentum across payers to promote alignment in policy (e.g., coverage for COVID-19 care) and drive pivots in clinical practice (e.g., expansion of telehealth) to reduce barriers to accessing critical health care services during the pandemic.

For example, with shelter-in-place orders shuttering the doors of many outpatient health care facilities, CMS granted waivers for telehealth to expand access to patients while minimizing risk of exposure to COVID-19. When implementing flexibilities for telehealth, CMS worked with the Office of Civil Rights within HHS to enable the use of popular video-enabled mobile applications (e.g., FaceTime, Skype), which were not originally designed to be compliant with the standards set forth in the Health Insurance Portability and Accountability Act (HIPAA). Other key flexibilities include the temporary relaxation of many site-of-care restrictions on health care delivery, from CMS's "Hospital Without Walls" program to a commitment to reimburse services relocated to off-campus sites at traditional outpatient prospective payment rates (CMS, 2020c). Beyond federal action, many state insurance commissioners and Medicaid programs also introduced new flexibilities and requirements for commercial health plans (e.g., requiring waivers of cost-sharing, requiring guarantees of network adequacy) (Sidley Austin, LLP, 2021). Additionally, special enrollment periods for state-based (in 2020) and federal (in 2021) insurance marketplaces enabled plans to expand access to health insurance for individuals who may have lost coverage during the pandemic (Anderson and Drake, 2020).

Health Plan Responses

New federal and state mandates, rules, waivers, and guidance supported a rapid transformation in the health care payment and delivery landscape. In some cases, commercial payers changed their policies due to new requirements imposed by legislation and federal and state regulatory action. For example, the Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security (CARES) Act required all payers in the U.S. to cover the cost of COVID-19 diagnostic testing without cost-sharing. Likewise, states across the country directed health plans to expand access to virtual care, including eliminating originating site requirements and reimbursing telehealth visits at parity with in-person visits.

In addition to complying with regulatory requirements, some payers took further action. In some cases, commercial insurers implemented changes in health plan design that regulators recommended, but did not require. For example, several Medicare Advantage organizations waived cost-sharing for both COVID-19 and non-COVID-19 care for the duration of the pandemic, actions that CMS had encouraged but not required (Cubanski and Freed, 2020). Many payers also temporarily waived prior authorization requirements with varying degrees of specificity, from indication-specific authorizations (e.g., behavioral health) to facility-level policies (e.g., transfers to post-acute care) (AHIP, 2020a). In other cases, payers leveraged the momentum of new state and federal flexibilities to introduce changes with broader scope. For example, while Medicare's March 2020 policies for telehealth are set to expire at the conclusion of the public health emergency, select commercial insurers independently announced in 2020 that their plans would permanently extend coverage of telehealth services (BCBST, 2020). Likewise, although Medicare's advance payment program concluded in April 2020, several commercial insurers continued their provider refinancing and stimulus initiatives and designed these programs to serve as on-ramps for practices to transition into alternative payment models (APMs) after the public health emergency (BCBSNC, 2020).

The concerted actions of payers across the country may have played a key role in supporting the dramatic increase in the uptake of and appetite for telehealth in the U.S. One analysis found private health care claims for telehealth services increased from 0.15% in April 2019 to 13% in April 2020, a more than 8,000% increase (FAIR Health, 2020). Additionally, CMS reported that the weekly number of beneficiaries in FFS Medicare receiving telehealth services increased from 13,000 to nearly 1.7 million during the pandemic (Verma, 2020a). While the increased utilization of telehealth has not completely offset the decrease in in-person visits, and levels of telehealth use have declined significantly as the U.S. begins to remove physical distancing restrictions, nationwide telehealth usage still substantially exceeds pre-pandemic levels, particularly among large provider organizations

TABLE 6-2 | Payer Strategies to Support the Transition to Virtual Care

Focus Area	Payer Strategies
Patient Barriers to Access	• **Communication:** Member outreach initiatives and patient-facing websites • **Accessibility:** Online toolkits for sign up, scheduling, and reminders
Provider Barriers to Access	• **Communication:** Technical assistance, learning collaboratives, webinars, practice outreach • **Administration:** Clarification of billing processes, alignment of case management
Expanding Service Offerings	• **COVID-19:** Triage, testing coordination, patient guidance and education • **Non-COVID-19:** Chronic disease management, home visits and case management, adaptation of specialty-specific services
Expanding Delivery Capacity	• **Network Growth:** Increasing number of in-network providers; leveraging vendor platforms to alleviate strain on providers • **Provider Support:** Financial support for alternative care sites (e.g., Federally Qualified Health Centers)
Integrating Digital Health Tools	• **COVID-19:** Mobile applications for symptom assessment • **Non-COVID-19:** Support tools for mental health (e.g., anxiety, depression)

(greater than 6 clinicians) and within select specialties (e.g., behavioral health, endocrinology) (Fox and Sizemore, 2020; Mehrotra et al., 2020). Although the key driver of utilization growth was the realignment of financial incentives, many payers also made process and operational changes to support patient access to services and increase provider comfort with virtual care modalities. These strategies spanned member outreach initiatives, streamlined billing processes, and coverage for and integration of new digital health products, as summarized in *Table 6-2*.

Regulators and industry experts reflecting on the scope of the payer sector's COVID-19 activities described above have posited that the magnitude and duration of the pandemic have generated an impetus to drive lasting sector-wide change (Ross, 2020). However, many pandemic-era policy flexibilities and operational changes are set to officially expire at the conclusion of the public health emergency, and the current lack of comprehensive policy proposals for long-term extension, coupled with the historical inertia of the health care system, present roadblocks to durable change. To truly achieve a "new normal," payers will need to make forward-looking decisions that build upon pandemic-era innovations in plan design (e.g., telehealth coverage, utilization controls), while policymakers will need to develop regulatory and legislative solutions that apply the momentum from COVID-19 to accelerate progress for pre-pandemic goals (e.g., transition to value). The next section outlines the challenges that payers will have to address to achieve these goals, including navigating the financial aftershocks of the pandemic and managing evolving stakeholder expectations about plan policies.

KEY PANDEMIC-ERA CHALLENGES FOR PAYERS

Although the pandemic accelerated long-overdue changes to payment and delivery, the destabilizing nature of the public health emergency has also exposed systemic challenges and vulnerabilities for payers, and the sustainability of payment and care changes implemented in the public health emergency is not yet clear. Health plans will need to navigate an uncertain market while adjusting to the new expectations of patients, providers, and employers, whose behaviors and incentives have shifted markedly after COVID-19 upended numerous health care norms.

This section outlines the key short- and long-term challenges for payers in the post-pandemic era, including:

1. Navigating the actuarial uncertainty resulting from the uncertainty of enrollment;
2. Managing evolving expectations for benefit design (e.g., cost-sharing, prior authorization);
3. Monitoring the risk of fraud and disparities arising from new regulatory flexibilities; and
4. Evaluating implications of COVID-19 for rate setting and risk adjustment in value-based programs (see *Figure 6-3*).

Uncertainty in Health Insurance Coverage

At its core, a viable insurance business requires accurate actuarial estimates of risk. In order to set premiums and service prices, payers need to predict what enrollment will be, which products their clients and patients will choose, what the levels of service use will be, and how regulatory changes may affect their operations. Notably, this forecasting must occur well in advance of marketing for the following year. The COVID-19 pandemic introduces significant new uncertainties into each of those parameters.

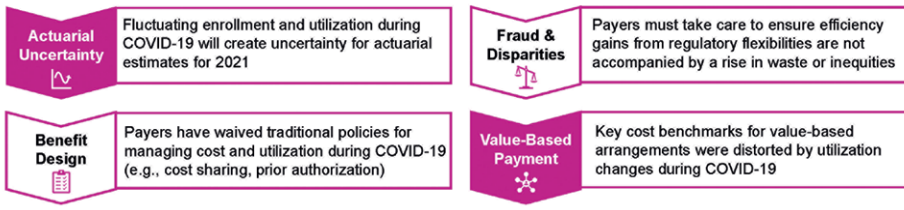

FIGURE 6-3 | Key Challenges for Payers for the Post-Pandemic Era

Consider first the challenges of enrollment. Due to the prominence of employer-sponsored insurance in the U.S., rates of health care coverage are a likely casualty of the pandemic-induced economic recession. Analyses suggest nearly three million Americans lost employer-sponsored health insurance between March and September 2020, with losses disproportionately affecting Latinx individuals (McDermott et al., 2020a). While the post-pandemic implications for U.S. payers will differ significantly from the aftermath of previous economic recessions due to the presence of the Affordable Care Act (ACA)—with the exchange and Medicaid expansion increasing options for coverage—many Americans may still struggle to afford the cost of health insurance, especially given that coverage losses were more likely to affect low-wage workers. Payers experiencing significant shifts in enrollment from commercial to Medicaid and ACA exchange products must attempt to predict how those trends will shift. Forecasting churn has been especially challenging given that compensatory Medicaid enrollment during the pandemic recession has been lagging thus far, and the magnitude and rate of change will continue to evolve in tandem with economic and pandemic-related developments (Frenier et al., 2020).

Furthermore, while health care utilization has rebounded substantially since the early days of the pandemic, the recovery has been uneven across specialties, and many providers continue to face financial uncertainty. As of October 2020, outpatient volumes had recovered from a nadir of 58% to be on par with normal levels of utilization (Mehrotra et al., 2020). However, the recovery is heterogeneous; for example, weekly visits exceed pre-pandemic levels for specialties such as dermatology (+17%) and adult primary care (+13%), but remain below baseline levels for specialties such as pulmonology (−20%) and behavioral health (−14%). At the inpatient level, overall volumes still remain below pre-pandemic utilization rates, with medical service lines (e.g., cardiology, nephrology) recovering more quickly than surgical service lines (e.g., orthopedic surgery, general surgery) (Strata Decision Technology, 2020). Financial stability remains a concern for many providers, particularly primary care physicians, of whom one-third report volumes more than 30% below pre-pandemic levels and a quarter report pandemic relief to have run dry as of September 2020 (PCC, 2020b).

While many aspects of utilization have returned toward pre-pandemic levels, employers nonetheless anticipate pent-up demand to increase medical costs in 2021. Insurers have cited additional potential for both upward (e.g., from COVID-19 testing) and downward (e.g., from avoided care) pressures on spending (McDermott et al., 2020b; PriceWaterhouseCoopers, 2020). To be clear, health insurers generally remained profitable during 2020, and will likely be required to provide substantial rebates to members and the government due to regulatory requirements for medical loss ratios (McDermott et al., 2020b). Several states also established risk-sharing corridors in 2020, and CMS issued new guidance in December 2020 to

clarify health plans' obligations for rebates based on pandemic-induced changes in medical loss ratios (CMS, 2020d). However, continued spikes in caseloads and unpredictability in utilization does create challenges for health plans. For example, the increase in COVID-19 cases and costs in the fourth quarter of 2020 led to substantial declines in operating income for several major health plans, illustrating the volatility of the pandemic (Tepper, 2021a; Tepper, 2021b).

The potential for additional waves of infection in 2021 adds further uncertainty to efforts to estimate enrollment and calculate premiums. For example, insurers have reported that pandemic-induced declines in utilization—and the subsequent changes in risk code selection—create challenges for health plans to accurately price their services (Bannow et al., 2021). Likewise, the severity of subsequent cases and the advent of new treatments (e.g., antibody therapies) and vaccines (e.g., vaccine administration costs) for COVID-19 will affect cost forecasts for payers. Furthermore, new public health restrictions may create new delays in non-COVID-19 care delivery while also exacerbating existing health burdens (e.g., chronic disease management, mental health), creating further uncertainty for payers in the future. Lastly, even employer clients who did not implement layoffs may feel pressure to change their benefit structures and place even more cost-sharing on employees, which in turn could have short- and intermediate-range effects on care-seeking behavior and outcomes such as complications from delayed treatment. Payers will therefore face much greater uncertainty in their actuarial estimates for 2021 than they are accustomed to.

Evolution of Benefit Design

Payers will have to reconsider whether and how to adapt their benefit structures and care management approaches to ensure sufficient access to high-value care for patients. Some key areas of focus are detailed below:

Cost-Sharing

Prior to the pandemic, the benefit structure of commercial health insurance had evolved toward greater patient cost-sharing, with average deductibles quadrupling between 2006 and 2017 (KFF, 2017). As noted above, delayed medical care in 2020 due to COVID-19 may incentivize employers to favor greater cost-sharing to control elevated medical costs in 2021. However, cost-sharing today—which by law, excludes COVID-19 testing and treatment—may already present untenable barriers to routine management of chronic diseases or acute care, especially when layered on top of the fear and logistical challenges of obtaining in-person services during a pandemic. Suspicions of reduced emergency department visits and hospitalizations for patients with strokes or myocardial infarctions, and

higher-than-expected numbers of home deaths during COVID-19, reinforce this concern (De Filippo et al., 2020; Diegoli et al., 2020).

During the pandemic, many payers introduced waivers for cost-sharing—primarily within Medicare Advantage—with some payers eliminating all cost-sharing for primary care and behavioral health services in this population. Health plans will need to evaluate the appropriateness of either allowing these policies to expire or extending them beyond COVID-19. Furthermore, the presence of indication-specific cost-sharing waivers (e.g., for COVID-19) raises the question of whether similar policies should be adapted for other diseases, especially given that smart medical management in the era of chronic illness requires strategies focused on increasing access to specific services rather than creating barriers to utilization. For example, over 34 million Americans have diabetes, yet many health plans have cost-sharing policies for diabetes medications, with such policies associated with reductions in medication adherence (CDC, 2020; Snider et al., 2016). While cost-sharing may be a useful tool for curbing the utilization of low-value services, the COVID-19 experience should prompt payers to reconsider the appropriateness of such policies across different clinical indications, with the principles of value-based insurance design providing an avenue to promote better outcomes while also addressing disparities in care (Choudhry et al., 2014; Chernew et al., 2007).

Prior Authorization

Insurers' usual focus in care management has been to reduce utilization by requiring providers to receive preapproval before being reimbursed for health services, a process known as prior authorization. During the pandemic, many insurers reduced or waived prior authorization requirements for different aspects of COVID-19 care, including durable medical equipment (e.g., respiratory services), diagnostic testing, patient transfers, and inpatient or emergency medical care (AMA, 2020). A key question for payers is whether they will extend such flexibilities to non-COVID-19 indications. Administrative expenses for prior authorization have been estimated in the billions, and critics claim that the existing process places undue financial liability on patients (Cutler, 2020; Gaines et al., 2020). Physician groups have urged for simplification of prior authorization processes, including identifying supporting payment models (e.g., lower authorization burden under APMs), implementing procedures for automation, and developing criteria for use to minimize provider burden (AMA, 2018).

Guardrails for Oversight

During the pandemic, many payers made time-limited commitments to paying for telehealth at rates equivalent to in-person visits. While trends in adoption vary

across populations and specialties, supporting the long-term uptake of telehealth services will require health plans to develop policies and payment strategies to support this transition in care delivery.

First, it will be important for payers to ensure that reimbursement policies account for the spectrum of telehealth services. Telehealth encompasses both audio and video services, and virtual care can also include integration with digital health products and remote patient monitoring services. Different care platforms have distinct advantages and limitations, and health plan policies will need to account for the value of different use cases, including frameworks for adjudicating when virtual care is and is not a medically appropriate substitute or complement to in-person care (Jaklevic, 2020). Plans will also need to invest in data collection and intervention evaluation, given that rigorous evidence on telehealth's capacity to effectuate cost reductions and outcomes improvements remains nascent.

Second, as virtual care becomes a permanent feature of care delivery, payers will need to equip themselves to evaluate the risk for fraud and abuse. For example, a 2019 federal investigation revealed how a scheme defrauded the Medicare program of $1.2 billion by using telehealth to inappropriately prescribe medical equipment (FBI, 2019). The Office of the Inspector General within HHS identified an additional $4.5 billion in so-called "telefraud" schemes during its September 2020 report (Muchmore, 2020). Clarifying the need for and scope of guardrails will require payers to perform audits and other analyses of services rendered during the pandemic. For example, payers may not have had time to build in claims edits to disallow services like chemotherapy or diagnostic imaging to be billed under "telehealth." Consequently, mechanisms for appropriate oversight will be necessary to ensure that telehealth does not replicate the existing challenges of waste within the health care system. One avenue for developing guardrails without replicating the administrative burdens associated with in-person care would be to leverage alternative payment models, as population-based financing strategies can naturally disincentivize against the unnecessary utilization of both in-person and virtual services.

Third, considerations of telehealth's efficiency should be paired with concerns about equity. Payers need to judge when and how shifts to virtual care may have exacerbated disparities in access and care quality. For example, video-based services may not be as accessible for rural communities with limited access to high-speed internet, or among low-income households where multiple family patients might be relying on a single device for remote work or learning. In these instances, payers could improve outcomes by helping providers ensure a safe, rapid return to in-person services, such as through direct outreach to affected patients or incentives for providers to prioritize specific cases.

From a regulatory perspective, many states issued waivers of scope-of-practice laws and credentialing requirements during the pandemic to allow providers

licensed in one state to provide telehealth services to patients in another state to accommodate demand for virtual care during the public health emergency. Payers will need to monitor the extension or expiration of these waivers, which in turn may affect network development for telehealth. It is possible that patients and providers who are now accustomed to new modes of accessing and delivering care may react negatively if regulators and payers revert wholesale back to historical policies. Payers could seize the opportunity to leverage consumer sentiment and advocate for more and permanent reciprocal licensure agreements across states.

Securing the Future of Value-Based Payment

For the significant percentage of providers in value-based payment arrangements, payers will have to decide how to reconcile such contracts for time periods directly affected by COVID-19 and how to amend them for future years. Shifts in enrollment and visit patterns, whether in-person or virtual, could change the number and makeup of patients who are attributed to providers in value-based payment arrangements based on claims patterns. Arrangements with spending targets set as a percentage of medical loss ratios or prospectively set cost trends could result in providers receiving payouts from pandemic-related drops in utilization rather than through their own care management efforts. Even arrangements that rely on actual market-based cost trends could prove problematic for payers and providers, as it remains unknown whether COVID-19-driven changes in utilization were homogeneous across all providers in a given community.

Quality Measurement and Risk Adjustment

Because of lockdowns, the migration to digital care, and changes in care-seeking behavior, providers are justifiably anxious that quality measurement—a key component of many value-based payment arrangements—could yield distorted results for 2020. As a result, many payers have offered relief in quality scoring during the pandemic. For example, CMS will allow providers in the Medicare Shared Savings Program to pick the "better of" quality scores for 2020 or 2019 in quality scoring. This offers the benefit of preventing some providers from being unfairly penalized by COVID-19, but also carries the downside of limiting rewards to providers that did achieve meaningful performance improvements over the measurement period (CMS, 2020e). Nevertheless, payers will still need to work with measure stewards such as the National Committee for Quality Assurance to ensure that measure specifications will account for disruptive changes like the shift to telehealth. Furthermore, to the extent that spending performance and trends are risk-adjusted, payers and their risk adjustment vendors will need to

consider not only variation in COVID-19 infection rates and treatment, but also variable changes in non-COVID-19 care as a result of the pandemic.

Securing Buy-In for Value

Payers were already collaborating with providers to move away from volume-based to value-based reimbursement prior to the pandemic, with over a third of all health care spending before COVID-19 occurring under APMs before COVID-19 (HCP-LAN, 2019). With providers experiencing substantial financial and operational pressures during the pandemic, advocates exhorted payers to take actions ranging from offering advance payments to practices under FFS arrangements to relieving providers under value-based contracts from methodologic uncertainties and exposure to downside risk in the short term (Dafny and McWilliams, 2020). Calls for payers to take action were amplified after financial records indicated that prominent insurers registered medical loss ratios (MLRs) below 80% and also realized substantial profits during the second quarter of 2020 due to pandemic-induced declines in utilization (Abelson, 2020; Livingston, 2020a; Livingston, 2020b). While payers who meet government-determined criteria for MLRs will be required to provide consumers with rebates, the broader increase in gross margins per member per month (e.g., 35% increase in Medicare Advantage) spurred calls for health plans to increase their contributions to health system and public health needs (McDermott et al., 2020b; Plott et al., 2020).

Although the financial impacts of the pandemic (e.g., membership loss, cost-alleviation activities), actuarial uncertainty (e.g., about pent-up service demand), and obligations to clients (e.g., self-insured employers) may present challenges for payers, COVID-19 does create a unique value proposition for health insurers to accelerate the realignment of financial incentives to promote delivery system transformation. Proposed strategies have ranged from conditioning provider relief payments on investments in value-based capabilities and commitments to transitioning to APMs, which can include partial or fully capitated arrangements (Duke-Margolis Center for Health Policy, 2020a). Existing value-based arrangements may also merit reconsideration, as many APMs are built on top of the chassis of FFS, and the current retrospective approach to reconciliation is unlikely to offer providers the necessary financial certainty given how revenue gaps have widened during the pandemic (Pittman and Edwards, 2020).

Payers will consequently face several challenges when securing buy-in for value. For one, commercial payers will need to make a defensible case to clients that continuing to pay per-member per-month fees for infrastructure and care coordination are worthwhile investments to not only continue but also significantly improve providers' financial resiliency. Adding to this challenge is

the long-term view required for payers and their clients to realize the returns on investments in APMs given evidence on the time period required for providers to successfully transition to risk-bearing arrangements (Bleser et al., 2019).

Such decisions are but one example of how payers are "sandwiched" in multi-directional relationships with providers, regulators, and clients, creating challenges for the future of value-based payment across different plans and products. Payers offering Medicare Advantage plans will need to navigate how drops in utilization in traditional Medicare in 2020 (and likely 2021) will affect both future rate-setting and future CMS decisions to adjust pre-existing concerns around upcoding and risk adjustment. Payers covering employed populations will need to seek voluntary alignment in policies between self-insured employer clients and fully insured populations, and all payers will need to set payment policies with an aspiration of transparency so that providers can understand them, while also adhering to state or local mandates (e.g., for benefits, network adequacy).

Going forward, payers have important, stabilizing roles to play to ensure that patients get the care they need, high-value providers can survive and thrive, and clients feel confident that their health care investments are justified and appropriately spent. Payers will need to be creative and nimble in both responding to and anticipating COVID-19 challenges and avoiding unintended consequences.

OPPORTUNITIES FOR SECTOR-WIDE PERFORMANCE IMPROVEMENT

The COVID-19 pandemic required payers to engage with providers and policymakers to facilitate rapid transformation of care delivery during the pandemic. However, early trends of reversion to past behavior and the looming expiration of regulatory flexibilities pose challenges to the durability of these changes. Sustaining health system transformation beyond COVID-19 will require payers to intentionally pursue sector-wide performance improvement. Several of these opportunities will require the preservation of regulatory changes and the continuation of shifts in payment and practice patterns that have occurred during the pandemic. Others, such as revising APM designs or broadening the use cases for COVID-19 tools, will require further infrastructure investments. Notably, the mechanisms for sector-wide improvement will differ depending on the payment models that health insurers are using; for example, the prevalence of telehealth flexibilities prior to the pandemic was substantially higher among providers participating in APMs as compared to FFS (Zhao et al., 2020). Consequently, this section categorizes the key opportunities for sector-wide improvement along two domains: FFS opportunities (e.g., telehealth adoption, utilization controls) and value-based opportunities (e.g., APM growth, social determinants of health) (see *Figure 6-4*).

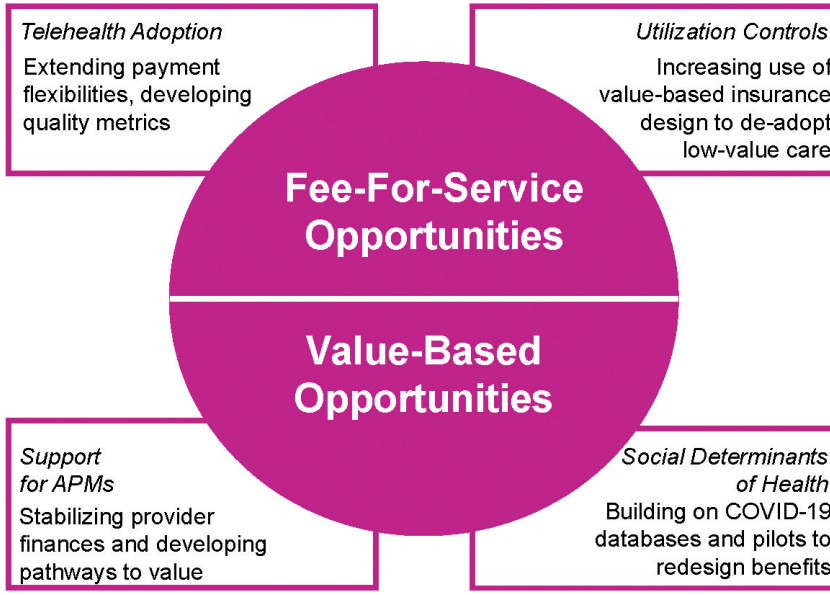

FIGURE 6-4 | Opportunities for Sector-Wide Improvement

FFS-Based Opportunities

Despite the growth in APMs over the past decade, the majority of physician office visits are still reimbursed under FFS, and the majority of APMs still rely on an FFS architecture (HCP-LAN, 2019; Zuvekas and Cohen, 2016). While the pandemic has re-highlighted the instability of FFS and increased interest in APMs, which span bundled payments and partially and fully capitated arrangements, it is likely that FFS will still remain a prevalent approach to health care payment for the foreseeable future. However, payers can build on two key COVID-19 levers—telehealth flexibilities and utilization controls—to increase the value and convenience of care under FFS.

Telehealth Adoption

The adoption and proliferation of telehealth has been a silver lining success story of COVID-19. After CMS implemented payment parity for telehealth services, many commercial payers followed suit, in some cases extending payment parity for services across specialties. Most commercial payers eliminated all cost-sharing for telehealth care related to the diagnosis and management of COVID-19-related symptoms. Multiple payers also eliminated cost-sharing for all telehealth use (primary care, urgent care, behavioral health care) for the 2020

calendar year to reduce the chances of exposure, and many payers also announced payments for a broader set of telehealth services, many of which can now be billed by non-physician health care practitioners.

A recent survey of health care providers reported that almost half expected to use telehealth at the same or greater levels post-pandemic, a marked change compared to pre-2020 levels of utilization (OASPE, 2020). This is meaningful for several reasons. First, telehealth has important benefits for patients, such as convenience, continuity, affordability, and speed. This may improve access to care overall and, in particular, for services that require frequent "touches" or have traditionally experienced access challenges. For example, mental health services, including screening for conditions like depression, are one area where the benefits of telehealth may far outweigh the additional costs or tradeoffs between remote and in-person care. Examples of additional high-value use cases for telehealth are summarized in *Figure 6-5*. Second, the technology required to conduct telehealth visits has existed for years. The sector has overcome inertia generated by the lack of financial incentives and cultural resistance to change to achieve widespread adoption and use.

Despite the benefits and uptake of telehealth during the pandemic, there remain several open questions. First, payers must work with health care providers and other stakeholders to learn how to best deploy telehealth at scale to those who need it most in a way that improves patient experience and outcomes. One area of focus is to use telehealth to bolster existing provider-patient relationships, rather than as a temporary substitute due to office closures. For example, incorporating telehealth into the continuum of surgical care (e.g., virtual options for pre- and post-operative visits) could improve access and efficiency. Successfully deploying telehealth as a means to enhance care continuity and coordination will require

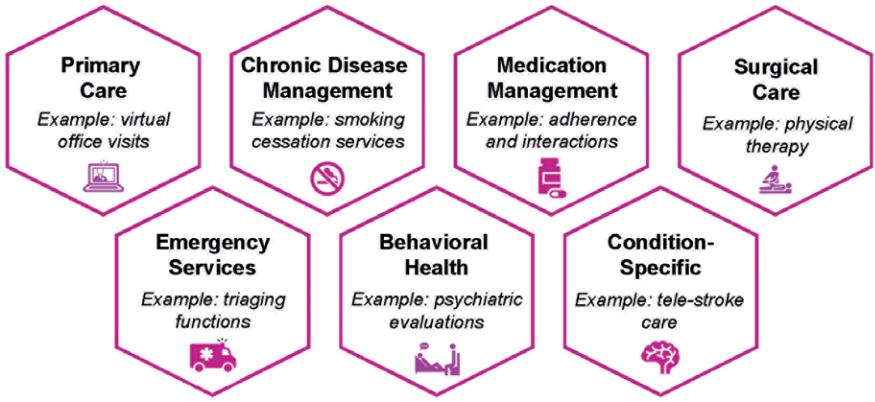

FIGURE 6-5 | Select Examples of Clinical Use Cases for Telehealth

devising and tracking appropriate quality and experience metrics, some of which may have to be adapted for monitoring telehealth use rather than in-person visits specifically. In a related innovation proposal, the National Quality Forum has suggested a framework for telehealth quality measurement (NQF, 2017a).

Second, payers must proactively work to address ways that technology-based care could exacerbate existing access gaps and racial, ethnic, socioeconomic, geographic, and other disparities in care. Nearly 20% of Americans still lack access to smartphones, including almost half of senior citizens (Pew Research Center, 2019). Additionally, some communities continue to experience significant gaps in home-based internet access (FCC, 2018). Payers will need to consider these gaps and barriers to patient engagement, including access to devices and hardware, comfort with technology, and levels of health literacy in order to design effective programs. This will likely require tailoring the design of telehealth programs to the specific needs of certain populations and will also likely require payers to invest directly in telehealth solutions rather than depend wholly on health care providers. The importance of payer investments may be particularly important for complex populations with multiple medical or interconnected social needs. Furthermore, payers may choose to provide more intensive support to providers serving safety net populations, such as federally qualified health centers.

Utilization Controls

As noted in the preceding section on "Key Pandemic-Era Challenges for Payers," payers rapidly evolved their policies for cost-sharing and prior authorization to streamline access to care and facilitate rapid payments to providers during COVID-19.

The opportunity for payers moving forward lies in consolidating these efforts into a more systematic, strategic, and equitable approach to supporting patients to get high-value care and forego low-value care. In the case of prior authorization, the recent expansion of CMS's Medicare Prior Authorization Model for Repetitive, Scheduled, Non-Emergent Ambulance Transport—which saved $650 million over four years—is an example of how payers can develop tailored strategies for utilization controls that reduce costs without compromising care quality and access (CMS, 2020f). Moving forward, payers will need to work with providers to achieve a convergence between pandemic-era pilots and standard process controls for health plans. A more expansive adoption of value-based insurance design principles could help payers appropriately redesign utilization controls such as cost-sharing to reduce waste in chronic disease management (e.g., for durable medical equipment selection) and increase the affordability of comparatively higher value services (Mattina, 2020). Previous work, including some under the auspices of the National Academy of Medicine, offers examples of low-value

services—several of which experienced significant declines in utilization during the pandemic—that would be appropriate candidates for exclusion during benefit redesign (Kim et al., 2020; IOM, 2013). Payer-provider partnerships may also accelerate progress, although this will likely require alignment vehicles like value-based payment models to engage providers. For example, payers and providers can collaborate to develop alternative care pathways to reduce low-value service utilization (e.g., for managing joint pain), and insurers can help support the development of high-value provider networks (Sorenson et al., 2020).

Value-Based Opportunities

Although FFS remains the dominant form of health care payment in the U.S., the expansion of APMs and resulting evidence of cost savings prior to COVID-19, coupled with increased interest in models such as capitation during the pandemic, creates a window for health insurers to accelerate the transition to value across the system. Payers can start by increasing their support for APM arrangements, and can frame payment reforms as an extension of pandemic-era efforts to stabilize provider finances (Gondi and Chokshi, 2020). Payers can also build on the investments in technical capabilities (e.g., risk stratification of populations, remote patient monitoring) and focus on non-medical needs from COVID-19 to design payment models capable of better addressing the social determinants of health.

Support for APMs

The COVID-19 pandemic has exposed the vulnerability of a FFS system—long seen as the "safe" status quo—to providers. Those providers who were prepaid for the populations they serve were better positioned to rapidly transform their practices to meet their patients' needs and manage the financial uncertainties of the pandemic. For example, several fully capitated primary care practices were able to rapidly reorient their care models to focus on keeping patients safe at home while avoiding unnecessary hospital admissions (Ikram et al., 2020; Roiland et al., 2020). To support these providers, some payers developed prepayment models to accelerate the transition to telehealth for primary care practices in their networks (Koller and Shih, 2020). Furthermore, numerous plans offered relief payments, with particular focus on independent physician practices, to help providers bridge cash flow shortfalls during the public health emergency. The implications extend beyond primary care; for example, preliminary reports from Maryland and Pennsylvania highlight the value of APMs for hospital payments—so-called global budgets—during the pandemic (Levy et al., 2020; Fried et al., 2020; Peterson and Schumacher, 2020).

These experiences have revived discussions about risk-based payment models nationwide and reinforced the importance of collaboration between public and private payers. To help existing value-based initiatives weather the pandemic, CMS made a number of changes to ongoing models including suspending or postponing them, giving participants greater flexibility in which metrics are assessed, and adjusting baselines and benchmarks (Verma, 2020b). Some commercial payers developed bridges from pandemic-era payment initiatives to value-based models for their providers. CMS also announced the Community Health Access and Rural Transformation (CHART) Model—which builds on the experience of the Accountable Care Organization (ACO) Investment Model—which will use advance payments to strengthen the resiliency of health financing for rural practices (CMS, 2020g; Trombley et al., 2019). These initiatives are emblematic of efforts by many payers to forgive losses and continue paying prospective fees to support activities like care management to help providers maintain financial stability.

Investing in the Social Determinants of Health

Many payers developed new capabilities to understand the social context of their patients and accordingly manage their non-medical needs during COVID-19. These efforts included systematic screenings for social needs, the development of geographical maps to identify patients with needs related to the social determinants of health, and the direct provision of services. For example, Blue Shield of California developed a "Neighborhood Health Dashboard" that was used to create California's Vulnerability Index to guide the deployment of services and resources for COVID-19 recovery (Blue Shield California, 2020c; Bright Health, 2020). Humana made well over one million proactive phone calls to its highest risk patients to assess social needs, layered those results on a national registry of results from over three million surveys about health-related social needs, and leveraged patient-level predictive models to assess risk of social isolation in the deployment of a nationwide basic needs team to deliver interventions addressing social context related to the pandemic. Payers also offered supplemental benefits during the pandemic, from Humana's delivery of nearly one million meals to its patients to Bright Health's coverage of non-emergency transportation.

These efforts illustrate the untapped potential for payers to implement systematic strategies to identify, measure, and address structural inequities surrounding access, quality, and outcomes. The challenge for payers will be transforming these one-off, pandemic-era pilots into coordinated efforts to make meaningful and sustainable progress on health disparities. APMs can provide a powerful vehicle for achieving these goals. Several models prior to the pandemic illustrate the feasibility and value of this approach for different domains in the payer sector, including North Carolina

Medicaid's Healthy Opportunities Pilots, the expansion of supplemental benefits under Medicare Advantage, and CMS's Accountable Health Communities Model (Crook et al., 2021; CMS, 2020h; Cohen et al., 2020; Hostetter and Klein, 2020a).

Moving forward, payers could use the data collected during COVID-19 to help inform the design and evaluation of supplemental benefits for Medicare Advantage. These benefits, which now include social support services, have had limited uptake by commercial insurers to date, with plans reporting evidence gaps and the complexities of decision-making as the key challenges (Thomas et al., 2019). Payers could also consider developing metrics and financial incentives that reward progress on disparities, and explore the feasibility of risk adjustment for the social determinants of health (NASEM, 2016; OASPE, 2016).

TRANSFORMATIVE SECTOR-WIDE POLICY, REGULATORY, AND LEGAL CHANGES

While the pandemic is still ongoing at the time of this paper's publication, it is already evident that the adaptive responses to COVID-19 can offer a model for payers' long-term transformation. However, it is important to acknowledge that the health system is biased towards inertia; indeed, early trends of reversions to past practices of payment and delivery coupled with the impending expiration of statutory authority for COVID-19 flexibilities create the risk that the system's "new normal" will not meaningfully differ from the "old normal." As described in the preceding section, payers will need to play an active role in driving durable, sector-wide change. These efforts must be paired with policy planning, regulatory guidance, and legislative changes to build on the temporary momentum for health care transformation generated by COVID-19 (*Boxes 6-1–6-4*) and also improve the payer sector's preparedness for future public health emergencies (*Boxes 6-5–6-6*). Priority areas for consideration within those two domains include:

1. Accelerating the transition to value-based payment;
2. Extending flexibilities for virtual health services and capabilities;
3. Rethinking benefit design using the principles of value-based insurance;
4. Aligning incentives and investments to address health inequities;
5. Creating mechanisms for collective action during public health emergencies; and
6. Coordinating payment reforms with public health functions.

Accelerating the Transition to Value-Based Payment

The development of APMs over the past decade enabled the health care system to make meaningful progress towards the goal of better care at a lower cost.

An implicit consequence of APMs—enhancing the financial resiliency of providers—took on explicit importance during the pandemic as COVID-19 exposed the longstanding vulnerabilities of a payment system grounded in FFS (Gondi and Chokshi, 2020). Delivering on this new impetus for payment reform requires policy guidance and regulatory action to accelerate the transition to value-based payment.

First, as recommended by a bipartisan group of former CMS Administrators, regulators could offer loan forgiveness for Medicare payments conditioned on a commitment from providers to transition from an FFS arrangement to an APM in the near future, with APMs ideally exhibiting the characteristics of Category 3B or Category 4 models as outlined by the Health Care Payment Learning & Action Group (McClellan et al., 2020a; HCP-LAN, 2017). Commercial payers can complement such regulatory actions by creating pathways to value for providers in their own networks. These immediate steps can create a foundation for financial resiliency beyond the pandemic.

Second, as new providers enter APMs, regulators should consider how extending other COVID-19 flexibilities can smooth the transition. For example, in April 2020, CMS issued a waiver that provided site-of-care flexibilities for health services traditionally delivered in hospital outpatient departments. Regulators could consider incorporating elements of the waiver into existing (e.g., Oncology Care Model) and new (e.g., Hospital at Home) payment and delivery models focused on specialty care (Bekelman et al., 2020). Likewise, using APMs as the vehicle to extend COVID-19 flexibilities for telehealth (e.g., via the "meaningful use" provisions suggested above) could enhance care coordination and mitigate the risk of unnecessary utilization.

Third, regulators should consider how to create pathways to value for providers for whom APMs are not currently available. For example, specialists' participation in APMs is generally lower due to the lack of condition-specific payment models. In the interim, CMS could encourage such providers to participate in evidence-based care transformation programs while regulators work to develop appropriate new APMs (Duke-Margolis Center for Health Policy, 2020b). Likewise, safety net providers have struggled under value-based arrangements such as the Merit-based Incentive Payment System (MIPS), and are underrepresented in several demonstration models (Khullar et al., 2020; McCullough et al., 2019). A truly resilient system of health care financing should incorporate the principles of equity-focused design (HCP-LAN, 2020). Using the experience of Maryland and Pennsylvania, CMS could work with states to explore opportunities to develop new multi-payer APMs inclusive of all types of practices within defined geographies.

Fourth, APMs provide a framework for payers and providers to sustain pandemic-induced efficiency improvements to care delivery. Strategies to increase access to care during COVID-19 (e.g., by virtualizing components of the patient journey

where clinically appropriate) can be broadened to new use cases after the pandemic and promote leaner and more convenient models of care. However, achieving long-term reductions in operating costs will require realigning financial incentives to support changes in site-of-service and resource utilization. For example, Hospital at Home models can improve care convenience and health outcomes, as well as free up inpatient capacity, and new regulatory flexibilities have supported their growth during the pandemic (CMS, 2020i). Developing APMs such as a bundled payment for a defined episode of care can offer payers and providers an avenue for scaling Hospital at Home beyond COVID-19 that promotes both resource efficiency and accountability for outcomes (Hostetter and Klein, 2020b).

Lastly, payers should use the framework of value-based payment to operationalize the additional priority actions for the sector outlined in this section. For example, APMs can offer payers and providers the necessary flexibility to support care delivery models that blend together in-person visits, virtual platforms, and alternative care sites. Likewise, APMs such as capitated models can provide a framework for payers to redefine benefit categories to better meet patient needs while disincentivizing the utilization of low-value care. Furthermore, APMs can help foster accountability for health equity by realigning financial incentives to focus provider investments and accountability for addressing health disparities.

Priority areas for accelerating the transition to value-based payment are summarized in *Box 6-1*.

Extending Flexibilities for Virtual Health Services and Capabilities

A lasting legacy of the COVID-19 pandemic will be the substantial expansion of virtual health services and capabilities in the American health care system. These capabilities include modality changes for patient encounters (e.g., audio or

BOX 6-1

Considerations for Accelerating the Transition to Value-Based Payment

- Leverage pandemic-era initiatives to stabilize provider finances to create new pathways encouraging providers to enter into APMs
- Use APMs as a vehicle for scaling site-of-service flexibilities beyond COVID-19
- Broaden the accessibility of value-based payment programs for all provider types, with a focus on embedding accountability for health equity into APM design

video-enabled telehealth services) and new tools for supporting remote patient monitoring and chronic disease management (e.g., different types of digital health products).

For example, the utilization of telehealth expanded substantially in 2020 compared to 2019, with the percentage of physician office visits conducted via telehealth reaching a peak of nearly 14% in April 2020 before approaching a temporary equilibrium at approximately 6% as of October 2020 (Mehrotra et al., 2020). Utilization growth was enabled by Medicare waivers and state insurance department mandates to reimburse virtual service delivery at parity with in-person care, with broad discretion across provider types (e.g., physician, nurse) and virtual platforms (e.g., Zoom, FaceTime) (CMS, 2020j). These flexibilities have significant implications for improving the accessibility and convenience of care across the spectrum of care delivery, and the response of providers and patients during the pandemic coupled with new partnerships across sectors to diversify, integrate, and scale virtual models suggest that telehealth will continue to be a growing component of care delivery. However, the scientific literature still lacks a rigorous evidence base demonstrating the comparative cost-effectiveness of virtual care delivery platforms—a gap that payers will need to help fill by drawing from data generated during COVID-19 and developing infrastructure for future evaluations.

Consequently, while regulators should certainly extend reimbursement flexibilities for platforms where the evidence demonstrates improvements in care delivery, payers must take proactive steps to ensure that the virtualization of health services is not accompanied by the replication (and potential exacerbation) of existing cost centers. A key consideration is that COVID-19 telehealth flexibilities were rooted in the construct of FFS, rendering temporary payment policies susceptible to the same long-term inefficiencies in the payer sector (e.g., siloed delivery, wasteful spending from unnecessary utilization) (Berenson and Shartzer, 2020). Once the risk of COVID-19 is attenuated and in-person office visits are safe to resume, payers will need to develop reimbursement policies that treat telehealth as a component of coordinated care rather than an isolated substitute. Regulators could approach this challenge by using APMs as the vehicle for developing telehealth flexibilities after the conclusion of the public health emergency, from episode-based arrangements for telehealth use in condition-specific settings (e.g., tele-stroke) to fully-capitated arrangements to integrate telehealth into the care continuum (e.g., Direct Contracting).

First, deploying telehealth under risk-based payment arrangements could provide clarity and consistency to providers about reimbursement while

supporting the optimal use of telehealth within integrated care models. Indeed, HHS has noted that previous telehealth proposals submitted to the Physician-Focused Payment Model Technical Advisory Committee "expressed skepticism that a FFS model would be able to provide enough incentive for providers to invest in innovating to explore how to employ telehealth optimally" (OASPE, 2020). Second, population-based payments by design have built-in disincentives against unnecessary use and provide a natural vehicle to measure care quality, enabling payers to rigorously analyze the capacity of telehealth to enhance the patient experience and clinical quality in different care settings. For example, the Medicare program could consider incorporating "meaningful use" policies for telemedicine use into participation requirements for APMs (Navathe and Liao, 2020). Likewise, both public and private payers could collaborate to develop new quality measures for telehealth using the National Quality Forum's framework (NQF, 2017a).

The appropriate continuation of CMS's telehealth expansion policies from the pandemic will require additional guidance and resources. For example, the evolution of telehealth from a standalone service to an integrated component of care delivery will require virtual care platforms to be embedded into electronic health records. Regulators will need to ensure that recent interoperability rules, with their provisions on standardized infrastructure for application programming interfaces, provide sufficient guidance for payers and developers (ONC, 2020). Likewise, while many providers began using telehealth during the pandemic, formalizing virtual services into everyday care planning beyond the pandemic will require practices to make long-term investments in information technology infrastructure and workforce development. Financial support from payers may help practices, particularly those operating in safety net environments or rural geographies, to develop the competencies needed for effective telehealth implementation, as was the case for the ACO Investment Model (Trombley et al., 2019). Furthermore, payers, providers, and policymakers will also need to collaborate to ensure that virtual care platforms do not recreate the inequities of existing delivery models.This will require addressing challenges ranging from lower accessibility to and uptake of different types of telehealth services among specific populations, tailoring virtual services to patients' social context (e.g., optimizing language interpreter services for telehealth), and investing in infrastructure for measurement to support the identification of disparities in access and quality for racial and ethnic minorities and individuals of lower socioeconomic status (Thronson et al., 2020).

Key considerations for extending flexibilities for virtual health services and capabilities are presented in *Box 6-2*.

BOX 6-2

Considerations for Extending Flexibilities for Virtual Health Services and Capabilities

- Leverage APMs as the vehicle for extending COVID-19 flexibilities for telehealth utilization and reimbursement
- Collaborate with providers and regulators to develop sector-wide standards for care quality and clinical appropriateness of virtual health services
- Dedicate resources to addressing potential inequities in patient access and the quality of virtual care

Rethinking Benefit Design Using the Lens of Value-Based Insurance

At the beginning of the pandemic, 68% of Americans reported that health care costs would be a factor when seeking care for COVID-19 (Collins et al., 2020). Consequently, cost-sharing waivers—both those promulgated by COVID-19 relief legislation and implemented voluntarily for an expanded set of services (e.g., telehealth, behavioral health)—have been critical for expanding access to health services during the pandemic.

However, cost-sharing has long been a deterrent to care-seeking in the U.S. 33% of Americans delayed care due to cost in 2019, a trend that is likely to continue given that premiums and deductibles have outpaced the growth in median household income for the past 18 years (Collins et al., 2019; Saad, 2019). Experiments dating back nearly 40 years illustrate how blunt utilization controls can negatively affect patient health, particularly through disruptions in chronic disease management (Newhouse, 1993). In the case of prescription drugs, recent research on Medicare Part D illustrates how increases in out-of-pocket prices for life-saving medicines can reduce consumption and increase mortality (Chandra et al., 2021). Yet, importantly, research demonstrates that plans can minimize these effects without increasing expenditures by leveraging the principles of value-based insurance design and offering pre-deductible coverage of key services (Wharam et al., 2020; Agarwal et al., 2018). Such strategies will be increasingly salient for payers given the emerging evidence of negative health outcomes for patients during the pandemic due to interruptions in care continuity for non-COVID-19 indications (Blecker et al., 2020).

This literature, coupled with the experience from COVID-19, illustrates how payers can achieve the twin goals of expanding patient access to care (by waiving cost-sharing)

BOX 6-3

Considerations for Rethinking Benefit Design Using the Lens of Value-Based Insurance

- Adjust cost-sharing policies for chronic disease management using the principles of value-based insurance design
- Advance regulatory support for value-based insurance design to streamline patient access to evidence-based strategies for chronic disease management
- Evaluate evidence on utilization trends during the pandemic to support the de-adoption of low-value health services

while reducing unnecessary utilization and spending (through value-based insurance design). The synergies between these two principles should inform benefit design as payers evaluate whether to extend pandemic-era cost-sharing waivers. Regulatory change and legislative action could further support payers in their efforts to carve out low-value services and broaden access to necessary care. For example, the federal government expressed support for value-based insurance design in the Fiscal Year 2021 rule for health insurance plans offered on the ACA's market exchanges (HHS, 2020). Legislators also introduced bipartisan legislation prior to COVID-19 intended to broaden the definition of preventive care to include evidence-based health services for chronic disease management. Such a change would both build on the principles of the cost-sharing waivers introduced during the pandemic, and help to improve the affordability and accessibility of necessary care (116th Congress, 2020).

Priority actions for rethinking benefit design post-pandemic are summarized in *Box 6-3*.

Aligning Incentives and Investments to Address Health Inequities

COVID-19 has laid bare the stark and longstanding disparities in population health in the U.S., with the virus disproportionately affecting communities of color and low-income populations. While payers have made commitments to addressing disparities and taken action to address patients' social needs during the pandemic, long-term action across the sector will be needed to support meaningful progress for health equity.

First and foremost, payers should approach each of the priority actions outlined in this section using the lens of health equity. For example, when working to

accelerate the transition to value-based payment post-pandemic, payers and regulators should incorporate lessons from recent evidence pointing to disparities within existing models (Lewis et al., 2017). Likewise, when extending telehealth flexibilities, payers and policymakers should take proactive steps to ensure equitable access to new care modalities.

Second, payers should build upon pandemic-era investments in risk stratification to support more robust and systematic screenings and services for social needs. Several payers developed tools to identify the highest-risk patients in their populations and coordinate the delivery of both health and social services. Payers could consider scaling this infrastructure and extending newfound collaborations with community-based organizations to support improvements in long-term population health. Standardizing screening processes and improving data collection and data sharing capabilities will be key enablers for operationalizing cross-sector partnerships (Crook et al., 2021). Likewise, commercial insurers could leverage data from COVID-19 to inform the development of more robust non-medical benefits, particularly for health plans offering products in Medicare Advantage and Medicaid Managed Care. APMs can be a useful lever for supporting investments in the social determinants of health, with promising examples of ACOs coordinating social services under capitated contracts.

Third, payers will need to incorporate an explicit focus on health equity into their measurement and evaluation programs. COVID-19 illustrated the importance of collecting key demographic information and providing transparency on access and outcomes for marginalized populations. Dedicating resources (such as Blue Cross Blue Shield of Illinois's Health Equity Hospital Quality Incentive Pilot Program) and promoting accountability (such as the National Quality Forum's framework for identifying, measuring, and reducing disparities) are examples of areas of future development for the sector (BCBSI, 2020; NQF, 2017b).

Key considerations for promoting health equity are presented in *Box 6-4*.

BOX 6-4

Considerations for Aligning Incentives and Investments to Address Health Inequities

- Incorporate the lens of health equity when designing APMs and evaluating COVID-19 flexibilities for extension
- Build on pandemic-era partnerships for health equity, and standardize and scale screening tools and data sharing functions for the social determinants of health
- Develop financial incentives and quality measures with an explicit focus on addressing health disparities

Creating Mechanisms for Collective Action During Public Health Emergencies

Efforts to improve the sector's baseline efficiency may also improve public health preparedness, given evidence that providers operating in APM arrangements were better equipped to both adapt care delivery processes and weather the financial instability of COVID-19 (Ikram et al., 2020; Roiland et al., 2020). To enhance the sector's overall capacity for emergency response, policymakers could consider the following opportunities, with a focus on increasing cross-sector coordination and financial flexibilities.

The declaration of a public health emergency by the HHS Secretary triggers many flexibilities to enable state and federal governments to rapidly maneuver and respond to the crisis at hand. However, the system does not activate an automatic response on the part of commercial payers, who must either act unilaterally or await further guidance from regulators and legislators. The resulting delays (e.g., due to the time required for the passage of relief legislation) can present barriers to the mobilization of capital and the responsiveness of the health system. Indeed, although many plans took similar steps—often due to state and federal requirements—during the pandemic (e.g., medication refill requirements, cost-sharing), many practices were only recommended rather than required, leading to potential variation in insurer responses. For example, patients throughout the pandemic have faced questions around out-of-pocket costs for COVID-19 testing, treatment, and vaccination, and health plans' coverage and payment for COVID-19-related health services have varied substantially (Kliff, 2021a; Kliff, 2021b). Likewise, while CMS flexibilities were set to the duration of the public health emergency, commercial insurers often set individualized timeframes. While health plans generally extended flexibilities as the pandemic progressed, the shifting goalposts and lack of consistency created potential challenges for providers and patients.

Policymakers could therefore explore the creation of potential administrative or regulatory mechanisms that would prompt specific responses from payers when a public health emergency occurs. For example, this paper has outlined the multitude of benefit adjustments that payers have made during COVID-19. Payers and regulators could investigate if there is a minimum package of benefit adjustments that would be necessary during a pandemic (e.g., automatic coverage of medical countermeasures, waivers for prescription refills). These benefit adjustments might vary by population (e.g., children, adults, seniors) and would likely require coordination with the National Association of Insurance Commissioners due to the existing heterogeneity in state policies for health plans. Evaluating evidence from COVID-19 will therefore be critical to inform future policy changes.

Relatedly, a challenge for the payer sector early in the pandemic was the lack of specific codes for COVID-19 diagnostics and therapeutics. In response, CMS issued guidance in March 2020 that laboratories could bill two general COVID-19 testing codes (U0001 and U0002) when facing delays implementing the new COVID-19-specific code developed by the Current Procedural Terminology Editorial Panel (87635) (CMS, 2020j). To mitigate these challenges for future public health emergencies, regulators could consider defining an "empty" billing code that would be activated once an emergency is declared, and developing a financial threshold with actuarial certification to ensure that payers can appropriately reimburse providers without delay during the early days of a public health emergency. These examples, while far from exhaustive, illustrate the kinds of issues where payers might benefit from proactive regulatory guidance and industry consensus to increase the sector's nimbleness and responsiveness during future crises. Regulators may consider requesting the Office of the Assistant Secretary for Planning and Evaluation to study how a potential administrative mechanism for coordinating action across commercial payers might function in practice.

Priority actions for supporting collective action during emergency situations are summarized in *Box 6-5*.

Coordinating Payment Reforms with Public Health Functions

As noted in "The Payer Response to COVID-19," payers launched a number of initiatives to support the public health response, including scaling up COVID-19 testing, leveraging data analytics for disease surveillance, and coordinating with health departments to augment contact tracing capacity. However, these initiatives

BOX 6-5

Considerations for Creating Mechanisms for Collective Action During Public Health Emergencies

- Work with federal regulators and state insurance commissioners to determine a minimum package of benefit adjustments for health plans during public health emergencies
- Collaborate with regulators to define billing codes for activation during public health emergencies
- Investigate administrative mechanisms for coordinating action across commercial payers

were performed on an ad hoc basis, and formalizing partnerships and identifying additional opportunities for collaboration could help improve the public health response during future emergencies.

First, payers could leverage financial incentives to support disease detection and containment during future infectious disease outbreaks. Regulators could incorporate bonus payments into existing systems that would reimburse practices that enroll in test-and-trace initiatives and support specimen collection efforts during emergency situations (McClellan et al., 2020b). Provider attestation to activities supporting detection and containment could either be captured using existing vehicles (e.g., as an "Improvement Activity" within MIPS) or through specialized mechanisms developed by regulators in collaboration with public and private payers. Relatedly, given the challenges associated both with the quality (e.g., missing demographic information) and timeliness (e.g., frequent delays in reporting) of COVID-19 testing data, regulators could encourage the standardization of data collection through the "Promoting Interoperability" measures of MIPS, and explore the use of financial incentives to encourage timely reporting of laboratory results (Mostashari and McClellan, 2020). Given the government's dual role as a regulator and payer, public sector payers such as Medicare and Medicaid should help to lead the creation of these collaborations and drive the uptake of these new standards for public health-oriented data collection and payment policies.

Second, partnerships between payers, the biomedical research field, and health product manufacturers and innovators could accelerate the development of medical countermeasures. Health plan databases on membership and claims can provide useful information to support the risk-stratification of patients for trial eligibility as well as collect real-world data on the use of medical products. For example, UnitedHealth partnered with Eli Lilly to organize a clinical trial evaluating the effect of monoclonal antibodies on COVID-19, with the trial drawing from the insurer's Medicare Advantage membership due to the potential benefit of such therapies for high-risk populations like the elderly (Minenyer, 2020). Likewise, CMS developed a clinical trials incentive for COVID-19 in the MIPS program to encourage providers to report data on COVID-19 outcomes to established registries and enroll patients in relevant clinical trials (Kadakia et al., 2021). These initiatives could be broadened beyond COVID-19 to support biomedical innovation more broadly, while also improving the agility of researchers to generate evidence during public health emergencies.

Third, data sharing on health plan membership remain an under-utilized resource for the public health sector to monitor population health outcomes. For example, CMS used real-time Medicare claims data to evaluate the distribution

BOX 6-6

Considerations for Coordinating Payment Reforms with Public Health Functions

- Develop financial incentives to improve reporting of laboratory testing data during public health emergencies
- Foster partnerships with researchers and industry to support clinical trials enrollment and evidence generation
- Leverage membership and claims data and improve data sharing capabilities with public health to support disease surveillance and population health monitoring

of vaccines during the H1N1 pandemic (Lurie and Experton, 2020). However, these initiatives are often one-offs and face challenges such as barriers to data sharing. For example, during COVID-19, data exchange between health plans and vaccine registries has been challenging, limiting insurers' ability to monitor uptake (and consequently identify gaps in access, such as for marginalized populations). Additionally, gaps in claims data for COVID-19 vaccinations limit payers' capabilities to support post-market safety surveillance. Developing clearer data standards and improving communication and coordination between health departments and health care payers can create new opportunities to support disease surveillance beyond the pandemic.

Key considerations for coordinating payment reforms with public health functions are presented in *Box 6-6*.

CONCLUSION

COVID-19 has illustrated how misaligned financial incentives and the fragmentation of services across sectors contribute to inefficiencies and inequities in the American health system. The pandemic has both provided momentum to implement long-overdue changes in health care delivery (e.g., flexibilities for virtual care) while highlighting the need to accelerate ongoing efforts to transform payment systems (e.g., the transition to APMs). Notably, COVID-19 has also fostered new, innovative partnerships between payers and other sectors, such as collaborations with public health departments to improve disease surveillance, coordination with community-based organizations to meet patients' social needs, and joint ventures with the pharmaceutical industry to advance biomedical innovation. Yet while these initiatives highlight the potential for COVID-19 to drive the transformation of policy and practice in the U.S. health

care system, meaningful change will require payers to navigate the still-evolving volatility of insurance markets, balance competing obligations and relationships to parties across sectors, and overcome longstanding inertia within the health care system.

In this paper, leaders from the payer sector have sought to highlight the range of regulatory flexibilities and health plan responses to the pandemic, and outline how preexisting obstacles and COVID-19-specific vulnerabilities create short- and long-term challenges for the sector. To improve the resiliency and equity of health care financing in America for COVID-19 and beyond, the authors have identified a series of priority actions for policymakers, including accelerating the transition to value-based payment, extending flexibilities for virtual health services and capabilities, rethinking benefit design using the principles of value-based insurance, aligning incentives and investments to address health inequities, creating mechanisms for collective action during public health emergencies, and coordinating payment reforms with public health functions. Regulators and sector leaders can use these policy considerations to begin shoring up America's payment and delivery systems to weather both the financial aftershocks of COVID-19 and the forthcoming population health challenges of the 21st century.

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7

HEALTH PRODUCT MANUFACTURERS AND INNOVATORS COVID-19 IMPACT ASSESSMENT: LESSONS LEARNED AND COMPELLING NEEDS

Mathai Mammen, MD, PhD; Vasant Narasimhan, MD, MPP; Richard Kuntz, MD, MSc; Freda Lewis-Hall, MD; Mojdeh Poul, MBA, MEng; and Adam H. Schechter

INTRODUCTION

In the waning days of 2019, global news outlets began reporting on a "mysterious viral pneumonia" infecting residents of Wuhan, China (BBC, 2020a). The first recorded death from what we now know as COVID-19, or the disease state resulting from infection with the SARS-CoV-2 virus, was a resident of Wuhan on January 11, 2020, and the first confirmed case of COVID-19 in the United States was on January 20, 2020 (BBC, 2020b; Harcourt et al., 2020). The World Health Organization declared COVID-19 a global pandemic on March 11, 2020, and since then, COVID-19 has claimed the lives of 828,000 Americans and 5.26 million individuals worldwide (New York Times, 2022).

Although there were some examples of effective local, state, and national responses, there were critical issues and inconsistencies in the U.S. national pandemic response that resulted in delayed and insufficient availability of testing early in the pandemic, shortages of basic supplies including personal protective equipment (PPE), and strained health system capacity. Even with the advent of efficacious vaccines and therapeutics, COVID-19 and future novel viruses are expected to remain a significant global health threat. Both the direct and indirect effects of the pandemic have disproportionately affected communities of color in the U.S., as the virus has had a much higher mortality rate in Asian

and Pacific Islander, Black, Latino, and Native American patients as compared to white patients (Gold et al., 2020; Killerby et al., 2020; Stokes et al., 2020). Yet, even as the pandemic reveals or greatly exacerbates critical system fragilities, the conditions of the pandemic have also driven rapid progress in some areas, such as greater acceptance of telemedicine.

The *Emerging Stronger After COVID-19* series of discussion papers, of which this paper is one, will examine nine sectors of the health care system, assessing both their existing vulnerabilities and their greatest opportunities for driving system-wide transformation toward effective, efficient, and equitable care for all Americans in the wake of COVID-19 (Artiga et al., 2020).

MAJOR ORGANIZATIONAL COMPONENTS AND INTERACTIONS WITHIN THE HEALTH PRODUCT MANUFACTURERS AND INNOVATORS SECTOR

Health product manufacturers and innovators (HPMI) research, develop, and produce a broad range of products and services that are critical to the health and well-being of people in the U.S. and around the globe. HPMI rely on a global supply network to provide components and ingredients to manufacture and operate these critical products and an extensive distribution system to ensure the delivery of these technologies across the U.S. and globally.

Despite the efforts of HPMI aimed at improving and extending lives, the COVID-19 pandemic has highlighted a range of vulnerabilities across the sector. This paper presents an individual assessment of the experiences and dynamics over the course of the COVID-19 pandemic through the lens of five specific sub-sectors—diagnostics, hospital supplies and personal protective equipment, Class III medical devices per the Food and Drug Administration's (FDA) classification system, therapeutics, and vaccines—to uncover the vulnerabilities and opportunities for sector-wide transformation (see *Figure 7-1*). Within each sub-sector's analysis of its experiences with COVID-19, the authors unravel the challenges each sector faced in continuing operations while responding to the domestic and global demands of the pandemic. Collectively, these vulnerabilities underscore the need for coordinated strategies to ensure the U.S. is well positioned to respond to the current and future public health crises and to enhance the sector's overall effectiveness, efficiency, and equity. As such, this paper concludes with a synthesized overview of priority actions that will aid in the navigation of future pandemics and other public health crises.

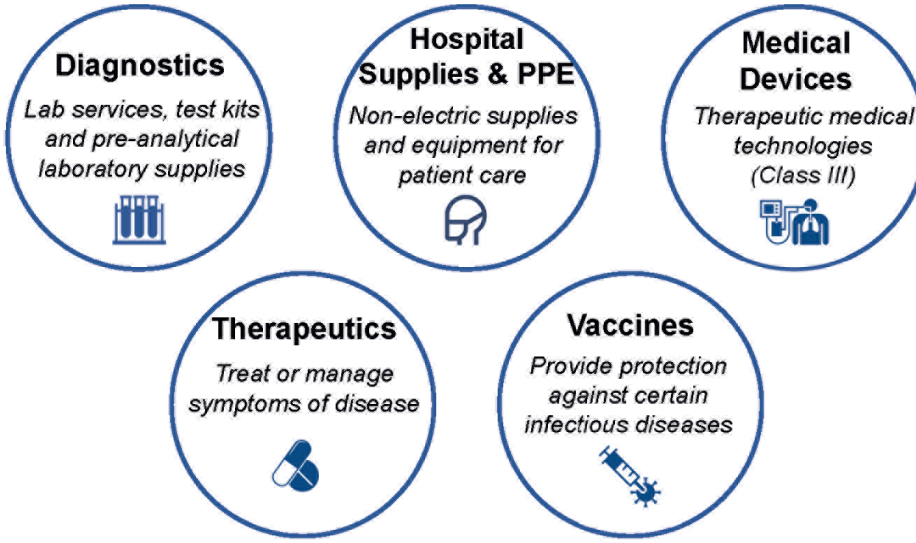

FIGURE 7-1 | Profile of the Health Products Sector

Individual Sub-Sector Analyses of COVID-19 Experiences, Dynamics Observed, and Vulnerabilities

Diagnostics

Overview and Response: Diagnostics

The diagnostics sub-sector offers a wide variety of products and services, including various diagnostics related to COVID-19. In this paper, the authors focus primarily on PCR molecular diagnostic testing, which is considered the gold standard in diagnosing whether a person is currently infected with the SARS-CoV-2 virus.

The diagnostics sub-sector includes manufacturers of test kits as well as pre-analytical supplies (such as swabs and tubes) and both public and private labs. Public health laboratories perform research, disease surveillance, emergency response support, and some diagnostic and reference testing for the public health agencies they serve, particularly for diseases with significant biosafety risks. Private labs include independent labs, hospital labs, and physician office labs. Some labs develop and validate their own tests that they perform as services (laboratory-developed tests, or LDTs), some labs run tests using manufactured test kits, and some do both. Private labs serve a broad array of customers, including physicians; patients; consumers; hospitals and health systems; employers; managed care organizations; biopharmaceutical, medical device and diagnostics companies; and governmental agencies.

At the start of the COVID-19 pandemic, a particularly prominent response shortfall was the failure to rapidly launch a comprehensive national strategy for the coordinated development and dissemination of tests for COVID-19. Then, in late January 2020, once the U.S. started to develop COVID-19 tests, national health leaders permitted only the use of government-created test kits, which were unable to be produced in numbers sufficient to match demand. Further constraining supply was the discovery of technical flaws in these test kits, which resulted in the decision to halt testing to rectify the issue (Armour et al., 2020; Davis, 2020; Shear et al., 2020).

As a result of these shortfalls, and the response to them, dynamics around diagnostics changed in at least two notable ways. The first was the somewhat sudden and widespread public awareness of the vital role diagnostics play in the nation's ability to understand and track the spread of COVID-19 — as well as to help treat and manage the disease.

Secondly, the U.S. saw a rapid expansion of COVID-19 testing capacity. Within days of the February 29, 2020 FDA guidance creating a pathway for private labs to develop and offer validated COVID-19 tests in addition to state and local public health labs, diagnostics companies responded by bringing tests to market and rapidly ramping up capacity ahead of determinations of payment or reimbursement (FDA, 2020a). Examples of ramping up capacity ahead of payment included purchasing equipment, complex machines, and testing and collection supplies; incurring costs for PPE; and investing in additional site cleanings for protection against COVID-19. Companies that develop diagnostics expanded the accessibility of testing to reach as many people as possible, including health care workers, first responders, the hospital inpatient population, nursing homes, the elderly and the vulnerable, as well as those in underserved communities—through doctors, hospitals, other health care providers, retail pharmacy chains, drive-through testing sites and company websites.

Aside from COVID-19 testing, routine testing for non-acute conditions such as diabetes and cancer was paused during lockdown. Labs engaged with health care industry leaders and technology companies to raise awareness through national, large-scale campaigns such as Stop Medical Distancing, a program designed to explain the difference between social distancing and medical distancing to inform people about the importance of continuing to receive timely medical care (Cision PR Newswire, 2020).

Companies also offered employers and schools services for their return-to-work and return-to-school strategies. For example, certain labs offered return-to-work solutions, including some offerings using medical staff to administer health questionnaires when employees arrived, temperature screening, and specimen collection. One service offered employers access to testing solutions such as an at-home collection test kit,

a finger stick antibody blood test, and flu vaccination services. The diagnostics sub-sector also developed novel laboratory-based tests, began offering at-home specimen collection and testing to expand access and reduce demand for PPE, and launched combination COVID-19 and flu tests.

Beyond greater testing capacity and access, new treatments and ultimately new vaccines, two of which have already received emergency use authorizations (EUA) and one FDA approval, are critical. To that end, many of the same laboratories and test kit manufacturers launched antibody tests, and some are providing testing to support COVID-19 therapeutic and vaccine research studies and clinical trials.

Vulnerabilities and Opportunities: Diagnostics

The increased attention prompted by the pandemic to the need for better testing capacity uncovered vulnerabilities affecting both public and private labs and in how public and private efforts are coordinated to create surge capacity.

As mentioned earlier, at the onset of the COVID-19 pandemic, demand outstripped supply, leading to longer times for people to receive the results of their tests. One of the reasons was due to a focus on government-created testing. There is acknowledgement that involving private-sector laboratories earlier would have allowed for a more rapid scale-up of testing capacity. If labs had begun receiving information earlier, when other countries were facing the crisis, they could have helped earlier (Boburg et al., 2020). Once private labs were allowed to provide testing under emergency-use conditions, the U.S.'s ability to test for the virus dramatically expanded. The authors of this manuscript believe that engaging both public and private labs early in the national response to COVID-19 would have helped scale up testing supplies and infrastructure more quickly.

The lack of excess capacity at labs, both public and private, was also evident during surges in COVID-19 outbreaks. Despite the sub-sector's significant efforts in the early days of the pandemic to increase the number of testing platforms available, the complexity of the machines, limited supply of machines and reagents, and staffing shortages made it difficult to scale quickly enough. Estimates of how many tests were needed varied widely (Tromberg et al., 2020). Some experts predicted the need for millions of tests per day. However, some forecasts may have been referring to COVID-19 tests needed for diagnosis, screening and population-level surveillance, including both PCR as well as antigen tests, while others may have been referring to PCR tests, the gold standard for personal diagnosis. In any case, it was not until September 2020 that the U.S. may have hit 1 million diagnostic COVID-19 PCR tests performed in one day, according to news reporting citing estimates from The COVID Tracking Project (The COVID Tracking Project, n.d.; Shumaker, 2020).

The response to the COVID-19 pandemic was also marked by fragmented and conflicting communication from various authorities and thought leaders. As the public searched for answers during the pandemic, they were confronted with no "single source of truth." This threatened to erode public confidence and likely resulted in people who did not need testing using up limited capacity (Abbott and Lovett, 2020). In some cases, patients were unsure who should be tested, which test should be performed, and where a specimen could be collected. Further compounding the confusion was the fact that some doctors' offices were temporarily closed beginning in March 2020 (CMS, 2020). As an attempt to mitigate some of these challenges, companies sought to help educate people about where and how to be tested, delivering important COVID-19 information to millions of people through social media, traditional media, and direct email channels, and sharing information with millions more via websites and through trade associations (ACLA, 2020; Labcorp, 2020).

The single biggest vulnerability for the diagnostics sub-sector illuminated during the pandemic is the need for a fuller understanding of, and plan to address, the complexity and multifaceted nature of the global supply chain. While the diagnostics supply chain is often thought of as the test, the machine, and the result, in reality, it entails all the components necessary to collect the specimen, extract it, ship it, and test it—from nasal swabs to reagents, pipette tips, sterile tubes, dry ice, and complex machinery. Announcements of testing capacity based solely on machinal capabilities could be misleading without a reference to dependence upon the availability of necessary supplies. For example, while machines might be able to process a million tests per week, such a claim could be meaningless if there were only enough reagents to process a thousand tests. In addition to understanding that the supply chain is complex and contains many parts, it must be recognized that the supply chain is global. In the beginning of the pandemic, nasal pharyngeal swabs were being sourced primarily from Italy. When Italy was affected by the pandemic, obtaining swabs for U.S. use became a major challenge, not only affecting COVID-19 testing but also routine testing for conditions such as strep throat and sexually transmitted infections. Similarly, shutdowns in other countries such as China strained America's supply chain.

Finally, while speed is critical in a pandemic, so is continuing to monitor, maintain, and ensure the accuracy and reliability of tests. In the early days of the COVID-19 experience, a number of manufactured antibody test kits of poor quality were left unregulated and flooded the market, only to be withdrawn, further confusing the public and threatening to undermine confidence in tests and testing as a whole (FDA, 2020b). This included confidence in LDTs. Though, unlike test kits, LDTs continued to be regulated under the Clinical Laboratory Improvement Amendments (CLIA). This issue highlights the need for Congress

to advance legislation to establish new, transparent validation pathways for all in vitro clinical tests to facilitate the prompt availability of accurate and reliable tests while preventing an influx of inferior products.

Hospital Supplies and Personal Protective Equipment

Overview and Response: Hospital Supplies and Personal Protective Equipment

The hospital supplies and personal protective equipment sub-sector develops products intended for use by physicians, nurses, hospital personnel, researchers, lab technicians, and others in health care. The sector serves a wide range of businesses including hospitals, clinics, and pharmaceutical companies. Products include a multitude of medical and surgical supplies, such as respirators, gowns, gloves, disinfectants, and sterilization products.

As soon as suppliers of health and safety products across the U.S. learned of the SARS-CoV-2 virus spreading in China in late 2019, they began putting measures in place to prepare. Manufacturers of hospital supplies and personal protective equipment began accelerating production and sourcing of PPE, notably respirators, in early 2020 (Stankiweicz, 2021; 3M, 2020a). A heavier than normal flu season was emerging in the Southern Hemisphere in the fall of 2019, portending a similar trend in the winter in the Northern Hemisphere. Signs of the novel and virulent coronavirus, in addition to unfolding natural disasters in Australia and the Philippines, triggered more steps for such manufacturers to prepare as requests for PPE started skyrocketing.

As the COVID-19 pandemic unfolded, manufacturers of hospital supplies and personal equipment were pressured to make appreciably more health and safety products. Global demand for N95 respirators and other respirators far exceeded the supply for the entire industry (rising as high as 20 to 40 times above normal levels). Some companies were prepared to handle normal fluctuations in supply and demand, having built and maintained excess surge capacity for worldwide disease outbreaks and natural disasters. Companies accelerated the process of adding new manufacturing equipment and production lines by diverting engineers, experts, and other resources from other departments to hospital supplies manufacturing efforts (Gallucci and Seetharaman, 2020; Miller, 2020). However, even with the addition of significant capacity, the unprecedented demand caused by the global pandemic outpaced production and supply.

By March 2020, production faced additional challenges as countries went into lockdown to help stop the spread of COVID-19 and companies halted nonessential operations. Manufacturers of health and safety products and suppliers of key raw materials assessed whether their operations fit

government guidelines related to being critical to the pandemic response. Once that determination was made, they implemented safety measures such as those published by the U.S. Occupational Safety and Health Administration (OSHA) to reduce the risk of exposure for their essential employees and continued producing critical supplies such as PPE and hand sanitizer, among other products (OSHA, 2020).

To further ramp up production of critical hospital supplies, the U.S. federal government began invoking the U.S. Defense Production Act (DPA) in spring of 2020, which gave the Executive Branch certain authorities to partner with and accelerate domestic industries during national emergencies. DPA authorities were used across several health care sectors including companies like 3M, Hill-Rom, Royal Phillips, and Vyaire Medical.

Health care providers also sought to extend the use of their PPE stocks by conserving respirators through clustering or isolation of patients with the same disease in order to support a crisis capacity strategy of not needing to change PPE after every patient contact. They also reused disposable respirators through decontamination procedures approved by the FDA via emergency use authorization (EUA).

Across suppliers of hospital supplies and personal protective equipment, collaborations played a critical role in the pandemic response. Many companies outside of health and medicine halted supply of their traditional products to supply PPE and other needed supplies for frontline health care workers and first responders. In addition, some initiated collaborations with companies to support the health care industry. A spirit of cooperation developed as hospital supply manufacturers connected with the automotive, industrial, or academic sectors to address various imminent health care needs. These collaborations with other companies to meet global challenges offer a model for potential future innovation.

Vulnerabilities and Opportunities: Hospital Supplies and Personal Protective Equipment

In the course of the sector's response to COVID-19, manufacturers of hospital supplies and personal protective equipment faced a number of trade challenges and export restrictions that impeded their ability to more quickly obtain critical raw materials and finished products such as PPE for health care workers and first responders. Access to raw materials was limited due to border closings and slowdowns in procurement, which highlighted the importance of supply chain diversity and resilience. These issues surface opportunities that include a more robust global supply chain, a comprehensive national response plan with visibility into stockpiles, and a framework to promote cooperation and incentivize information sharing sooner and faster during a public health crisis.

Trade challenges restricted the ability of hospital supply and equipment manufacturers to respond even faster during the pandemic. Some governments imposed restrictions on companies exporting the PPE made in one country to customers in other countries (Mildner et al., 2020). At one point during the pandemic, more than 40 countries imposed PPE export restrictions, and almost 165 countries imposed tariffs (Evenett, 2020). Trade barriers in some countries even extended to raw materials required to manufacture PPE. Occasionally, trading partners would retaliate by erecting reciprocal trade barriers for the same or other products or raw materials. Extensive, interconnected global supply chains in medicines and medical equipment makes this an issue faced by every nation around the world.

Limited supply chain diversity and redundancy among some producers also poses another sub-sector vulnerability. Certain companies experienced difficulty acquiring enough raw materials to consistently meet the needs for their factories. Many worked rapidly and concurrently to hire and qualify new vendors. Some manufacturers assumed additional costs for suppliers' expansion expenses or to expedite their new production equipment by air shipment. Moving forward, all manufacturers need to ensure that they have a broad supply chain of raw materials required for making health care consumables. Potential issues may emerge if manufacturers do not maintain a broad base of global suppliers, close to their factories, that can quickly increase production of raw materials when necessary. The global supply chain is only as strong as its weakest link, a reality experienced clearly early during the COVID-19 pandemic.

A granular view of what different states and localities needed at which time across the nation was lacking as manufacturers sought to optimize their production and distribution efforts. Some state health systems had adequate supplies and began preparing for future peaks of COVID-19, while others were working to obtain enough supplies for daily operations. Coordinated, national response plans with visibility to national, regional, and local stockpiles could enable a more effective and coordinated response to crises by shifting resources to outbreak hotspots.

Companies are subject to anti-trust laws that prevent them from sharing competitively sensitive information with competitors about their sales and distribution. One tool to help accelerate appropriate information sharing during a crisis is the use of a Voluntary Agreement overseen by the government under Section 708 of the Defense Production Act. This portion of the DPA gives the federal government the authority to work with the private sector to collect information and coordinate the manufacturing and distribution of critical health care products and equipment during a crisis. This can be a particularly effective means to help efficiently distribute PPE across the sector. And the additional certainty, structure, and protections afforded by a Voluntary Agreement under Section 708 of the DPA may help encourage greater openness and provide an incentive for other manufacturers and distributors to participate.

Therapeutic Medical Devices

Overview and Response: Therapeutic Medical Devices

The medical device industry manufactures a wide variety of products. For the purpose of this paper, the authors focus on therapeutic medical technologies, generally falling into the FDA class III classification.

Therapeutic medical devices are typically devices that are introduced or implanted into the body percutaneously, through a body orifice or minimally invasive surgical incisions. As such, these devices are highly sophisticated and rely on intensive research and development phases, requiring significant time, resources, and financial investments. Having the potential of moderate to severe risk, therapeutic medical devices are subject to high regulatory requirements and require intensive pre-market prospective clinical studies and trials, as well as post-market clinical studies. Operations and clinical procedures involving medical devices may be categorized by a patient's medical condition and acuity: emergency operations and procedures for life-threatening conditions; necessary, but not urgent, procedures; and elective procedures. The application of these technologies often requires medical device industry representatives' assistance during procedures performed in hospitals and ambulatory surgical centers (ASCs).

Soon after the onset of the COVID-19 pandemic, medical technology industry representatives experienced a high variability of entry policies implemented by medical facilities to limit the potential of viral spread. These variable policies included SARS-CoV-2 polymerase chain reaction (PCR) or antigen testing requirements along with testing frequency and test sourcing, PPE sourcing (hospital versus medical technology company), representative physical positioning in procedures and operations, and inventory management. These policy variabilities and changing dynamics reduced the number of procedures at some health care systems and complicated the interactions of medical device representatives with clinical staff and patients. For example, some representatives had to source their own PPE due to unexpected changes in hospital inventory levels while also adhering to variable physical positioning mandates. These mandates, or rules regarding personnel access and distancing for representatives, not only varied significantly within hospital settings (e.g., operating rooms, catheterization labs), but between hospitals as well. Inventory management (sourcing, stocking, and maintenance of supply levels) was further complicated early on by changing medical device inventory management between medical technology representatives and hospital procurement and warehousing staff.

In response, many medical technology companies and an industry group (AdvaMed) created their own taskforces to work directly with hospital systems and organizations such as the American Hospital Association and Association

of Perioperative Registered Nurses to standardize entry to health systems and procedure/operation participation while ensuring reduced COVID-19 exposure to patient, hospital personnel, and industry representatives.

Many of the hospitals affected by and, in many cases, overwhelmed by COVID-19 have also historically been involved in the execution of clinical studies and trials of medical devices. As early as April 2020, it was widely evident that initiation, execution, and continuation of new and ongoing non-COVID-19 clinical studies and trials were potentially distracting and interfering with the needed hospital human resources that were being repurposed from clinical research to COVID-19 patient management and care. Thus, medical device manufacturers and innovators worked with hospitals, research partners, regulatory bodies, and other relevant stakeholders to:

- assess the impact of COVID-19 on health care research partners and support them accordingly (e.g., reduction in non-COVID-19 clinical studies and in-kind representative support),
- temporarily pause clinical studies and trials where it was determined that local resources would be better allocated to COVID-19 activities,
- convert follow-up procedures (where possible) for those already enrolled in studies to remote methods to ensure participant, clinical site staff, and employee safety while maintaining proper sponsor oversite (via telephone or video conference whenever possible), and to widen the windows for follow-up from that designated in the protocol,
- document COVID-19-related impacts on clinical studies and trials, such as adverse events, COVID-19 diagnoses, and protocol deviations, and
- establish and engage ongoing communication with sites to ensure proper adjustment of activities as the pandemic situation continues to evolve.

To respond to the rapid increase in demand for intensive care unit (ICU) care beginning as early as February 2020, U.S. medical device manufacturers of ventilators and ICU monitoring equipment required over a five-fold increase in production to meet the U.S. and global demands (Hillrom, 2020; Medtronic, 2020). This raised the need for business continuity planning as many of the products required components sourced from suppliers that were overwhelmed with demand. This rapid increase in demand resulted in a wide variety of integrated delivery networks (IDN) and manufacturer responses to deal with the pandemic. In terms of ventilators and ICU monitors, medical device competitors worked together to ramp up production, and non-medical device technology industries contributed by developing new manufacturing lines to provide the critical components needed for ventilator and monitoring equipment.

The COVID-19 pandemic thus produced unprecedented levels of collaboration across competitive manufacturers, where a common goal to fight the pandemic rose above the commercial concerns of collaboration. While engineers were making critical product decisions, the U.S. FDA was essential in streamlining the approval of needed technology to patients suffering from the pandemic by dedicating additional resources to the review process. Some examples included the approval of new non-traditional ventilator component suppliers, such as SpaceX, to provide against the growing unmet demand, and expedited approval of splitter ventilator systems that allowed more than one patient to be supported by a single ventilator (Crotti, 2020).

After the initial shock of the COVID-19 pandemic and early adaptations implemented by the health care industry, medical device manufacturers worked with partners to evaluate how to resume elective procedures. To achieve this objective, three essential elements needed to be in place: material availability, people readiness, and hospital capacity.

Material Availability

Leveraging the supply chain momentum of the initial phase of the disease outbreak (between February and April 2020), manufacturers retooled supply chain processes by establishing cleaning and testing protocols so that medical testing sites were safe for employees, contractors, and logistics partners. Likewise, new collaborations were formed between various manufacturers and regulatory bodies to meet the rising demand for medical devices such as ventilators. This helped alleviate the fear of working among employees who could have been exposed to COVID-19 and successfully ramped up production in anticipation of demand. On the other hand, to deal with the non-uniform rescheduling and cancellation of surgical procedures in various states, manufacturers partnered with IDNs to determine the potential peak rates and dates of procedures by counties such that factory shutdowns and increases in production could be planned accordingly.

People Readiness

As noted in the diagnostics and therapeutics sections of this paper, patients' willingness to reengage with the health care ecosystem was a major challenge during the early to mid-stages of the COVID-19 pandemic (see *Figure 7-2*). More than two-thirds of Americans (68%) say they or someone in their household delayed or canceled health care services due to COVID-19 (Johnson & Johnson, 2020). This was driven by multiple factors, including lack of medical knowledge about one's own existing health conditions, inconsistent and unclear messages from the government on the nature of the virus, and uncertainty in the economic

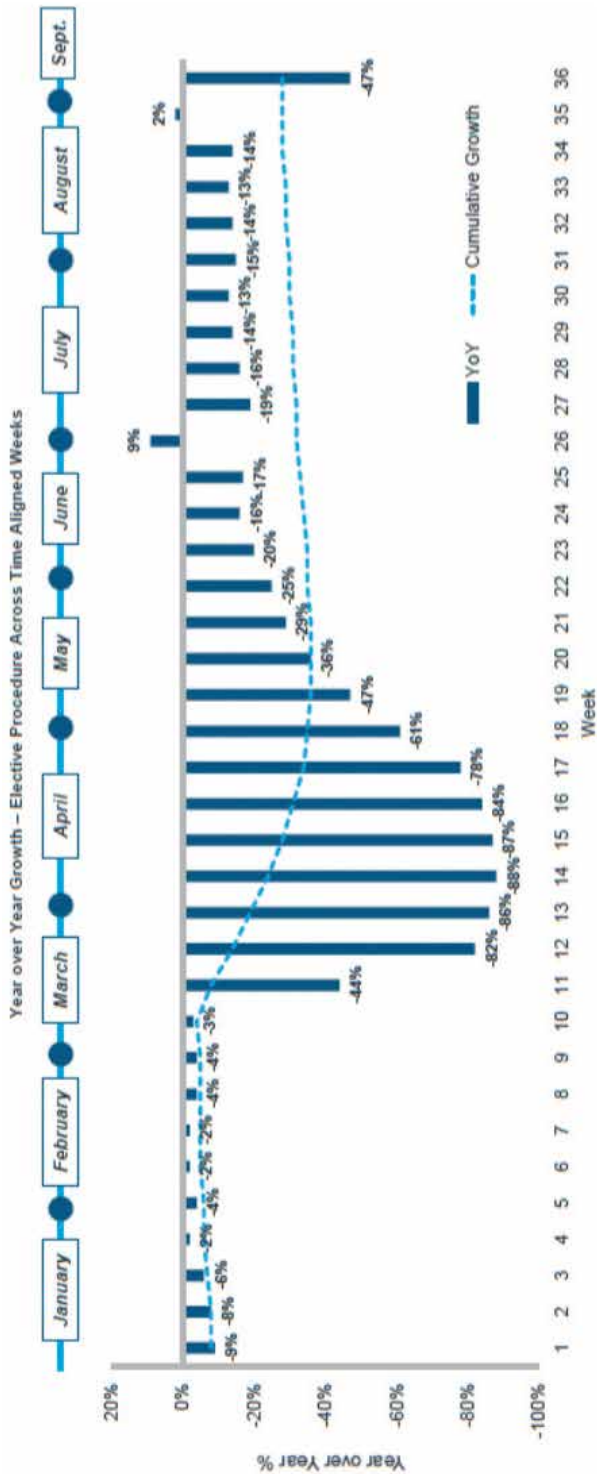

FIGURE 7-2 | Elective Procedure Volume Weekly Trends
SOURCE: IQVIA Institute Medical Claims Data Analysis 2020.

climate and personal finances. Medical device manufacturers started campaigns such as "My Health Can't Wait," a public information effort and resource hub, designed to inform and raise awareness of patients to prioritize their health and reach out to their health care professionals about the risks of deferring care (Johnson & Johnson, 2020).

Hospital Capacity

A major milestone in the safe restart of health and medical procedures was realized when hospitals built up capacity and optimized resources to serve non-COVID-19 patients. This action paved the way for restarting medical device engagement with front-line procedures.

As the health care system began stabilizing in its response to COVID-19 by acclimation to new workflow adaptations and non-pharmaceutical interventions (NPIs), medical device manufacturers aimed to advance promising policies already in place, and recover clinical study enrollment where safety concerns for patients and staff were perceived to be reduced.

Vulnerabilities and Opportunities: Therapeutic Medical Devices

As witnessed in other sectors of the health system, therapeutic medical device manufacturers experienced supply chain disruptions during COVID-19 due to shortages of materials, transportation limitations, and other factors. The lack of sufficient resilience and diversity in supply chains and distribution was, in large part, due to a focus on efficiency optimization and reducing redundancies that were prevalent prior to the COVID-19 pandemic. However, the rapid increase in the therapeutic medical technology demand overwhelmed suppliers and further highlighted the need for additional supply chain redundancy.

Information latency has been another major challenge aggravated by the pandemic. Given that medical device industry is highly fragmented with roughly 5,300-5,600 companies of various sizes, it can take months to develop an accurate industry-wide view on trends to evaluate the impact and recovery of COVID-19-related disruptions (MEDPAC, 2017). This is due to the lack of stable information sources, underinvestment in information technology systems by hospitals, and the over-reliance on human relationships such as those between surgeon and clinical representatives. Such factors resulted in information and decision decentralization. It is therefore challenging to make a data-driven decision on which devices to manufacture and where and how to distribute them during a health crisis. Due to the delegation of regulatory response to states, there were many different regulatory guidelines across the country, with varied reactions to the crisis overall.

The absence of centralized structure left room for situations where states were bidding against each other to acquire limited medical devices and other materials. Greater communication and coordination are necessary to ensure the fair distribution of a limited set of materials during future public health crises.

More coordinated communication at the federal and state levels is also necessary as it related to continued operations of medical device trials and procedures during pandemic events. In the early stages of the COVID-19 pandemic, state and federal guidance differed in specificity. For example, the CDC focused on general guidance that could be applicable anywhere across the U.S., while some states initially ordered stronger mandates than federal guidance required. Some states mandated that if 25%+ of hospital beds were occupied by COVID-19 patients, then elective procedures would have to be put on hold, while others made it optional or subject to the discretion of the hospitals (The State of Texas Governor's Office, 2020). Furthermore, ASCs were not as impacted by the guidance and mandates issued (depending on the state) and hence continued business as usual. This variability required a nuanced approach in how both manufacturers and end consumers were able to engage with providers in each geography. Thus, there is a strong need for clear and fact-based guidelines from federal government and regulatory bodies during future pandemic events, allowing for clear action by all parties throughout health and medicine.

Therapeutics

Overview and Response: Therapeutics

Therapeutics refers to a class of pharmaceutical agents used for the treatment or management of disease symptoms. Manufacturers of therapeutics comprise a broad range of companies with differing therapeutic foci, operational capabilities, and global footprints. During the COVID-19 pandemic, therapeutics manufacturers worked to identify treatments for COVID-19 and associated secondary complications while continuing to deliver brand and generic medicines.

The development of therapeutics against COVID-19 initially focused, for the sake of speed and limited historic research in understanding coronaviruses, on repurposing existing medicines screened from within the industry's extensive treatment libraries. Early identified candidates included virus-directed small molecules such as direct acting antivirals (e.g., remdesivir), immunosuppressive and anti-parasitics (e.g., hydroxychloroquine), immune modulating monoclonal antibodies to target the cytokine response (e.g., Interleukin-6 monoclonal antibodies), and immune modulating small molecules (e.g., dexamethasone). These efforts were encouraged through accelerated regulatory pathways, as seen by FDA approval of remdesivir in October 2020 (only seven months after WHO

declared COVID-19 a global pandemic, in contrast to an average approval time of 12 years in a non-pandemic context) (FDA, 2020c). In parallel to these efforts, preclinical research for novel therapeutics against COVID-19 rapidly expanded, with efforts in target definition, screening, and hit-to-lead optimization. These efforts include all modalities of biological therapeutics (e.g., small molecules, biologics, RNA-based therapies) of which there are over 300 candidates under consideration across various therapeutic approaches (Boston Consulting Group, 2020).

The COVID-19 pandemic provided an opportunity for institutions and organizations to work together in an effort to maximize biomedical research resources in testing preclinical compounds and prioritizing promising drug candidates. In April 2020, NIH launched the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership, which brought together government, industry, non-profit, philanthropic, and academic organizations (Collins and Stoffels, 2020). Through ACTIV, NIH identified opportunities within COVID-19 therapeutics development in three areas: developing a streamlined manner to identify preclinical treatments, accelerating clinical testing of promising therapeutics, and improving clinical trial capacity and effectiveness.

Therapeutics manufacturers also invested in maintaining the flow of medicines and progressing treatments for COVID-19 by accelerating use of digital technologies. Machine learning techniques have been used to support faster and more precise drug discovery and development, including the identification of drug targets, responder groups, and new indications; qualification and quantification of surrogate endpoints; and acceleration of the time to drug formulation. Other tools have also critically afforded the opportunity to ensure patients still receive medical guidance and access to therapeutic treatments through opportunities to accelerate development via targeted patient recruitment and site optimization and faster clinical trials via remote monitoring.

Vulnerabilities and Opportunities: Therapeutics

Despite the efforts of many therapeutics manufacturers to address COVID-19, the sub-sector encountered challenges during the pandemic. Globally, there was a swift and extraordinary research response to address the unprecedented crisis. However, development of COVID-19 therapeutics was hampered by poor coordination, limited incentives for collaboration, and lack of prioritization of research questions and resources (Angus et al., 2021). Within the U.S., the intent of the NIH ACTIV was to efficiently set priorities, design trials, and foster collaboration and coordination across clinical trial networks. Given that the U.S.

clinical research enterprise does not function as a single national coordinated system, and since therapeutics innovators are often multinational corporations, many investigational programs to evaluate COVID-19 therapeutics were conducted external to ACTIV.

Without a system of national prioritization, inefficiencies in the research infrastructure essential to delivering therapeutics highlighted critical vulnerabilities that must be addressed in the coming years. The authors of this paper have chosen to focus on the vulnerabilities and opportunities that emerged during the early stages of the pandemic, namely in the areas of therapeutics development and clinical trial design. While there are additional vulnerabilities and lessons learned, they are not covered in depth in this paper.

These vulnerabilities included:

1. difficulty with providing patient care due to the significant decline in physical interactions between patients and their health care professionals, and
2. challenges to global operations and workforces due to factors such as the closure of national borders, export restrictions, disruptions to clinical trials and interactions with external innovation partners (especially small biotech enterprises and academia), and management of virtual global employee bases.

Relatedly, COVID-19 also highlighted the strains on the supply of equipment and therapeutics—including select critical generic drugs—particularly those used in the hospital setting.

In response to these vulnerabilities, the industry was able to utilize digital technologies to assist with the challenges of patient care. Similarly, the industry collaborated with regulatory bodies around the world to identify opportunities for flexibility within existing regulatory frameworks that allowed protocol modifications to ensure the continued development of therapeutics without undermining patient safety or clinical trial data integrity.

Difficulty with Providing Patient Care

Physical distancing measures and the surge in COVID-19 cases across U.S. hospital systems impacted patient care and patterns of pharmaceutical usage in a number of ways. First, as initial concerns over pharmaceutical supply were raised early in the COVID-19 pandemic, many hospital systems and patients overstocked medicines for chronic diseases. In the course of the pandemic, there was also a significant difference in the number of new prescriptions for acute conditions versus new or existing prescriptions to treat chronic conditions, with demand for prescriptions to treat acute conditions far less than those used to treat

chronic conditions. Prescriptions across all conditions by the end of March 2021 returned to 94% of the pre-pandemic baseline as per *Figure 7-3* (IQVIA Institute, 2020a).

Second, diagnosed and undiagnosed acute diseases and treatments requiring hospital visits (e.g., parenterally administered cancer treatments) saw a 33% reduction in prescriptions in April 2020 compared to April 2019 (Sullivan et al., 2020). More than two-thirds of Americans (68%) say they or someone in their household delayed or canceled health care services due to COVID-19 (Johnson & Johnson, 2020). This delay, caused by physical distancing protocols, patients' fears, and the health care system's focus on COVID-19 may lead to unintended health consequences in the future (DeJong et al, 2020). For example, during the pandemic, the weekly number of newly diagnosed cancers, spanning six types, fell 46.4% (Kaufman et al., 2020). Additionally, parenterally administered non-oncology treatments saw even greater declines in volumes—56% of the April 2019 rate in April 2020 (Kaufman et al., 2020).

Finally, therapeutics research relies on a seamless interface between investigators and clinical care providers. Local investigators enrolling potential subjects in a trial rely on clinical colleagues to refer patients for screening. At the height of the pandemic, hospitals, emergency rooms, and urgent care clinics were overwhelmed with managing acutely ill COVID-19 subjects, while many office-based general and specialty clinics were closed to reduce the risk of transmission of COVID-19. Similarly, researchers themselves were pulled away from working on clinical trials to provide clinical care where the pandemic threatened to overwhelm emergency medical systems. The health care workforce was stretched so thin that the American Medical Association even published resources dedicated to caring for caregivers on the front lines (AMA, 2021). Given the logistical challenges associated with precise execution of investigational therapeutics trials, clinical colleagues may have viewed participation in a study as a distraction, while prioritizing clinical care for acutely ill subjects (Angus et al., 2021).

Challenges to Global Operations and Workforce

Industry experts were concerned that drug production could be heavily impacted due to severity of the pandemic in Asia and Europe, two regions that manufacture significant quantities of ingredients and/or finished pharmaceuticals. Ultimately, therapeutics manufacturers were able to sustain the supply of needed drugs well through the pandemic as companies used dual-sourcing to lower the risk of local dependency and greater inventory strategies. However, the development of further redundancy in the system—including alternative shipping methods—is important for future pandemics.

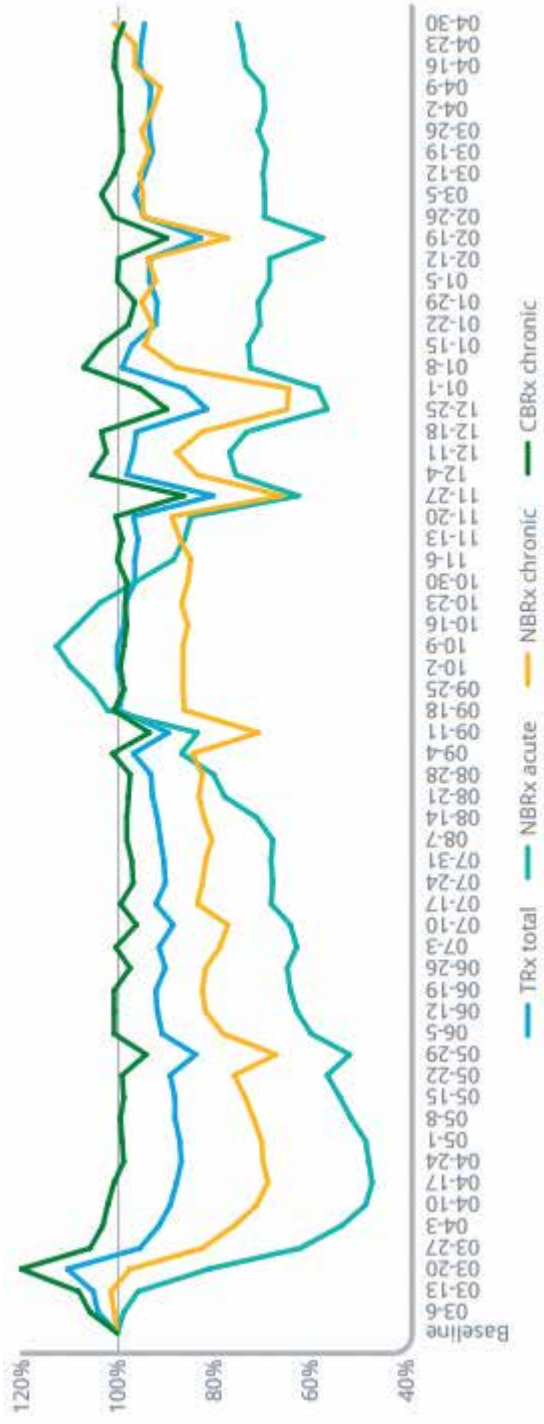

FIGURE 7-3 | Weekly Volumes of New Prescription (Rx) of Branded Therapeutics
SOURCE: IQVIA Institute National Sales Perspective and IQVIA Institute National Prescription Audit.

Clinical operations were also heavily disrupted across the industry despite use of virtual platforms where possible. Estimates indicate as high as roughly 80% of non-COVID-19 clinical trials across the industry paused or stopped during the COVID-19 pandemic (van Dorn, 2020). In light of this, the virtualization of clinical trials is a key opportunity area for further development and validation by agencies for the future. Finally, workforces were supported heavily to work remotely and the success of this unplanned pilot has accelerated a move toward distributed working across the industry.

Acceleration of Digital Technology Use

Necessitated by physical distancing measures instituted to prevent the spread of COVID-19, the introduction of new or existing technologies to meet existing and emerging health needs have been integral to replacing previous physical interactions and enabling real-time clinical decision making, applying targeted treatments, and improving patient engagement. This uptake of digital tools includes rapid growth in telehealth utilization (43.5% of Medicare primary care visits were provided via telehealth in April 2020 versus less than 1% in February 2020), online pharmacy refills (total prescriptions filled online increased 25% year-to-year at start of pandemic), and virtual clinical trial monitoring. However, patients receiving a prescription for a new medicine for the first time (new to brand prescriptions) via telehealth services were down from between 18% to 44% relative to pre-pandemic rates depending on the specialty (IQVIA Institute, 2020a; IQVIA Institute, 2020b; OASPE, 2020). These figures demonstrate the significant decline in number of patients being both diagnosed by a health care provider and subsequently receiving a prescribed medicine where appropriate.

Regulatory and reimbursement frameworks that required physical visits to health care professionals led to the underutilization of digital solutions that already exist and potentially disincentivized further expansion of these technologies. Whether this level of digital interaction can be maintained after the pandemic subsides and whether the initial positive effects are sustainable in a post-pandemic setting will in part depend on clarity of reimbursement for provider networks and the acceptance of these research modalities within clinical trials regulations. Early indications for telemedicine indicate a reduction in use from the peak of the pandemic but a new base level of 1% of all health care engagements done via telemedicine before the emergence of COVID-19 versus 9% as of April 2021 (see *Figure 7-4*). The broad implementation of telehealth during the COVID-19 pandemic is more thoroughly discussed in this paper's companion pieces focusing on care delivery and digital health (forthcoming) (Balser et al., 2021).

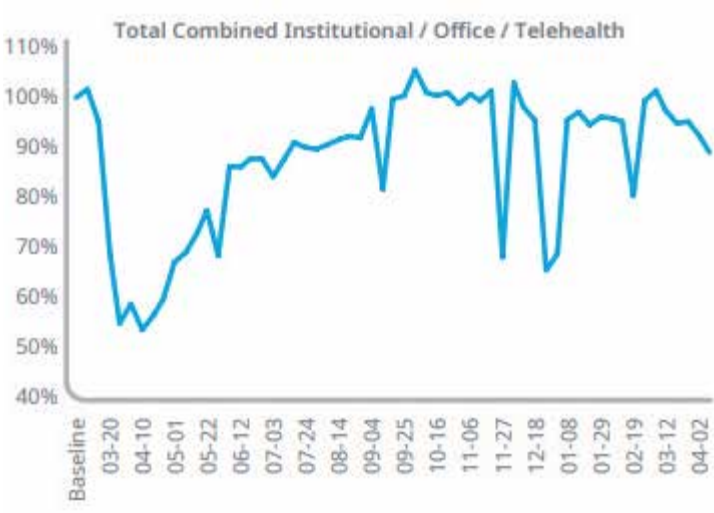

FIGURE 7-4 | Telemedicine Use Among Healthcare Provider Organizations
SOURCE: IQVIA Institute Medical Claims Data Analysis, April 2020.

Changes to FDA Guidance and Protocols

The FDA demonstrated a willingness to listen to challenges faced by the health care system and acted rapidly to provide guidance on emerging needs by introducing adaptability in addressing COVID-19-mediated clinical trial impacts. This included patients directly receiving investigational medicinal product (IMP) at their home as opposed to the IMPs being provided at the research site by the trial staff, virtual clinical trial monitoring, local bioassay assessments (as opposed to the standard centralizing assessments), tele-visits, home nursing, and remote electronic access for data source verification. These nimble flexibilities were applicable both for COVID-19 and non-COVID-19 therapeutics and vaccines.

Prior to the COVID-19 pandemic, the FDA had encouraged use of novel clinical trial methodologies to mitigate the effect of missing data (e.g., due to patient withdrawal from trial participation) on trial integrity and endpoint assessment. These same methodologies can also be used to analyze datasets of on-going clinical trials disrupted by the pandemic. In June 2020, FDA released a guidance document to provide recommendations to sponsors on methods to consider for minimizing the impact of COVID-19 disruptions on trial integrity (FDA, 2020d). Some of these disruptions have led to "unforeseen intercurrent events; that is, they affect either the interpretation or the existence of the measurements associated with the clinical question of interest while others prevent relevant data from being collected and result in a missing data problem" (Akacha et al., 2020). The estimand framework developed by the International

Council on Harmonization provides strategies to assess and mitigate the risk of seriously compromising the integrity and interpretability of clinical trials, as also acknowledged by the FDA and the European Medicines Agency (Collins and Levenson, 2020; EMA, 2020; ICH, 2020). These considerations provide guidance on the handling of missing data due to, "for example, the inability to perform important procedures like biopsies during the pandemic or government restrictions," which prevented subjects from attending scheduled visits (Akacha et al., 2020; Kunz et al., 2020).

Furthermore, suitable adaptive design methodology is available to, for example, implement unplanned interim analyses of an ongoing trial with the aim to better assess the impact of the disruptions due to the pandemic or help resizing the trial in terms of its duration or sample size (Kunz et al., 2020). Finally, supportive approaches could aim to integrate data from external sources, supplement the control arm, or merge trial data with results from previous or concurrent trials (Hemmings, 2020). Regulatory authorities will need to consider approvals based on a higher-than-normal level of uncertainty and use relevant post-approval data to complement the pre-registration study(s), where feasible.

Vaccines

Overview and Response: Vaccines

The field of vaccine development includes manufacturers and innovators involved in the research and development, manufacturing, sales, and distribution of vaccines.

Vaccine discovery and development is a failure-prone, lengthy, and expensive process, frequently costing over $1 billion from start to finish, and manufacturing is technically challenging and expensive. A large portion of vaccine development projects never make it to regulatory approval. Despite substantial industry and government efforts, only about two dozen vaccines have been successfully developed and deployed in the last 100 years (CDC, 2018). In spite of these challenges, vaccines have made significant contributions to global health, including the eradication of smallpox and near eradication of polio (Greenwood, 2014). Additionally, they have been credited by the CDC for saving nearly $406 billion in potential health care expenses associated with prevented disease and $1.66 trillion in total societal costs, like loss of productivity, since 1994 (HIV Medicine Association, 2019).

When SARS-CoV-2 emerged, the field had no off-the-shelf vaccines available for this entirely new virus. However, the U.S. government, U.S. regulators, and numerous global biopharmaceutical companies acted quickly and collaboratively to accelerate the vaccine development process, which traditionally takes a decade or more, to yield over 200+ distinct vaccine candidates, 11 candidates

in Phase 3 trials, and two approved for distribution with Emergency Use Authorization (EUA) and one fully approved as of October 1, 2021 (FDA, 2021a; FDA, 2021b; WHO, 2021). Developing, manufacturing, and distributing a vaccine in a year is a landmark achievement in health care. The high efficacy against serious disease of the first three candidates (over 90% effectiveness) places the COVID-19 vaccines on par with other highly effective vaccines in use today (e.g., measles) (Palca, 2020; Thomas et al., 2020).

While vaccine developers are solving many challenges in the development process, it is also essential to anticipate potential supply chain and distribution issues. A recent report by the U.S. Government Accountability Office highlighted the challenges of scaling up mass production of the vaccines, which would interfere with the effective rollout (Van Beusekom, 2020). Given the need for hundreds of millions of vaccine doses in the U.S. and billions globally, there is a dire need for manufacturing capacity, achievable through new capacity or by shifting capacity from other products. Furthermore, there is a limited supply of products such as glass vials, stoppers, needles, and syringes that are typically not rate-limiting but proved at various times in the last year to be unexpected bottlenecks for the immensity of scale required (Abrams Kaplan, 2020). Beyond goods and materials, pandemic-related disruptions such as changes in worker availability and export restrictions could severely impact the supply chain's ability to meet the demand. Lastly, in terms of distribution, it is important to recognize that there are different requirements for storage and transportation depending on the vaccine. For example, the vaccines from Pfizer/BioNTech and Moderna preferably require freezing at −94 degrees Fahrenheit and −4 degrees Fahrenheit respectively for safe storage, which pose meaningful challenges when trying to inoculate the global population. Both vaccines can be stored at higher freezer temperatures, but for a limited duration (FDA, 2021c; FDA, 2021d). The vaccines from Johnson & Johnson and AstraZeneca, on the other hand, can be stored at refrigerated temperatures (Hopkins, 2020). As the industry moves into the critical phase of delivery, supply resilience will need to be front-of-mind for every link in the value chain.

While upholding the highest safety and regulatory standards, several factors facilitated the delivery of multiple vaccine candidates to the public in 18 months. One factor was the use of new biologic platforms that had been developed by investments made in past years, supported by reliable intellectual property systems (e.g., mRNA and adenovirus platforms). Additional factors included:

- earlier and frequent engagement with regulators,
- expedited regulatory reviews,
- vast investments in private and public resources for vaccine development and delivery,

- enhanced collaboration within and between public and private sectors (see *Table 7-1*),
- at-risk manufacturing at commercial scale well ahead of entering the vaccine candidate into human trials, and
- compression of Phase 1/2a dose ranging studies and manufacturing timelines.

Beginning in May 2020, coordinated government support for promising vaccine candidates was provided through Operation Warp Speed (OWS), a partnership among the Department of Health and Human Services, the Department of Defense, and private-sector companies. The aim of the partnership was to "accelerate the development, manufacturing, and distribution of vaccines, therapeutics, and

TABLE 7-1 | Examples of Collaborations Which Emerged During COVID-19

Company	Collaboration	Vaccine type	Description
Johnson & Johnson	Beth Israel Deaconess Medical Center; BARDA	Non-replicating viral vector	DNA sequence for coronavirus **spike protein** delivered via adenovirus type 26 vector
Pfizer	BioNTech	mRNA	Genetic instructions for the coronavirus **spike protein** are encoded in mRNA, delivered via lipid nanoparticle
Moderna	NIAID; Lonza	mRNA	Genetic instructions for the coronavirus **spike protein** are encoded in mRNA, delivered via lipid nanoparticle
AstraZeneca PLC	Oxford University	Non-replicating viral vector	DNA sequence for coronavirus **spike protein** delivered via chimpanzee viral vector
GlaxoSmithKline	Sanofi	Protein-based	Coronavirus-derived protein produced in insect cell lines, extracted and delivered alongside an adjuvant to target **spike protein**
CanSino Biologics	Precision NanoSystems	Non-replicating viral vector	DNA sequence for coronavirus **spike protein** delivered via adenovirus type 5 vector
Sinovac	Dynavax	Inactivated virus	Combination of chemically inactivated SARS-CoV-2 and immunological agent to target **spike protein**
Novavax	Takeda, Emergent BioSolutions, Serum Institute of India	Protein-based	Coronavirus-derived protein produced in insect cell lines, extracted and delivered alongside an adjuvant to target **spike protein**

SOURCE: Department of Health and Human Services. 2020. COVID-19 Vaccines. Available at: https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html (accessed December 19, 2020).

diagnostics for COVID-19" without compromising on safety, quality, or efficacy (HHS, 2020). OWS has impacted vaccine development through over $10 billion dollars of support for vaccine development efforts, manufacturing capacity scale-up, and at-risk manufacturing, and through coordination with FDA on technical matters and with Department of Defense on vaccine distribution channels. As of February 2021, the White House COVID-19 Response Team assumed the responsibilities of OWS. Government support also continues to be available through the participation of NIH Vaccine and Treatment Evaluation Unit trial sites in Phase 3 clinical trials for preventive vaccines, such as the Moderna mRNA vaccine and the Johnson & Johnson vaccine (COVID-19 Prevention Network, 2021; NIH, 2020).

Vulnerabilities and Opportunities: Vaccines

In responding to COVID-19, the field of vaccine development contended with several vulnerabilities brought to the fore by the pandemic. The authors of this paper have chosen to focus on the vulnerabilities and opportunities that emerged during the early stages of vaccine manufacturing and innovation, namely in the areas of discovery, development, and clinical trial design. While there are additional vulnerabilities and lessons learned in areas like distribution and supply chain capacity, they are not covered in depth in this paper.

One potential risk in the traditional approach that has been adopted for vaccine development for COVID-19 is the limited diversity of candidate vaccine designs as a result of the limited variety in their antigen targets. Specifically, all the vaccines are monovalent, relying on one antigen protein, which is SARS-CoV-2 spike protein (Gardner et al., 2020). If the protein target had yielded safety or efficacy issues in humans, all candidate vaccines would be at risk of being unstable and unsafe. Though Phase 3 testing has proven that this is not the case, industry-wide vaccine development effort might have faced an overall lower degree of risk if incentives were in place to drive increased target diversification. The parallel pursuit of alternative protein antigens, multivalent vaccines, and T-cell vaccines would have mitigated the risk and increased the overall likelihood of success. A related vulnerability that may yet play out is the possibility of mutations occurring to the spike protein, this would impact the entire collection of vaccines. Several variants of the virus have now emerged, including variants with one or more mutations to the spike protein. New vaccines or boosters accounting for these variants will need to be brought forward quickly if needed.

The limited diversity of approaches in vaccines R&D also reflects the limited diversity of biopharmaceutical R&D overall. This limited diversity is understandable in the context of market dynamics, where the industry disproportionately invests in diseases for which reimbursement and pricing is

well-established such as cancer, autoimmune diseases, and rare diseases. However, the lack of investment into understanding virus strains impedes the industry's understanding of future pandemics, making vaccine development challenging, and reflects a more general lack of investment in basic and translational science and technology. Areas in need of substantially increased government investment include (Note: Examples provided refer specifically to pandemic preparedness and are not encompassing of all research needs):

- **Fundamental human biology** – e.g., in the case of pandemic preparedness, better understanding of the innate immune response to infections and how it differentiates "friend vs. foe"
- **Therapeutic modality research** – e.g., the use of RNA therapeutics for rapid response to pandemic threats either as antiviral or as vaccine
- **Human toxicology science**
- **Manufacturing science** – especially of new therapeutic modalities
- **Clinical trial design** – e.g., modifications to design that allow for non-placebo-controlled trials in conjunction with the use of data science to generate better controls and identify other ways to assess comparator arms

While the areas listed above are critical, it is equally important that investments encourage diversity with regards to the entire clinical trial ecosystem, from enhanced, culturally appropriate recruitment of trial participants to recruitment and training of diverse investigators and site coordination staff. It is important to incentivize research in primary care and, further, ensure that trials address a diverse and representative population. Achieving this requires a commitment to identifying new investigators, trial sites, and more sustained commitment in underrepresented communities to establish trust and confidence in the clinical trial process.

A second vulnerability illuminated by COVID-19 involved data sharing and application across governments, global health bodies, and industry parties. Historically, the stakeholders involved in vaccine development, manufacturing, and distribution were siloed, preventing data from being shared across organizations to maintain a competitive advantage. Furthermore, the available data on prevalence and impact of diseases were inconsistent and of low quality. This led to the creation of the COVID-19 R&D Alliance, which was organically established by heads of pharmaceutical R&D companies to improve information sharing, helping vaccine developers move quickly and with confidence without jeopardizing competitiveness or intellectual property rights (COVID R&D Alliance, 2020). While this proved effective as a short-term solution to data sharing during the pandemic, a longer-term arrangement is not assured. Therefore, it is important

that the lessons learned from the Alliance be codified to inform the response to future infectious disease outbreaks.

In standard vaccines development, Phase 1 studies test for safety and tolerability of the candidate vaccine and yield data on immune measurements of antibodies and T-cells that are induced by the vaccine. In subsequent, lengthier Phase 2 and 3 studies, vaccine efficacy, or protection from the disease is measured. At the end of a Phase 3 study, it is possible to quantitatively relate the magnitude of immune measurements to the magnitude of efficacy, thereby providing a roadmap to other vaccine developers and an ability to move subsequent vaccines forward more quickly than would otherwise be possible. Consideration should be given to how best to rapidly construct immune-efficacy correlates (i.e., the nature and magnitude of the various forms of immune induction by the vaccine, and how they predict its efficacy), and how best to incentivize early vaccine developers to share these roadmaps to accelerate solutions across the full industry ecosystem. In the case of the present pandemic, such roadmaps have not happened. Additionally, there is an opportunity to apply advanced analytics to real-world data to accelerate clinical trials and deliver vaccines faster.

The COVID-19 pandemic also highlighted the opportunity to incorporate alternative clinical trial designs to randomized control field trials to deliver a vaccine more quickly. Once randomized clinical vaccine trials are underway, time to completion is inversely proportional to the incidence rate of infection. For example, when there is less freely circulating virus, the clinical trial takes longer to complete, and the inverse is also true. An alternative form of trial, the human challenge trial, has been used for some viruses, including influenza and respiratory syncytial virus. These human challenge trials involve exposing consenting subjects to a weakened strain of the virus in controlled and safe environments. While the data generated has limitations (given the use of weakened strains) and there are ethical considerations (given that subjects are intentionally infected), challenge trials are substantially smaller and faster than randomized control trials since they are uncoupled from disease incidence and many believe that careful adoption of them would benefit society. The UK government has been an early adopter of human challenge trials, investing £33 million to carry out the first human challenge trials to accelerate a COVID-19 vaccine (Roberts, 2020). While well worth exploring, it remains unknown as to whether these types of trials could fully replace more traditional Phase 3 studies.

Today's vaccine clinical trial protocols enroll subjects to be randomized equally between an arm that receives a vaccine and an arm that receives a placebo. Recruiting large numbers of placebo patients takes time, is expensive, and raises ethical questions about giving individuals a placebo in regions of high disease burden. Using real-world data (structured and unstructured electronic health

records, claims data, imaging, genetics, and laboratory data) in a circumstance-matched (propensity-matched) set of subjects to construct an "external control arm" (sometimes called "synthetic control arm") would reduce the need for as many placebo-dosed subjects. The net effect would be to reduce the time to recruit and conduct the trial and reduce the number of subjects that are intentionally left unvaccinated. Additionally, with EUAs issued to the Moderna and Johnson & Johnson vaccines and full authorization to the Pfizer/BioNTech vaccine, there is an ethical dilemma in keeping individuals in a placebo arm for other randomized clinical trials, especially considering that companies are intentionally enrolling vulnerable populations that are especially in need of protection by a vaccine. Several alternatives to placebo controls exist, such as head-to-head randomized trials that compare a novel candidate vaccine with a previously authorized vaccine, or multigroup platform trials (Joffe, 2020). Synthetic control arms are another alternative; however, the technical and regulatory hurdles of a synthetic control arm are significant and would need to be addressed to gain broader adoption.

INEQUITIES OBSERVED DURING COVID-19 BY HEALTH PRODUCT MANUFACTURERS AND INNOVATORS

The COVID-19 pandemic has highlighted the acute and chronic nature of disparities in the U.S. health care system. Most well-known are racial disparities in rates of COVID-19 infection, hospitalizations, and mortality. As shown by several recent studies, Black, Latino and Indigenous peoples have been disproportionately impacted by COVID-19, and factors such as age, gender, economic, and environmental factors further exacerbate these effects (Brimmer et al., 2020). For example, in a recent study involving 2,595 patients tested at a Milwaukee hospital for COVID-19 from March 12 through March 31, 2020, Black patients were 5.4 times more likely to test positive than other races. Males had increased risk of testing positive (1.5 times more likely than women) as did people of increased age (twice as likely if over 60 years old) (Gallup, 2020). Strikingly, ZIP code explained 79% of the overall variance in positive test results. Economic variance across ZIP codes further delineated outcomes. "After adjusting for ZIP code, Black patients were 1.9 times more likely to require hospitalization, while those living in poverty were 3.8 times more likely" (Muñoz-Price et al., 2020).

Certain comorbidities such as cancer, chronic kidney disease, chronic obstructive pulmonary disease, heart disease, obesity, sickle cell disease, and type 2 diabetes, which disproportionately affect some minority communities, have been identified as factors contributing to poorer outcomes for patients with COVID-19. Some additional diseases have limited reported data but might

contribute to an increased risk for severe illness from COVID-19, including asthma, cerebrovascular disease, hypertension, immunocompromised states, and liver disease. Minority communities are particularly susceptible to these diseases due to the interplay of structural inequities across the social determinants of health (SDoH) including housing conditions, economic stressors, and limited access to nutritious food.

As major drivers of health inequities, SDoH have been the topic of much discussion. Yet, they are seldom addressed in the design or implementation of systems of health care. For example, despite efforts described earlier in the diagnostics section of this paper to expand the accessibility of testing through site identification on the internet, drive-through testing and at-home kits, certain underserved communities experienced disparities in access to COVID-19 testing. Part of the reason is that these solutions do not solve the issue of patients without access to a car, or of those without a home address where a specimen collection kit could be mailed. Lack of access to the internet was also a barrier for some patients. Similarly, the lack of predictability of reimbursement and the variety of cost and out-of-pocket burdens on patients likewise has a direct bearing on these health inequities. These examples suggest the need for careful analysis of the entire range of factors impacting health status, along with acknowledgement of and strategies to address implicit bias in health care, and health access as health solutions are designed and rolled out.

Another set of critical issues that have been given considerable attention is the inclusion of communities at greater risk of infection, hospitalization, and death from COVID-19 in clinical trials of diagnostics, therapeutics, and vaccines. COVID-19 vaccine sponsors have faced difficulties in recruiting diverse populations for Phase 1 and 2 trials (despite a desire to do so), resulting in approximately 90% of volunteers being white (Radcliffe, 2020). This illuminates the overall lack of diversity in the clinical trial process, especially of Black, Latino, and Indigenous populations. Without representative patient populations enrolled in clinical trials, results may not fully reflect the clinical response (efficacy, side effect profile, etc.) that will be seen in the real world.

Attempting to increase inclusion in clinical trials during the pandemic has had its own unique set of challenges. However, some of the strategies developed prior to and during the pandemic in addition to innovations in design and execution of clinical trials serve as a solid foundation. These modifications include the use of virtual visits and monitoring, ensuring inclusion and exclusion criteria do not inadvertently exclude diverse patients, and increasing capacity of minority investigators and centers serving minority communities. Fundamental changes are necessary to make representative inclusion sustainable.

TRUST AND COMMUNICATION ACROSS ALL SUB-SECTORS OF HEALTH PRODUCT MANUFACTURERS AND INNOVATORS

Trust and communication were vulnerabilities that appeared across all five sub-sectors discussed in this paper during the COVID-19 pandemic. Inequities across HPMI point to a larger problem of lack of trust in health care, national preparedness, and public health countermeasures. The biopharmaceutical industry and health care overall are amongst the lowest-rated industries in the U.S. for overall public sentiment (along with oil and gas and the government), though polls indicate that there has been an improvement in the public perception of the biopharmaceutical industry during COVID-19, due largely to the role the industry has played in responding to the pandemic (Gallup, 2020; Snyder Bulik, 2020).

As HPMI mobilized to address challenges across supply chain networks, the politicization and associated spread of misinformation related to repurposed or new therapeutics and critical supply availability negatively impacted efforts to slow or halt the spread of COVID-19. The touting from some quarters as to the health benefits of newly developed and existing therapeutics (e.g., azithromycin, hydroxychloroquine, chloroquine, REGN-COV2) to treat symptoms associated with COVID-19 reflected inconsistencies in communication of efficacy from clinical trial data and, in some instances, were bolstered by issuance of EUAs. However, the FDA revoked some EUAs after certain drugs were proven to provide no clinical benefit and were shown to increase risk (FDA, 2020e). Although industry responses strived to maintain public confidence in private-sector COVID-19 countermeasures, various communication obstacles remained. During the pandemic, primary modes of industry engagement and communication with the public were limited. Consumers received downstream updates from the federal government on COVID-19 safety and containment measures and guidance on the purchase of PPE (CDC, 2020a; FDA, 2020f). However, these communication streams, among others (e.g., social and mass media platforms and health department COVID-19 sites), contended with misinformation about vaccine development procedures, COVID-19 test quality and availability, and PPE distribution.

A considerable increase in counterfeit masks and respirators posed an additional obstacle to maintaining and fostering public security and trust. Shortages in these critical supplies led to increases in the marketing of unsafe and substandard masks and respirators to hospitals, clinics, and the public at large (3M, 2020b). With counterfeit supplies posing a threat to industry standards and the health and safety of those who wore these substandard masks and respirators, companies and federal agencies took quick action to alert health care workers, first responders, consumers, and the general public (3M, 2020c; CDC, 2020b). In addition,

companies and federal agencies moved quickly with warnings about false rapid COVID-19 tests and unverified vaccine research and development protocols to protect consumers and to combat what was being deemed as "an erosion of public trust in science" (FDA, 2020g; Trogen et al., 2020).

A lack of trust in biomedical science is especially acute in subsets of minority communities due to a history of discrimination in science, misguided R&D practices by various stakeholders, and a lack of access to accurate information. This problem exacerbates the fact that these populations are at the highest risk of infection and death from COVID-19 (CDC, 2020c). Many sources point to scarce representation of and discrimination against minority populations across the STEM workforce as sources of mistrust (Funk and Parker, 2018). Despite the nation's STEM workforce having grown more diverse over time, numbers in these fields are still far below the level of diversity represented in the general population (NASEM, 2019). These concerns have also extended to the low levels of diversity relative to the general population in clinical trial enrollment for therapeutic procedures and drug development—an issue the FDA continues to address in its most recent guidance on enhancing the diversity of clinical trial populations (FDA, 2020h; Knepper et al., 2018). Finally, memories of medical injustice, as was present in cases such as the Tuskegee syphilis study, still raise suspicion among minority communities most affected by health disparities (Jamison, 2020). Acknowledgement of and action to address key structural inequities that have perpetuated mistrust of biomedical science in minority communities should remain a sector priority as it considers ways to enhance effectiveness of future pandemic responses.

Information and activities that address building trust in biomedical science need to be more diligently studied. Diversification in clinical trial enrollment and disaggregation of clinical trial data signal efforts to better represent the general population in the design, implementation, and efficacy of solutions for pandemic preparedness. Additional considerations for indemnification coverage frameworks, along with viable mechanisms to compensate individuals in the event of unintended harm from emergency use of rapidly developed products could promote wider public confidence in industry efforts and sustained sector action to ensure equitable distribution of pandemic resources as a priority. Sub-sectors across HPMI—whether or not they have been primarily or peripherally cited for practices that have contributed to public mistrust—have a responsibility to assess and reform their practices if necessary to become more trustworthy among those (especially minorities) who would use their products and services. The need for consistent and coordinated communication and proactive, innovative actions to combat mistrust and misinformation is clear. Policy makers, the HPMI sector, and the health care industry need to work together to solve these problems that have been present all along but were exacerbated and made more evident by the COVID-19 pandemic.

CONSOLIDATION OF PRIORITY ACTIONS NEEDED ACROSS THE FIELD OF HEALTH PRODUCT MANUFACTURING AND INNOVATION

Across all sub-sectors of HPMI, several vulnerabilities exposed by COVID-19 have been described above. These vulnerabilities suggest a clear set of critical areas of opportunities, seen in *Figure 7-5*.

1. **Support for Science:** Encouraging the diversity of basic scientific approaches toward research, development, and implementation to support the development and implementation of diagnostics, vaccines, medical equipment, and treatments for coronavirus infections, influenza, infectious diseases, and other global health threats.
2. **Data Sharing:** Setting standards and processes for data collection, sharing, and application across governments, global health bodies, and industry parties in ways that are mutually beneficial but that also maintain competitive dynamics.

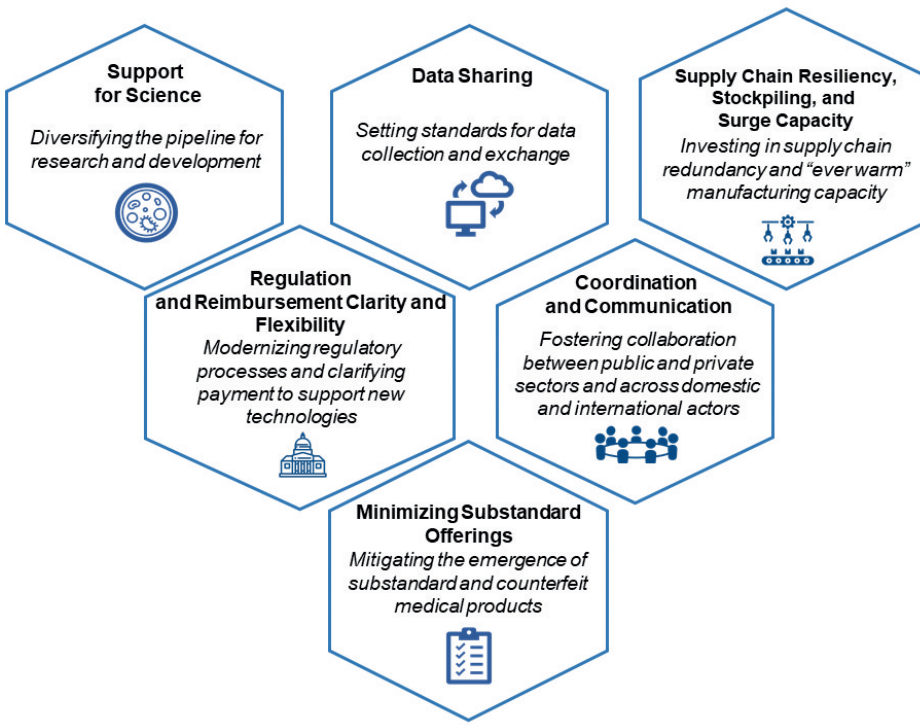

FIGURE 7-5 | Opportunities for Sector-Wide Transformation

3. **Supply Chain Resiliency, Stockpiling, and Surge Capacity:** Establishing supply chain and infrastructure redundancy, including the availability of "ever warm" manufacturing capacity and stockpiling.
4. **Regulation and Reimbursement Clarity and Flexibility:** Enhancing efficiency and effectiveness through modernizing regulatory processes and providing clarity on coverage and reimbursement to support and incentivize innovation.
5. **Coordination and Communication:** Driving improved domestic and international (private sector and government) stakeholder coordination to enable consistent and transparent communication.
6. **Minimizing Substandard Offerings:** Addressing and mitigating the emergence of substandard, falsified, and counterfeit PPE, treatments, and diagnostics during a public health crisis.

The authors of this paper have proposed a set of discrete federal policy actions to address these vulnerabilities and improve efficiency, efficacy, and equity across the U.S. health care system. Supporting detail pertinent to each HPMI sub-sector is below each overarching policy area.

IDENTIFIED POLICY OPPORTUNITIES FOR HEALTH PRODUCT MANUFACTURERS AND INNOVATORS

Support for Science

Proposed policy: The budget proposed by the President of the United States to Congress should contain unified policy across agencies such as NIH, BARDA, FDA, Centers for Medicare and Medicaid Services, CDC, National Institute for Occupational Safety & Health, OSHA, NSF, VA, DOD, and DARPA, with guidance for allocation across areas of greatest need, including basic science, applied technology, advanced development of diverse scientific approaches, and training of medical technologists and academic labs to improve response time and probability of technical success in future pandemics. Every year the budget should contain a section that lists projects and initiatives that would encompass a domestic, unified preparedness agenda across federal agencies. It would provide guidance to Congress across appropriations committees and serve as both a strategy document and a clear description of what is required to ensure preparedness for ongoing and future pandemics.

In the U.S., the NIH funds most medical research dedicated to uncovering the root causes of disease through research grants to more than 2,500 institutions across the country. The research undertaken by NIH-funded investigators is a critical foundation for scientific discovery, enabling health care companies to build on this research and develop new health care products. Furthermore, NIH-funded research often allows otherwise risky and massive investments of money, time, and manpower to be focused on shepherding medical treatments through regulatory approvals.

Investment in fundamental research and new technologies to address potential future pandemic viruses would substantially improve America's public health preparedness. For example, such investment could include sequencing strains of coronavirus that are incubating in zoonotic species such as bats to better understand potentially emerging diseases. The availability of protein sequence data for dozens of strains could yield a dataset that allows vaccine innovators to act well in advance of a pandemic.

Within the therapeutics and vaccines sub-sector, government funding should focus on a few select programs per biological target for a given indication. Sustained investments in both early-stage research at NIH and advanced development activities at the Biomedical Advanced Research and Development Authority (BARDA) are needed. This approach would encourage pursuit of a more diverse set of vaccine and therapeutics candidates, leading to a higher probability of successful approvals. The new science entity proposed by President Joseph Biden in Spring 2021, known as the Advanced Research Projects Agency for Health (ARPA-H), is currently under design and may also provide funding channels appropriate for investment into innovative, breakthrough medical treatments (NIH, 2021; The White House, 2021).

There are also challenges to large-scale manufacturing for each vaccine platform. The government should invest in fundamental research in manufacturing at scale on new platforms of interest (e.g., viral vectors, mRNA, novel adjuvants) with the capability of responding to multiple pandemic threats. It is critical that these investments target improved yield, speed, and purity of these scale-ups by also focusing on the accompanying technologies that support the production of vaccines at scale, such as the purification and bioprocessing machinery used in the engineering of vaccine modules.

Federal investment should extend beyond biological and biomedical science disciplines. For the hospital supplies and personal protective equipment sub-sector, sustained funding in materials science can bolster innovation of new formulations of materials that strengthen the integrity and effectiveness of vital supplies such as PPE and test swabs. By inventing alternative materials with similar or improved chemical and physical properties as their predecessors, these

materials can be readily manufactured "on shore" and the sector can avoid global supply disruptions.

For the diagnostics sub-sector, support for science must involve funding for more training programs to address shortages of medical technologists and to train academic lab staff to assist in pandemics in compliance with CLIA.

Proposed policy: Address the lack of diversity in the clinical trial system by reducing barriers to enrollment of representative minority populations, those from low socio-economic backgrounds, and children in clinical trial recruitment, and increasing the numbers of diverse clinical investigators, coordinators, and site staff.

COVID-19's disproportionately devastating impact on minority communities in the U.S. has focused attention on the underrepresentation of communities of color in clinical trials. This underrepresentation is due to systemic obstacles as discussed in the Trust and Communication section of this paper, from lack of diversity in clinical trial investigators, historical events leading to distrust of the medical establishment, and socioeconomic factors such as inadequate access to affordable transportation to clinical trial sites and childcare. As there are a variety of causes of this problem, it will take a variety of policy solutions, including investment in and greater partnership with diverse communities, to achieve meaningful change.

While the FDA has developed guidance documents focusing on enrollment practices and Health and Human Services (HHS) has developed an action plan on inclusion of demographic subgroups in clinical trials, a broad range of stakeholders, including trial sponsors, need to take additional efforts to expand clinical trial diversity. The health care industry needs to create dialogue and relationships with a more diverse array of stakeholders to advance initiatives aimed at successfully recruiting underserved and underrepresented patients and apply new tools to increase enrollment of diverse populations in clinical trials. Clinical trial practices can mitigate barriers by leveraging lessons from successful recruitment efforts and educating communities about the importance of clinical trials and the importance of diverse participation. Targeted outreach efforts can be employed to increase the diversity of investigators and site staff. Additional efforts to broaden trial participation could include conducting decentralized clinical trials that ease burdens on participants, ensuring that materials are translated and culturally appropriate, and making necessary investments to conduct trials with community health centers and physically locate sites where communities of color reside. Foundationally, HPMI can remedy diversity blind spots by recruiting talent that represent a variety of perspectives and cultivating the early entry of people from diverse backgrounds into STEM fields through science apprenticeships and scholarship programs.

Data Sharing

Proposed policy: The Federal Trade Commission, Department of Justice (DOJ), FDA, CDC, the Office of the National Coordinator for Health Information Technology (ONC), and the Office of Inspector General (OIG) should develop a framework for industry stakeholders to enter data-sharing agreements during national emergencies for pre-clinical and clinical development results in a way that is mutually beneficial while also maintaining competitive dynamics and addressing privacy concerns.

Impediments to sharing of patient data among hospitals and health care systems is not a new challenge related to the pandemic. However, the pandemic has highlighted the imperative to address the barriers to the flow of these data, not just for future pandemics, but throughout health care.

In collaboration with HPMI, regulators such as the Federal Trade Commission, DOJ, and relevant HHS agencies such as the FDA, ONC, CDC, and OIG should create a legal and regulatory structure that incentivizes data sharing and ensures trust and competition by maintaining traditional protection of intellectual property and trade secrets, but allows HPMI to share other manufacturing, safety, and early efficacy and validity data amongst themselves and with the federal government. This type of agreement may require review of antitrust guidelines and applicable privacy laws, and the timing of data sharing should be done in consideration of competitive dynamics. Where there are international interfaces for data sharing, there should be clear protocols established and alignment of the governance and requirements to enable relevant data to be shared in a protected and secure manner between different territories. Data sharing at the international level must take into account that several countries have data localization and privacy laws that would restrict the export and sharing of personal data.

For the medical devices sub-sector, there is an opportunity to enable and encourage information sharing via consortia and government guidance to improve data completeness, accuracy, and latency. Affordable Care Act initiatives today mandate this type of sharing in primary care and eye care — which could be expanded to hospital products for the betterment of all parties. Unfortunately, the health care industry is currently moving in the opposite direction. Many states have begun to discuss restricting the sharing of data, and California has passed a Consumer Privacy Act which allows consumers to opt out of the sharing of their information (State of California Department of Justice, 2018). It is critical that these types of regulations do not extend to health data that is used for research and clinical purposes (in a HIPAA-compliant manner). During times of crisis, this type of data sharing will also help to identify safe opportunities for localized therapy for medical devices.

For the hospital equipment sub-sector, as companies worked with government agencies like the Federal Emergency Management Agency (FEMA) and others to distribute products, agencies needed to ensure that companies' competitive information remains proprietary and is not being shared with other companies. Stronger protection of sales, supply chain, and distribution information in emergency scenarios may encourage greater openness and an incentive for other manufacturers to participate.

In addition, more clarity to manufacturers and distribution networks about supply levels at health care systems and other essential sub-sectors from federal, state, and local governments would help appropriately targeted and coordinated PPE distribution during an emergency. During the pandemic, many networks could have benefited from needs-based assessments across various levels to inform distribution plans. A federal dashboard or control tower structure would provide more visibility to companies regarding where the distribution of their product is needed most.

Lastly, many of the drivers of inequities in health outcomes are poorly understood. The potential exists to strengthen data collection, sharing, analysis, and application, specifically regarding demographic data needed for public health analyses. Platforms and repositories such as the National Interoperability Collaborative, which accelerated understanding in other areas of study such as rare diseases, may be applicable in informing a response to future public health emergencies. Strengthening demographic data collection and diversity of participants could inform a more equitable approach to distribution of supplies as companies work to support communities most in need.

Proposed policy: In cooperation with FDA, CDC, and ONC, develop guidelines and data standards for health authorities and appropriate industry stakeholders to report and accept pre-defined data during national health emergencies to allow for more rapid and effective responses.

Within the therapeutics, vaccines, and medical device sub-sectors, data standards should be adopted to enhance analytics of baseline epidemiologic trends and to improve the interpretability of therapeutics developed to treat COVID-19. Furthermore, within the therapeutics sub-sector, mechanisms should be in place to facilitate sharing compound libraries that enable rapid screening.

For the vaccines sub-sector, it is essential to establish a platform with a standardized format for vaccine innovators to share safety and efficacy data following early trials to increase the overall availability of data and to improve the statistical accuracy and efficiency of vaccine creation, with appropriate limitations for patient data protection and protection of proprietary information. Further, with the availability of vaccines, real-time data capture should be facilitated, which can be vital in vaccine surveillance and monitoring post-market safety.

Although the diagnostics sub-sector reports public health data about infectious diseases to local health departments and federal entities on a regular basis, the COVID-19 pandemic highlighted the opportunity for data-reporting systems and procedures that are faster, more complete, and more transparent — and not duplicative or demanded in non-standard formats. To that end, demographic data needed for public health analyses, but not necessary for performance of laboratory testing, should be collected and reported directly to public health authorities by health care providers who have direct contact with patients, not by laboratories that typically have no such direct contact with patients and to whom such data is typically not reported by ordering health care providers. Laboratories should report test result data in a standard format to public health authorities to help with contact tracing without duplication of reporting to multiple entities for the same jurisdiction. Public health authorities should be adequately resourced and have the technical capabilities to receive required data in standard electronic formats and should not demand reporting of data that they are not capable of receiving in such formats.

Supply Chain Resiliency, Stockpiling, and Surge Capacity

Proposed policy: Ensure federal policies encourage manufacturers and laboratories to invest in and maintain sufficient redundancy at all levels of the supply chain across geographies and distribution channels.

Federal policies, particularly relating to trade, customs, and manufacturing, should encourage manufacturers to maintain sufficient redundancy at all levels of the supply chain, including ensuring the reciprocity of the free flow of medical goods across borders. Within the diagnostics, medical devices, and hospital supplies and personal protective equipment sub-sectors of HPMI, a resilient supply chain requires a holistic view of all components needed from start to finish. For example, having an abundance of testing machines will have minimal positive effect on a public health crisis without supplies to collect specimens or reagents to run the tests. There must be coordination between every link in the supply chain. To accomplish such coordination, mechanisms and infrastructure should be established for standardized communication of supply needs and supply availability among and between manufacturers, their customers, and government, where appropriate. Congress and the current Presidential administration should invest in an IT system that has pre-identified supplies and suppliers that can be called upon in real time to assess the supply chains and surge capacity of suppliers.

To avoid shortages, products must be continually shipped and received. In the early stages of the COVID-19 pandemic, global air cargo throughput decreased ~20% year-to-year, primarily due to a sharp decline in passenger demand and

the grounding of commercial air traffic, creating logistical challenges never seen before (E-Trade for All, 2020).

In addition, contingency supply chains and dual mechanisms play critical roles in ensuring redundancy. Policies should incentivize manufacturers to build and maintain robust supply networks to mitigate the risk of delayed shipment or other breakdowns along the supply chain (including local supply chains to avoid geographic bottlenecks during future crises). Border closures or delays due to changes in customs procedures or decline in the number of personnel to conduct inspections can impact essential supplies from reaching their destination in a timely manner. Correspondingly, all stakeholders should consider which critical components should be stockpiled and/or manufactured in the U.S. and at what volumes to ensure patient access, if global logistics are interrupted. Consideration should be given to whether a North American "compact" might expand manufacturing and strengthen supply chains across the U.S., Canada, and Mexico.

Particularly for medical supplies and equipment relied upon by health care providers, policy makers should evaluate the public health implications of trade restrictions for flow of goods through their borders. Countries that erect export restrictions may score a short-term win, but supply chains inevitably adjust and flow around them, leaving "islands" with less access to supplies. Additionally, public-private partnerships should be developed to ensure mobility through prioritized and effective distribution of limited resources. Government planners that work with manufacturers with the capacity to manufacture at scale, with access to needed raw materials at scale, and with access to existing and robust distribution channels are able to get product quickly to those who need it the most. Centralized government direction during a crisis and public-private partnerships can help ensure that supply chain systems and distribution networks focus on public health priorities. Governments should facilitate the appropriate collection and analysis of distribution and use data to help ensure resources are properly distributed to those who need it the most.

For the therapeutics and vaccines sub-sectors, policies should protect and preserve industry's ability to procure active pharmaceutical ingredients and medical components from multiple, diverse sources, which are essential to ensuring patient access to life-saving and preventative medicines, medical technologies, and treatments.

Proposed policy: As has been suggested in previous reports, Congress should appropriate robust, sustainable funding to incentivize the building and maintenance of continuous "ever-warm" manufacturing capacity and stockpiles (Bipartisan Commission on Biodefense, 2015). The HHS Assistant Secretary of Preparedness and Response should lead a process to

describe what supplies, medicines, and devices should have an "ever-warm" manufacturing capacity able to respond to immediate spikes in demand. This process should work in coordination with updates to the Strategic National Stockpile strategy, which focuses on which products should be maintained by the government and which should be maintained in vendor-managed inventories that are funded by the government.

The U.S. Strategic National Stockpile and state stockpiles, which are designed to provide supplies, medicines, and devices during public health emergencies, should be viewed as an insurance investment ready in the event that a catastrophic disaster strikes. If not used in the short term, it is not a wasted investment, just as buying home insurance is not viewed as a wasted expenditure.

Particularly for responding to pandemics, epidemics, and natural disasters, excess surge capacity is critical to meeting the rapid and enormous spike in demand for all manner of health care products and services. For example, a way to be prepared for the next inevitable health crisis is to invest in a national "stockpile" of diagnostic machines and platforms at key public and private labs that are up to date, running, and calibrated, with spare capacity supported by the supply chain architecture (Gottlieb and McClellan, 2020). This includes investing in both private and state-run health labs for seasonal and pandemic event operations. Equally, policymakers should provide clear guidelines on required stockpiles of emergency use equipment to be maintained at provider sites, manufacturers, and elsewhere. Additionally, a consistent and coordinated approach, based on public-private collaboration, should be taken to allocate hospital capacity (e.g., beds) for emergencies and non-crisis-related ongoing procedures in a standardized fashion to reduce morbidity and mortality in future crises.

Relatedly, within the therapeutics and vaccines sub-sectors, multi-stakeholder efforts should focus on increasing capacity for biologics and vaccines manufacturing to shorten the period between product development and its broad availability to the public. Emergency global procedures for rapid repurposing of existing facilities, as facilitated by virtual inspections and concurrent reviews by national health authorities using previously agreed upon criteria, would support such efforts. The government should expand use of "warm base" facilities that provide a minimum level of funding and task orders each year to ensure availability of priority facilities during a pandemic.

For hospital supplies and medical devices stockpiles, procedures should be developed to ensure replenishment of expired products. National stockpile programs need a robust and transparent distribution framework, accurate data, and tactical plans to ensure supplies reach those in need. Policymaking efforts at both federal and state levels should be oriented toward ensuring the availability, integrity and funding of stockpiles for future health emergencies.

The federal government could encourage these capacity-building efforts by incentivizing the industry to invest in new capacity-increasing technologies. Modular manufacturing, robotics, and digitalization of supply chains will be critically important for future pandemics. Investments in digitalization would enable supply chains to improve end-to-end visibility, which will help in making better and faster trade-off decisions. For instance, while 3D printing is currently expensive, it can quickly change production capacity. It would also help in vaccine and therapeutic research by speeding up processes and producing the necessary tissues for testing. 3-D printing of biopharmaceuticals could likewise be introduced to help with shortages during disruptions.

Regulation and Reimbursement Clarity and Flexibility

Proposed policy: Provide clarity on indemnification coverage for rapidly developed products in cases of emergency use to boost the public's confidence in being vaccinated and in their government.

HPMI and various others in the policy arena have long held that a comprehensive indemnification coverage framework is critical across the vaccines, therapeutics, medical devices, and hospital supplies sub-sectors—especially in emergency use pandemic situations. For instance, COVID-19 vaccines are critical to control the pandemic. This is a major undertaking requiring a significant portion of the world population to be vaccinated (Hamzelou, 2020). Achieving this objective requires a high and sustained level of public confidence in these vaccines. Key tools in supporting this confidence are no-fault vaccine injury compensation programs (WHO, 2018). These are not intended to provide a "free pass" for willful misconduct, criminal activities, or violations of regulatory requirements. While pharmaceutical companies developing COVID-19 vaccines are working to follow all applicable laws, regulations, safety protocols, and principles of good manufacturing practices designed to ensure the safety of vaccines, liability protections ensure that there is an appropriate framework in place to address the unique risks posed by a pandemic.

Governments must assure availability of public health EUA regulatory powers as part of their public health laws to enable rapid access to substantially equivalent supplies, such as PPE, without regulatory delays.

Proposed policy: Provide regulatory and reimbursement flexibility in defined circumstances to encourage greater use of innovative approaches, such as emerging technologies, aimed at increasing health care system effectiveness and efficiency. Regulation should be transparent and provide clear guidelines on when flexibility is permitted, such as during national health emergencies.

Within the therapeutics sub-sector, there is a need to improve clinical trial data acquisition and enhance clinical trial participant recruitment and retention with the incorporation of some of the flexible trial modalities introduced during the early stages of the COVID-19 pandemic, when physical distancing protocols were at their most strict. Methods such as home nursing study visits for drug administration or endpoint evaluation, direct to patient shipment of investigational medicinal product, remote electronic medical record access, remote monitoring, greater acceptance of real-world evidence, electronic informed consent, and methods for imputation of missing data should be assessed for their potential as tools to improve trial operations outside of a pandemic situation.

For the vaccines sub-sector, it is important to adapt regulatory policies to support innovative trial design. Specific proposals include:

- convening of an ethics committee to evaluate the use of human challenge trials to significantly accelerate vaccine creation timelines,
- adoption of synthetic control arms that draw on real-world data to simulate comparator sets of patients such that control arms are smaller, and
- leveraging of advanced analytics to accelerate standard randomized controlled studies through predictive modeling of incidence rates.

It is imperative to modernize reimbursement in the U.S. to offer the opportunity to increase patient access and reduce costs across the health care system. One way to support this reimbursement modernization is to make permanent the reimbursement flexibility instituted during the COVID-19 public health emergency. Changes should be implemented as appropriate across the entire health care spectrum, not just for prescription drugs, so that the significant savings from appropriate medication usage can be deployed in other payment systems.

To encourage the use of value-based pricing models, it is important to incorporate analyses that use real-world evidence for outcomes-based reimbursement processes and for decisions regarding labelling and standard of care. For the vaccines sub-sector, achieving this objective would require incentives and regulatory guidelines in support of the development of validated, real-world endpoints for registrational studies and real-world evidence generation for reimbursement. Use of this data is highly dependent on their validity, traceability, and ability to meet clinical endpoints agreed on with regulators.

In addition, traditional government contracting mechanisms are not suited for rapid development and manufacturing activities needed during a pandemic. Echoing previous recommendations, Congress should consider providing additional authorities to relevant agencies (e.g., BARDA, DOD) that would allow

for flexible "plug-and-play" contracts to support the development of multiple vaccine and therapeutic candidates (Bipartisan Commission on Biodefense, 2015).

Lastly, for the diagnostics sub-sector, there should be a quick path to reimbursement at levels appropriate for what a pandemic requires. In addition, diagnostics should be covered by public and private health plans without patient cost sharing, medical management, or utilization limitations, and they should be available at a reasonable price that enables sustainable access and continued growth of capacity. Since COVID-19 and other pathogens may be transmitted by asymptomatic individuals, coverage exclusions for asymptomatic individuals—or for purposes such as enabling return to work or school or for surveillance—are counterproductive and should be avoided. Since delays in result delivery times during pandemics are typically caused by spikes in demand and supply shortages, varying test reimbursement based on result delivery time will not decrease result delivery time. Punishing labs by cutting reimbursement during demand spikes will exacerbate result delays due to reduced resource availability. In addition, such policies could have unintended consequences, such as a disparate adverse impact on certain patient populations, for example, patients in rural areas who are geographically more distant from labs. Therefore, such variable reimbursement proposals should be avoided.

Coordination and Communication

Proposed policy: Develop a robust national strategic plan for pandemic preparedness and response. The plan should highlight key elements of comprehensive supply strategy, coordinated communication to the public, regulatory laws to align industry responses, and mechanisms to pressure test pandemic response structures.

A clearly defined public health defense strategy would help address the dynamically changing demands and needs at different stages of a crisis, and suggest how to balance the tradeoffs between quality, speed, and cost at key junctures. Components of this plan should articulate a strategy for how to use various tests and how to effectively distribute stockpiled hospital products in times of public health emergency. Establishing early, continuous, and action-oriented dialogue between industry and the various HHS departments during public health crises is critical to making quick decisions, especially to ensure timely and equitable access to testing, vaccines, therapeutics, and medical devices.

For the diagnostics sub-sector, the focus at the start of the pandemic response was on PCR molecular diagnostic testing, which was and continues to be important as the gold standard for use in diagnosing COVID-19. However, other forms of testing also became available that can play important roles in certain scenarios, including point of care, antigen, and antibody tests. Outlining a clear role for

each test at each juncture of a public health crisis—and engaging both public and private labs from the outset—furthers public understanding and efficient resource deployment. In addition, it took too long to scale up low-cost, widely available testing for surveillance. The focus on quality was and is important, but there also needed to be a focus on quantity for lower-cost alternatives and point-of-care testing. While these tests may have lower reliability, they still serve a significant purpose for screening and surveillance.

Testing is also used in vaccine development. As noted in an October 2021 white paper from the American Clinical Laboratory Association (ACLA): "Assessing the effectiveness of a vaccine is directly related to its ability to induce immunological response. Tests measuring anti-SARS-CoV-2 IgG concentrations and neutralizing antibody titers to the SARS-CoV-2 virus targeted to spike protein and receptor binding domains have been used in the phase 2 and phase 3 clinical trials to correlate with the efficacy of vaccines under development." Therefore, as the science evolves, as the ACLA puts it, "There may or may not be a role for similar SARS-CoV-2 serological assays to determine the efficacy, durability, and the need for a booster dose" (ACLA, 2021).

Finally, allocation of tests and supplies should be accomplished through coordination and communication of capacity and need rather than through mandates. It is important to recognize and accommodate different suppliers' and service providers' operational models—specifically, national labs that work across the country versus in a state or region.

For the hospital supplies and medical devices sub-sectors, there is an opportunity in the U.S. for this plan to assess which items and quantities of supplies are set aside for emergencies and to call for the development of systems for assuring stockpiles are at adequate levels to assure minimum response expectations required for various disaster scenarios, including pandemics (see the section of this paper titled Supply Chain Resiliency, Stockpiling, and Surge Capacity). Globally, what most plans are lacking is a metaphorical appendix within each plan of the needed goods and services for frontline workers to conduct their daily duties. Adopting a methodology that helps ensure a continuous supply that is able to be used prior to its expiration date, perhaps with incentives to encourage manufacturers to participate, is an important option for public-private partnership.

Laws like the DPA are important tools in the U.S. government's response to a public health emergency. However, when invoking the DPA, the playing field among competitors is not always even. The federal government might consider calling on all manufacturers in a sector to participate in accelerating manufacturing so that a few companies are not disproportionately burdened. Involving all entities within the health product manufacturers and innovators sector might indeed help accelerate increased access to additional levels of much-needed supplies.

It is critical that a national preparedness plan be developed in coordination with an international joint task force that would explore opportunities for global regulatory cooperation ("pandemic proofing") and for coordinating global scientific messaging. For development of the national preparedness plan as well as for development of proposals for sector-specific responses, an advisory panel composed of qualified and representative government and private-sector subject matter experts might offer a formal mechanism to present a consistent, evidence-based set of recommendations for the pandemic's response.

In addition, efforts to increase medical awareness should be implemented in a clear, consistent, and localized manner to avoid confusion, uncertainty, and misinformation while boosting public confidence in seeking care. This is relevant for all health care sub-sectors that depend on a citizenry remaining actively engaged in behaviors that stem the spread of disease, especially during a pandemic. For the diagnostics sub-sector, in particular, it is important that providers, test kit manufacturers, laboratories, and the public have clear, timely, and actionable guidance and recommendations from government authorities and thought leaders regarding prioritization of testing and how to access it.

Proposed policy: Encourage greater collaboration through partnerships between governments and the private sector.

In early April 2020, the NIH, FDA, BARDA, FEMA, academia, and pharma R&D leaders met to identify how to rapidly accelerate the response to COVID-19. A key outcome was the formation of the ACTIV public-private partnership. In this partnership, all industry partners agreed to contribute their clinical trial capacities toward the shared goal of bringing forward therapeutic and vaccine candidates. This partnership was different from others in the past in that regulators were involved from the very beginning, enabling a speedier formation (Collins and Stoffels, 2020). Another example of fruitful public-private partnerships during the pandemic is the Gates Foundation/Wellcome Trust/MasterCard COVID-19 Therapeutics Accelerator, where up to $125 million in seed funding helped to identify, assess, develop, and scale up new treatments for COVID-19 (Bill and Melinda Gates Foundation, 2020). The partners are committed to equitable access, including making products available and affordable in low-resource settings. However, ongoing and enhanced government engagement across public and private partners should be encouraged. This translates to federal agencies taking a holistic approach to connecting with hospital supply manufacturers, raw material developers, and trade associations such as the ACLA and the Association of Clinical Research Organizations at the start of a public health crisis. Such partnerships should be encouraged as they have the potential to accelerate the development of new vaccines, therapeutics, diagnostics, and hospital supplies, and broaden their reach.

Minimizing Substandard Offerings

Proposed policy: Establish a procedure to update, communicate, and monitor standards for diagnostics, hospital supplies and equipment, and medical devices over the course of a pandemic to ensure product integrity and reduce circulation of sub-standard and/or counterfeit products.

There should be a government- and industry-wide efforts to monitor, mitigate, and prevent sub-standard, falsified, and counterfeit medicines, health care products, and health care services during public health emergencies.

For the diagnostics sub-sector, public confidence in testing is in part dependent upon the awareness of the manner in which tests have been validated for their intended use and public education regarding different regulatory pathways that can be taken for validation. While there should be a mechanism for tracking the status and quality of both manufactured test kits and LDTs that have been submitted to the FDA for EUA, there should also be a mechanism for tracking LDTs that have been validated by laboratories under CLIA. Congress should advance legislation to establish new, transparent validation pathways for all in vitro clinical tests to facilitate the prompt availability of accurate and reliable tests while preventing an influx of inferior products, which we saw during this pandemic's early stages.

Finally, for the hospital supplies and personal protective equipment sub-sector, export restrictions and global supply shortages led to a significant increase in fraud, counterfeiting, and price gouging of certain products as health care customers and governments sought to procure the supplies and equipment they needed. Governments should coordinate with law enforcement, customs authorities, and the private sector to set science-based performance standards that prevent fraudulent and counterfeit products from appearing in global and domestic markets. The effect can be dramatically improved when stakeholders in this arena also employ advanced barcoding and authentication systems to address counterfeit issues.

CONCLUSION AND VISION FOR THE FUTURE

The global COVID-19 pandemic has tested the HPMI sector and led it to respond and adapt to crisis in a multitude of ways. While the pandemic has revealed significant vulnerabilities, it has also demonstrated important resiliency, adaptability, and contributions of the sector.

The COVID-19 pandemic also has highlighted several opportunities for needed change. By leveraging the collective learnings and experiences gathered from across the sector, reforms and actions can be developed to ensure strengthened

post-pandemic health care. With careful reflection, the COVID-19 pandemic can act as a much-needed catalyst for actions to correct long-present issues in the American health care system.

As health product manufacturers and innovators, the authors of this paper propose greater investments in areas of unmet need, updated guidelines that incentivize innovation, processes to improve cooperation and coordination, and reward structures that incentivize desired behaviors among stakeholders. Such priority actions will fundamentally change the context in which manufacturers and innovators operate, resulting in improved effectiveness, efficiency, and equity overall. For example, incentives for HPMI to invest in areas of high unmet need that may have otherwise been financially unsupportable is crucial. Additionally, sustained funding and relevant trade policies will enable those manufacturers and innovators to add much-needed redundancies to their supply chains without negatively affecting operational efficiency.

The authors of this paper recognize that putting these action priorities into practice will be challenging. However, with the right operations, resources (e.g., funding, personnel, material, technology) and prioritization mechanisms, they will result in a more efficient, efficacious, and equitable health care ecosystem. As health product manufacturers and innovators, we are committed to doing our part in achieving these priority actions with a spirit of service, deeply vested in assuring that our nation's patients, frontline health care workers, and society more broadly have access to the diagnostics, hospital supplies and personal protective equipment, devices, therapeutics, and vaccines they need.

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CONFLICT-OF-INTEREST DISCLOSURES

Dr. Lewis-Hall discloses that she is a member of the board of directors for SpringWorks Therapeutics, Exact Sciences, and 1Life Healthcare; she is a consultant for PhRMA; and she is an advisor to SAAMA Technologies, Topography Health, and Catalio. **Dr. Mammen** discloses that his employer received funding from the US government to develop a COVID-19 vaccine; that his employer collaborated with BCG; that his employer's COVID-19 vaccine has received emergency use authorization in the US, European Union, and other countries; and that Johnson & Johnson is a multi-faceted company that has pharmaceutical, consumer, and medical devices businesses. **Dr. Narasimhan** discloses that his employer is currently undertaking an internal drug discovery program toward a pan-Coronavirus Mpro inhibitor; that his employer has an option and license agreement to develop, manufacture and commercialize two Molecular Partners' anti-COVID-19 DARPin® candidates; and that his employer has initial agreements with Pfizer-BioNTech and CureVac to manufacture their COVID-19 vaccines, and with Roche for the production of the API for Actemra/RoActemra®. **Dr. Schechter** discloses that in preparing this paper, Labcorp consulted with the American Clinical Laboratory Association, the national trade association representing leading clinical laboratories.

8

BIOMEDICAL RESEARCH COVID-19 IMPACT ASSESSMENT: LESSONS LEARNED AND COMPELLING NEEDS

Nakela L. Cook, MD, MPH; and Michael S. Lauer, MD

INTRODUCTION

The COVID-19 pandemic, a public health emergency of unprecedented scale and consequences, has revealed vulnerabilities in our health care system and public health infrastructure, yet also serves as a remarkable learning opportunity for transformational changes. Effects of the COVID-19 pandemic touch every aspect of life in ways not previously imagined—the biomedical and health research enterprises are no exception. Preexisting stresses in the research sector's workforce, processes, and organizations have been exacerbated in the sector's quest to effectively generate meaningful information in response to the pandemic and deliver research in new and innovative ways. The COVID-19 pandemic revealed the necessity to enhance the ability for researchers to share data through interoperable and customizable systems to enable rigor, reproducibility, and efficiency. This properly stewarded data essential for research is available and actionable, but trust remains a critical issue in establishing and maintaining data sharing entities (CDC, 2020a).

Despite the rapid innovation occurring during the COVID-19 pandemic, longstanding problems remain. The disproportionate burden of COVID-19 cases and outcomes amongst lower-income populations and communities of color underscores the need to address the lack of diversity of clinical research participants as a top priority. The type of causal, clinical, and population-related intervention studies that may have a critical impact on outcomes in this pandemic necessitated the inclusion of a large, diverse pool of participants most adversely affected and traditionally underrepresented in research. Government funding focused on community engagement in research can certainly be a lever to

promote diversity in study participation, as regulatory bodies seek to ensure the safety and efficacy of therapies across diverse populations (HHS, 2019). This paper describes the current status of research and the challenges, lessons learned, and the potential, if the challenges are overcome, for a longer-term impact beyond the pandemic to enhance the resilience and diversity of the biomedical research workforce. These lessons learned can also be applied to help advance the rapid translation of research into practice (from basic science to clinical and population settings to applied public health), promote the sharing of data for delivering near real-time results in a clinical setting, and elevate community and participants as equal partners in research.

OVERVIEW OF THE RESEARCH LANDSCAPE

Within weeks of identifying a novel coronavirus known as SARS-CoV-2 and its disease manifestation, COVID-19, institutions, researchers, public research funding agencies, and the private sector pivoted to critical research efforts across a broad continuum of COVID-19-related issues. The earliest efforts focused on uncovering the disease's fundamental epidemiology (including public health surveillance studies to elucidate transmissibility) and analyzing data of new cases, hospitalizations, deaths, and demographic information (including age, race/ethnicity, and sex). Together with fundamental research of SARS-CoV-2 and COVID-19, clinical research priorities also quickly emerged.

Research discoveries generally aligned and emerged with the progression and priorities of the pandemic. During the initial weeks of the pandemic, clinical research began characterizing symptoms, clinical manifestations, outcomes, and risk factors for poor outcomes—an essential foundation for developing diagnostic and testing technologies, prevention (individual and social behaviors), and therapeutic approaches (e.g., pharmaceuticals). As the pandemic progressed, public-private collaborations for vaccine development and efforts in the private sector toward developing therapeutics and vaccines occurred at an unprecedented pace, enabled by a foundation of investment in basic science discoveries. In addition, health services and care delivery research efforts centered on necessary adaptations to health care. Underpinning these changes were the debates occurring in other areas of the research ecosystem.

With the intensified focus on racial injustice and structural racism throughout the United States, dissemination research and implementation science proved to be critical avenues for research focused on underserved populations and those at greatest risk for the most severe disease outcomes (Brownson et al., 2021; Williams et al., 2019). These discussions included best practices to engage participants and

communities to build trust in the process of research and subsequent scientific outcomes. Remarkable progress on the virus and the disease emerged because of the rapid pivots necessitated by the pandemic. Decades of research, much of it in targeted fundamental science, the great majority of it publicly funded, enabled these pivots, as well as post-pivot progress.

Despite the many challenges, there were remarkable successes. Less than 11 months after SARS-CoV-2 was first discovered, at least two vaccines were developed, tested, and found to be more than 90 percent effective in pivotal trials (Fauci, 2020). Multiple large-scale treatment trials were completed, with some demonstrating therapeutic efficacy and others not. New large-scale diagnostic testing technologies were developed and launched. The success of vaccine research arguably exemplifies factors for success in biomedical research: prior basic science discoveries ready to be leveraged, existing infrastructure that can be repurposed when needed, and public-private partners who harmonize protocols, bring together existing networks, and share resources (Fauci, 2020).

As the nation's largest public funder of biomedical research, the National Institutes of Health (NIH) leveraged existing infrastructure to establish a public-private framework for the goal of accelerating the development of therapeutic interventions, vaccines, and diagnostics through five strategies (NIH, 2020a):

1. Invest in NIH and NIH-funded researchers to increase fundamental and foundational knowledge of SARS-CoV-2 and COVID-19.
2. Speed innovation in COVID-19 testing technologies through NIH's recently launched Rapid Acceleration of Diagnostics (RADx) initiative, which aims to deliver rapid, widely accessible testing strategies to the public (NIH, 2020b).
3. Participate in public-private partnerships, such as NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, and federal partnerships such as Operation Warp Speed (OWS) to forge approaches that would speed identification, development, evaluation, and manufacture of promising candidate therapeutics and vaccines (NIH, 2020c).
4. Support studies on preventative treatments and behavioral and community prevention practices to identify and implement effective approaches for promoting individual and community safety.
5. Ensure that diagnosis, treatment, and prevention options are accessible and available for underserved and vulnerable populations that have been at the greatest risk for the most severe disease threats.

Similarly, the Centers for Disease Control and Prevention (CDC), at the forefront of the public health response to the COVID-19 pandemic, established

The Science Agenda for COVID-19 to guide the development of the evidence base needed for public health actions, guidance, and policy to curb the impact of SARS-CoV-2 and ultimately bring the COVID-19 pandemic to an end (CDC, 2020b). The agenda presents six priority areas:

1. COVID-19 disease detection, burden, and impact, especially as it relates to understanding disproportionate impacts on people at increased risk for health disparities and inequities;
2. transmission of SARS-CoV-2;
3. natural history of SARS-CoV-2 infection;
4. protection in health care and non-health care work settings;
5. prevention, mitigation, and intervention strategies; and
6. social, behavioral, and communication science.

Other research funders, including non-profit entities, created research agendas focused on their unique missions and opportunities to contribute to the pandemic response. The Patient-Centered Outcomes Research Institute (PCORI) established efforts focused on adaptations to health care delivery and vulnerable populations through its engagement, comparative clinical effectiveness research, and dissemination and implementation purview. PCORI also established the large-scale Healthcare Worker Exposure Response and Outcomes registry to understand the extensive impact of COVID-19 on the health and emotional well-being of both medical and non-medical health care workers (Moses et al., 2015). Medical specialty societies, such as the Infectious Disease Society of America, identified priorities for COVID-19 research more broadly and funded several research efforts. Other such organizations did the same in areas related to the intersection of COVID-19 with diseases as their mission.

The private sector mounted an expedited response for fundamental discovery related to SARS-CoV-2, the rapid development of diagnostics, preventive and therapeutic options, and vaccines (Bio, 2020). The vast collaborative efforts with U.S. government agencies, nongovernmental entities, and the World Health Organization (WHO) drove the identification of the most pressing needs and independent and joint efforts for solutions. Despite these rapid efforts and the focus of research ecosystem leaders, experts, and entities to respond to the pandemic, the state of the research ecosystem before the pandemic and the devastating impacts of the pandemic on the research workforce raise concerns to address in the future.

THE RESEARCH WORKFORCE

Pre-Pandemic Concerns

Before the onset of the COVID-19 pandemic, the U.S. biomedical and health research workforce was under stress related to "hyper-competition," inequality, lack of diversity, and loss of early and mid-career scientists, to name a few. This pressure on the research workforce is driven by the number of researchers competing for research awards, despite the shrinking pool of available funds to support the research enterprise. In the late 1990s and early 2000s, the U.S. government deliberately doubled public funding for biomedical and health research, leading to a period of enormous optimism (Larson et al., 2012). U.S. institutions responded by erecting new research infrastructure and substantially increasing their graduate and post-doctoral student bodies (Stephan, 2010). As might have been expected, many more newly-minted scientists entered the workforce within a few years, eager to set up their independent research operations.

In 2003, the budget doubling for publicly funded research ended. Over the next ten years, budgets remained nominally flat, with continuous low-level inflation eating away at real purchasing power (NIH, 2020d; NIH, 2020e). For example, in fiscal year (FY) 2020, the biomedical research and price index increased by 2.5 percent, meaning that to maintain the same amount of purchasing power as the NIH did in FY 2019, the NIH would need to increase its budget by 2.5 percent (Forrest et al., 2021). Simultaneously, the workforce continued to increase in size, and institutions continued to act as if never-ending growth would be the norm (Alberts et al., 2014; Lauer, 2020a). At NIH, applicant numbers for research grants increased by nearly 50 percent, while the number of funded scientists barely changed (Lauer, 2016).

Within a few years, the workforce faced a "payline crash" as the proportion of applications funded fell from over 30 percent to well under 20 percent (NIH, 2020f). Thought leaders entered a new reality of "hyper-competition," with a surplus of scientists competing for fewer dollars and a wealth of postdoctoral researchers competing for fewer faculty positions (Kimble et al., 2015; Alberts et al., 2014). The faculty positions were less attractive to potential career researchers, with far fewer being "tenure track" and more dependent on external funding for support (Bourne and Vermillion, 2017; AAMC, 2010). In 2015, changes in the industry were also reported with reduced early-stage research support and focused support for medical devices, bioengineered drugs, and late-stage clinical trials (Moses et al., 2015). Across public and private investments, health service

research received only 5 percent of science funding, and U.S. government research funding declined from 57 percent (2004) to 50 percent (2012) of the global total (Whicher et al., 2020).

Other stress-inducing forces have also been at play over the last 20–30 years. In the early 1990s, academic institutions ended mandatory retirement. Many successful scientists opted not to retire, leading to the aging of the research workforce greater than expected by demographic changes alone (Blau and Weinberg, 2017). Early-career scientists found themselves crowded out by later-career scientists, who began receiving increasingly disproportionate funding shares over time. In the late 2000s, NIH instituted policies to ease competitive stresses on early-career scientists (Lauer et al., 2017). These policies mitigated the adverse trends described to funding tending toward late-career scientists, but in turn, led to new competitive stresses on mid-career scientists (Charette et al., 2016). "Science of science" literature has shown that scientific advances occur uniformly throughout individual scientists' careers, meaning that under ideal circumstances, the research enterprise should enable early-, mid-, and late-career scientists to conduct their work, regardless of career stage (Fortunato et al., 2018; Sinatra et al., 2016).

Career-stage demographics were not the only sources of concern. Extensive literature has shown that women, Black, and Latinx/Hispanic scientists are underrepresented, despite representing increasing proportions of graduate school and early career cohorts of biomedical researchers (Valantine et al., 2016). Within academic medicine, women represent smaller proportions of the workforce as one moves up chains of leadership (Jena et al., 2015). While women comprise over half of the medical students and nearly half of lecturers or instructors, the proportions fall dramatically as they progress throughout the hierarchy toward tenured professorships and institutional leadership roles and positions. Similar patterns have been observed for scientists from underrepresented groups, with disproportionately fewer represented in the highest academic ranks or securing independent research funding (Ginther et al., 2011). The root causes for the stresses facing women scientists and scientists from underrepresented groups are complex but likely to include cultural inertia in an enterprise dominated by well-funded older White men, issues related to family and childcare responsibilities, as well as outright harassment, discrimination, and family-unfriendly environments (Blackstock, 2020; NASEM, 2018a; Carr et al., 2015; Mason et al., 2014).

In summary, even before COVID-19, the biomedical research workforce faced several serious threats from increasing hyper-competition and inequality, with disproportionate stresses on early- and mid-career scientists and women

and underrepresented minorities (Katz and Matter, 2019; Lauer et al., 2017; Charette et al., 2016; Valantine et al., 2016; Alberts et al., 2014). To address these issues, Congress; the National Academies of Sciences, Engineering, and Medicine; the NIH; and others have responded with reports and initiatives aiming to ease transitions for the "Next Generation" of researchers and increase diversity and inclusivity (NASEM, 2018b; NIH Advisory Committee to the Director, 2018; Lauer et al., 2017; Powell, 2016). However, the COVID-19 pandemic negatively affected the morale and the capacity of researchers to respond to the pressing needs and vital importance of immense research agendas.

COVID-19 and Its Impact on the Biomedical Research Workforce

March 2020, the COVID-19 pandemic created nearly instantaneous changes in the research environment, shutting down many of the sector's operations (CRS, 2020). Public health officials worldwide initiated mitigation strategies mandating social distancing, which translated into an immediate inability of scientists and their staff to access their physical workspaces (CGR, 2020). Universities canceled the remainder of the Spring 2020 academic terms, forcing students and faculty to stay at home despite their expectations to return within weeks. As the pandemic progressed, universities canceled successive terms and switched most, if not nearly all, academic operations to online platforms. While some operations (e.g., teaching basic chemistry or English literature) continued, others could not. Laboratories and clinical research activities requiring access to in-person space and use of tangible resources cells, animals, human participants, specialized equipment, and physical clinics—were limited, substantially slowing down efforts as lab staff either changed or suspended their work. There were numerous other disruptions: canceled or transformed-to-virtual scientific meetings and conferences, interrupted supply chains, and suboptimal communications for day-to-day work. Cumulatively, these impacts had devastating consequences on the research ecosystem. From the inability to conduct non-COVID-19 scientific research to the reductions in collaboration and funding of other research because of the pandemic, research on other long-standing pressing issues was paused. The research ecosystem will experience implications of this pause long beyond when the pandemic recedes.

The pandemic made clear the interdependency of the biomedical research ecosystem on the health care and population health systems as hospitals prepared to care for patients affected with the most severe complications caused by

COVID-19, and universities and academic health centers diverted efforts toward COVID-19-related needs such as research, testing, and academic planning and technology. With their priorities shifting away from their traditional operations because of the pandemic's urgency, universities shut down their revenue-generating operations, including providing patients with "elective" services and hosting students in dormitories and university housing for in-person training and learning (Khullar et al., 2020). As a result, academic hospitals reported up to $3 million per day in losses due to the emergence of COVID-19 as the sole priority of the health care and public health systems (Knott and Wrabel, 2020). In academic and research institutions, financial stresses also led to furloughs and other resource cutbacks, including the culling of animal colonies and the dramatic reduction of clinical trial enrollments (Grimm, 2020; Medidata and Dassault Systems, 2020). Many universities have announced freezes or substantial reductions in new hiring and promotions in addition to administrative staff layoffs (Woolston, 2020). One analysis found a 70 percent reduction in U.S. faculty job openings (Langin, 2020). In addition, many clinicians were asked to cease research activities and focus entirely on patient care. The prolonged impact of the pandemic set back many ongoing research studies, further hampering broad research agendas.

Biomedical research rapidly shifted focus toward COVID-19, with laboratories and clinical research groups worldwide working furiously to advance scientific understanding of SARS-CoV-2 and develop and test candidate diagnostics, therapeutics, and vaccines. The scientific challenges were daunting, especially as the biology and pathophysiology of SARS-CoV-2 and COVID-19 were not well understood. For scientists already engaged in virus-related work, there was a new "boom" with billions of dollars of Congressionally allocated funding available to meet urgent public health needs. Nevertheless, scientists not engaged in COVID-19-related research confronted serious challenges, such as a lack of research career opportunities, funding, and crowding out due to the entire nation's focus on COVID-19-related activities (Chen, 2020).

There are concerns that financial and organizational shocks related to the COVID-19 pandemic have disproportionate effects on scientists already under stress (Myers et al., 2020). These negative effects emerged because of the shifting priority of pandemic response and control over the activities of research entities, with no capacity, planning, or resources in mitigating research losses. Worldwide surveys have shown productivity falling among women, especially those faced with increased childcare and education responsibilities as schools and childcare facilities have closed. Data early in the pandemic indicate that women posted few preprints and published fewer papers, fueling concerns that previous progress on

enhancing gender diversity in the scientific workforce may be lost (Viglione, 2020). As the pandemic entered into the final months of 2020, reports from academia and academic medicine suggest common and concerning trends, including mothers leaving the workforce and loss of women in leadership, with these adverse trends particularly severe among Black women (Kramer, 2020; Gabster et al., 2020). These disparities indicate the need to better support researchers who may be supporting families and by association need to maintain stable wages.

The longer-term effects of COVID-19 on the research workforce are unclear, however, as the pandemic continues. Data collected from two large-scale NIH surveys, one of more than 200 institutional leaders and another of more than 45,000 researchers, confirm that researchers are concerned about the trajectory of their careers, research productivity, and mental health, especially in light of ongoing social and political stresses (Bernard and Lauer, 2021). Leading correlates of researcher concerns included early career status, laboratory-based work, Asian ethnicity, resource constraints impeding the ability to write research grants, and caretaker responsibilities. Funders have responded by enabling extensions, sometimes funded, and increasing funding for investigators at early career stages (OHDSI, 2021). Specifically related to mental health impacts, more than 65 percent of researcher respondents cited societal and political events along with physical and social isolation as adversely affecting their mental health and well-being. These concerns and stressors were particularly marked for early career investigators, caretakers for young children, and Black investigators who noted civil unrest tied to racism.

Interestingly, research funders continue to see increasing numbers of both COVID-19 and non-COVID-19 research grant applications, conduct grant peer review—entirely virtually—and issue new awards, even as the future of the scientific environment faces flux and uncertainty (Lauer, 2020b). Emerging perspectives published in academic journals argue that the COVID-19 pandemic exacerbated existing systemic issues affecting research, a system that appears to cater to senior researchers, and has called for a "reset" with early-career scientists (Gibson et al., 2020).

However, attention to the reset's specifics must reform the research ecosystem while preventing the unintended consequences of the 2003 NIH budget doubling. The pandemic is still not over: for biomedical research entities, funds continue to shift toward pandemic control, response, and therapeutics as many universities and K–12 schools keep their physical presences partially or wholly shuttered. As a result, the pandemic continues to prevent researchers from safely conducting experiments while halting the revenue-generating operations and activities that enable their research to be funded.

HEALTH AND BIOMEDICAL RESEARCH APPROACHES

Background

The health and biomedical research approaches invoked to address the COVID-19 pandemic span the comprehensive continuum of the research ecosystem, including:

- fundamental and mechanistic studies of SARS-CoV-2 and basic biology and pathophysiology of the virus and human response;
- public health surveillance studies focused on transmissibility and effective non-pharmaceutical prevention interventions as well as data of new cases, hospitalizations, deaths, and demographics;
- epidemiologic research to elucidate risk factors and outcomes for prediction, prevention, and treatment;
- diagnostic research and device studies aimed to develop testing technologies;
- clinical research focused on the characterization of clinical manifestations, emerging syndromes, and management of SARS-CoV-2 infection as well as other chronic conditions or comorbidities in the setting of COVID-19;
- clinical research providing insights on treatment outcomes and variation in treatment patterns;
- pharmacological studies identifying approaches for therapeutics and vaccine approaches for prevention;
- health services and care delivery research centered on necessary adaptations for care delivery, including telehealth for routine and chronic care management;
- health policy research examining different strategies emerging for mitigation and containment; and
- dissemination research and implementation science to move evidence to practice and application and attend to underserved populations and those at greatest risk for the most severe outcomes, including best approaches to engage participants and communities in research, building trust in science, and advancing health equity.

Research Initiatives During the COVID-19 Pandemic

Just as the COVID-19 pandemic led to sudden and possibly transformative effects on the biomedical research workforce, it also facilitated changes in the process of research and the establishment of unique research initiatives. Suddenly, the global community found itself facing a severe life-threatening novel infection, meaning that the human population was ill-equipped to address it on multiple

levels: individual human immune systems, individual people with their worlds seemingly turned upside down, strained underresourced and knowledge-poor public health systems, and a scientific enterprise unable to produce immediate answers.

Instantly, the research sector's work increased in relevance and importance. The public looked to the scientific enterprise to deliver recommendations and action steps guided by rigorous evidence. Scientists and the research sector needed to explain the origins, nature, and magnitude of the pandemic, communicate effective non-pharmaceutical interventions and countermeasures, and develop safe and effective therapeutics and vaccines to halt the spread of the virus.

This response was in stark contrast to the pre-COVID-19 world. Before COVID-19, critics noted the biomedical research was highly inefficient, with the system requiring inordinate expense and time to develop new therapies for diseases like cancer, diabetes, Alzheimer's, dementia, and autism (Sertkaya et. al, 2016; Kramer et al., 2012). As scientists began to shift their attention toward COVID-19, the response from the sector lamented numerous fundamental problems: longstanding coronavirus threats had been ignored, research efforts were fragmented and chaotic, most COVID-19 clinical trials were too small or poorly designed to answer questions definitively, and science and public health were too vulnerable to political forces (Johnson, 2020b; Mukherjee, 2020; Pundi et al., 2020; Cheng et al., 2007). Despite progress in developing COVID-19 vaccines and testing potential therapeutics, the research sector's systemic problems will continue to reduce its performance and future sustainability unless lessons learned in the COVID-19 pandemic are used for sector transformation.

Against the tragic backdrop of record deaths and transmission of COVID-19, the research sector took unprecedented action to facilitate the testing, clinical, and therapeutic-based responses to the pandemic. These include the rapid installation and execution of public-private partnerships to develop testing technologies, treatments, and vaccines; the successful leveraging of existing clinical trial and research networks as well as standardized measurement protocols (e.g., the PhenX Toolkit); and the rapid increase in the rate of scientific communication (PhenX Toolkit, 2020). In addition, the pandemic has borne witness to the potential of pharmaceutical and private companies as significant partners with the expertise and capital not just to develop vaccines and therapeutics but as entities that can scale up the manufacturing and distribution of these therapeutics. This section of the biomedical research sector assessment will review the research sector's attempts to rise to the pandemic's occasion, with attention to its unprecedented actions but also its necessity for systems transformation and reform to be sustainable and successful without the motivation of future crises.

Public-Private Partnerships During the COVID-19 Pandemic

Innovative public-private partnerships emerged during the COVID-19 pandemic to compensate for and move away from the nation's high morbidity and mortality from COVID-19. These partnerships were highly innovative and produced significant value, as they led to a vaccine being developed, tested, and approved in 11 months, an unprecedented achievement. They also provided valuable lessons learned to inform preparations for the next pandemic, as gaps still remained in executing a coordinated, cross-sectoral approach of the scale, scope, and complexity required to meet the escalating needs and trends.

OWS and ACTIV

With the passage of the CARES Act, Congress allocated nearly $10 billion in dedicated funds to develop COVID-19 countermeasures through an extensive private-public coalition called Operation Warp Speed (OWS) (116th U.S. Congress, 2020; HHS, 2020). The allocation of OWS was to be coordinated through the Biomedical Advanced Research and Development Authority (BARDA) and the NIH. The OWS coalition included multiple government departments and agencies, including the Department of Defense, U.S. Food and Drug Administration, the Department of Health and Human Services, and the Department of Veterans Affairs, and private firms. The coalition planned to move research and implementation rapidly through fundamental changes in how biomedical interventions were traditionally developed and tested. These changes included coordinated development of protocols (instead of companies each developing their protocols) and manufacturing candidate vaccines and therapeutics at an industrial scale even before demonstrating safety and efficacy. To accomplish its work, OWS set itself to coordinate closely with other critical efforts, including ACTIV and RADx (NIH, 2020b; NIH, 2020c). These efforts to produce therapeutics and vaccinations for COVID-19 were closely watched due to the nation's rapidly deteriorating public health situation.

In April 2020, NIH and private industry leaders announced the development of the ACTIV project, described as "an unprecedented partnership for unprecedented times" (Collins and Stoffels, 2020). The partnership developed a collaborative research framework that aimed to accelerate and streamline processes for prioritizing resources; identify candidates for study; design and execute master protocols; address safety and regulatory needs; and bring together multiple government agencies, nonprofit foundations, and private companies. The partnership was led by an executive committee consisting of leaders from the NIH, U.S. Food and Drug Administration (FDA), and private pharmaceutical

companies. They rapidly convened four working groups to address the critical gaps in COVID-19 research and development:

1. **Preclinical,** responsible for increasing access to animal models and for identifying informative assays;
2. **Therapeutics clinical,** responsible for prioritizing and testing potential therapeutic agents as well as developing master protocols for clinical trials;
3. **Clinical trial capacity,** responsible for developing survey instruments, developing an inventory of clinical trial networks, and guiding the deployment of innovative solutions; and
4. **Vaccines,** responsible for accelerating the evaluation of vaccine candidates, identifying biomarkers to speed approval, and providing evidence to address safety concerns.

By July 2020, the OWS-ACTIV approach resulted in substantive national research infrastructure changes, enabling the design and execution of definitive therapeutics and vaccine trials. For example, the National Institute of Allergy and Infectious Diseases (NIAID) established the COVID-19 Prevention Trials Network (CoVPN) by merging four existing clinical trials networks: the HIV Vaccine Trials Network, the HIV Prevention Trials Network, the Infectious Diseases Clinical Research Consortium, and the AIDS Clinical Trials Group (COVID-19 Prevention Network, 2020; NIH, 2020g). In addition to conducting vaccine and therapeutics trials, the CoVPN created a customized secure data collection platform to identify potential trial participants (NIH, 2020g). The PCORI-funded PCORnet, the National Patient-Centered Clinical Research Network, represents another national network leveraged to enroll participants in a streamlined fashion in one of the ACTIV protocols. These efforts also included other attempts by the nation's legislative branch to support research and development of diagnostics to support the control and mitigation of the pandemic's virulent impacts.

RADx

In April 2020, Congress also appropriated $1.5 billion to support research into and the eventual development of SARS-CoV-2 diagnostic tests that could be scaled up to widespread use within six months. Within days, NIH launched the RADx initiative with an ambitious goal: the ability to test 2 percent of the U.S. population (or 6 million persons) per day by December 2020 (NIH, 2020b). Public health authorities considered rapid, user-friendly, large-scale viral testing as a critical component to a successful systematic response that would enable the

economy to "reopen" even as efforts to develop treatments and vaccines were ongoing.

The RADx effort had four components (Tromberg et al., 2020):

1. **RADx-Tech,** aimed to identify, develop, and deploy testing technologies ready for use by Fall 2020. RADx-Tech rapidly implemented a novel approach, by which thousands of candidate technologies were rapidly screened, with promising approaches quickly advanced to Phase 1 (validation and risk review) and Phase 2 (clinical tests, regulatory approval, and scale-up) development over just a few months.
2. **RADx-Advanced Technology Platforms (or RADx-ATP),** aimed to scale up technologies already felt mature enough for rapid deployment.
3. **RADx-radical (or RADx-rad),** aimed to develop less mature, nontraditional technologies that might not be ready for scale-up and deployment until later.
4. **RADx-Underserved Populations,** aimed to establish community-engaged implementation projects targeted at underserved populations most vulnerable to COVID-19 disease.

By December 2020, the combined efforts of OWS, ACTIV, CoVPN, and RADx and their components could already claim several successes, including:

- Completion and publication of a definitive trial showing that an antiviral drug, remdesivir, generally improves health outcomes for patients hospitalized with COVID-19 (Beigel et al., 2020).
- Completion of a definitive trial showing that the addition of baricitinib, an immunomodulator, to remdesivir, led to reduced recovery time and accelerated improvement in clinical status for patients hospitalized with COVID-19 (Eli Lilly and Company, 2020).
- Launch of at least four large-scale definitive vaccine trials with realistic completion by the end of the calendar year 2020 or early calendar year 2021 (Kalil et al., 2020). As of December 2020, two trials of mRNA vaccines were completed, with each vaccine demonstrating more than 90 percent efficacy.
- Launch of several large-scale definitive trials to evaluate the possible benefits of monoclonal antibodies and anticoagulants (NIH, 2020h; NIH, 2020i).
- Identification of 16 varied diagnostic testing platforms considered ready for scale-up and manufacturing (NIH, 2020j). Some of these technologies may generate accurate and rapid point-of-care test results with relatively low maintenance requirements. Such technologies would be of particular value in remote and underserved communities.

RECOVERY Platform, the United Kingdom

Meanwhile, research networks worldwide realized some remarkable—and rapid—successes, synergizing with U.S. efforts to use science as a tool to combat the pandemic. Perhaps the most notable international contribution to the research sector was the United Kingdom's employment of a platform trial (NIH, 2020k). In this trial, a group of patients enrolled in a single clinical trial or platform are asked to answer multiple questions about a single disease. The platform, titled RECOVERY, tasked investigators with randomizing over 11,000 COVID-19 patients to four treatment groups (hydroxychloroquine, azithromycin, lopinavir-ritonavir, and dexamethasone) in addition to a usual care control (Normand, 2020). This one control group was used for all four tested therapies in the trial. The investigators were able to enroll large numbers of patients and execute trials rapidly by leveraging close coordination, minimal data collection, robust national data registries, and public health infrastructure, and focus on hard clinical endpoints. One of the RECOVERY trials demonstrated that dexamethasone reduces mortality in patients requiring supplemental oxygen therapy or mechanical ventilation (RECOVERY, 2020). At the time of this writing, dexamethasone is the only therapy that has been shown to reduce COVID-19 mortality. The RECOVERY results were so striking and considered by many to be so robust that other steroid trials were halted (RECOVERY Collaborative Group, 2020a). Nonetheless, a meta-analysis including RECOVERY and other trials showed that steroid therapy reduces mortality among critically ill patients with COVID-19 (Prescott and Rice, 2020).

Other platform trial programs included the United Kingdom's public-private Accelerating COVID-19 Research & Development (ACCORD) network, which developed a master protocol to run several candidates of therapeutic agents through Stage 1 and Stage 2 trials (DHSC, 2020; RECOVERY Collaborative Group, 2020b). The WHO established the Solidarity network to conduct a large-scale clinical trial of remdesivir, hydroxychloroquine, interferon beta-1a, and lopinavirritonavir (Wilkinson et al., 2020). All four treatments were found to have no significant effect on mortality or disease course for patients hospitalized with COVID-19 (Wilkinson et al., 2020).

While the dexamethasone finding can rightfully be considered a success, so can the RECOVERY trial "failures" be considered successes because their large samples and strong design allow for robust findings and can help guide clinicians away from interventions with limited or no efficacy in improving outcomes. For example, the RECOVERY investigators published their findings showing no benefit for the antiviral combination lopinavir-ritonavir (REACT, 2020). This large-scale trial, with over 4,000 patients enrolled and over 1,000

endpoints, confirmed the findings of a previously published but much smaller trial.

EARLY LESSONS FOR THE RESEARCH SECTOR

Scientific Collaboration and Communications

The COVID-19 pandemic highlighted trends in the evolution of scientific communication and information sharing. Within a remarkably accelerated timeline, there was rapid sharing of SARS-CoV-2 sequence information online, signaling an important culture change during a time of crisis, demonstrating that research collaboration had positive public health benefits (NIH, 2020l). Data and technology were leveraged in health care systems and shared for real-time clinical information describing risks, outcomes, and variations in care patterns (WHO, 2021). These approaches, driven by the willingness to collaborate and share, can be transformative for other research processes and initiatives if they are continued beyond the COVID-19 pandemic.

In scientific publishing, the COVID-19 pandemic realized the research sector's endeavors to reduce the publishing times of peer-reviewed results. There has been a longstanding frustration over how long it takes to publish peer-reviewed articles in mainstream biomedical journals (WHO, 2020). Over the last 5–10 years, biomedical researchers are increasingly posting their findings in large-scale preprint servers; this practice has been encouraged by funders (including the NIH and private foundations) and permitted by journals (ASAPBio, 2020a; ASAPBio, 2020b; Vale, 2015). Preprint servers have long been used by scientists in fields like physics, chemistry, astronomy, mathematics, and economics; only more recently have basic biomedical scientists also adopted this practice. Some sectors of clinical research remain resistant to preprints, perhaps because of concerns that unreviewed work might be prematurely praised and inappropriately translated into practice (NIH, 2017). However, about 90 percent of the highest impact journals now allow preprints, and over the past couple of years, the *New England Journal of Medicine* allows authors to post preprints, as was done with the RECOVERY dexamethasone trial, which was posted as a preprint and then later published as a peer-reviewed manuscript (Massey et al., 2020; NEJM, n.d.; RECOVERY, 2020; Lauer et al., 2015). Amidst the COVID-19 pandemic, the National Library of Medicine launched a preprint pilot by which preprints can be searchable in PubMed Central and discoverable in PubMed (Horby et al., 2020). The pilot begins with preprints reporting on NIH-supported COVID-19 research and, in future phases, will progress to include other NIH-supported research in an effort to speed dissemination and enhance rigor.

There has also been an explosion of scientific communications related to COVID-19. According to one NIH-run communication tracking site, between March 2020 and October 2020, over 70,000 communications directly related to COVID-19 were posted, including over 56,000 peer-reviewed articles and 14,000 preprints, a challenging volume of information for researchers and policymakers (Funk, 2020). One effort by Amedeo, a medical literature site, promotes and assembles abstracts of the ten most relevant COVID-19 research papers daily, enabling the dissemination of relevant information that has been compiled in a far more extensive, periodically updated 300-page "COVID Reference" and several associated chapters on topics such as comorbidities, epidemiology, and transmission (NIH, n.d.).

The explosion of scientific activity and the apparent need to communicate results promptly has led to new challenges for biomedical journals and the scientific enterprise as a whole (COVID Reference, n.d.). For example, the editors of *JAMA* note that they received 11,000 manuscripts over a few months in 2020; in the corresponding period in 2019, they received only 4,000 manuscripts, reflecting an almost tripling of submissions due to COVID-19 (Saitz and Schwitzer, 2020). The journal has adapted its processes for considering manuscripts, including greater reliance on full-time editors, an internal review for certain types of papers, insistence on external review for papers thought likely to impact clinical practice, and, when appropriate, requests for additional data, data analyses, or confirmation of data accuracy. There are concerns that the rush to publish and a "fog of war" mentality may make the biomedical research publication system more vulnerable to disseminating questionable reports (Bauchner et al., 2020). Indeed, early in the COVID-19 pandemic, two high-profile publications from Surgisphere, a little-known entity, had to be rapidly retracted when the authors were unable to reproduce the primary data (Rabin, 2020).

Highlighted Challenges and Gaps

The COVID-19 pandemic has highlighted several inherent challenges in the conduct of modern biomedical research (Piller and Servick, 2020). These include over-reliance on mathematical models, inaccurate data interpretations due to confirmation bias, and assessing the value of therapies using uncontrolled data (e.g., convalescent plasma (Ridley, 2020)). Other problems noted by the authors include a lack of harmonization across research and development and clinical trial activities, costly replication efforts, and the overestimation of peer review's reliability. These gaps, along with other well-described problems in the scientific enterprise, stem in part from known human biases and heuristics and

from difficulties linked to current systems of funding and publishing science (FDA, 2020).

Other key problems in the U.S. include fragmented data infrastructures, in part paralleling a fragmented health care system, and a long-standing disconnect between clinical care and clinical research: it has been pointed out, for example, that at best, only 4 percent of American COVID-19 patients have been enrolled in clinical trials (Maxmen, 2020; Tversky and Kahneman, 1974). COVID-19 demonstrates that the decades-old question, "Why not randomize the first patient?" remains as pertinent as ever (North et al., 2020). Too much belief in observational studies or in small-scale trials may not only lead to erroneous conclusions but may also hinder our ability to get needed large-scale trials done (Chalmers, 1977). To this point, a review of characteristics and expected strength of evidence of COVID-19 studies registered on ClinicalTrials.gov revealed few large multicenter trials had the potential to generate high-quality evidence and a large proportion of studies with an expected low level of evidence (Califf et al., 2020). Caution was raised about the rapid dissemination of low-quality evidence due to potential harmful influence on public opinion, government actions, and clinical practice.

Foundational Strategies for Transforming Health and Biomedical Research

Transforming health and biomedical research beyond the COVID-19 pandemic requires incorporating lessons learned from the pandemic, facilitating emerging insights from cutting edge technologies, embracing partnerships and collaboration, advancing open science and data sharing, embedding a learning ethic throughout health care, and emphasizing patients and communities as full participants in the research enterprise to advance health equity.

Embracing the emergence of new technologies such as genetics and genomics, data science, including machine learning and artificial intelligence, and digital and precision health are critical for transforming health and biomedical research. It is critical to align these transformations with a health care and research landscape rapidly evolving toward precision medicine, an approach stating that moving toward the best available care for every individual requires care providers and researchers to access immense health and disease-related data sets linked to individual patients (NRC, 2011).

Genomics and other "-omics" have emerged as approaches for person-centered health care with the capability for risk stratification with deeper phenotyping and tailoring therapeutics with predictive responses. Technological advances are

converting data from smartphones and wearable devices, search engines, claims, electronic health records (EHRs), public records, patient portals, aggregated research data, and other sources into actionable information in health care settings. Artificial intelligence and machine learning are being leveraged to enhance diagnosis and treatment. During the COVID-19 pandemic, rapid genetic sequencing of SARS-CoV-2 was a critical step in research response and testing, and vaccine development. Genomic studies of patients with COVID-19 focus on describing variability in susceptibility, infectivity, and disease severity (Pundi et al., 2020). Digital health with smartphone technology is emerging as a critical tool for surveillance, tracking, prediction of illness, and adverse event reporting for vaccine safety monitoring (Geller et al., 2020; Natarajan, 2020).

Incorporating lessons learned from public-private partnerships and collaborations such as OWS and ACTIV, the research enterprise can accelerate and streamline processes for prioritizing resources. The research sector can also coordinate and establish a cohesive approach for studies with shared priorities; convene multiple government agencies, nonprofit foundations, and private companies; and fundamentally enhance the infrastructure for research to enable synergistic and complementary approaches. While leaders from the government and the private sector rapidly assembled the ACTIV and RADx networks, the research enterprise will be better able to address ongoing and future threats to public health by having a robust research infrastructure in place (Collins and Stoffels, 2020; Tromberg et al., 2020). Collaboration extends to data science approaches that advance data sharing within and across research and health sectors to accelerate evidence development, validation, and access to data sources in a pandemic and beyond.

While the benefits of increased collaboration and transparency were observed during the crisis, the competitive nature of academic and industrial science has made collaboration and transparency difficult to enact more broadly. There are legitimate concerns regarding academic career advancements as well as the protection of intellectual property (IP). However, improving sharing data and cross-sector partnerships has the potential to advance research more rapidly from the lab to the clinic and patients. Resolving IP concerns in sharing and using clinical data should also be explored. Although links between academia and industry have improved in recent decades, there are still too few examples of strong partnerships that emphasize advancing basic research to the application of knowledge and solutions.

This COVID-19 pandemic has revealed the long-term necessity for integrating clinical and research enterprises that create learning health environments. This integration must be adaptable in approaches to care delivery by leveraging clinical

data for research to understand risks, outcomes, and variations in treatment; and embedding clinical trials and observational studies with the capture of clinical encounter data as outcomes.

While vital during the pandemic, science communications and information and data sharing across clinical communities will continue to prove essential for the future of a robust health and biomedical research enterprise. The pandemic also exposed the important interplay between the front-line clinician and the evidence generated and developed for rapid implementation and translation into practice. Further, the heightened focus on health equity has emphasized the imperative to address the social determinants of health and the urgency of combatting systemic racism as pathways to eliminate the marked disparities in risk, incidence, and outcomes in the COVID-19 pandemic and beyond. Public awareness and the centrality of research to end the COVID-19 pandemic, as well as an intensified recognition of the importance of health equity, have also emphasized the importance of communication strategies and the engagement of patients and the public as full research participants. Ensuring this participation will facilitate research that reflects the demographics of those affected and the trust of those who are the true consumers of the evidence produced. The trust of research participants, patients, and the broader public is a long-recognized challenge and one of the most important issues to address in the setting of the COVID-19 pandemic and the rising urgency of combatting health inequities fueled by racism and the social determinants of health.

DATA SHARING

Background

Data sharing within and across research and health sectors holds the potential to advance processes that nimbly adapt to address the evidentiary needs in a pandemic and support rapid response and public health and clinical decision-making. Before the COVID-19 pandemic, efforts to promote data sharing and build interoperability across data sets were gathering momentum, though challenged by technology, hesitancies regarding issues such as data misuse or competitive challenges to ongoing publication, and privacy concerns. Some report the lack of interoperability between clinical systems has impeded efforts to identify outbreaks, track mortality rates, and deliver efficient patient care amidst the COVID-19 pandemic (CDC, 2020c). The heightened urgency for data sharing and data sharing systems spurred by the COVID-19 pandemic provides a window to accelerate progress toward realizing principles exemplified

in several research funders' data sharing policies and Open Science efforts (Anders, 2020; NIH, 2020m). Work to harmonize data collection will need to continue apace if the power of data science analytics and tools such as artificial intelligence and machine learning techniques are to be applied successfully across large data sets, which can be available broadly for research purposes. Currently, data is collected and stored from a wide array of sources and formats, hampering research efforts.

Data Sharing During COVID-19

Thoughtful approaches to data sharing have emerged during the COVID-19 pandemic, including a focus of efforts on data curation, de-identification, and inclusion of appropriate statistical expertise (PCORI, n.d.). A recent comprehensive report with recommendations on data sharing in COVID-19 for four key research areas—clinical data, omics practices, epidemiology, and social sciences—offers best practices from the NIH, including the following (Gewin, 2020):

- The need to develop software and invest in information technology to support infrastructure for pandemic response and early publication and release of data outputs, aligned with FAIR (findable, accessible, interoperable, and reusable) principles and using a generally applicable metadata element set across sectors.
- Establishment of data governance that documents methodologies used to collect, define, and construct data, and establishes standards for "trustworthy" data repositories.
- Frameworks and standards for data cleaning, data imputation, and data provenance.
- Incorporation of legal and ethical considerations around participant and patient information tailored to this crisis. These considerations should promote the openness of individual participant data and trial documents as much as possible when balanced with protecting participant privacy and mitigation of risks related to data use or misuse.

The NIH has encouraged NIH-supported clinical research programs and researchers to adopt the standardized set of health care data classes, elements, and vocabulary specified in the United States Core Data for Interoperability (USCDI) to enable consistency in shared clinical research data (Walker, 2020). The use of USCDI complements the HL7® Fast Healthcare Interoperability Resources® (FHIR®) standard and will facilitate the use of clinical data, such as EHR data,

in research studies. The use of the USDCI standard will also promote structured clinical data for research with the potential to enhance collaboration, facilitate data aggregation and interoperability, and enhance discovery (NIH, 2020n). While encouraged broadly across all NIH-supported work, the USCDI standard provides a critical mechanism to bring coordination and collaboration to a broad set of COVID-19 research activities, including clinical trials, and to promote aggregation and validation of observational analyses using real-world data. While these achievements are notable, data-sharing policies can be evaluated, strengthened, and improved with collaboration from experts to advance more robust data sharing based on the principles of FAIR data sharing (Sim et al., 2020).

Another example of improved data sharing is the National COVID Cohort Collaborative (N3C) Data Enclave, which creates an innovative analytics platform with a curated set of EHR data of people who were tested for COVID-19 or have had related conditions. The enclave serves as a centralized and secure data platform with a harmonized data set and analytics capabilities for an online query, visualization, and collaboration (Brennan, 2020). Given the ability to generate enormous, robust data sets, the approach taken by the N3C Data Enclave may be ideal for enabling machine learning and other rigorous statistical analyses across large and diverse patient populations to rapidly identify patterns relevant to clinical dilemmas.

In addition to these efforts, the NIH has funded the NIH Disaster Research Response (DR2) Program, a pilot program that aims to create a disaster research system including coordinated research data collection tools. Specific to COVID-19, several data collection tools (case report forms, instruments, surveys, questionnaires) are collated and each instrument's source is verified. While considering the significant expense, resources, and time involved, the program is also striving to provide access to study protocols, study designs, and data dictionaries to enhance timeliness for end users, as well as support data interoperability and harmonization. Another important resource is the PhenX Toolkit, which provides access to many of the COVID-19 instruments in the DR2 collection but is broken down into specific topic areas for improved ease of use (NCATS, 2020; PhenX Toolkit, 2020).

While a centralized approach may facilitate coordination amongst disparate efforts, provide standards to facilitate data aggregation, support repositories for clinical trials data, and enable sufficient power to conduct nuanced clinical analyses, other approaches may facilitate the use of routinely collected EHR data for many different purposes. One such example of a data infrastructure leveraged for COVID-19 response is the PCORI-funded PCORnet,

the National Patient-Centered Clinical Research Network established to improve the nation's capacity to conduct health research and to learn from the health care experiences of millions of Americans to enable large-scale research to be conducted with enhanced accuracy and efficiency. To position the PCORnet infrastructure to rapidly respond to the national need to answer critical patient-centered questions related to the novel coronavirus and COVID-19, PCORnet Network Partners are capturing complete, longitudinal health care data on their COVID-19-positive patient population, including EHR data from patient care in the delivery system, and claims information or other records representing care received outside the delivery system. This real-world data is transformed into a standardized format called the COVID-19 PCORnet Common Data Model (CDM) that is easily queried via a distributed network model. The distributed model is designed to promote patient data security. Research questions or queries obtain data and aggregate de-identified results before the data request is returned to the request's source. The entire process is performed locally at the network site. The data remains at the network site behind institutional firewalls, maintaining security.

This new COVID-19 CDM accelerates the traditional timeline of transforming new data into the CDM from months to days. The PCORnet Coordinating Center releases weekly queries to characterize this cohort of COVID-19-positive patients across all sites and provide detailed information on demographics, care settings, and pre-existing conditions. The PCORnet Network Partners are collaborating with the CDC to support COVID-19 surveillance efforts using this COVID-19 CDM infrastructure resource, the FDA-Reagan-Udall Foundation COVID-19 Evidence Accelerator initiative to examine therapeutics, and the NIH to create cohorts of emerging COVID-19 syndromes for natural history studies. Furthermore, the Patient-Centered Outcomes Research Trust Fund for data infrastructure administered through the Department of Health and Human Services will be focusing on data infrastructure issues related to building data capacity for research on patient outcomes associated with the COVID-19 pandemic.

Other efforts beyond PCORnet are facilitating the application of observational data to derive insights relative to the COVID-19 pandemic. For example, the Observational Health Data Sciences and Informatics (OHDSI) collaborative is a multi-stakeholder, interdisciplinary, open-science effort to promote data standards and harmonization. The collaborative pivoted to bring out the value of observational health data through large-scale analytics applied to understand COVID-19 outcomes from studies focused on deep phenotyping to the examination of risks and treatments (Richardson et al., 2020). Both PCORnet

and OHDSI contributions to research during the COVID-19 pandemic underscore the critical nature of using clinical and patient-level data to ensure quality evidence is created, reviewed, and disseminated during times of crisis. Additionally, data acquisition and analytics for non-COVID-19-related health research is being supported through nonprofit organizations (e.g., Michael J. Fox Foundation) and for-profit entities (e.g., Blackfynn). Efforts encouraging the adoption of data sharing and harmonization platforms and practices across the research ecosystem, public, private, and nonprofit domains could produce a high return on investments, produce higher quality data, and accelerate research in times of crisis.

In addition to NIH efforts at the federal level, agencies such as the Office of the National Coordinator (ONC) for Health Information Technology published coding and guidance, relevant rules, regulations, and laws, and key interoperable data sets on their website. These resources helped facilitate the support of care, payment, research, and public reporting via the LOGICA platform, in addition to guidance on recording and reporting situational updates via the HL7 platform. The platform also helped advance research on the pandemic by using the COVID-19 Interoperability Alliance and its 600 data sets, enabling the use of interoperable and customizable data sets and platforms. Additionally, the ONC's response included publishing technical guidance on the adoption of other coding, record-keeping, and reporting mechanisms such as the SNOMED CT, LOINC, and the ICD. Finally, the website also published relevant guidelines per the CARES Act promoting compliance with HHS and its associated agencies, CDC, and the FDA (ONC, 2021).

As efforts such as these examples continue to build momentum, the research and broader health enterprise will be continuously challenged to find approaches to data sharing and create broadly accessible yet appropriately governed data platforms, interoperable solutions, and transparent reporting of analyses and results. Furthermore, a deeper understanding of participant choice and interest, as well as transparency around data sharing, will be critical for ongoing progress. Multiple purposes and applications will drive data sharing, and a variety of solutions are likely to be needed (e.g., centralized data repositories or federated data networks), particularly over time. The experience and momentum gained during this period of rapid innovation to address long-standing infrastructure and interoperability challenges, as well as policy issues related to incentivizing data sharing or promoting patient privacy and responsible data governance, should be capitalized upon to fuel future evolutions in scalable models able to meet specific research needs, knowledge, or outcomes desired, or accommodate other non-research-related factors.

RESEARCH PARTICIPANTS

Background

The transformation of the research workforce, research processes, and data sharing protocols, while essential to accelerating research results into practice, is not sufficient without the participation of many diverse participants and researchers in clinical studies and public health surveillance systems. Such a prospect necessitates the engagement of participants and communities as partners in research throughout the entire life cycle of clinical studies and translation into practice, from concept to implementation, with a focus on transparency throughout. Furthermore, such approaches build trust as a basis for participation in COVID-19-related clinical studies, including those who have been the most adversely affected by the COVID-19 pandemic, who are often also communities underrepresented in research and suffer marked health disparities.

Research Participants in the Setting of COVID-19

Despite remarkable progress in research and innovation and improvements in health over the decades, disparities are still clearly evident (NIH DR2, n.d.; AHRQ, 2018). Nowhere is this more clearly elucidated than in observations of outcomes from the COVID-19 pandemic. COVID-19 death rates by age and race/ethnicity, aggregated from CDC data, are substantially higher for Hispanic/Latinx, Black, Asian, and Indigenous people: for these populations, the death rates from COVID-19 compared to White people are 2.3, 1.9, 1.0, and 2.4 times respectively (CDC, 2021). Inequalities in COVID-19 infection and outcomes also exist for American Indian and Alaska Native populations, carrying 57 percent of cases while comprising only 9 percent of the total population in New Mexico (Ford et al., 2020). However, these disproportionate impacts are not unexpected due to longstanding inequities in health and health care, social conditions, and income inequalities that promulgate crowded housing conditions and necessitate "essential" jobs, in addition to documented similar disparities in prior epidemics, including influenza (Artiga and Orgera, 2020; Chowkwanyun and Reed, 2020; Webb Hooper et al., 2020).

Furthermore, the disparities witnessed in the COVID-19 pandemic by race/ethnicity are direct calls to action for the research community: to interrogate the social construct of race and intervene upon the complex multicomponent drivers of outcomes represented by the variable of race, including traditionally studied issues of geography and socioeconomic factors, as well as structural racism,

discrimination, and bias and its biological and socioeconomic implications (Evans, 2020; Williams and Cooper, 2020; Yancy, 2020).

The research community's challenge is that COVID-19 necessitates research with the communities most adversely affected and distrustful of the biomedical enterprise. To flatten the curve or eradicate COVID-19, research and public health efforts will need to understand what makes for culturally appropriate and practical guidelines. For example, developing guidance for safety precautions in multigenerational homes or identifying approaches to mitigate risk when staying home is not a viable option for workers without sick leave or lack of flexibility in a work environment (Chowkwanyun and Reed, 2020).

Meanwhile, vaccine trials require the recruitment of participants with high exposure rates, many with barriers to participation in research, and distrust of an enterprise that has historically marginalized, mistreated, and in some cases, actively harmed them. Making demonstrable progress necessitates educating and preparing the country for vaccines, addressing vaccine confidence, expanding surveillance and monitoring systems, and examining the determinants of vaccine response. With this devastating crisis comes a lesson and an opportunity to evolve research to engage traditionally marginalized communities to serve as equal partners in research.

To be successful in containing COVID-19, this is not optional. The COVID-19 pandemic presents a tremendous opportunity to engage the public around the rapidly evolving nature of science, ingrain the importance of behavioral and preventative non-pharmaceutical interventions such as physical distancing, quarantining, handwashing, and wearing masks in the setting of any infectious threat, and the ability of vaccines to eliminate such a threat, even beyond COVID-19.

Ensuring that historically marginalized communities serve as equal partners requires the research community to address the disproportionate burden for low-income and diverse individuals to participate in clinical trials (Vyas et al., 2020). Overcoming barriers such as distrust, lack of insurance, fear of medical costs, lack of sick leave, lack of information about the clinical trials process, language barriers, cultural and literacy competencies, and general time and resource constraints requires acknowledging, understanding, and addressing these issues in a tailored and specific way (Johnson, 2020a; Clark et al., 2019; Occa et al., 2018). Meaningful engagement of both research participants and historically marginalized communities in research and application of findings from the development of a concept through study design, study conduct, and implementation can help bring long-existing problems and subsequent solutions to the fore. This meaningful engagement can serve as a pathway toward the diverse participation in trials that the COVID-19 pandemic necessitates (George et al., 2014).

Experience at PCORI has demonstrated that engagement is feasible and benefits those involved by generating enthusiasm for research, building trust, and

enhancing successful recruitment and retention (Hemphill et al., 2020; Forsythe et al., 2019; George et al., 2014). The NIH Community Engagement Alliance (CEAL) program provides trustworthy information through active community engagement and outreach to those most significantly affected by the COVID-19 pandemic, including Black, Hispanic/Latino, and American Indian/Alaska Native individuals, with the goal of building long-lasting partnerships as well as improving diversity and inclusion in research related to COVID-19 (NIH, 2020l). Engaging communities as partners can build research capacity for short- and long-term impacts in diverse or underserved communities. Research entities should partner with stakeholders and individuals from hospital and clinical systems, as well as trusted voices in neighborhoods and communities – these individuals and groups could help build research capacity for short- and long-term impacts in diverse or underserved communities.

PUBLIC ENGAGEMENT WITH RESEARCH

Background

Community, patient, and participant engagement in research begin with articulating the value and utility of research to the public and building trust among individuals, organizations, and broader communities. The COVID-19 pandemic presented an opportunity to implement these principles, as the imperative of science and research is currently being discussed in the media and in communities in the nation. Leveraging, learning from, and galvanizing awareness about research and its inextricable link to health and health care in the U.S. and globally is an opportunity for the research community to improve. Efforts to introduce fundamentals about research could go further now than ever before and facilitate essential efforts to engage the public as partners in the research process and disseminate key research findings. For example, PCORI recently released a new evidence-based learning package called Research Fundamentals, which uses plain language to provide foundational knowledge about the research process, patient-centered outcomes research, and how stakeholders may engage in research (Crocker et al., 2018). This package is a first step in further disseminating research and communicating its value to the broader public, a perennial challenge for the health system.

Public Engagement with COVID-19 Research

Helping all stakeholders, regardless of research experience, to feel included to participate in and shape research studies is more important now than ever.

With the COVID-19 pandemic sparking increased interest in the research process, despite challenges to public confidence in science, researchers should take care to learn from study participants and communities by listening to their interests and needs, sharing decision-making power, and communicating effectively and honestly throughout the study's process. As the current pandemic requires at least 150,000 diverse research participants to enroll in vaccine clinical trials alone, the research enterprise must not miss the opportunity to enable broad public and patient engagement in research.

Aspects of a continuously learning health care system, including the transparent integration of research with clinical care and public health activities, the timely return of results to patients, and rapid dissemination of findings to clinical care, will be critical to overcoming barriers to participation in research. Moreover, diversifying the front line of research to reflect the communities most adversely affected by the COVID-19 pandemic will be critical to the success of treatment and vaccine trials. Polling data from February 2021 reveal that 61 percent of Black adults would be willing to receive the vaccine or had received at least one dose, compared to 69 percent of White adults (Funk and Gramlich, 2021). That was up from 42 percent in November 2020. Research on engaging diverse communities in research has revealed that strategies to include Black and Latinx participants in trials require the research enterprise to acknowledge the challenges intrinsic to recruiting participants of diverse backgrounds, recognize the increased costs to address barriers to participation, and ensure successful implementation of an effective vaccine within the communities most affected (Gramlich and Funk, 2020; Stephenson and Okikutu, 2020). Studies also documented that Black adults are more likely to participate in clinical research if the questions they ask are answered and if requests for additional time for consideration of receiving a vaccine are granted (Quinn et al., 2016).

Now that vaccines have been developed, the research community's challenge is the implementation of strategies to vaccinate millions successfully and equitably. To rise to this occasion, an effective vaccine is first required. However, an effective vaccine must be guided by principles of health equity and aligned with the meticulous integration of lessons from implementation science on community engagement ahead of launching trials; testing strategies that leverage community leaders, health care extenders, and social and community pillars; and culturally and linguistically appropriate materials. In addition, scientists generally do not have the marketing or public relations expertise needed to begin to shift public opinion of science. The critical impact of basic and applied science in fighting the COVID-19 crisis must be clearly highlighted moving forward to present why investing in science matters for society at large. These efforts underscore

the importance of garnering and sustaining trust, ensuring access and availability of developed vaccines, and developing or leveraging relevant and culturally appropriate infrastructure to reach all Americans (Occa et al., 2018; Wendler et al., 2006).

This task is a tall order for the biomedical, public health research enterprise, necessitating innovation, partnerships, and breaking from the tradition of research designed and implemented only in labs, hospitals, and academic centers. Stemming the tide of COVID-19 will require research that is patient-, participant-, community-, and public-centric. In addition, the application of lessons learned from research in this devastating pandemic is also required to create a long-term public health impact.

HEALTH AND BIOMEDICAL RESEARCH LEADER OPPORTUNITIES

As the health and biomedical research leadership reflects on the opportunities and responsibilities laid bare in the setting of the COVID-19 pandemic, development of research infrastructure, ongoing collaboration across and within the sector, and accessibility of science and engagement of the public in research have emerged as critical priorities.

Amidst a pandemic, research leaders in the public sector have the opportunity, in partnership, to develop priorities and timelines and promote coordination and collaboration across agencies, the private sector, and institutions. The research sector could also advance policies to enhance sharing of scientific and epidemiologic data and communication. In consideration of future pandemics and transformation of the research enterprise, public sector research leadership has the opportunity to leverage emerging technology for surveillance and event reporting; prospectively establish research infrastructure with public-private partnerships, clinical trial networks, and recruitment and implementation science as integral components to pandemic preparedness; and consider policies for accelerated emergency resourcing, funding, and decision-making. Maintaining the pipeline of researchers and research in an emergent setting is another priority for the future health of the biomedical and health research sector.

Research leaders in the private sector can continue, with scientific rigor at the forefront, to advance and invest in cross-industry collaboration, public-private partnerships, and sharing of information and resources that promote complementary efforts toward diagnostics, therapeutics, and vaccines.

Research leaders in institutions have critical opportunities to advance pathways for efficient and effective rapid scale-up of research operations for national

priorities and emergencies. Research leaders can also leverage and promote opportunities after the pandemic to facilitate the integration of research and clinical practice to capture clinical data for outcomes assessment and enable a future where data is shared to hasten the speed of scientific discovery. Institutional leaders across the research sector are critical to the diversification and stability of the research workforce pipeline. With the challenges of the ecosystem evident, the need to double down efforts for diversification and retention of that pipeline has never been clearer.

SUMMARY AND PRIORITIES

Assessing the Impact

The COVID-19 pandemic will have long-standing implications for the research enterprise, which may not return to pre-pandemic operations. A critical priority over the next 6–12 months will be to assess, in both quantitative and qualitative terms, the ongoing and longer-term impact of the pandemic, including opportunities for research to continue to help mitigate and overcome the pandemic, ensuring the future of the research enterprise is protected, and learning and transforming research to capitalize on lessons from the pandemic response. The Council on Governmental Relations posted a working paper in August 2020 describing a Research Impact Metric by which institutions can assess their operations. The working paper describes a new "Pandemic Normal" characterized by ongoing slow-downs, changes in operations (e.g., shift work, required protective equipment), supply challenges, core facility disruptions, slowed hiring and promotion, and perhaps above all, a great deal of uncertainty (CGR, 2020). A recently published landscape review described some of the uncertainties: the trajectory of federal funds and policies, the role of charitable foundations, the impact of declines in non-research revenues on research operations, whether future shut-downs may be needed as the pandemic worsens, what the long-term effects on research collaborations (positive and negative) will be, how changes in rapid scientific communication and peer review will evolve, whether research will return to "normal" levels of productivity and on what timeline, and what will happen to the scientific workforce (Baron et al., 2020).

Research Workforce: The Path Forward

COVID-19 has exacerbated stressors on the research enterprise with disparate impacts on the workforce, particularly those underrepresented in science and

early in their scientific careers. An essay published earlier this year noted that returning to normal may not be the desired goal since the previous normal was not ideal, bringing with it long-standing academic research challenges, including a complicated system that favors senior-level researchers (Gibson et al., 2020). As in many other areas, the pandemic offers opportunities for learning and transformation. Several priorities and considerations include:

- Focused attention on those underrepresented in science by overcoming systemic problems in building a research enterprise that includes scientists from diverse backgrounds through eff orts that commit to racial/ethnic and gender equity in research processes and provides solutions to barriers for retention.
- Focused attention on those early in career by incorporating successful efforts to streamline application processes and policies piloted during the pandemic and extending advantages for investigators early in their careers. Actionable examples are research awards only for early-career scientists with less preliminary data at the time of application, revised application and review policies that are blind to career stage and focus on research topic and approach, and instructions to reviewers to disregard situations directly related to the COVID-19 pandemic, such as temporary declines in productivity (NIH, 2020o; Radecki and Schonfeld, 2020; Lauer, 2019).
- Focused attention on efforts overcoming any pandemic-related productivity losses and challenges, financial and otherwise, for scientists attempting to restart their research programs. These efforts should consider the potential of using multiple sources of funding from nonprofits, federal and state governments, the private sector, and individual donors. Funders could incorporate several approaches to expedite the case-by-case evaluation of challenges faced by applicants and awardees with the principle of being as flexible and accommodating as possible when responding to administrative and research delays during the pandemic. Three priorities for the research ecosystem are emerging with building anticipation of efforts to regenerate and restart research and training programs and enable future systems transformations. These priorities include:
  - Supporting early-career scientists and their research.
  - Rescuing meritorious and established investigators who are at risk for losing or unable to regain a substantial portion of their research funding.
  - Funding several high-priority clinical studies in which completion of minimum enrollment and follow-up thresholds are critical for study completion and methodological integrity.

Public-Private Collaboration and Communications

The pandemic also provided some initial guiding principles on best practices on public-private partnerships (PPP) and communications. These lessons should become more evident as future assessments of PPPs are undertaken.

- Internally, communication, coordination, and collaboration across researchers, clinicians, public and private sectors, and policymakers, such as the OWS-ACTIV approach of prioritizing and executing critical research.
- Externally, the translation and synthesis of research findings through various media mediums for broader public consumption and knowledge, especially to build and regain trust in the biomedical research ecosystem.

Research Processes and Data Sharing: Implications for a Longer-Term Impact

The enterprise has been challenged to rapidly establish clinical studies and associated infrastructure to translate research into practice, balance speed and rigor, promote the sharing of data and interoperability between platforms for delivering real-time results in clinical settings, and build public trust in validated research findings. Learnings in a pandemic provide opportunities for a longer-term impact. Priorities and considerations include the following:

- Coordination across efforts (e.g., federal, private, funders, and academic institutions) for coherence, efficiency, and increased effectiveness. An example of such efforts is an overarching set of research priorities across disciplines and methodologies with role delineation within the sector for activities and development of shared research infrastructure leveraging existing and new entities and networks for the implementation of research protocols.
- Clarity in implications of trials and studies based on design and limitations, including encouraging journals to publish negative studies to eliminate alternative clinical approaches to care that are not grounded in scientific evidence.
- Tailoring of study designs (observational or randomized) to specific questions with a shared understanding of strengths and limitations in addition to ensured reliability of data sources.
- Continued resolve and facilitation of requirements for researchers to share data sets and documentation for reanalysis and reuse consistent with, but not limited to, the NIH and PCORI data sharing policies.

- Data governance requiring data sharing, infrastructure that supports sharing, and standards that promote interoperability as key to support these aims.
- Governance that promotes the inclusion of stakeholders, specifically communities and patients, to generate solutions to concerns related to data misuse and privacy.

Research Participants and Public Participation in Research

This pandemic has created an imperative for communication, collaboration, and coordination across sectors that could not be stronger. Actions and considerations include the following:

- The establishment of meaningful partnerships and trust with affected communities as research partners is central to the path forward to combat high levels of distrust of scientists and researchers. Partnerships begin with the identification and involvement of community brokers and subsequently identified community entities in understanding the purpose of research studies, setting research priorities, and translating information to communities.
- Engagement of stakeholders, patients, and communities leveraging community brokers toward building trust and trustworthiness and enhancing diverse participation in research.
- Broad scientific communications enhance the value of research conveyed to the public and build trust among individuals, organizations, and broader communities.

In the face of unprecedented challenges and urgent necessity, the biomedical and health research enterprise has the potential to deliver the discovery, translation, and implementation science related to vaccines and therapeutics required to end the COVID-19 pandemic. To propel the entire sector toward a holistic approach, it is crucial that all components of the research ecosystem collaborate on a multifaceted transformation that enhances the resilience and diversity of the research workforce and innovates in funding processes and partnerships to maintain the viability of research efforts during a crisis. The research sector of the future accelerates the translation of knowledge to care and public health action, delivers on long-standing data sharing efforts, and coordinates across health and health care. Essential to the sector's efforts to innovate and achieve is the elevation of communities and participants as equal partners in research while engaging the public in science.

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None to disclose.

9

QUALITY, SAFETY, AND STANDARDS ORGANIZATIONS COVID-19 IMPACT ASSESSMENT: LESSONS LEARNED AND COMPELLING NEEDS

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INTRODUCTION

The stark reality of the COVID-19 pandemic challenged the very systems established to ensure the nation's safety and quality. The pandemic resurfaced long-endemic challenges within the health care quality and standards ecosystem and identified novel challenges that cannot be ignored. This paper examines:

1. the health care quality and standards ecosystem pre-pandemic;
2. vulnerabilities in quality and standards organizations exposed by COVID-19;
3. quality and standards organizations' responses during the pandemic;
4. opportunities to improve the national response to improving quality and safety overall with a particular focus on readiness in the case of disasters, pandemics, or other national emergencies;
5. sector-wide policy, regulatory, and legal changes that might be transformative; and
6. priorities moving forward.

The quality and safety focus of the American health care system has a long history, dating back to the 19th and early 20th centuries. Quality of care is generally understood as providing the right care for the right person at the right time—every time. Several seminal laws and publications over the last 60 years have

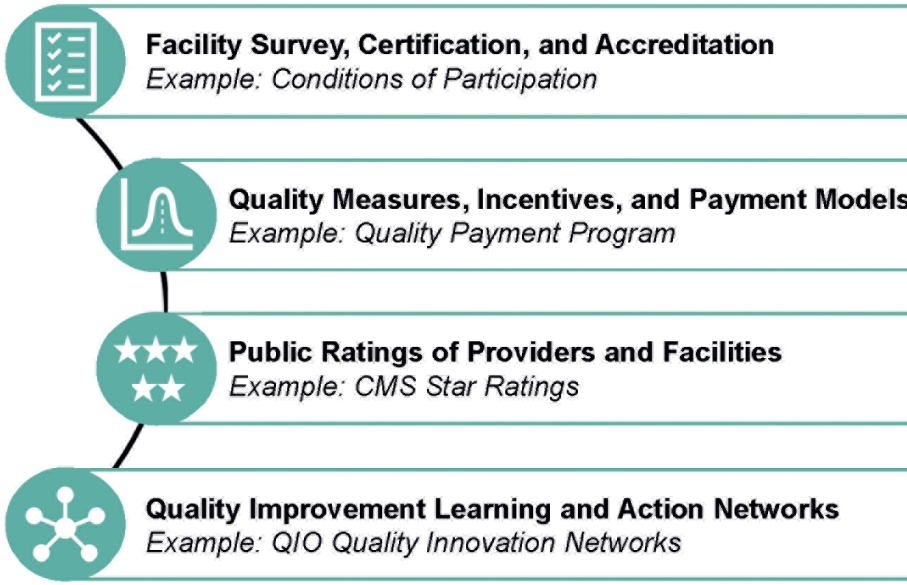

FIGURE 9-1 | Key Levers for Care Quality and Safety

shaped the current quality landscape in profound ways and have been cataloged in numerous publications (McGlynn, 2020; Moody-Williams, 2000; IOM, 2001; IOM, 2000). These publications generally point to several landmark occurrences that have shaped the evolution of quality measurement, improvement activities, and safety standards over the years. The evolution has centered around four main levers (see *Figure 9-1*):

1. survey, certification, and accreditation of facilities, laboratories, health plans, and providers;
2. quality measurement, incentives, and payment reforms;
3. public ratings of providers and facilities; and
4. quality improvement learning and action networks.

Survey, Certification, and Accreditation

The role of government in establishing quality and safety standards for the health care system became prominent with the implementation of the 1965 Medicare legislation, in which Congress explicitly tied payment to the achievement of minimum health and safety standards, commonly known as conditions of participation (CoPs). Initially, the CoPs focused on medical staff qualifications, nursing services, and utilization review, but have since evolved to include minimum

standards for various other important safety issues, including infection control, emergency preparedness, quality assurance, performance improvement, and medication management. States also established health and safety requirements for facility licensure. State standards for health and safety must, at a minimum, align with the CoPs but may go above and beyond the federal requirements.

While the state government and federal surveyors perform inspections for many facilities (primarily nursing homes), the Centers for Medicare & Medicaid Services (CMS) has approved several national accreditation organizations (AOs) to perform survey functions (CMS, n.d.a). One of the largest AOs is the Joint Commission. Founded in 1951, the "Joint Commission accreditation can be earned by many types of health care organizations, including hospitals, doctor's *[sic]* offices, nursing homes, office-based surgery centers, behavioral health treatment facilities, and providers of home care services" (The Joint Commission, n.d.).

In 1990, the National Committee for Quality Assurance (NCQA) was established as a nonprofit organization that accredits quality programs for health plans, physicians, and other providers. NCQA developed the first set of standards for health plan quality using a set of evidence-based requirements and measurements.

The Evolution of Quality Measurement, Incentives, and Payment Reform

Despite the establishment of standards to ensure high-quality care throughout the 1980s and 1990s, numerous academic research studies demonstrated the substantial burden and threat that poor-quality care (often described as overuse, underuse, and misuse) continued to have on public health (Chassin and Galvin, 1998). The culmination of this body of research was the publication of the Institute of Medicine (IOM) report *To Err Is Human* in 1999, followed several months later by the IOM report *Crossing the Quality Chasm* and the subsequent publication by Elizabeth McGlynn in 2003, demonstrating that most Americans receive less than 60% of recommended care (McGlynn, 2003; Leape et al., 1991; Lohr and Schroeder, 1990).

The response to these disturbing findings was significant, beginning with an accelerated effort to measure the quality of care in the United States, to make those measurement results transparent through public reporting, and ultimately to tie payment to performance on quality and cost. Quality measurement has an established academic pedigree beginning in the 1960s with the structure/process/outcome Donabedian framework (Donabedian, 1988). In recent years, the focus has shifted to measuring health outcomes, most notably including patient-reported outcomes (FDA, 2009). This focus also includes cost, and patient

experience to focus improvement efforts and facilitate comparisons between hospitals, health plans, and other organizations.

Another important dimension of quality measurement involves recognizing the challenges that communities of color, as well as people with low incomes, low levels of education, and other social drivers of health, experience in achieving optimal health and health care (James, 2019). An integral part of delivering high-quality health care includes gaining an understanding of the social determinants of health (SDOH) of patients and communities in their respective contexts. SDOH are defined by the World Health Organization (WHO) as the "conditions in which people are born, grow, live, work, and age" (WHO, n.d.). However, while measuring quality has increased in importance across health systems, efforts to implement measures and metrics reducing health inequities have been lacking (Anderson et al., 2018).

Increasingly, payers are tying performance on quality measures to payment, which continues to evolve in the effectiveness of connecting payment to performance to improve quality under the fee-for-service system. The move toward alternative payment models (i.e., payment approaches that provide added payment incentives for high quality, cost-efficient care by public and private payers) has had more success but has been slower to spread in many parts of the country (Baicker and Chernew, 2017).

Despite its potential value, performance measurement currently faces multiple challenges, including a proliferation of measures leading to confusion and inefficiency in reporting and collecting data, the burden associated with capturing and reporting data, and the lack of appropriate data to calculate important metrics. Lack of alignment between public and private payer measures often places providers and clinicians in the position of reporting on multiple slightly different measures that may not provide value to clinical care delivery (The MITRE Corporation, 2016). In fact, in 2017, CMS began addressing these issues through its Meaningful Measures Framework that includes criteria to reduce measures that have achieved a high rate of performance across the majority of providers, are no longer supported by evidence or are supported by a better measure available, show the cost outweighs the benefit, or other such criteria (CMS, n.d.b).

Broad adoption of electronic health records (EHRs) by hospitals and clinician practices has been an important accelerator of quality measurement and assessment. However, the authors of the paper would agree that the pace of improvement has been incremental rather than transformational. Important gaps in the adoption of EHRs persist, and experience with the use of electronic quality measures has been challenging. However, with the maturation of digital standards and development of platforms for the exchange of electronic data, the use of digital measures holds promise for the future of reducing the burden and improving alignment and value in clinical care.

PUBLIC RATINGS OF PROVIDERS AND FACILITIES

Public reporting of quality measures and standards grew out of a need for transparency in the health care system as questions began to rise from consumers about care practices. NCQA was one of the first to develop "report cards" for health plans starting in the early 1990s to address appropriate delivery of needed care. In 2003, the Consumers Union Safety Campaign developed a model law and promoted state laws to publicly publish hospital infection rates and raise public awareness about the problem. This campaign also led to changes in the Medicare program to require public reporting of hospital-acquired infections.

Today, consumer-facing public reports provide demographic and performance information about a clinician or health care facility to help people make choices. An additional, albeit indirect, impact of these reports is an increased focus on improvement by providers (Prang et al., 2021). There is also an ongoing effort to ensure that report cards are meaningful and presented in a transparent, user-friendly manner with the intent of helping patients and families make decisions and increasing their somewhat low rates of consumer use (Moody-Williams, 2020).

Public ratings of the quality and safety of health plans and providers have exploded in the past several years through the development of star ratings on the CMS Compare sites (recently consolidated into one site known as Care Compare), U.S. News and World Report ratings, and the Leapfrog Safety ratings, to name a few. Notably, these systems do not consistently agree with one another (Bilimoria et al., 2019). Multiple studies have found that many people do not routinely consult these reports, but the percentage of people surveyed who do find quality performance reports useful has grown significantly over the past 20 years. An ongoing challenge is clarifying which areas and circumstances (e.g., need to choose a health plan) consumers find most compelling and how to present relevant information most effectively.

Quality Improvement Learning and Action Networks

While regulations stemming from the original Medicare law and subsequent statutes established a minimum floor of quality and safety for health care facilities, there was a recognition of the progress needed to drive improvements in care (U.S. Congress, 1965). In 1972, Congress established the Professional Standards Review Organizations, which evolved into the modern-day Quality Improvement Organizations (QIOs) to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. Under the direction of

CMS, the QIO Program is one of the largest federal programs dedicated to improving health quality for Medicare beneficiaries. The program has evolved from a reliance on inspection and chart review to using quality improvement science for learning and action (Moody-Williams, 2020).

The Institute for Healthcare Improvement (IHI) has increasingly influenced the spread of best practices and the establishment of a culture of safety within health care organizations (Berwick, 1989). The Agency for Healthcare Research and Quality (AHRQ) was established in the 1990s to study and contribute to health care quality improvements (AHRQ, 2019). Before being explicitly required by the Affordable Care Act, multiple federal components, including Federally Qualified Community Health Centers, the Veterans Health Administration, Defense Health Agency, Indian Health Services, and CMS have collaborated to improve quality and safety (Meyer et al., 2003; QICTF, 2000; The Commonwealth Fund, 2000). Both public and private sector efforts have resulted in selected sustained improvements in quality and safety and new approaches to improvement, such as substantial reductions in central line-associated bloodstream infections and patients' experiences of care (AHRQ, n.d.a).

VULNERABILITIES IN QUALITY AND STANDARDS ORGANIZATIONS EXPOSED BY COVID-19

The COVID-19 pandemic brought to light the importance of the various levers for achieving quality and safety and the vulnerabilities that exist in the current system. Following the declaration of the COVID-19 pandemic by the World Health Organization, the response from the public and private health care sectors was significant. Health care professionals, government agencies, and public health officials quickly began to implement traditional means of ensuring quality and safety only to realize that standard quality metrics and emergency preparedness requirements would not be sufficient for the escalating needs of this global pandemic. Existing vulnerabilities in the quality measurement, assurance, and improvement system were magnified, calling for attention to health and health care inequities, lack of coordination between public health and health care delivery quality and safety metrics, effectiveness, and inadequate data infrastructure and interoperability (see *Figure 9-2*).

Health and Health Care Inequities

COVID-19 has further revealed widespread health inequities that are impossible to ignore. Rates of COVID-19 infection have been as much as two to three times higher in Black, Latinx, Asian-American and Pacific Islander, and Indigenous

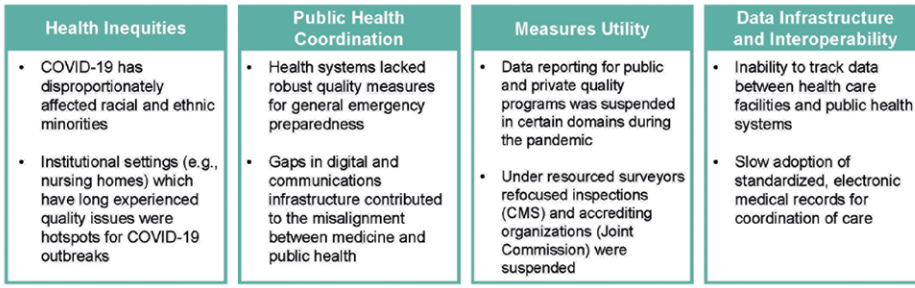

FIGURE 9-2 | Vulnerabilities in Quality and Standards Exposed by COVID-19

communities compared to their White peers (Ioannou et al., 2020; Rentsch et al., 2020). The CMS data snapshot from January 1, 2020, through August 15, 2020, reveals that Black beneficiaries have more than twice as many cases per 100,000 than White beneficiaries with Black beneficiaries recorded at 2,799 per 100,000 compared to 1,272 per 100,000 for White beneficiaries. Indigenous communities, listed by the study as American Indians/Alaskan Natives, had a rate of 2,152 per 100,000 with Hispanic cases at 2,627 per 100,000 (CMS, 2020a).

The reasons for these disparities are multifactorial and long-standing. Before entering the health care system, communities of color usually experience poorer levels of health. For example, Black, Latinx, and Indigenous individuals often experience a higher degree of comorbidities compared with White peers, increasing their vulnerability to serious disease. These disparities are caused by social, political, and economic inequality that is underpinned by decades of structural racism and neglect (Selden and Berdahl, 2020).

Communities of color and communities that have been made to be vulnerable experienced higher incidence of infection with COVID-19 than their White peers. The most proximal cause was the exposures of these communities to sources of COVID-19 infections because of their concentration in person-facing essential jobs in the service sector, including workers in public transit, transportation, logistics, food, beverage, janitorial services, and childcare and social services. These jobs, which often cannot be performed from home and require interaction with people, also often do not provide paid sick leave or family leave, adequate protective equipment, or comprehensive health insurance and health care services. Importantly, while, as described above, communities of color and communities that have been made to be vulnerable may have needed to interface with health care services more than their White counterparts during the COVID-19 pandemic, these groups have been and continue to be harmed or neglected by the health care system at higher rates than their White counterparts, leading to a lack of trust in health care institutions and professionals.

Also concerning is the fact that communities of color and communities that have been made to be vulnerable often experience higher barriers to accessing quality care. Initial research has highlighted the increase in mortality from COVID-19 because of these access gaps—clinical disparities in the same studies reduced once individuals from these communities received the necessary treatment for the disease (Ogedegbe et al., 2020). The impact on in-hospital mortality among those infected has been mixed, with population-based studies demonstrating higher death rates for persons of color, while studies from the Veterans Health Administration and the Ochsner Clinic in Louisiana found no significant mortality differences (Price-Haywood et al., 2020). Notably, these findings do not capture potential long-term morbidity issues, such as cardiac function and cognitive problems.

For decades, the calls to address the inequality in health and access to care for these populations have gone largely unanswered. The IOM called for action to address health care disparities in its 2003 report, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* (IOM, 2003). The report notes that Black, Latinx, and Indigenous populations tend to receive a lower quality of health care than White populations, even when controlling for access-related factors, such as patients' insurance status and income (IOM, 2003). Key barriers to obtaining high-quality treatment include racial biases and stereotyping, as well as language and geography barriers (IOM, 2003). By law, AHRQ has reported to Congress annually on health care disparities since 2003, with each successive report finding no or only marginal improvements.

Ten years after the publication of *Unequal Treatment*, the Centers for Disease Control and Prevention (CDC) published the 2013 *Health Disparities and Inequalities Report*, which examined "disparities in deaths and illness, use of health care, behavioral risk factors for disease, environmental hazards, and social determinants of health at the national level" (CDC, 2013). Due in part to the endurance of these problems despite public health research efforts, terms such as cultural familiarity and behavioral risk factors for disease are falling out of favor and being replaced with holistic concepts about root causes, such as racial bias, structural racism, and implicit bias that are drivers of increased morbidity and mortality for communities of color at the national level.

Public Health and Health Care Sector Coordination and Measures Effectiveness

The pandemic demonstrated the stark divide between our public health and clinical care systems. For decades, public health has been underfunded at all levels of the government, which hampered U.S. pandemic preparedness and response.

In addition, the quality and safety focus areas for public health and clinical care have been poorly aligned, with health systems focused more on specific clinical areas such as treatment for acute cardiac conditions and avoidance of localized nosocomial infections; public health systems are traditionally more focused on communicable disease control and prevention of chronic disease and injuries. There was no existing data infrastructure across these systems that included key variables and metrics around readiness to inform preparedness and the response capacity of the health care system. As a result, most health systems did not have data or systems for collecting and sharing information about personal protective equipment (PPE), essential staffing, or ventilator shortages at the start of the crisis. The locus of control between the federal, state, and local governments was not always clear, with emergency response responsibilities resting in multiple federal government agencies and varying forms of state-local governance structures for public health, which can generally be described as centralized, decentralized (or home rule), mixed, and shared state and local governance. Each model presents its unique coordination challenges. The state-local mixed models are described in more detail in *Public Health COVID-19 Impact Assessment: Lessons Learned and Compelling Needs* (DeSalvo et al., 2021).

Within the health care sector, multiple organizations and systems compete for business in a market-based system, with little guidance, much less metrics, for cooperation and collaboration during a public health emergency (NASEM, 2018).

The broad quality frameworks for payers and providers have created a large infrastructure and set of resources that focus on tackling dissimilar requirements and metrics across markets and providers, supporting the disparate data and reporting systems. The resources devoted to this enterprise generate revenue and enable provider incentives—but this "teaching to the test" does not contribute enough to the health of individuals, and activities such as support for SDoH are not always rewarded.

The complex and layered measurement system was largely built through federal and state legislation. Measurement currently serves multiple agendas. The wide-ranging focus and cumbersome data capture and reporting system leave the health sector unable to tackle novel or emerging specific issues, particularly crises such as COVID-19, which required such comprehensive cross-sector collaboration. Without an overarching strategy or direction, the current system is one in which no outcomes are prioritized—there is no ability to create consistent directional change for the health of a population.

Data Infrastructure and Interoperability

While the U.S. maintained a national stockpile of PPE and ventilators, the lack of a digital and communications infrastructure for early detection and preparation

for the COVID-19 pandemic, along with limited visibility of the Strategic National Stockpile, limited the ability to equip clinical settings and the public adequately. Crucial data and information did not flow between public health agencies or the medical care system and standards organizations. Additionally, a lack of investment in systems to support digital data capture in post-acute care settings widened the quality information gap. Lack of testing contributed greatly to the rapid spread of COVID-19. Still, even when testing was available, the spread occurred much earlier and more widely than could be known because of the lack of an infrastructure to surface and share such data.

Although everyone performing a COVID-19 test captured test results in digital format, the systems and rules governing the flow and aggregation of those data were not sufficient for the task of tracking the pandemic in real time. Instead, new platforms emerged using person-to-person outreach and mining data from dozens of sources manually to produce trusted tracking information.

Long-standing and oft-lamented shortfalls such as insufficient interoperability, slow creation and adoption of data standards, inadequate adoption of EHRs across the health care system, and a need to focus more precisely and consistently on the most urgent quality issues now stand out even more starkly than before the pandemic. One paper noted that among the weaknesses highlighted by the pandemic is the inability of the U.S. to develop clinical guidelines, related decision supports, and quality measures quickly (Hamlin et al., 2020). EHRs, registries, health information exchanges, artificial intelligence, and other tools are insufficiently leveraged to gather syndromic surveillance data and assess trends in near-real time. These same weaknesses have contributed to the inability to develop and deploy digital quality measures across care settings pre-pandemic, which could address the shortcomings of traditional quality measures such as the lack of inclusion and exchange of clinical information to drive substantive quality and safety improvements. These shortcomings of the quality infrastructure left our nation without ongoing insight into and accountability for safety and quality during a crisis.

QUALITY, SAFETY, AND STANDARDS ORGANIZATIONS SECTOR RESPONSE DURING THE COVID-19 PANDEMIC

The quality, safety, and standards community was called upon to respond quickly to mitigate and control the COVID-19 pandemic. CMS and other payers suspended data collection for some quality measures to help ensure that providers were singularly focused on patient care. Underresourced federal and state survey and oversight activities shifted primarily to a focus on infection control. AOs that

typically conduct an in-person assessment either suspended surveys or shifted to a virtual mode for some cases. Federal and state surveyors continued onsite surveys but combined them with virtual surveys for those that were more focused on critical areas such as infection control and abuse and neglect. Payers, including CMS, liberalized telemedicine policies to ensure access to care while minimizing the exposure risk of both clinicians and patients. The impact of these policy changes on the quality and safety of patient care is unknown and will need to be studied, including its impact on people without reliable or sufficient access to information and communications technologies.

To increase the ability to care for patients with COVID-19, hospitals canceled elective surgeries and, where possible, expanded the physical capacity to care for the expected influx of patients and to separate physically those infected with COVID-19 from other patients. In addition, many hospitals and other facilities enacted policies intended to safeguard the health and safety of health care workers, patients, and their family members, such as limitation of visitors and other personnel in direct patient care areas and universal symptom screening of all entering a facility.

The following describes the sector's response using the following levers:

1. survey, certification, and accreditation of facilities, laboratories, health plans, and providers;
2. quality measurement, incentives, and payment reforms; and
3. quality improvement learning and action networks.

Survey, Certification, and Accreditation

Hospitals and other providers are required to meet minimum standards for emergency preparedness as part of the Medicare CoPs. The CoPs currently require that health care providers collaborate with appropriate local authorities as part of their emergency preparedness policies. However, the pandemic has demonstrated that this collaboration is often ineffective or absent, again likely due to a lack of data sharing and communications infrastructure. There is an opportunity to address these deficiencies through a more intentional alignment of safety priorities and incentives between public health and clinical health care systems.

Accrediting bodies also had to shift their focus and operations rapidly in response to COVID-19. One of the largest AOs, the Joint Commission, suspended routine in-person surveys for health care organizations to enable health systems to prepare and implement rapid COVID-19 response efforts. For organizations with expiring accreditation status, the Joint Commission extended accreditation

due dates to prevent the disruption of Medicare payment mechanisms (The Joint Commission, 2020a). Limited accreditation surveys resumed in June 2020, with virtual surveys being tested in several sites (Academy of General Dentistry, 2020). The resultant impacts of virtual surveys on the public's health and safety remain unknown and should be studied. Attention should also be paid to the effectiveness of accreditation requirements to determine which requirements should be retired in favor of standards that reflect health care system readiness for future pandemics and are more likely to support quality and safety.

In March 2020, CMS also suspended nonemergency inspections, allowing inspectors to focus on COVID-19 and abuse (Academy of General Dentistry, 2020). The impact of these suspensions and narrowing of focus will be evaluated over time for continuous improvement. Still, future analyses will likely reveal which quality areas should be prioritized and which may be less important to the overall health and safety of patients and residents. This transformation could be an important opportunity to remove requirements that are of little to no value.

CMS placed particular focus on nursing home surveys because they are both a care setting and a full-time home for their residents. Over 100,000 deaths from COVID-19 occurred among nursing home patients, thought to be related to the challenges of controlling infections in a congregate setting, physical infrastructure challenges, and health-related challenges of frail older people. Prior to COVID-19, fewer than 4,000 of the nation's 15,400 Medicare-certified nursing homes voluntarily reported health care-associated infections (HAIs) to the CDC's National Health Safety Network (NHSN), which provides health care facilities with a system to track infections and prevention measures.

The CDC rapidly developed a new COVID-19 module for reporting data that subsequently became required for reporting through an Interim Final Rule with Comment published on May 8, 2020. Under this rule, noncompliance on reporting standards could result in the imposition of civil money penalties (CMS, 2020d). Within weeks, at least 95% of nursing homes began to report data in the four pathways within NHSN's Long-term Care Facility Component, providing valuable information on "resident impact, facility capacity, staff and personnel, supplies and PPE, and ventilator capacity and supplies" (CMS, 2020b).

The CDC data are critical to guiding nursing home-focused surveys, training, resource allocations, and quality improvement activities and interventions. As of November 21, 2020, states had completed 42,267 surveys. While most surveys were conducted in-person, virtual surveys were also conducted to provide rapid assistance. Survey findings often pointed to a breakdown in basic infection control processes such as proper hand hygiene, doffing and donning PPE, social distancing, staff screening, and precautions (CDC, 2020). The findings point out that it is not

sufficient to just have regulations in place. Training, technical assistance, oversight, and enforcement must also be in place to ensure adherence to quality and safety standards. While reporting of HAIs through the NHSN is not currently required by CMS, there is now an opportunity to take regulatory action to implement such a requirement. While this may add a burden to providers, a review of the impact of the suspension of other requirements may demonstrate less impactful requirements that could potentially be retired.

The authors observed that laboratory entities were somewhat burdened by testing regulations for the CMS. Laboratory testing on humans, except for research, is governed by the CMS through the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and is estimated to include around 260,000 CLIA-regulated laboratory entities (CMS, 2020c). During the pandemic, the CMS established new reporting requirements for hospital and critical access hospitals CoPs to enable the collection of COVID-19 incidence and impact data. The requirements compelled all CLIA-regulated laboratories to report COVID-19 testing results directly to the HHS Secretary (GAO, 2020).

While the reporting is necessary to determine the prevalence of COVID-19 in the community, these reporting requirements attracted criticism for their substantial impact on CLIA-regulated laboratory entities. Providers noted that the reporting of COVID-19 laboratory data was initially burdensome and not well coordinated, resulting in multiple reporting platforms and potentially duplicate reporting between federal, state, and local requirements. In addition, providers who used point-of-care antigen testing were required to obtain a Certificate of Waiver and follow the CLIA requirements, established by Congress, for which some providers had no prior experience.

Quality Measurement, Incentives, and Payment Reform

The pandemic created unique demands on the health care and public health sector, raising questions about the current system's long-term sustainability and its ability to coordinate activities across sectors. Quick action halted quality efforts that were not specifically necessary during the pandemic so that providers could focus on caring for patients. Health care quality data reporting was mostly suspended, first by CMS but followed rapidly by private payers and states. During COVID-19, payers recognized that quality measure data collection and reporting for services furnished might not reflect the true performance level on measures such as cost, readmissions, and patient experience. One paper suggested that suspension was the only practical response because so much of current quality reporting is still dependent on manual processes considered overly burdensome (Austin and Kachalia, 2020).

However, some suspensions warranted reversal as the pandemic persisted. One such example was the suspension of the Payroll-Based Journal system staffing data for nursing homes. Although initially suspended, the waiver of nursing homes' requirement to submit staffing data through the Payroll-Based Journal system was rescinded in August 2020, and nursing homes were required to begin to submit data by August 14, 2020. In this case, the need for staffing data for nursing homes because of staffing shortages outweighed the potential burden during a public health emergency.

While the ease, timeliness, effectiveness, and relevance of quality measures remain a critical issue for analysis and alignment, the importance of measurement for quality improvement and system-wide action should not be underestimated. While there were no direct measures associated with pandemic performance, quality measurements can indicate poor systemic performance during a pandemic. For example, CMS publishes health inspection and quality ratings based on their Five-Star Quality Rating System for all CMS-certified nursing homes. A study conducted by the CDC during March 2020 through June 2020 of 123 outbreaks in West Virginia nursing homes concluded that star ratings may be correlated with COVID-19 outbreak risk; facilities with 2- to 3-star and 4- to 5-star ratings were less likely to experience a COVID-19 outbreak by 87% and 94% respectively than 1-star facilities. The CDC concluded that because star ratings are a composite measurement tool, there is an opportunity to learn which health standards measures had the most significant impact. In addition, this small study suggested further efforts to improve the current systemic problems of inequitable access to quality care and good health along with the various social drivers of health (Bui et al., 2020).

While some measures were suspended, other quality measures and incentives were developed to encourage clinician participation in deploying novel treatments and therapeutics. CMS leveraged its existing value-based care initiatives and payment and reimbursement mechanisms to promote COVID-19 vaccination as part of their ongoing value-based care initiatives for Medicare Exchange and Advantage plans (CMS, 2021a). CMS also partnered with the CDC to incorporate patient and personnel vaccination as part of quality measures in nursing homes and dialysis facilities (CMS, 2021a). To encourage a culture of quality care and outcomes, the CMS Merit-based Incentive Payment System Program also began offering credit for clinicians participating in COVID-19 clinical trials and registries (CMS, 2021c). In March 2021, Medicare began paying approximately $40 per required dose of COVID-19 vaccines (CMS, 2021b). While the overall impact of these efforts remains to be seen and should be systematically assessed, the registries have presented a compelling and innovative mechanism to obtain new information and datasets related to the COVID-19 pandemic.

Quality Improvement Learning and Action Networks

Quality improvement networks were activated immediately to provide training and support to the health care system, with particular attention to nursing homes. CMS directed the Quality Innovation Network-QIO (QIN-QIO) and the CMS Quality Improvement Contractors, to focus their technical assistance on providing nursing homes with onsite or virtual training in areas of identified concern, particularly in COVID-19 outbreak hotspots (CMS, 2021d). CMS also worked with the CDC to implement a national training program for nursing home staff and management.

States also provided intensive assistance to nursing homes through the CDC-supported state-based HAI prevention programs. State coordinators worked closely with public health partners to assist with data analysis, infection prevention and control processes, and real-time support.

In September 2020, AHRQ partnered with the University of New Mexico's ECHO Institute in Albuquerque and IHI to establish the National Nursing Home COVID-19 Action Network (AHRQ, n.d.b). Through this collaboration, the network delivers a 16-week training program to increase the adoption and implementation of evidence-based prevention, response, and treatment practices to protect nursing home residents and staff and reduce social isolation (AHRQ, n.d.b).

These examples of using quality improvement learning and action networks could potentially facilitate the dissemination of critical prevention and response strategies, and treatment guidelines, while including other considerations unique to nursing home residents and COVID-19, such as mental health, HAIs, and the increased likelihood of severe disease.

OPPORTUNITIES FOR IMPROVEMENTS IN QUALITY, SAFETY, AND STANDARDS SECTOR

The pandemic revealed a profound lack of infrastructure for evaluating the public health system and significant failings of the current quality measurement infrastructure for the health care delivery system. These systems need to get stronger and smarter—time is of the essence in distilling a full understanding of opportunities for improvement and to implement structural change.

The following are a set of urgent actions that can reinforce and improve the quality, safety, and standards sector, focused on:

1. ensuring strategy and infrastructure preparedness;
2. digitizing and sharing critical information across sectors;
3. improving population health measures;
4. streamlining metrics; and

5. addressing inequities that can be taken to transform readiness, bolster the public health infrastructure, and improve health outcomes.

Ensuring Strategy and Infrastructure Preparedness

To address the critical vulnerabilities in America's public health preparedness, we can no longer implement infectious disease preparedness by applying superficial lessons learned from past infectious disease threats and ecological disasters toward future and novel threats. Instead, we should revisit the consensus definition of preparedness at the national, state, and local levels, with attention to planning and execution and robust health surveillance and vulnerability detection.

Health systems, leaders, and professionals must expand our understanding of preparedness to include readiness for and responsiveness to emergent and sustained threats. Preparedness must begin to signify the ability to rapidly develop and deploy a dynamic and responsive action plan to meet existing and emerging challenges. These challenges are likely to include simultaneous threats to public health in the form of climate change, regional and ecological reservoirs of known and novel disease, national and regional outbreaks and epidemics, global pandemics, mass refugee migration, and cyberthreats. In many instances, such a strategy should enable local flexibility to tailor responses matched with local threats, needs, and assets while accounting for the risk of emerging infectious diseases globally.

A new preparedness measurement strategy should include structural measures for enhanced preparedness, process, and outcome measures to support emergency responses. Derived from a global preparedness plan or strategy, there should be a set of implemented and functional structures to support the strategic goals. There also should be process measures designed to assess the adequacy of response to disasters and other public health threats.

Finally, the adequacy of the preparedness and response to an event should also be assessed according to individual and population outcomes. These measures might include both short-term metrics to assess interventions with rapid results over the days and weeks immediately following an emergency. Metrics could capture long-term measures such as six-month hospitalization and mortality following disasters or changes in health indicators for those developing chronic diseases after an emergency. To drive innovation, the preparedness measurement strategy could potentially capture the emerging capacities of virtual care and telemedicine at scale while accounting for the varying access to sufficient and reliable access to information and communications technologies.

Establishing a robust measurement strategy enabled by a new and robust data infrastructure will be critical if we are to transform our system from one that struggles through disaster, lamenting gaps and inadequacies that we only come

to fully appreciate after the fact, to one that anticipates emerging threats, reacts quickly, prepares adequately, and successfully mitigates the impact on the health and well-being of our citizenry.

Digitizing and Sharing Critical Information Across Sectors

Common to clinical care and public health and preparedness systems is the need for timely access to accurate digital information and efforts to increase access to this information. This access, if expanded, provides greater investment in robust and interoperable health IT infrastructure and a system of data integration delivering the right information to the right place at the right time and from every setting where health care is provided. Data would be transmitted across local, state, and regional public health departments, schools, and every outpatient health delivery entity, as well as short- and long-term institutional living facilities.

Further, this must be done in a way that maintains privacy and protects the overall system from the constant threats of cyberattacks. Reaching this goal requires continued adherence to current rules and an acceleration of additional interoperability standards and rules across the sector and public-private collaborations among data aggregators and data users to create a system and process for safe, secure data access. Transformation in interoperability and investments in data sharing infrastructure should aim to create a nimbler system to allow development, collection, calculation, and analysis of new metrics in real time to respond to emerging threats and directly apply to the crises at hand. Achieving this aim will require a sustained focus on removing barriers to a cross-sectoral approach (acute care, outpatient, post-acute, and public health) that emphasizes harmonization of data and rapidly disseminated interpretation of findings through investment and expansion of applied informatics throughout the system. Innovations and investments in data science, informatics, governance models, and cross-sectoral collaboration will enable the best epidemiologists and scientists globally to innovate new methods of distilling critical information from data to support public health.

In addition, EHRs, registries, health information exchanges, artificial intelligence and other tools must be better leveraged to gather syndromic surveillance data and assess trends and treatment efficacy in near real time. The ecosystem must also support digital quality measures to address shortcomings with traditional quality measures in all care settings.

Improving Population Health Measures

The time has also come to create and implement local, state, and regional metrics for population health status and assessment of vulnerabilities using

sensible geographic demarcations such as census block groups and shared accountability among providers serving those areas. Investments must be made in the public health entities (Federally Qualified Health Centers, local health departments, correctional health services, and so forth) serving highly vulnerable areas followed by direct financial incentives and additional investments for improved performance and decreased population vulnerability over time, similar to the model for implementing EHRs. Along with a new system of metrics that increases the use of digital measures, there must be an expansion of payment incentives directed at the health care delivery system. This expansion should focus on mitigating population health vulnerabilities caused by the social and environmental determinants of health equaling or exceeding current financial incentives of fee-for-service payment models. Federal, state, and private payers must continue to modernize the health care delivery quality measurement system that, in addition to fully digitizing quality measures, applies novel technological solutions that eliminate the burden of data sharing and reporting in the public health sector. To enhance the adoption of these measures, efforts could potentially enhance population health measures for increased transparency and accessibility. Ongoing public reporting of population-level measures may promote public awareness while building support for transformations in care delivery systems.

Streamlining Metrics

The arduous process for data capture, implementation of novel measures, and removal of measures that are no longer useful must be addressed. Similarly, the multiple agendas the measurement system is serving as well as the lack of prioritization of outcomes should be further studied. It is critical to reimagine a system that supports the innovation necessary to drive system transformation, improve outcomes, and reduce cost, particularly for underserved populations and Medicaid. We should also seize on the learning from COVID-19 by evaluating current measures post-pandemic to determine if there was any relationship or predictive value to the measures and the success of nursing homes, hospitals, or other care settings to manage patients with COVID-19.

Addressing Equity

Finally, to address the inequities laid bare by the pandemic, there must be new metrics and incentives for achieving equity in health care delivery (OASPE, n.d.; Bogard et al., 2017; NASEM, 2019). It will be important to act on the urgency created by this pandemic to develop new access to care metrics and to use well-functioning metrics and measures to accompany population and provider quality

measures. De facto segregation in care, derived from structural racism in housing and lack of access to adequate care, is a substantial driver of racial and ethnic health care disparities. In addition, metrics and measures of health care workforce diversity and integration across the workforce pay scale are needed. Recent studies have demonstrated that communities of color and communities that have been made to be vulnerable experience better outcomes when receiving care from clinicians with shared identities (Greenwood et al., 2020).

Additional innovations should include patient-reported outcome measures focused on the experiences of discrimination in health care delivery, payment models incentivizing providers to implement innovations anticipating and addressing health care disparities, and a requirement for anti-racism training as part of provider training, and accreditation, board certification, and continuing education for individual and institutional health care providers. Inequities in care delivery can be addressed and eliminated in health care delivery with investment and commitment to make these changes.

To ensure a commitment to constantly improving health systems, research could be conducted on the effectiveness of specific training programs to ensure that efforts to address health inequities and implicit biases are informed by evidence and consistent stakeholder education. Using this evidence, a proof of concept for how health equity could be incorporated into the star ratings for Medicare Advantage Plans to offer a sound, empirically tested starting point (Agniel et al., 2019). Beyond using existing measures and indices, health equity in care research could also investigate the possibility of using new measures that reflect timely access to care, equity, and racism to inform and enable systems transformation.

Finally, health equity should be intentionally incorporated into the design of Alternative Payment Models by CMS and private payers. The CMS Innovation Center's Accountable Health Communities model is a good start (Huges and Zephyrin, 2020). This and other models could be strengthened by an explicit goal of improving health equity, broadening the definition of the SDoH to include structural drivers of health inequities (e.g., racism, housing policies) and use a measurement framework for health equity (Huges and Zephyrin, 2020; Ogedegbe et al., 2020).

SECTOR-WIDE POLICY, REGULATORY, AND LEGAL CHANGES THAT MIGHT BE TRANSFORMATIVE

COVID-19 was a test of whether the U.S. health care system can pivot to measure, motivate, and optimize the most important and relevant health outcomes, and the quality, safety, and standards sector did not pass the test.

Moving forward, policy changes at federal, state, and local levels in CoP reform, payment reform, and equitable distribution of resources to achieve better outcomes for underserved populations will be crucial for the transformation of the quality, safety, and standards organizations sector.

CoP Reform

While the implementation of standards for emergency preparedness for all Medicare-certified providers in 2016 was an important development, the pandemic requires policy makers to quickly understand and address gaps and potential enhancements to the current regulatory landscape. Institutionalized populations perhaps fared the worst. Settings such as nursing homes, long-term care facilities, and psychiatric care centers became environments of disproportionate spread because of a variety of factors that must be evaluated to inform ongoing enhancements in federal and state oversight of health and safety standards—for nursing homes in particular.

The current regulations were borne of a series of devastating hurricanes (Katrina, Sandy) and expanded due to an all-hazards approach because of Ebola and H1N1. However, in the context of an ongoing, chronic disaster such as COVID-19, current regulations need ongoing review to consider prolonged stresses on the health care system and on health care workers. CMS provided over one hundred flexibilities through Section 1135 waivers of certain CoP requirements in an effort to expand available sites of care, address workforce capacity and scope of practice barriers, and help health care providers contain the spread of COVID-19. Ongoing efforts are necessary to determine if any of the flexibilities should be made permanent and additional efforts necessary to continually strengthen requirements around infection control and prevention, worker safety, repeated surges of patients, and especially coordination and collaboration across health care providers within communities and with local organizations. Similarly, states should review their licensure requirements for long-term care facilities and other health care institutions to identify enhancements that go above and beyond federal requirements depending on their local experiences and needs.

Payment Reform

The Health Care Payment Learning & Action Network, a collaborative network of public and private stakeholders, note that the health care system must reform payment structures, mechanisms, and incentivizes to encourage value, quality, and outcomes. These components can produce a system, which spends strategically to deliver better care for a healthier population. Transforming the health care

system requires system-wide and multisectoral collaboration and partnerships to reimagine care organization and delivery (HCPLAN, n.d.).

The fee-for-service payment model encourages waste, discourages innovation, and makes it difficult for practitioners and systems to know which patients they are accountable for. Systems and practitioners in a capitated environment benefit from successful efforts to make care delivery more efficient. They know who their patients are, understand the budget they must operate within, and have clear incentives to coordinate care and drive toward the best outcomes.

The last several years have seen numerous experiments in alternative payment models implemented by public and private payers with varying degrees of success—some quite successful—defined as lowering costs and improving quality. Given the inequities and quality shortfalls that the pandemic has exposed, now is the time to double down on payment reform and accelerate the move toward systems with the capabilities of capitated systems. Incentives for better coordinated care, moving care into the home, seamless sharing of data and information across providers, and reduction of waste are essential to the sustainability of our health care system and to optimize our ability to keep people healthy during a pandemic or other disaster. A closer look at the need for health care reform can be found in *Health Care Payers COVID-19 Impact Assessment: Lessons Learned and Compelling Needs* (DeSalvo et al., 2021).

Equitable Distribution of Resources to Achieve Better Outcomes for Underserved Populations

Based on the long-standing records of health care disparities in the U.S., it should be no surprise that the impact of COVID-19 disproportionately affected Black, Latinx, and Indigenous populations. Although many causes of health disparities often originate outside the health care system because of structural racism and discrimination, it is the responsibility of health systems and care practitioners to address the specific needs of:

- Black/Latinx populations;
- Native and tribal communities;
- individuals residing in congregate or institutional settings (e.g., prisons, nursing homes, mental health facilities) (Jimenez et al., 2020); and
- people in rural health settings.

Despite the formidable challenge, the U.S. must establish quality measures and standards to address pre-existing issues combined with the devastating effects of a pandemic. First, there must be conscious efforts by all to focus on acknowledging

and owning responsibility for disparities and a commitment to eliminating them. There is little need for additional studies to prove that disparities exist, but there is a great urgency to eliminate them. It must be acknowledged that racism is embedded in systematic ways both in the health care delivery system and in society broadly that impact adequate access. Health care organizations cannot solve these challenges without the help of public health and community organizations and must also work with community leaders who have the requisite trust with the community to develop sustainable solutions. Addressing racism and health disparities does not lend itself to a purely medical model, a list of quality measures that focuses only on the disease process or interventions that rely on an individual clinician's actions. It will be imperative to articulate and execute a shared accountability approach that involves cohesive action from multiple actors and their interdependencies across social, economic, and political systems. This unified approach should be supported by sector-specific time-bound goals, actions, metrics, and incentives.

Learnings must be identified and documented as the system adjusts to address urgent needs rising from the pandemic. Then, when the pandemic is under control, the system should apply those learnings toward the transformation of health care and other sectors to achieve greater equity. For the immediate needs, the CDC outlines certain recommendations for addressing disparities during the COVID-19 pandemic, such as ensuring increased testing, contact tracing, isolation, and disease management in populations more likely to contract COVID-19 (NASEM, 2018). Ideally, data must drill down to the county and neighborhood levels to ensure the equitable distribution of testing, contact tracing, and vaccination. These targeted responses are critical and do not support the frequently held notion that improvements to the system overall will somehow reduce disparities. There must be relentless efforts to implement anti-racist policies to combat the earned mistrust of health care and public health interventions in Black, Latinx, and Indigenous communities.

There is also a demonstrable link between vaccine acceptance and the perception of fairness, experience of racism in health care, and perception of one's own risk of being the victim of discrimination within Black communities (Quinn et al., 2017). However, health care providers have not engaged in efforts to address the problems that continue to drive inequity directly. Communication about the importance of vaccine administration and safety must come from trusted sources (Quinn et al., 2017). There must be targeted logistical efforts to achieve equity in making vaccines available and safely administered to communities of color and communities that have been made to be vulnerable, as well as ensuring appropriate and continual follow-up with these communities. These accommodations could

include workplace vaccinations and incentives to help people who cannot miss work to receive vaccines during workdays. Data and metrics must be closely followed and made publicly available to provide reliable information on progress in this area or lack thereof (NASEM, 2020).

Post-pandemic activities must include collective and earnest efforts to address inequities and health disparities that existed prior to COVID-19. These efforts include opportunities to reduce inequities including development and refinements of disparities indexes and then holding providers and health systems accountable by tying reduction of disparities to payment. In addition, the expansion of digital capture of health information affords an opportunity to capture information more fully about the exposure and impact of individual interactions with systemic racism across sectors. For example, it is possible to digitally map patients to residence in historically redlined and subsequently economically divested communities, to capture experiences of interaction with police and corrections systems as well as performance of public primary and secondary schools that children attend. Collecting these data in health care and public health sectors can provide essential information to improve prevention and health outcomes. This information could also inform efforts to develop holistic efforts targeted toward geographic areas most harmed by systemic racism.

The expansion of enrollment and use of patient portals during COVID-19 could be leveraged to capture patient-reported information about trust in providers, experiences of racism, perceived risk of discrimination, and other critical predictors of access to preventive care among disadvantaged groups. Attention to metrics in this area becomes particularly important as goals for payment move away from fee-for-service models to value-based care.

Along with indisputable gaps in the current quality, safety, and standards organizations ecosystem, the pandemic also revealed heroic responses of clinicians and frontline health care workers, as well as their leaders. In addition to providing clinical care, many contributed to journals and online platforms to share key insights and lessons learned, led efforts to locate PPE, and identified childcare options for clinicians who had to work through the most intense surges of COVID-19. Moreover, early in the pandemic, thousands of health care professionals volunteered to serve in the hardest-hit communities. More recently, many clinicians are energetically identifying and addressing misinformation propagated through social media. Priorities for moving forward must recognize the importance of professionalism generally and these contributions specifically, and anticipate the observed fatigue and burnout experienced by many providers. It will also be essential for leaders to restore trust with clinicians who did not feel supported throughout the pandemic.

PRIORITIES MOVING FORWARD FOR THE QUALITY, SAFETY, AND STANDARDS ORGANIZATION SECTOR

COVID-19 has presented an incredible opportunity to rethink the quality, safety, and standards organizations sector's design and functioning. The health ecosystem must respond to the urgent call for equity in health care delivery and health outcomes by defining goals, developing and deploying metrics, and aligning resource distribution and payment policy. The most urgent priorities include:

- Ongoing systematic review of CoPs in consideration of requirements related to prolonged stresses on the health care system, including how various care settings can work more closely together to address issues of a surge of hospitalizations, support for home care, and coordination of discharge or transfer from one setting to another.
- Acceleration of the work begun pre-COVID-19 to strengthen and modernize the quality measurement strategy and infrastructure. Investments in and design of new models and standards for collaboration between health care and public health systems should be significantly increased. These collaborations should be fueled by and assessed with digital data to drive learning, innovation, and impact.
- Expanding and rapidly accelerating the shift away from fee-for-service models and toward alternative payment that promotes value and optimizes population wellness, resilience, and patient outcomes. Payment reforms to facilitate quality improvement should be aligned with specific strategies to reduce known disparities and promote equity. Payment reforms should be tracked with metrics that can assess performance at the individual, population, and health system levels.
- Investing in the expansion of digital data capture in public health and congregate settings, ensuring the data are fully interoperable and expanding public-private partnerships to accelerate innovation and agility in the digital information and measurement space. Finally, these changes must be driven by prepared, capable, and committed leaders from across all sectors. An improved and agile data infrastructure must be guided by policy interoperability across sectors, the commitment to shared goals, and recognition of critical interdependencies.

Building a renewable source of leaders in the public and private sectors can be enhanced by cross-disciplinary and multidisciplinary leadership training programs and experiences to foster shared learning by health care business leaders, public health leaders, and clinical leaders beginning with early stages of

career development. Attention should be given to the skills that will be needed to drive significant change, including anti-racism, behavioral economics, rapid-cycle testing and learning, practice transformation, and change management, to name a few.

With robust strategic investments and partnership by the public and private sectors and a cadre of leaders committed to transformational change, the quality, safety, and standards organization sector can emerge from the COVID-19 pandemic smarter, fairer, and stronger than before.

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None to disclose.

10

HEALTH SYSTEM TRANSFORMATION: COMMON PRIORITIES ACROSS SECTORS

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INTRODUCTION

"[T]he influenza pandemic that erupted in 1918 was the first great collision between nature and modern science. It was the first great collision between a natural force and a society that included individuals who refused to either submit to that force or to simply call upon divine intervention to save themselves from it, individuals who instead were determined to confront this force directly, with a developing technology and with their minds."

—John Barry, "The Great Influenza"

In the century following the 1918 influenza pandemic, nature and modern science have collided repeatedly, from the global efforts to eradicate diseases such as smallpox and polio to the devastation and eventual pharmaceutical control of HIV/AIDS and in the past two decades, the emergence and mitigation of pathogens such as SARS, H1N1, Ebola, Zika, and MERS-CoV. During each public health emergency, individuals, families, and communities displayed resilience and led advocacy efforts for improvements in access, outcomes,

and equity of care; clinicians cared for the ill; health departments detected and monitored health threats and implemented population-level interventions to inform, educate, and protect the populations in their jurisdictions; and innovators developed new tools for diagnosis, treatment, and prevention. In the aftermath of each crisis, policymakers and leaders in health and health care sectors proposed steps to improve readiness for future outbreaks, but have found it difficult to sustain preparedness in practice. For example, while the United States ranked first in the world for pandemic preparedness in the 2019 Global Health Security Index, it has faced humbling challenges addressing health system needs during the COVID-19 pandemic (Cameron et al., 2019).

America's readiness to respond to infectious disease outbreaks following the centennial of the "Great Influenza" was put to the test in the final month of 2019, when global news outlets first reported a "mysterious viral pneumonia" in Wuhan, China (Wee and Wang, 2020). The first U.S. case of COVID-19 infection was confirmed on January 20, 2020, and the Secretary of Health and Human Services officially declared a public health emergency on January 27, 2020, which activated new authorities for regulators and financial resources to aid health departments to detect and contain pathogens (HHS, 2020; Holshue et al., 2020). Still, the government response was slow. Over the following weeks, SARS-CoV-2 (the virus that causes COVID-19) began to spread rapidly across the world, with reports from other countries detailing the virus's toll on individual and population health, the strain it was already placing on health systems, and the need for public health restrictions with a scale and scope unprecedented in the modern era.

Infections began increasing exponentially in the U.S. in March 2020, with the number of confirmed COVID-19 cases rising from less than 50 to nearly 200,000 over the course of the month (JHU, 2020). Elected officials issued stay-at-home orders, leading to the closure of schools, offices, and retail businesses (Bosman and McKinley, 2020). Hospitals and clinicians struggled to care for the growing volume of patients, which soon outpaced the inpatient capacity of health systems in early epicenters such as New York City and required the rationing of limited supplies and services, known as crisis standards of care. In the U.S., a lack of access to accurate and rapid diagnostic tests, longstanding shortages in staffing, fragmented data systems, a weak digital infrastructure, and inadequate funding limited health department efforts to trace the disease's spread and control the outbreak (Christopher et al., 2021; HHS OASH, 2016). For individuals, families, and communities, misinformation campaigns on social media obscured or criticized credible information sources, creating confusion and mistrust. Alongside months of inadequate access to essential health care resources, individuals, families, and communities were also excluded from problem solving and decision-making about standards of care, closures in their communities, and

other critical safeguards. Health systems experienced shortages of essential medical supplies such as personal protective equipment (PPE), especially during the early stages of the pandemic, leaving health care providers and the general public even more vulnerable (Arangdad and Godfrey, 2021). Across the first year of the pandemic, over 3,600 health care workers' deaths were attributed to COVID-19 (KHN and The Guardian, 2021). Meanwhile, at the policy level, a breakdown in coordination between federal, state, and local governments, the politicization of public health guidance, and widespread misinformation fostered uneven approaches to lockdowns and re-openings, and further fractured public trust.

As COVID-19 infections surpassed one million cases in the U.S. by the end of April 2020, the federal government announced the creation of multiple public-private partnerships, including Operation Warp Speed, to accelerate the development of diagnostics, therapeutics, and vaccines for SARS-CoV-2 (Trump White House, 2020). While the research and development (R&D) of medical countermeasures is typically a years-long process, R&D teams were able to successfully accelerate study timelines to a matter of months—while maintaining accepted standards of methodological rigor—thanks to substantial financial investments in clinical research as well as collaborations between academia, industry, and government. By the end of 2020, the Food & Drug Administration (FDA) had authorized hundreds of diagnostics, multiple therapeutics, and even the first COVID-19 vaccines to receive Emergency Use Authorizations (EUAs) (FDA, 2020a). These achievements were remarkable, but the potential global benefits of these innovations have been influenced by limited vaccine availability in many countries, as well as by widely varying personal decisions fueled by the politicization of public health and the spread of misinformation, even in the most economically developed countries.

The damage done by the pandemic has been devastating and disruptive. By April 2022, the SARS-CoV-2 virus had infected over 80 million Americans and taken the lives of more than 950,000—with over 6 million deaths globally (CDC, 2022a; WHO, 2022). The pandemic has disproportionately affected older people, people of color, and individuals from low-income backgrounds, with COVID-19 exposing and exacerbating longstanding inequities in social determinants of health and population health in the U.S. (CDC, 2021a and CDC, 2021b). Indeed, economic inequality, structural racism, and inadequate access to health care were rooted deeply in communities across the U.S. long before the identification of COVID-19, which only increased the susceptibility of under-resourced populations to infection, hospitalization, and fatality from the disease (Maani and Galea, 2020).

Consequently, the pandemic revealed the best and worst of American health care: a system powered by remarkable capabilities for care provision and scientific

FIGURE 10-1 | COVID-19 Stakeholder Sectors Legend

developments, but too often facing structures, incentives, and data gaps that limit the capacity of evidence-based outreach and population health interventions to address the health priorities of individuals, families, and communities. To better understand the different facets of the pandemic response and identify opportunities for long-term transformation, a systems-level approach that accounts for the wide range of individuals, institutions, and issue areas comprising the U.S. health system is required.

To this end, the National Academy of Medicine (NAM) convened leaders from nine stakeholder sectors of the health and health care system to assess the impact and experiences within their sectors during the pandemic (see *Figure 10-1*):

- Patients, Families, and Communities[1];
- Clinicians and Professional Societies;
- Care Systems;
- Digital Health;
- Public Health;
- Health Care Payers;
- Health Product Manufacturers and Innovators;
- Biomedical Research; and
- Quality, Safety, and Standards Organizations.

The resulting series of sector-specific impact assessments highlighted unique but interrelated contributions and challenges as each sector worked to respond to COVID-19. Management, financial considerations, incentive structures, governance, accountability, and regulatory dynamics vary from sector to sector, leading to a tendency across sectors—and even within sectors—to operate within siloes. This is largely the cause of the fragmented response observed throughout the COVID-19

[1] To encompass all people (including those not served in a medical setting), this group is referred to as "individuals, families, and communities" throughout the remainder of this chapter.

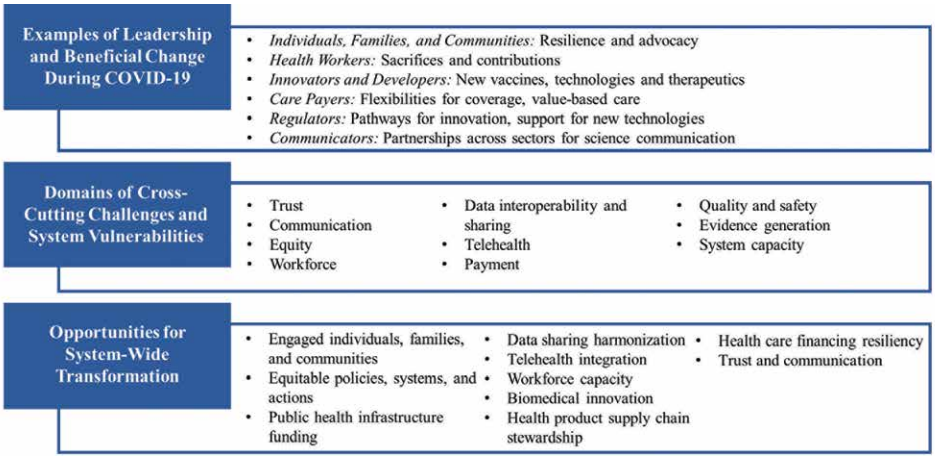

FIGURE 10-2 | Overview of Sector Changes, Challenges, and Transformation Opportunities

public health emergency. Still, strong efforts to forge collaboration and progress in policy and program activities during the pandemic illustrate the value and need for system-wide transformation towards a health system that supports collaboration on common, crosscutting issues in health, health care, and biomedical science.

This concluding chapter of the NAM's pandemic assessment summarizes the common experiences of the different sectors by highlighting examples of beneficial changes prompted by the pandemic (e.g., adjustments to payment and regulation) and examining the cross-cutting challenges and vulnerabilities exposed by COVID-19 (e.g., trust, workforce, technology, capacity). The final section of this chapter explores the crosscutting opportunities for near- and long-term system-wide transformation, using the NAM's framework for a continuously learning health system (as outlined in the 2013 IOM publication *Best Care at Lower Cost*) to foster effectiveness, efficiency, equity, and continuous learning for the future of American health care (IOM, 2013). An overview of this chapter's findings is summarized in *Figure 10-2*.

To be successful, these priority actions and opportunities must be underpinned by the critical components of trust, equity, and authentic relationships. Meaningful change will require all individuals to be able to recognize their own interests, perspectives, and culture at the center of their experiences throughout the health system and across the continuum of care. These foundational principles are the basis for transformative action across the themes presented and discussed in this chapter:

1. Centering health system actions and accountability on **individuals, families, and communities;**
2. Committing to the pursuit of **equity** as core to health system performance;

3. Securing the **public health infrastructure** for 21st century population health challenges;
4. Building a robust and integrated digital health and **data sharing infrastructure;**
5. Integrating **telehealth** into payment and delivery systems;
6. Investing in **workforce** capacity and readiness;
7. Streamlining **innovation pathways** for biomedical science;
8. Strengthening stewardship of the health product **supply chain;**
9. Restructuring health care payments to focus on **outcomes and population health**; and
10. Fostering **communication and collaboration** across sectors and stakeholders.

EXAMPLES OF LEADERSHIP AND ADVANCES DURING COVID-19

While the American health system often struggled during the COVID-19 pandemic—a result of both structural issues and underinvestment in pandemic preparedness and foundational and functional public health capabilities—stakeholders across the system took bold steps to respond to COVID-19 that may provide momentum for future system-wide transformation.

Throughout the pandemic, health care and public health workers across the country met the needs of their communities and called attention to the importance of preparedness, often suffering great personal costs to respond to the crisis. At the same time, actions by regulators, payers, and health systems have catalyzed telehealth utilization, and new investments and public-private partnerships have accelerated the development of new medical countermeasures for COVID-19. This section presents some of the ways in which individuals and organizations across the health system have contributed to the many developments, innovations, and advances that have helped America and the world arrive in 2022 with safe vaccines, therapeutic options, and a better understanding of disease control and prevention. *Figure 10-3* illustrates examples of leadership and advances made for:

1. Individuals, families, and communities;
2. Health workers;
3. Innovators/developers of health products and technologies;
4. Care payers;
5. Regulators; and
6. Communicators.

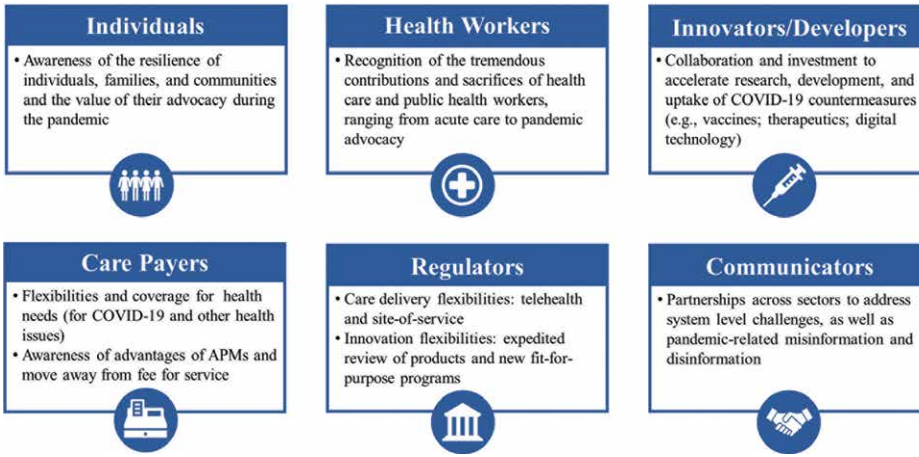

FIGURE 10-3 | Select Examples of Leadership and Advances During COVID-19

Individuals, Families, and Communities: Resilience and Empowerment

Although individuals and families are best positioned at the center of the health care system, their perspectives and voices are often absent from decision-making, system design, and policy considerations. This reality has substantial downstream consequences for health equity and outcomes. The sequelae of these system failures have been apparent during COVID-19, which has impacted individuals, families, and communities in myriad ways, from the direct harm of infection to the collateral impact on mental health, non-COVID-19 illnesses, and economic and social instability. All of these concerns have been amplified for communities of color, low-income populations, women, and other groups that are economically or socially marginalized.

For individuals and families navigating the system, U.S. health care often feels fragmented, contributing to a sense that it is inadequate and slow. These sentiments were exacerbated by the unique set of obstacles that COVID-19 raised. As evidenced in the chapter on patients, families, and communities (Chapter 1), COVID-19 has unmistakably devastated many communities across America. Although the consequences of the pandemic will reverberate for many years, they should be recognized alongside the many positive community responses and leadership from individuals and families displayed on matters including care, financing, and data and evidence generation.

Individuals, families, and communities have displayed remarkable commitment and resilience in the face of adversity throughout the pandemic. Many have

leveraged their voices against the shortcomings in health system responses, advocating for better access to essential health care resources such as PPE or COVID-19 testing sites, amplifying authoritative public health information, and fighting to ensure that research and innovation for COVID-19 centered on individuals (e.g., spotlighting the effects of "long COVID", highlighting racial disparities in clinical trials).

Health Workers: Contributions and Sacrifices

Clinicians, including a broad range of direct care providers and allied health professionals, represent the backbone of the American health system. From the outset of the pandemic, health care and public health workers rose to the occasion, working long hours and taking on significant personal risks to care for patients with COVID-19 and other critical illnesses. The health care workforce's leadership and service has elicited broad public support, from the salute to health care and public health workers that began in New York City and spread nationwide to the significant increase in applications to health professions schools (Murphy, 2020; Newman, 2020).

While health care workers' commitment to patient care during COVID-19 embodies the essence of their professional oaths and the legacy of service during previous infectious disease outbreaks (e.g., influenza, HIV/AIDS), their contributions to the pandemic response have come at a significant cost. The chapter of this Special Publication focused on clinicians and professional societies (Chapter 2) details how preexisting gaps in the workforce created issues for clinical capacity during COVID-19, and how shortages of PPE and other medical supplies left health care workers exposed to infection, resulting in thousands of cases of clinician infections and deaths (KHN and the Guardian, 2021). The recognition of individual contributions and sacrifices must be understood, therefore, in the context of systemic shortcomings and their consequences on the physical, emotional, and moral well-being of health care professionals (further described in the "Workforce" sub-section of "Cross-Cutting Challenges for COVID-19").

Innovators/Developers: New Health Products and Technologies for Pandemic Mitigation

Advances in Research and Development

Although significant research has been dedicated to understanding related coronaviruses over the past decades, SARS-CoV-2 emerged in 2019 as a novel pathogen. At the outset of the pandemic, health professionals faced the historical

reality that the development of new medical products—particularly therapeutics and vaccines—can span a decade and cost more than one billion dollars to develop and test (Gouglas et al., 2018). Two chapters of this pandemic assessment—on biomedical research (Chapter 8) and on health product manufacturers and innovators (Chapter 7)—detail how the academic, public, private, and non-profit sectors engaged in remarkable collaboration to accelerate the development of medical countermeasures for COVID-19. Programs such as the Rapid Acceleration of Diagnostics (RADx) initiative and Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership, both organized by the National Institutes of Health (NIH), are examples of the kind of system-wide initiatives that helped streamline development processes and timelines (e.g., by developing master protocols and organizing data sharing) (Collins and Stoffels, 2020; NIH, 2021; Tromberg et al., 2020).

Biomedical research professionals and health product manufacturers and innovators worked across the globe to adapt clinical trials amidst the unique circumstances and priorities of the pandemic era. In addition to navigating restrictions related to travel, quarantining, and enhanced safety precautions, researchers, manufacturers, and innovators sought to address ongoing racial diversity concerns by appropriately and sustainably enhancing the representation of people of color as clinical trial participants and investigators (FDA 2020b; LaFraniere et al., 2020; Nephew, 2021; NIH, 2020; North et al., 2020). A number of tools have been used to improve cost reduction, efficiency, timeliness, generalizability, and synergy among clinical trials worldwide, including innovative trial design and implementation methodologies (e.g., flexibilities for trial duration, sample size modifications, platform trials, utilization of incidence prediction data to aid in clinical trial site placement and diverse recruitment, in-person/remote interactions during trials) and supportive approaches to data collection and analysis (e.g., tokenization of data, connecting trial data with electronic health records) (FDA, 2020b; Hahn et al., 2020; Kunz et al., 2020; Normand, 2021; Van Dorn, 2020). Regulatory authorities should consider the continued use of such flexibilities to benefit clinical trials where feasible (EMA, 2020; FDA, 2020d; Meyer et al., 2020).

There have been many examples of accelerated scientific innovation during the pandemic. One lasting legacy will be the successful design, testing, evaluation, and distribution of vaccines for COVID-19 in an extraordinarily short time without compromising the safety or quality of vaccine development (WHO, 2021). Under challenging financial, operational, and technical circumstances, leaders across the global health system successfully worked together to focus resources for COVID-19 vaccines, and, by December 2020, two vaccines received EUAs from the FDA (FDA, 2022a; FDA, 2020c). Yet challenges surrounding access, vaccine

refrigeration and storage, and trust slowed vaccine rollout and required significant and ongoing mitigation strategies. As of April 2022, the FDA has fully approved two vaccines and provided an EUA for one other, but equitable vaccine access and vaccine hesitancy still hamper vaccine uptake in the U.S. and abroad at the time of publication (FDA, 2022b; Gill and Ruta, 2022; Saelee, 2022).

Despite these barriers, innovative immunization tools and strategies throughout the pandemic enabled over 255 million Americans to receive at least one dose of a vaccine, over 215 million Americans to be fully vaccinated, and over 100 million Americans to receive at least one vaccine booster as of the time of writing (CDC, 2022b). Continued advancements in biomedical research will need to address the obstacles to research and development faced along the way (e.g., workforce shortages, health system research capacity, trial disruptions due to investigational site access restrictions, diverse participant recruitment issues, and other racial disparities) (Chastain et al., 2020; FDA, 2020d; Helfand et al., 2020; Nephew, 2021; North et al., 2020). Meanwhile, it is important to recognize the history of investments and discovery leading to the scientific achievements achieved during COVID-19. The pace of vaccine development and other medical product milestones realized during the pandemic were unprecedented. These achievements were possible only because of decades of basic science research. At the same time, it is important to recognize that individuals across the world still face many limitations in terms of access and delivery for these same vaccines and therapeutics (Frisch et al., 2021; Johnson, 2021).

Advances in Digital Technology

From artificial intelligence to telemedicine, a number of facets of digital innovation have offered bright spots in the U.S. pandemic response. As the risk of disease transmission made in-person engagement and care infeasible, the rapid deployment of a diverse telemedicine toolkit ensured that essential services could still be provided. These tools were prone to geographic and population-level disparities in the form of the nation's "digital divide," but, as a whole, remote patient monitoring, mobile health tools, and synchronous/asynchronous care were essential to preventing care gaps across the U.S. (Maliha et al., 2021; Perrin et al., 2020). The accelerated uptake and use of digital platforms has supported case investigation, contact tracing, and other essential functions of state and local public health throughout the COVID-19 public health emergency (CDC, 2019; Gunasekeran, 2021). Also key has been the implementation of artificial intelligence, helping to manage an often overwhelming amount of data and empowering significant tools for pandemic response (e.g., intelligent chatbots, accelerated therapeutic development, life-saving decision support systems) (Brothers, 2020; Lyons, 2020; Magrabi et al., 2019). While these tools still have

much to gain from a refreshed digital infrastructure and improvements to data interoperability, they demonstrate the remarkable benefits that digital solutions can provide for health system effectiveness, efficiency, equity, and continuous learning (AHA, 2019; Llupia et al., 2020; Peiffer-Smadja et al., 2020).

Care Payers: COVID-19 Insights for Payment Reform

There are a number of shortcomings to the system of reimbursement for health services in the U.S.: the misalignment of financial incentives contributes to unnecessary and low-value service utilization, and information gaps and opaque access and coverage processes can delay access to care (Leavitt et al., 2016; Shrank et al., 2019). However, as COVID-19 disrupted care delivery across the health system, payers and policymakers took rapid action to adjust payment policies, yielding insights for future coverage flexibilities and payment models.

Flexibilities and Coverage for Health Needs During the Pandemic

The passage of emergency pandemic relief legislation included provisions to guarantee that insurers would cover many components of COVID-19 diagnosis and treatment (Keith, 2020). Regulators and clinicians worked together to develop codes for new pandemic-related health products (e.g., COVID-19 tests) and services (e.g., updates to Medicare Severity-Diagnosis Related Groups for inpatient COVID-19 care) (CMS, 2020a; Federal Register, 2020). To support service continuity for non-COVID-19 medical needs (e.g., chronic disease management), payers introduced temporary payment policies for telehealth and other site-of-service adjustments. Beyond these changes to reimbursement, health plans also introduced new financial and administrative flexibilities, ranging from premium deferrals to waivers of prior authorization and cost-sharing policies (AHIP, 2020).

Many of these policies and programs will terminate at the eventual expiration of the public health emergency, but the pandemic-era reimbursement and coverage flexibilities suggest opportunities for improving the efficiency and equity of health care payments in the future. For example, simplifying and clarifying the processes of prior authorization and cost sharing may be further explored to improve access and experiences (Gaines et al., 2020).

The federal Medicaid program and the Health Insurance Marketplaces played a critical role in protecting Americans' access to health insurance and health care during the public health emergency and related economic downturn despite the fact that millions of people across the nation lost their jobs and their employer-sponsored insurance, Medicaid and Health Insurance Marketplace enrollment increases provided an effective stopgap for continued coverage (CMS, 2021; HMA, 2020).

Support for Alternative Payment Models

COVID-19 highlighted a number of limitations inherent in traditional fee-for-service approaches to health care payments with respect to service coordination, data linkage, and population health (Shrank et al., 2021). As chronicled in the chapters of this Special Publication on care systems (Chapter 3) and clinicians and professional societies (Chapter 2), the cancellation and delay of both non-emergent procedures and a range of outpatient health services threatened the financial stability of care delivery organizations, ranging from primary care practices to academic medical centers (Khullar et al., 2020a; Rubin, 2020). Federal relief payments to providers, reimbursement flexibilities for telehealth, and the rebound in volumes for some specialties have partially alleviated this impact, but many providers continue to express concerns about the short- and long-term financial outlook for community practices and hospitals.

The financial impacts of the pandemic have not been evenly distributed across the health system. Clinicians reimbursed under alternative payment models (APMs)—where reimbursement is typically delinked from service volume—reported greater financial stability and operational flexibility during the first year of the pandemic (i.e., primary care providers in capitated, risk-adjusted arrangements have been better insulated from the financial consequences of office closures and were often more prepared to transition to virtual care models) (Ikram et al., 2020; Koller and Shih, 2020; Roiland et al., 2020). Likewise, hospitals reimbursed under global budgets (i.e., provided with a prospectively set, fixed amount of funding to care for specified populations over a time period) have been better positioned to weather the declines in procedure volume and adapt to meet the needs of COVID-19 (Fried et al., 2020). In general, health care systems with substantial levels of premium income from their own health plans have generally fared better during the pandemic (Bannow, 2020).

Amidst the dysfunctionality of fee-for-service payment structures, federal provider relief initiatives such as the Coronavirus Aid, Relief, and Economic Security (CARES) Act helped to mitigate severe financial losses, keep critical care avenues open, and enhance providers' abilities to adapt to the circumstances of the pandemic (Kaufman Hall, 2021; Socker et al., 2020). Although criteria and distribution systems for these relief avenues may not have been optimally efficient and equitable, they have given many systems the stability, resources, and flexibilities needed to pivot towards more resilient, innovative, and person-centered approaches to health financing and payment.

Payment reform alone is not a panacea for resolving the country's many health system inefficiencies. Uptake of APMs was lagging prior to the pandemic—with many APMs still including components of traditional fee-for-service models—and it is not clear how well current "value based" models achieve savings and outcome

improvements (Frakt, 2019; HCPLAN, 2019). As COVID-19 has renewed calls to improve the resiliency of health financing, however, payers, providers, and policymakers may be encouraged to accelerate the transition away from existing traditional fee-for-service patterns across the system and take up more sustainable approaches to reimbursement (Gondi and Chokshi, 2020).

Regulators: Pandemic-Era Flexibilities

The exigency of the pandemic led policymakers to issue temporary policies and flexibilities to increase the accessibility of health services, fill capacity needs for COVID-19, and accelerate the development of timely medical products. Select examples of beneficial changes that cut across different facets of the health care system are described below.

Regulatory Flexibilities for Care Delivery

Policymakers took several steps to shore up the capacity of care systems and delivery organizations so as to concentrate inpatient resources for COVID-19 patients while maintaining continuity in non-COVID-19 care where possible. For example, regulatory flexibilities for clinician licensing and scope of practice helped to fill capacity gaps in short-staffed hospitals in outbreak epicenters (Hentze, 2020). Likewise, flexibilities for telehealth (e.g., waivers of originating site requirements, use of consumer-facing platforms such as FaceTime and Skype) and site-of-service programs (e.g., support for Acute Hospital Care at Home) helped to shift the locus of care delivery away from overburdened hospitals and ensure access to many types of non-COVID-19 health services, at the same time protecting individuals from COVID-19 infection and spread (CMS, 2020b; CMS, 2020c).

The pandemic highlighted the value of more flexible and accessible care models, and the evolution of individual preferences after exposure to new care modalities and experiences during COVID-19 may provide opportunities and demand for new, person-centered innovations in care delivery. Potential long-term extensions of such flexibilities require consideration of additional issues such as patient privacy on virtual care modalities.

Regulatory Flexibilities for Medical Innovation

In response to public and industry demand to expedite pandemic response capacity, regulators issued temporary policies and developed fit-for-purpose programs to work with manufacturers to accelerate the development of diagnostics, therapeutics, vaccines, medical devices, and PPE to mitigate and treat COVID-19. For example, as demand for testing outpaced the capacity of the nation's public

laboratory network, especially given staffing shortages, the FDA issued policies aimed at expanding testing at commercial laboratories and allowed for validated COVID-19 diagnostics to be used prior to the completion of EUA requests (FDA, 2020c). Likewise, the FDA instituted numerous flexibilities to support adaptation to the pandemic environment, including allowing vaccine, medical device, and therapeutic developers to conduct clinical trials amidst COVID-19 restrictions (e.g., through rapid changes to study protocols, use of telehealth) and supporting digital health efforts (e.g., expanded use for home-based care) and other technologies. Beyond such policies, initiatives such as the Coronavirus Treatment Acceleration Program aimed to streamline the review of Investigational New Drug Applications and the initiation of new clinical trials (Hahn et al., 2020).

While in some cases, such policies encountered roadblocks and required iteration (e.g., regarding the validation of COVID-19 diagnostics), the steps taken by regulators overall enabled significant progress for product development and may provide lessons for accelerating medical innovation for other public health needs (Vandenberg et al., 2020).

Communicators: Communication and Collaboration to Address System-Level Challenges

Despite the fragmentation of the nation's health system, individuals and systems collaborated in a variety of ways to address broader impacts of the pandemic. Examples include:

- Public-private partnerships to develop medical countermeasures;
- Regional collaboratives between health systems and health departments to organize supply chains and clinical capacity;
- Collaboration between industry and public health to accelerate, increase, and improve testing and contact tracing;
- Coordination among health systems and communities to ensure that individuals and families affected by COVID-19 received a comprehensive level of care (encompassing clinical services, food banks, resources for treatment, and temporary housing for individuals with COVID-19 to protect family members); and
- Partnerships such as NIH's National COVID Cohort Collaborative (N3C) to foster collaborations to combine clinical data from various sources.

One prominent example of collaboration was a focus on communication across the health system and with the general public about existing and evolving data on COVID-19 infection, illness, and prevention. The pandemic has been exacerbated by what some have termed an "infodemic;" misinformation, disinformation, and

gaps in data (e.g., on race and ethnicity) have undermined public trust, weakened compliance with public health best practices, and limited the potential impact that interventions can have in producing equitable outcomes at a state, local, and national level (Christopher et al., 2021; WHO, 2020; Xiang and Lehmann, 2021). To improve the collection and exchange of authoritative and trusted information, partnerships were formed between sectors at multiple levels of the health system. For example, social media platforms worked to "verify" clinician accounts to identify them as trusted messengers for the lay public (Lunden, 2020). Likewise, partnerships between internet search engines and public health authorities served to filter and route individuals to evidence-based resources for public health (e.g., around best practices for quarantine and self-isolation) (Pichai, 2020).

Each of these initiatives was COVID-19-specific, but the new collaborations formed during the pandemic provide a useful foundation for advancing health and science communication as an essential service of public health. They also improve outreach to specific populations and help to promote health literacy across the country.

CROSS-CUTTING CHALLENGES AND SYSTEM VULNERABILITIES

Although every part of the health delivery system faced unique difficulties during COVID-19, many of the barriers to effective pandemic response cut across the health system and are the result of broader social and political trends, as well as of longstanding neglect and underinvestment in the nation's health system. The pandemic's disparate impact on under-resourced populations, in turn, has critical implications for the entire health system, including on diversity concerns in clinical trials and vaccine hesitancy along demographic, educational, and ideological lines that stem from misinformation and long-standing structural barriers such as racism (Agarwal et al., 2021; KFF, 2022b; Okoro et al., 2021).

Meanwhile, clinicians and professional societies, care systems, and health product manufacturers and innovators have struggled with system capacity—from supply chains to clinical workflows. Gaps in preparedness (rooted in pre-pandemic decisions) have been a common challenge, ranging from the reliance on critical supplies sourced in other parts of the world (experienced by health product manufacturers, innovators, and care systems) to funding cuts to initiatives such as the Hospital Preparedness Program and the Public Health Emergency Preparedness Program (experienced by state and local public health and care systems). All sectors of the nation's health system experienced challenges related to trust, communication, equity, workforce, data interoperability and sharing, telehealth, payment, quality and safety, evidence generation, and system capacity. *Table 10-1* notes representative examples of these challenges, followed by elaboration.

TABLE 10-1 | Select Examples of Cross-Cutting Challenges and Experiences of Sectors for COVID-19

Domain	Cross-Cutting Challenge	Sector Example
Trust	Mistrust of health-related messages due to politicization of expertise among scientists and health professionals.	State and Local Public Health and Patients, Families, and Communities: Lay public engaged with misinformation and incorrect data; lack of clarity surrounding trusted information sources.
Communication	Lack of engagement with and clear communication of best practices – especially with under-resourced populations; gaps in alignment across the government and with the private sector.	Biomedical Research and Patients, Families, and Communities: Populations facing structural barriers and historical legacies of injustice demonstrated hesitancy towards novel biomedical research and vaccines.
Equity	Disparate impact of COVID-19 on under-resourced populations; systemic underinvestment in population health; and lack of data on individuals' race, ethnicity, and language.	Patients, Families, and Communities and State and Local Public Health: Increased risk and prevalence of COVID-19 transmission and infection in communities that have been economically/socially marginalized.
Workforce	Underinvestment in workforce development, with issues ranging from workplace well-being to education and training.	State and Local Public Health, Care Systems, and Clinicians and Professional Societies: Health professional shortages, gaps in the public health workforce, and gaps in health IT skills relative to the volume/nature of intensive care and public health interventions needed, exacerbated by high levels of burnout and occupational distress.
Data Interoperability and Sharing	Limited within- and between-system compatibility and interoperability; lack of effective data standardization, platform consistency, and community accessibility.	State and Local Public Health, Care Systems, Health Product Manufacturers and Innovators, and Patients, Families, and Communities: Challenges exchanging data between health departments, health systems, manufacturers, and communities.
Telehealth	Limited broadband access and infrastructure to support increased use of telehealth among all populations and more established links between home care and health care, as well as challenges with payment parity	Clinicians and Professional Societies and Health Care Payers: Gaps in coverage and reimbursement for both COVID-19 and non-COVID-19 services.

TABLE 10-1 | Continued

Domain	Cross-Cutting Challenge	Sector Example
Payment	System fragilities associated with fee-for-service models; increased out-of-pocket costs for patients.	Health Care Payers and Care Systems: Financial distress for health systems under fee-for-service models.
Quality and Safety	Barriers to translating evidence to decision-making and poor health and safety outcomes for specific populations.	Clinicians and Professional Societies and Quality, Safety, and Standards Organizations: Development and dissemination of crisis standards of care for COVID-19.
Evidence Generation	Lack of agile and rapid clinical trial infrastructure, underinvestment in basic science, and gaps in evidence translation and population diversity.	Health and Biomedical Research, Clinicians and Professional Societies, and Health Product Manufacturers and Innovators: Ethical tensions between the desire to care for critically ill patients and the need for randomized clinical trials of new therapeutics.
System Capacity	Uneven distribution of capacity and insufficient supply chain redundancies.	Care Systems and Health Product Manufacturers and Innovators: Shortages of personal protective equipment, essential medicines, and other medical products.

Trust

In marked contrast with citizens in other high income countries, Americans' trust in the health system was already low prior to COVID-19. In a 2011-2013 survey, only 58% of Americans agreed that doctors in their country could be trusted, compared to peers such as Switzerland (83%), Denmark (79%), and the Netherlands (78%) (Blendon et al., 2014). Real issues around the high cost of medical care in the United States and the growing out-of-pocket burden for consumers (e.g., "surprise billing" for services presumed covered by insurance; shifting liability for drugs/medical products) have led individuals, families, and communities to increasingly mistrust clinicians, health care payers, and care systems (Gupta et al., 2020; Kearney et al., 2021).

During the pandemic, this low level of trust persisted: the percentage of survey respondents expressing either "a great deal" or "quite a lot" of confidence in the U.S. medical system declined from 51% in 2020 to 44% in 2021 (Gallup, 2020). As detailed in the chapter of this Special Publication focused on patients, families, and communities (Chapter 1), fragmentation and opacity in the U.S. health system—especially surrounding pandemic guidance, messaging, and response—further

eroded public trust. In addition, the larger trend of polarization in American politics seems to have infiltrated the health system during the pandemic, with surveys revealing stark divides in Americans' perceptions of pandemic response policies based on their political affiliation (Rothwell and Desai, 2020). This polarization can potentially damage the credibility of key messengers across the health care system and, in turn, limit the efficacy of the policies they put forward.

Distrust also accentuated the disparate impact of the pandemic on communities of color. Alongside gaps in effective engagement and communication, historical legacies of injustice and unethical experiments contributed to higher rates of vaccine hesitancy among Black communities (Okoro et al., 2021).

The issue of trust has significant implications for the entire American health system both during and beyond the pandemic. In the context of COVID-19, gaps in trust have undermined the efficacy of pandemic response policies (e.g., adherence to public health restrictions such as mask-wearing) and exacerbated occupational distress among the health care and public health workforce (e.g., threats against public health leaders, rumors of unethical/profit-seeking behavior among some clinicians) (Baker, 2020). These barriers to trust may inhibit efforts to build authentic partnerships between communities, public health providers, and health care entities seeking to address inequities in care. Repairing trust in the health system will require multi-level engagement and collaboration from each segment of the U.S. health system, including strengthening community-level relationships and instituting macro-level policy changes and actions that address deeper, systemic issues of equity and integrity entrenched across the health system (Khullar et al., 2020b). The "Principles of Trustworthiness," developed by the Association of American Medical Colleges, has the potential to serve as a useful tool in this regard (AAMC, 2022).

Communication

Barriers to effective communication during the pandemic are deeply related to these challenges of trust, especially as it surrounds audience alignment and the challenge of conveying nuanced, consistent, and evidence-based information. Throughout the pandemic, a lack of engagement with under-resourced communities has limited the reach of communication strategies with many communities and stymied hopes of increasing equity and effectiveness. Similarly, gaps in communication within and across government have compounded existing pandemic response difficulties. Moving past these will require new communication strategies centered on clarity, coordination, and the equitable engagement of all stakeholder groups.

Lack of Engagement with Under-Resourced Communities and Populations

The health system has struggled to effectively engage with and communicate best practices to the public, particularly with communities and populations that have been economically or socially marginalized. Many of these communities have suffered the brunt of the pandemic's impact. The persistence of misinformation and perceived distrust of the health system—in particular because of historical systemic injustices—represent a significant challenge, even though numerous examples of effective and equitable communication (e.g., translating materials into multiple languages, using a variety of media platforms, collaborating with reputable public health figures, engaging trusted sources of information in the community) exist across the health care system.

One visible challenge has been the underrepresentation of low income, ethnic minority, and other under-resourced groups in public and private clinical trials and studies (Chastain et al., 2020; Helfand et al., 2020). Health care product manufacturers and innovators made strong efforts to address this, and are now focusing on increasing representation of under-resourced groups (e.g., in registrational Phase 3 programs) beyond the pandemic.

Additionally, the need to provide tailored and effective messaging and authentic engagement to understand the concerns, anxieties, and access needs of individuals, families, and communities has had consequences beyond clinical trials, as evidenced by the manifestation and persistence of vaccine hesitancy in populations experiencing disadvantage because of structural economic and social factors (KFF, 2022b). As pediatric vaccines have become approved and available, vaccine hesitancy continues to limit the full potential of comprehensive pandemic mitigation (Suran, 2021). These issues are not unique to the pandemic, however, and will have consequences for population health far beyond COVID-19 (Dawes, 2020; Gee and Ford, 2011). They require new strategies to build authentic relationships; develop person, family, and community centered communication; and address the legacy of racism as a source of inequity throughout the health system.

Gaps in Communication Within and Across Government

Obstacles to an effective pandemic response have resulted from a lack of alignment across local, state, and federal governments, coupled with fragmentation within the U.S. health system. Communication difficulties, particularly surrounding misinformation on issues ranging from public health guidance (e.g., policies around mask-wearing, criteria for lockdowns and re-openings) to the procurement of medical supplies (e.g., accessing the Strategic National Stockpile),

have further contributed to the challenges in achieving nationwide alignment on key pandemic mitigation strategies.

The nation's public health system could serve as a case study to illustrate the issues of alignment. Governance of public health varies widely across the U.S., with some states operating centralized models and others relying on more decentralized approaches (ASTHO, 2012). This lack of alignment resulted in protocols that varied by individual public health departments and offices, creating a lack of coordination, both between health departments and between public health and the public. This confusion compounded the pressure of the pandemic, hindering outbreak control efforts and further diminishing Americans' trust in health institutions and systems.

Equity

Individual experiences paint a stark picture of the disproportionate impact of the pandemic on communities that have been economically and socially marginalized, underscoring the need for health care and public health systems to center actions and strategies on the needs of the individuals, families, and communities they serve. A lack of focus on equity—in terms of data collection, program design, and power sharing—has been a major driver of the disparities observed throughout the pandemic and the decades that preceded it (Christopher et al., 2021; NASEM, 2019a; Servick, 2020).

People of color are nearly twice as likely to be infected by SARS-CoV-2, more than three times as likely to be hospitalized following SARS-CoV-2 infection, and exhibit mortality rates nearly three times higher than those of White individuals. Compounding these trends are substantial access limitations faced by under-resourced populations; unfortunately, the populations most disproportionately affected by the pandemic often have the most difficulty accessing critical services. Yet, the inequities of the pandemic extend beyond the direct health impact of infection. For under-resourced populations, the economic instability inflicted by COVID-19 has exacerbated existing issues (e.g., stable housing and food insecurity), and added to an existing mental health burden. The underinvestment in population health fueling these trends highlights the need for the U.S. health system to dedicate attention and resources towards the social drivers of health alongside the myriad other gaps exposed by the COVID-19 pandemic.

Access Limitations for Under-Resourced Populations

While under-resourced populations are more likely to be affected by COVID-19, they are also more likely to experience difficulties accessing diagnostics and services and supports across the continuum of care. For example, research has revealed major racial and ethnic gaps in access to COVID-19 testing across the

country, with the supply of testing sites often inversely proportional to individual demand (Kim et al., 2020). Likewise, equity and access challenges emerged throughout allocation methodologies for medical supplies such as ventilators (which were later amended), distribution plans for new COVID-19 therapeutics such as remdesivir, and the appropriation of relief funds (Cunningham, 2020; Grogan et al., 2021; Kiptanui et al., 2021; Schmidt et al., 2021).

Furthermore, when COVID-19 vaccines became available in the U.S., low-income individuals—a population at greater risk of exposure and severe illness compared to those with higher incomes—often struggled to access appointments due to structural barriers (e.g., registration difficulties, lack of transportation) (Goodnough and Hoffman, 2021; Hughes et al., 2021). While such examples are specific to COVID-19, they represent only the latest manifestation of longstanding inequities in access to and distribution of health services in the U.S.

Underinvestment in Lifespan-Oriented Population Health

COVID-19 also exacerbated the shortcomings in how the U.S. health system supports meaningful health and well-being outcomes in individuals, families, and communities throughout their lives. Unfortunately, these shortcomings begin with pediatric populations. While children infected with COVID-19 have been less likely to experience severe illness than older populations, the pandemic has had a significant strain on their well-being (CDC, 2021b). Pandemic-era disruptions to educational and social activities and their impact on typical developmental trajectories have been a major concern for families; distressingly, emergency department visits related to mental health increased by 24% for children and 31% for adolescents (Kwai and Peltier, 2021; Leeb et al., 2020). Combined with delays of routine health services such as well visits and a pervasive context of marginalization based on race, geographic placement, and economic status, it has become increasingly clear that efforts to support population health and well-being must begin with equitable and comprehensive pediatric care (AAP, 2020; Santoli et al., 2020).

The experience of older adults throughout the pandemic has demonstrated the necessity of extending this life stage approach to the aging population as well. Adults aged 65 and above experience a markedly higher risk of COVID-19 hospitalization and death than younger individuals (CDC, 2021c). This can be partially attributed to comparatively high rates of chronic illnesses among this population, but nursing home representation is also an important source of disparities, accounting for nearly one-third of COVID-19 deaths and posing major issues related to loneliness and isolation for residents and family members navigating visitation restrictions (CDC, 2021d; CDC, 2021e; NASEM, 2022; The New York Times, 2021). In addition to the toll of the SARS-CoV-2 virus itself, the prolonged isolation of residents of long-term care facilities is associated with

severe consequences for health and well-being (e.g., functional decline; despair; suicidality; nutritional issues) (Abassi, 2020; NASEM 2022; Perissinotto, 2012). While the visitation policies contributing to these issues have been modified over the pandemic's course, future efforts to respond to public health emergencies must better reflect the lived experiences and priorities of long-term care residents and their families.

A life stage, population-centered approach may have mitigated these disparate outcomes by engaging wraparound, holistic strategies to prevent chronic disease, maintain mobility, and provide home- and community-based care in lieu of institutional care (Horwitz et al., 2020; NASEM, 2017; NASEM, 2019a). Likewise, increased attention towards the needs of long-term care relative to patient priorities and well-being could have helped to improve the pandemic experience for facility residents (NASEM, 2022). Instead, severe disparities for older adults pervaded the pandemic, exacerbated by the uneven distribution of chronic diseases and quality of care along racial, geographical, and economic lines (CDC, 2021d; CDC, 2021e; Gebeloff et al., 2020; Hege et al., 2021). Epidemiological data indicate that chronic conditions such as cancer, cardiovascular disease, and obesity elevate the likelihood of severe illness following COVID-19 infection (CDC, 2021c). The burden of such diseases is unevenly distributed in the U.S. among older adults, communities of color, and low-income individuals, creating the preconditions for the inequitable impact of the pandemic on these populations, especially when income, age, and race and ethnicity intersect.

For the millions of Americans caught in the health-poverty trap (i.e., poor health deriving from a state of poverty which is, in turn, further perpetuated by poor health), the morbidity and mortality associated directly and indirectly with COVID-19 is just the latest example of population health disparities (Maani and Galea, 2020). U.S. health care spending as a percentage of GDP has long outpaced expenditures in other high-income countries, but disparities in health outcomes and the number of preventable deaths along racial, ethnic, and economic strata remain entrenched, in part due to America's chronic inequities in resource distribution (Tikkanen and Abrams, 2020). For the U.S. to improve its preparedness for public health emergencies after COVID-19, policymakers need to take action to address the fundamental health-related and social needs of communities across the country.

Workforce

The health workforce has been a key driver of the successes experienced by the U.S. health system across the pandemic, with individual dedication, bravery, and innovation present in each facet of the COVID-19 response. At the system

level, however, a marked underinvestment in recruitment, education, and training for both clinicians and public health workers has resulted in substantial capacity and skill deficits relative to modern needs. Across the pandemic, this has been compounded by the pervasive burden of clinician burnout and occupational distress, contributing to high staff turnover and a concerning dearth of employee well-being. Meeting the realities of the pandemic to reduce both gaps in capacity and the rising rates of occupational distress will be key to successfully addressing population health needs of the future.

Underinvestment in Recruitment, Education, and Training

Capacity gaps have been evident across the health care system throughout the pandemic, particularly in terms of the public health and clinician workforce. Even as the responsibilities of public health and the complexity of 21st century public health priorities have expanded in recent years, health departments have lost tens of thousands of jobs over the past decade, with much of the remaining workforce lacking appropriate training and capacity (Bogaert et al., 2019; ASTHO, 2020). Likewise, the availability of clinical services is unevenly distributed in the U.S., with millions of Americans living in so-called Health Professional Shortage Areas (KFF, 2022a). Experts have long called attention to the gaps in the critical care workforce; these have been further strained during the pandemic due to the high volume of patients requiring intensive care. In addition, there is a need to fill skill gaps in informatics and data science to assure the integrity of the information infrastructure (Halpern et al., 2013; Lopez, 2020; Stechmiller, 2002). The long-term care workforce faces similar shortages, with the pandemic calling attention to the adverse effects of high turnover and low staffing on mortality rates, hospitalization rates, and emergency department visits for residents of nursing facilities (Ochieng et al., 2022).

As the pandemic evolves, concerns of "long COVID" and pandemic-related mental health issues in the general public will create further difficulties for clinicians, professional societies, and individuals who work for care systems, exacerbated by workforce gaps in specialties such as long-term care and mental health. Across the health care system, attention to workforce development also highlights the persistent lack of diversity in educational institutions and training programs for health professions; health care leaders must prioritize diversity and inclusion at all levels of recruitment, education, promotion, and training.

Burden of Occupational Distress

Increased individual and population health needs due to the COVID-19 pandemic, coupled with the shortages in clinical capacity described above, have

put tremendous occupational distress on the health care workforce, particularly for clinicians. Previous studies have documented the high rates of occupational distress—of which burnout is a prominent example—among clinicians, including the NAM's 2019 consensus study on clinician well-being (NASEM, 2019b). Burnout and occupational distress lead to depression, depersonalization, and possibly suicidal ideation for clinicians, as well as decreased patient satisfaction (NASEM, 2019b). COVID-19 magnified all of the existing pressures on the health care workforce, dislocating clinicians from professional support networks, families, and friends due to physical distancing measures and increasing the physical, emotional, and psychological toll brought on by caring for large volumes of acutely ill patients (Shanafelt et al., 2020). Furthermore, issues surrounding distrust, politicization of public health interventions, and false conceptions of unethical or profit-seeking motives by some clinicians have exacerbated moral injury across the health care workforce. Multi-sector health system leaders and policymakers will need to take steps to bolster the morale of the nation's health care and public health workers and commit to meaningful improvements in workplace wellness to reinvigorate workers as efforts are made to end the COVID-19 pandemic (Dzau et al., 2020).

Data Interoperability and Sharing

Data availability has been a limiting factor for various facets of the pandemic response, including disease surveillance, surge planning, clinical trial reporting, and health product manufacturing and innovation. The problems can be partially attributed to the fragmentation within the American health system, with individuals and institutions at all levels challenged by infrastructure gaps that prevent seamless data exchange, combined with economic and other incentives that work against data sharing and collaboration. Yet another challenge is presented by unstandardized data, with missing and heterogeneously presented data obscuring the information needed to make effective clinical decisions and assess population needs. If the nation hopes to create a seamless digital infrastructure for health system optimization, it will be critical to fix these issues.

Digital infrastructure capacity remains highly variable across the health system, creating significant barriers to collaboration and digital optimization. While American hospitals and office practices have largely transitioned to using electronic health records since the 2009 passage of the Health Information Technology for Economic and Clinical Health Act, digital progress lags in public health, where decades of underinvestment have left health departments under-resourced. Although programs such as the Centers for Disease Control and Prevention's "Digital Bridge" initiative have helped improve the ability of health

departments to exchange data, challenges remain: many health departments still rely on outdated tools such as fax machines and require external collaborators to develop tools such as disease surveillance dashboards (Lumpkin and Wiesenthal, 2020). Similar gaps exist in long-term care, where lagging electronic health record adoption and a lack of interoperable digital infrastructure limit the benefits that facility residents might accrue from a more coordinated system of care (NASEM, 2022).

These gaps in infrastructure contribute to gaps in coordination. Interoperability, or the digital compatibility of different systems with one another to support processes such as data exchange, continues to be a problem both within and between health systems. Barriers to data sharing have led to misalignment between policymakers, health systems, and health departments on issues including transmission of clinical data, the reporting of testing rates, planning for bed capacity, and supply chain issues (Miri and O'Neill, 2020). Indeed, supply chain challenges provide well-established examples of these barriers. Early in the pandemic, the absence of a centralized data structure to identify and distribute needed supplies created the conditions by which states engaged in bidding wars for medical devices (Weixel, 2020). The size of the U.S. medical device industry (roughly 5,300-5,600 companies of various sizes) (MEDPAC, 2017), combined with the decentralized information and decision structures of the U.S. health system (e.g., between delivery organizations, and jurisdictions) has complicated efforts to make scaled, data-driven decisions on device manufacturing and distribution needs. A universally interoperable digital data infrastructure would greatly improve cross-system communication and coordination.

In addition, data structure has often limited the functionality of data use: throughout the pandemic, data fields were often not standardized, with the resulting heterogeneity in reported information providing an incomplete picture for decision-makers across the health system. Missing data elements have particular consequences for health equity, as gaps in reporting on race, ethnicity, and other demographic characteristics obscure the disproportionate impact of COVID-19 on populations that have been marginalized (Krieger et al., 2020).

Telehealth

The expanded use of telehealth has certainly been a helpful development during COVID-19, enabling many individuals to continue accessing an array of health services despite office closures. At the same time, the increased utilization of virtual care modalities has highlighted potential access barriers for different populations. For example, surveys of Medicare beneficiaries indicate variation in access to video health care visits for low-income individuals and people of color

(Roberts and Mehrotra, 2020). Likewise, evidence from New York City indicates disparities in telehealth use for Black individuals (Chunara et al., 2020; Weber et al., 2020). While additional research is needed to further characterize the scope and components of the "digital divide" in health care, these trends, coupled with existing limitations in broadband access and infrastructure, represent concerns that need to be addressed to ensure that telehealth does not recreate the existing disparities observed in in-person care.

In addition to questions of access, payers, clinicians, and health systems have struggled to navigate the evolving reimbursement environment for telehealth. New regulatory flexibilities for payment parity provided clinicians with a financial lifeline during COVID-19; in the near and long-term future, it will be important to develop guardrails for fraud and abuse and adjust payment rates for the expanding suite of home-based health services.

Payment

The "stress test" of the COVID-19 pandemic has revealed inefficient and ineffective practices across the health system. In the domain of health care payers, a major example of this has been the demonstrated system fragilities associated with traditional fee-for-service health care payment structures. U.S. health care is largely oriented to a structure for health payments that incentivizes the provision of higher-cost secondary and tertiary care services over preventive services. Throughout the pandemic, this structure has not supported fluid, collaborative responses between public health and medical care. Similarly, with reward systems skewed toward the higher-revenue, non-emergency, in-person services that were substantially halted during COVID-19, the resulting disruptions to care delivery had significant financial consequences for hospitals, medical practices, and other actors across the health system. As an additional challenge, the cost of COVID-19-related care and the reduction in employer-sponsored health insurance coverage following pandemic-induced layoffs (although somewhat mitigated by Medicaid/insurance marketplace enrollment) spotlights concerns regarding the affordability and accessibility of health services in America (CMS, 2021). It is critical to understand these issues in order to address the concerns of individuals, families, and communities, and to ensure that health system incentives align with better care and resiliency in both typical and emergent situations.

System Fragilities Associated with Traditional Fee-for-Service

The majority of clinicians in the U.S. continue to be reimbursed under traditional fee-for-service arrangements and, as a result, experienced significant disruptions to their revenue streams following the cancellation of non-emergent

procedures and in-person office visits at the beginning of COVID-19. While financial relief and the rebound in health care utilization have helped alleviate this financial impact, the experience has renewed discussion about the fragility of volume-based reimbursement systems (Gondi and Chokshi, 2020). Beyond questions of financial stability, the incentives inherent to entirely volume-based fee-for-service approaches are often misaligned with health outcomes, reinforce the fragmentation of care delivery, and contribute to the continued utilization of low-value health services. As evidence emerges about the contrasting financial experience of providers in APMs compared to those in traditional fee-for-service arrangements, clinicians, payers, and care systems must evaluate opportunities in order to learn from the COVID-19 experience to improve the financial resiliency of the health system.

Spotlight on Affordability and Accessibility

COVID-19 has come at a high cost to Americans, with issues including significant variation in charges for diagnostic tests, and the high price of inpatient care compounded by the prevalence of "surprise billing" for COVID-19 testing and treatment (Curley, 2020; Kliff, 2021). Congressional action sought to expand coverage for COVID-19-related services and limit financial risk for U.S. residents, but such policies have not had universal penetration (e.g., for self-insured health insurance plans), creating potential financial complications (Eisenberg et al., 2020). Indeed, awareness of the potential for high costs and surprise billing may have led individuals to defer necessary COVID-19 diagnostics or treatments, building on existing trends of delaying care due to untenable costs (e.g., in primary care) (Huff, 2020).

Insecurity has been further heightened by the substantial impact of the pandemic on health care coverage rates. While enrollment increases in Medicaid and the health insurance marketplace established by the Affordable Care Act did substantially offset the pandemic's effect on employer- sponsored coverage, the fluctuation in coverage rates created short-term actuarial uncertainty for payers, illustrating the stark vulnerabilities that recession events can have on health service access (Agarwal and Sommers, 2020; CMS, 2021).

Quality and Safety

The pandemic has renewed awareness of the substantial variation in care quality and patient safety across the American health system. For example, issues surrounding infection control, staffing, and safety protocols in long-term care facilities—all of which predate COVID-19—have been acutely apparent during the pandemic. Likewise, the multiple touchpoints and handoffs for COVID-19

patients, from acute care to rehabilitation, illustrate the need to improve care transitions, especially for older adults. These issues, coupled with measurement and reporting difficulties during the pandemic, highlight the importance of coordination among standards organizations, professional societies, health systems, and others to ensure patient safety both at baseline and in emergency situations.

Quality Gaps in Long-Term Care Facilities

Long-term care facilities and other congregate settings, such as prisons, have often been COVID-19 hot spots, experiencing disproportionately high rates of infection, hospitalization, and mortality. Yet many of the basic operational difficulties (e.g., staffing shortages and turnover, gaps in PPE) and quality issues (e.g., around infection control planning, resident crowding) that hindered the pandemic response were preexisting concerns for long-term care facilities (McGarry et al., 2020). Many are the longstanding product of fragmentation across health system sectors and financing streams, with the pandemic underscoring the level of coverage and payment misalignment across Medicare and Medicaid; gaps in quality standards for staffing requirements; a lack of prompt, seamless, and robust communication between caretakers and family members; and considerations related to public transparency (Grabowski, 2020; Hado and Feinberg, 2020; NASEM, 2022). In order to address the major quality and safety concerns that currently face long-term care facilities, it will be critical to understand and place strategic attention on the full magnitude of the improvements needed (e.g., workforce dynamics, financing, oversight, communication).

Other issues relate to the capacity of the system and workforce, with high occupancy rates and a bias towards institutional care stretching the capacity of long-term care facilities and raising severe quality and safety issues. Furthermore, from an oversight perspective, while initiatives such as Nursing Home Compare have elevated quality issues (for nursing homes specifically), gaps in metric design and scope, coupled with attention and accountability gaps surrounding racial and socioeconomic disparities in long-term care, call for a more robust regulatory framework for long-term care in America (Konetzka et al., 2020).

Challenges Associated with Care Transitions

COVID-19 infections affect the full spectrum of care delivery, encompassing laboratory networks and outpatient diagnostics, inpatient triage and admission, inpatient discharge, and outpatient rehabilitation. As such, shortcomings associated with care transitions for COVID-19 patients have illustrated how health care system fragmentation can negatively impact service quality and safety.

For example, many hospitalized COVID-19 patients require physical rehabilitation services following their recovery from intensive care. While

hospitals have increasingly invested in in-house rehabilitation services and referrals to protect patients from post-ICU syndrome, gaps in care coordination (as well as staffing bandwidth and clinical capacity) have imposed hurdles for COVID-19 patients as they recover (Grabowski and Maddox, 2020). Likewise, reduced capacity, workforce burdens, and significant quality and safety concerns at institutional rehabilitation facilities have caused many individuals to turn to home health services, but home health providers face their own staffing and operational difficulties, and exhibit variability in service offerings and quality (Falvey et al., 2020; Tyler et al., 2021). Together, these examples illustrate the need to increase coordination and reduce fragmentation to improve accessibility and outcomes across the spectrum of care delivery.

Evidence Generation

As SARS-CoV-2 was a novel virus, researchers, clinicians, industry, and publishers across the globe collaborated to rapidly identify and disseminate insights to inform diagnosis and treatment. Even as researchers worked to launch new, large-scale studies, however, they encountered roadblocks ranging from the bureaucratic to the competitive to matters of capacity. The pandemic revealed gaps in clinical trial infrastructure surrounding trial recruitment and enrollment, trial design, and data infrastructure and sharing; all of these could be leveraged to strengthen evidence generation on a global basis. Accessibility and diversity proved challenging as well, with under-resourced communities and older age groups underrepresented in clinical trials, despite being the groups most affected by COVID-19. Overcoming these issues is altogether necessary to ensure that equity, efficiency, and effectiveness is embedded in future capacity for research, product development, and continuous learning within the health system.

Gaps in Clinical Trials Infrastructure

Throughout the COVID-19 pandemic, the large number of interventions requiring timely safety and effectiveness evaluations by large-scale clinical trials have revealed multiple opportunities to improve the nation's clinical trial architecture. Some of these opportunities for improvement include: efforts to manage enrollment in trials with the same products and research aims; continued commitments towards rigorous study designs and safeguards to produce high quality evidence; attempts to bring the trial to the patient and other methods to ease the burden of trial participation; robust data sharing mechanisms among companies pursuing the same disease with different mechanisms; and preparation of and considerations surrounding ethical dilemmas for clinicians delivering placebo treatments (Herper and Riglin, 2020; Bauchner and Fontanarosa, 2020).

Another set of key opportunities for clinical trial improvement focuses on data infrastructure. Throughout the pandemic, the lack of universal patient identifiers or consistent data sharing practices and capabilities has resulted in a clinical trial IT infrastructure that limits the full potential of evidence generation in the U.S. health system (Couzin-Frankel, 2021; Gottlieb, 2021; Maxmen, 2020; North et al., 2020).

Efforts to address these points throughout the COVID-19 pandemic have provided excellent examples that U.S. clinical trials can scale and implement to enhance resiliency across the pandemic and beyond (Gottlieb and McClellan, 2020). Initiatives such as NIH ACTIV and studies surrounding remdesivir leveraged existing clinical trial networks and public-private partnerships, streamlining the clinical trial process to ensure that funding, resources, and support were mobilized, coordinated, and focused around the products with the greatest degrees of scientific evidence for success (Beigel et al., 2021; Couzin-Frankel, 2021; NIH, 2021). Similarly, the mobilization of the nation's historic and well-established network of NIH-supported Vaccine and Treatment Evaluation Units (VTEUs), alongside other NIH- and CDC-supported clinical trial networks, provided a nationwide platform for large-scale clinical trials to rapidly evaluate the safety and efficacy of COVID-19 therapies and vaccines. Indeed, over 4,400 interventional studies for COVID-19 were registered on ClinicalTrials.gov as of April 2022 (NLM, 2022). International analogues are of great interest as well, with examples such as the United Kingdom's RECOVERY Platform providing insights into ways the U.S. could implement and enhance "platform" trial designs (Normand, 2021).

Embracing opportunities for improvement and implementing and scaling examples of success will be critical to advance evidence generation beyond the COVID-19 pandemic. If complemented with a robust national clinical trial infrastructure that improves trial recruitment and enrollment processes, leverages innovative trial designs where relevant, and fosters a secure and interoperable data infrastructure, innovative models can improve the readiness and responsiveness of clinical research in the U.S. at a scale previously unimagined (Gottlieb and McClellan, 2020).

Accessibility and Diversity

Gaps in racial/ethnic representation in clinical trials must be addressed, given that populations bearing the majority of the disease burden are less likely to be represented in studies of potential interventions (e.g., older adults, people of color), possibly due to issues related to distrust, cost, and limited accessibility (Chastain et al., 2020). This issue manifested during the pandemic, from varying degrees of racial and ethnic disproportionality in COVID-19 vaccine trials to the underrepresentation of older adults in studies of COVID-19 therapeutics (Artiga,

et al., 2021; Khalil et al., 2022; Helfand et al., 2020). Leaders of Operation Warp Speed worked to improve the representation of racial and ethnic populations during the vaccine development process, yet diversifying clinical trials in general will require engagement across health system sectors, outreach to build trust among under-resourced communities, and vigilance towards diversity and inclusion in clinical research (LaFraniere et al., 2020).

Gaps in Public Health Research Infrastructure

A foundational role of federal, state, and local public health departments is to provide ongoing assessment and evaluation of disease surveillance and monitoring, as well as of health care capacity and the effectiveness of local, regional, and national responses. Throughout the pandemic, the public health sector's capacity for generating evidence in these fields proved to be limited, due to a chronic neglect in support and maintenance of public health infrastructure, resulting in shortfalls in capacity, variations in capability, and historically siloed governance and operational structures (IOM, 1988; IOM, 2002; IOM, 2012).

In the decades prior to the pandemic, state and local public health departments have resorted to piecemeal funding approaches (e.g., grants and categorical vehicles). This approach left them without the resources they need to fully fulfill their foundational roles (HHS OASH, 2016). As a result, when COVID-19 reached the U.S., there was not enough laboratory testing equipment or staffing, which contributed to shortcomings in rapid disease detection, surveillance, monitoring, and mitigation throughout the pandemic's course. Outdated and insufficient public health data systems and technological infrastructure compounded these weaknesses, inhibiting efforts to report or exchange evidence in real time and reducing the amount of relevant information immediately available to decision makers and the public (Christopher et al., 2021; Kliff and Sanger-Katz, 2020). To ensure that state and local public health can generate and share the evidence needed to meet 21st century public health needs in the decades to come, it is critical to optimize this infrastructure atop a more robust and resilient financial structure.

System Capacity

As COVID-19 caseloads grew exponentially in the spring of 2020, it became evident that the U.S. health care system would face significant difficulties with regard to pandemic-mitigation capacity. Public health preparedness—or its lack—was a prominent example of these shortcomings, with chronic underinvestment and funding cuts over the course of decades resulting in major workforce gaps, outdated data infrastructure for disease surveillance, and under-resourced preparedness and response programs. Supply chain shortages provide another example of a capacity

gap in need of improvement: the everyday efficiencies that were built into the system over time to optimize administrative and operational processes were challenged by the protracted public health emergency. It is important to recognize these issues in order to ensure that the state of system capacity observed throughout the COVID-19 pandemic improves in advance of future public health crises.

Public Health Preparedness

Funding for public health emergencies in the U.S. has generally followed a "boom and bust" pattern, with temporary infusions of capital during and immediately after a crisis, followed by a gradual erosion of baseline and supplementary funding streams (Murthy et al., 2017). For example, gradual cuts to the Public Health Emergency Preparedness program and the Hospital Preparedness Program over time, coupled with a general decline in public investment in health care infrastructure, have caused system-wide challenges for pandemic response, especially in regards to overcoming barriers to coordination and communication throughout the ongoing public health emergency. To enhance public health preparedness, it is critical to bolster both the Public Health Emergency Preparedness program and the Hospital Preparedness program, as well as the programs that aid the development and acquisition of medical countermeasures (e.g., the Special Reserve Fund, Strategic National Stockpile, and Biomedical Advanced Research and Development Authority [BARDA]). Programs that strengthen the basic science undergirding product development, medical innovation, and disaster preparedness are also key (Cohen and Wu, 2020; Farberman et al., 2020).

Despite the fact that lawmakers eventually appropriated emergency funds to support the public health response, the resources were primarily directed to one-off measures (e.g., procuring supplies, supporting the temporary hiring of contact tracers) and have not sufficiently addressed longstanding systemic inadequacies in the public health and broader health system infrastructure (e.g., massive workforce gaps, outdated data systems). As policymakers plan for the post-COVID-19 future, they must not only restore funding to budget line items explicitly dedicated to emergency preparedness, but also recognize that public health capabilities, workforce, and infrastructure must be sufficiently resourced even in non-crisis times (Farberman et al., 2020).

Supply Chain Shortages

Established business practices for non-crisis situations emphasized the value of efficient supply chains based on "just-in-time" production. However, as demonstrated by events such as the spike in demand for tests that followed

the 2021-2022 surge of COVID-19 variants, it is apparent that the existing configuration of the supply chain can be improved to keep pace with the pandemic-level demand for supplies and health services (Stolberg and LaFraniere, 2021). Some challenges are structural in nature; the supply chains for many medical products are largely international, with limited domestic manufacturing capacity for specific high-need medical products (e.g., respirators, swabs, laboratory reagents). Other issues have surrounded delays in replenishing the Strategic National Stockpile following previous public health emergencies, existing shortages of many essential and acute care medicines (e.g., dexamethasone), and infrastructure gaps for monitoring and tracking medical supplies.

Although public-private partnerships and federal investment helped to alleviate shortages of many types of medical supplies and equipment (e.g., ventilators), other shortages have persisted throughout the pandemic, impacting individuals, providers, and health systems alike. Supply production and purchasing will naturally scale back as the pandemic recedes, but issues with producing, coordinating, tracking, and procuring medical supplies during COVID-19 should prompt discussions, formal agreements, and changes to protocols to ensure that the medical supply chain is more resilient at baseline and has built-in flexibility for future crises.

OPPORTUNITIES FOR SYSTEM-WIDE TRANSFORMATION

While the pandemic was not the genesis of the issues identified in its course, it has put them in stark relief. Leaders from across the health care delivery system agree that COVID-19 can, and must, be a catalyst for system-wide change. In order to maintain momentum for transformation, however, it is essential to build on the new ways of working that the pandemic allowed (e.g., partnerships, breaking down siloes), implement the ethos of a learning health system (e.g., by integrating evidence development and application), and strengthen the foundation of trust upon which the transformed system will stand.

This section synthesizes the crosscutting opportunities for health system-wide transformation, all based upon the critical components of trust and equity. Transformation will depend on the ability of individuals to recognize their own interests, perspectives, and culture at the center of their experiences with the health system, informed by authentic and trusting relationships across an equitable continuum of care. This process builds further trust, which will be critical to empowering transformational action in the following ways:

1. Centering health system actions and accountability on **individuals, families, and communities;**
2. Committing to the pursuit of **equity** as core to health system performance;

3. Securing the **public health infrastructure** for 21st century population health challenges;
4. Building a robust and integrated digital health and **data sharing infrastructure;**
5. Integrating **telehealth** into payment and delivery systems;
6. Investing in **workforce** capacity and readiness;
7. Streamlining **innovation pathways** for biomedical science;
8. Strengthening stewardship of the health product **supply chain;**
9. Restructuring health care payments to focus on **outcomes and population health;** and
10. Fostering **communication and collaboration** across sectors and stakeholders.

Centering Health System Actions and Accountability on Individuals, Families, and Communities

As the U.S. health care system has changed over the past half century, it has largely excluded the perspectives of individuals, families, and communities in the development of its dominant policies, programs, and practices. COVID-19 illustrated the consequences of this approach to health system design, on issues including access to care, representation considerations in biomedical research and public health data, and a lack of meaningful program success and accountability measures. The entire health system must have the shared imperative to center individuals, families, and communities, at all points across an individual's life. This includes on matters ranging from the design of facilities to the development of therapeutic protocols, the creation of access and linkage strategies, operations evaluation, health data sharing, and the use of continuous improvement initiatives. COVID-19 provides an opportunity to build on the work of biomedical research organizations to advance person-centered drug development, and the growth in virtual care delivery modalities during the pandemic points to the need for quality, safety, and standards organizations to develop new person-centered outcomes measures. Furthermore, efforts to equitably redesign the built environment of care systems create avenues to engage individuals, families, and communities in developing more inclusive spaces that align with both individual and population-level needs (e.g., implementing digital infrastructure in long-term care facilities that enhances connection and communication between patients, families, and caregivers).

It is critically important for this engagement to be meaningfully integrated, and meaningfully accountable to individuals, families, and communities as opposed to a box-checking exercise at the end of improvement process cycles. Many existing

BOX 10-1

Centering Health System Actions and Accountability on Individuals, Families, and Communities

- Understand and prioritize the health and health care goals that matter most to individuals, families, and communities.
- Ensure access to the health services that individuals, families, and communities need, when and where they need them.
- Provide active individual, family, and community roles in co-designing health, health care, and research initiatives.
- Orient data and accountability systems to the most important needs and goals of individuals, families, and communities.

governance, engagement, and accountability models exist (e.g., patient advisory boards), but COVID-19 provides the opportunity for health care system leaders to think creatively about how to actively and continuously engage and better integrate individuals, families, and their communities to build a more inclusive and impactful health system for all. As a starting point, leaders should consider modifying care delivery to allow individuals to decide where and how to access care. Innovations and adaptations highlighted in the chapters of this Special Publication, such as expanded use of telehealth, Hospital at Home, and home- and community-based services, are all examples of person-centered strategies worthy of further exploration. The development of data systems oriented to individual needs and goals will allow these innovations to reach their full potential. Leaders should ensure that these systems embrace and enhance engagement, accessibility, and inclusivity to benefit the individuals, families, and communities served, and focus attention on accountability measures that center on their needs and preferences.

Box 10-1 presents considerations for centering health system actions and accountability on individuals, families, and communities.

Committing to the Pursuit of Equity as Core to Health System Performance

If people are at the center of the health system, then equity must be the core criterion for system performance. Some level of inequity in health and health care outcomes has been omnipresent across the globe for as long as health care has been provided to individuals. Leaders aiming to improve the performance of

the health system must strive to understand these inequities by investing in data systems and processes that assess the level of equity achieved and track progress toward improving it (Christopher et al., 2021). Once tracked, the resulting data must be applied to accountability metrics that are structured to focus health system attention towards sustained equity improvements for individuals, families, and communities across their lifespans.

The factors leading to health inequities are complex, ranging from the economic to the cultural; in America, the additional dimension of prolonged structural racism and its sequelae presents an especially difficult—and compelling—fundamental challenge. Because of the pervasive nature of structural racism, solutions to ameliorate this historic injustice require leadership at every level and across all domains of society and economy. The American health system is no exception, and, indeed, offers special vantage points from which to catalyze change. From the perspective of public health, targeting and resourcing population health interventions can work to eliminate the health disparities experienced by communities of color; the clinician workforce may pursue increased numbers of Black, Latinx/Latino(a)/Hispanic, Asian and Pacific Islander, and Indigenous health professionals; the biomedical research sector may seek to increase the numbers of those currently underrepresented in clinical trials and of the personnel conducting those trials. While the form of initiatives may vary, the goal will remain the same: more equitable access, quality, experiences, and outcomes for the health of individuals and populations alike.

For equity to be the core index of health system performance, all stakeholders must collaborate across the health system to assess existing barriers and develop and enact policies, practices, and commitments required to combat many years of structural racism. It will be critical to ensure that existing inequities are not built anew into emerging initiatives by incorporating the lived experiences of the individuals, families, and communities who have borne the impact of these disparities for decades.

To ensure that the appropriate strategy is paired with the system level actions necessary for progress, it is also critical to establish or update funding and payment models to support seamless service links—between medical and social services, home and community care, clinician training, care system capabilities, fundamental public health and safety infrastructure, and the data and information infrastructure, which are all necessary in order to identify individual and community health problems at the earliest possible point. Most of all, there must be collaboration across the health system to ensure that the equity embedded in the performance of each sector builds to the benefit of equity throughout society.

Box 10-2 presents considerations for leaders to advance health equity.

BOX 10-2

Committing to the Pursuit of Equity as Core to Health System Performance

- Assess the level of equity achieved in sector performance and establish the data systems needed to track progress.
- Ensure that accountability measures are structured to drive a focus on equity.
- Identify and address the systems, policies, and barriers that create and perpetuate health disparities.
- Develop cross-sector strategies and activities that prioritize and focus on health equity as a sector-wide goal.
- Coordinate across sectors to develop and implement strategies for advancing equity across the health system.

Securing the Public Health Infrastructure for 21st Century Population Health Challenges

For many communities across America, the shortcomings in the response to COVID-19 only serve to illuminate fundamental gaps in the country's public health infrastructure. Numerous reports from the Institute of Medicine have documented how public health's chronic funding gaps, variable capabilities, and siloed governance and operational structures have hindered its ability to deliver on the mission of achieving health for all (IOM, 1988; IOM, 2002; IOM, 2012). Upgrades to governmental public health infrastructure are needed to ensure that health departments across America have the necessary resources to fund a baseline set of services. The Public Health Infrastructure Fund provides policymakers with a guide for restructuring resource allocation to ensure that all Americans have access to the essential services of public health (DeSalvo et al., 2019).

Yet upgrading public health infrastructure requires more than just resources; it must also include a more fundamental restructuring of the system overall, as well as its financing. The federal government has developed a roadmap, Public Health 3.0, for modernizing public health and addressing the upstream drivers of health. To realize Public Health 3.0's vision, health departments should re-organize funding that currently exists in categorical vehicles and grant-based cycles (HHS OASH, 2016); a sizable effort is needed to transform what is currently a network of often very small and inefficient units into a more practical size and number of functionally integrated units.

The movement towards more flexible and ongoing funding models for public health would strengthen the ability of health departments to respond to public health emergencies, address community-specific needs, and scale pandemic-era collaborations with care systems, digital health leaders and companies, and health care payers—as well as with other partners—to address 21st century population health challenges.

An immediate cross-cutting opportunity for collaboration is the transformation of public health data systems, where siloed reporting and a reliance on outdated infrastructure such as fax machines have severely hindered the response to COVID-19 (Christopher et al., 2021; Kliff and Sanger-Katz, 2020). As policymakers and system leaders work to modernize these systems, they should leverage collaborations to ensure that data systems are interoperable, connected to health information exchanges across state borders, and incorporate lessons from the federal government's implementation of the Health Information Technology for Economic and Clinical Health Act of 2009 (Gold and McLaughlin, 2016).

By transforming public health financing and data systems, leaders can build capacity for enhanced partnerships at local, state, and federal levels that bridge medical and population health-oriented interventions. Improved interdependencies between health, medical, and social service programs across jurisdictions (e.g., partnerships between health departments and state Medicaid programs) will augment the capacity of health departments to provide locally tailored interventions that center on individuals, families, and communities.

Box 10-3 presents considerations for improving public health infrastructure to address 21st century population health challenges.

BOX 10-3

Securing the Public Health Infrastructure to Address 21st Century Population Health Challenges

- Develop and implement funding strategies that support, sustain, and stabilize core public health functions.
- Establish and implement requirements for seamless data and IT systems at local, state, and federal levels.
- Streamline the number, organization, and function of public units, both locally and regionally.
- Build the public health workforce required to meet 21st century population health needs.
- Establish and implement medicine-population partnership networks at local, state, and federal levels.

Building a Robust and Integrated Digital Health and Data Sharing Infrastructure

The impact of shortfalls in data planning, structure, coordination, interoperability, and use is deep and wide across the health system. One of the important developments of the COVID-19 response, however, has been the increased use of digital technologies and data sharing across the health system. Throughout the pandemic, telehealth has been used to deliver care, enhance the functionality of remote monitoring devices, facilitate online pharmacy refills, and support virtual clinical trial monitoring. Innovative data sharing initiatives such as the FDA Evidence Accelerator have also served as "a forum for stakeholders across the health care spectrum to share real-world data and to generate ideas on how to deal with COVID-19" (Reagan Udall Foundation for the FDA and Friends of Cancer Research, 2022).

Despite these achievements, a number of barriers prevent better sharing and response to the troves of data generated by technologies to improve care, bolster emergency preparedness, accelerate product development, and empower quality improvement for care delivery and public health response. If the task for policymakers in the decade preceding COVID-19 was "wiring" the health system, the challenge facing leaders in the decade following the pandemic will be "harmonizing" the health system. This includes ensuring that infrastructure (e.g., outdated information systems in use throughout nursing homes and public health departments) keeps up with data collection practices, as well as developing the sharing capabilities needed to achieve health system transformation and continuously improve care quality, while simultaneously appropriately respecting and protecting individual privacy.

This call to action for harmonization cuts across all aspects of the health care system. In the field of medical device manufacturing and distribution, a centralized "dashboard" (providing visibility as to what products are needed and where they are needed most) may have been able to facilitate data-driven manufacturing and distribution decisions. Likewise, the use of real-world evidence in developing COVID-19 diagnostics and treatments, measuring quality of care, and making decisions about medical products was hampered by a lack of harmonization (Berger et al., 2017; Naidoo et al., 2021). Harmonized efforts to develop frameworks and platforms for defining how such evidence should be generated ahead of study initiation (e.g., master protocols), infrastructure for collecting and sharing information in a safe and secure manner, and processes that align with system-wide consensus on best practices for data use in policy and programmatic decisions (such as those outlined in the NAM's collection of Special Publications focused on advancing the Learning Health System

BOX 10-4

Building a Robust and Integrated Digital Health and Data Sharing Infrastructure

- Advance standardization and interoperability of IT systems across health-related organizations and sectors.
- Implement data sharing policies and protocols that empower secure data availability for action and the creation and dissemination of new knowledge.
- Establish core data standardization, reliability, and quality assurance requirements across health care.
- Foster technical and regulatory capabilities to support real-world evidence generation.

[https://nam.edu/publications-of-the-leadership-consortium/]) would help real-world evidence to reach its full potential (Greene et al., 2021; NAM, 2021).

At a foundational level, the harmonization of data sharing and digital health infrastructure would align with the ethos of a learning health system by ensuring that "evidence development and application flow seamlessly and continuously in the course of care" (NAM, 2021). During crisis situations such as COVID-19, this alignment would ensure that the right information is collected and is available to the right entities at the right time. In addition to driving substantive improvements in quality, safety, and accountability for both care delivery and public health response, and harmonization would also better position the health system to respond to emerging threats, coordinate emergency response by gathering syndromic surveillance data, assess trends, and analyze intervention efficacy in near real time. Indeed, preparedness for future emergencies would be enhanced with standardized data sharing practices, aligned privacy and data security standards, and interoperable digital health infrastructure across the entirety of the health system. This would allow for accelerated development, collection, calculation, and analysis of new metrics.

Box 10-4 presents considerations for building a robust and integrated digital health and data sharing infrastructure.

Integrating Telehealth into Payment and Delivery Systems

While virtual care delivery platforms predate the pandemic, COVID-19 has, without question, served as a forcing function for telehealth to achieve significant

BOX 10-5

Integrating Telehealth into Payment and Delivery Systems

- Develop telehealth tools and approaches to grow clinician, individual, family, and community confidence and comfort levels.
- Promote development and testing of telehealth technologies to continuously enhance the scope of care and satisfaction among clinicians and patients.
- Encourage use of effective telehealth activities and policies across professions, practices, and fields.
- Design and test payment and reimbursement models that promote the use of effective telehealth services.

penetration across the health system. The question facing the health system now is not whether telehealth is here to stay, but rather how telehealth tools and approaches can be used both confidently and comfortably by clinicians, individuals, families, and communities. As these virtual care platforms evolve, leaders must also reconsider how virtual care is delivered, reimbursed, and regulated.

These questions will require careful consideration from policymakers and coordinated approaches by leaders across the health system, who must take care to ensure that telehealth does not recreate existing inefficiencies (e.g., unnecessary utilization and spending) and inequities (e.g., the digital divide). One particular area of focus for clinicians and professional societies, care systems, and health care payers is reimbursement. Policymakers could consider using alternative payment models as the vehicle for adapting current regulatory flexibilities for telehealth following the conclusion of the public health emergency (Navathe and Liao, 2020). These reimbursement arrangements could create natural disincentives to fraud and waste, and align incentives to drive the integration of virtual and in-person care into a holistic delivery experience for all.

Box 10-5 offers considerations for integrating telehealth into payment and delivery systems.

Investing in Workforce Capacity and Readiness

As the U.S. works toward pandemic recovery, the workforce challenges of coping with COVID-19 will not easily recede. In fact, apart from the dramatically inequitable burden of COVID-19 infection and mortality that certain populations carried, one of the most stark lessons of the pandemic was the burden it placed

on the health system workforce at the frontline and beyond. Workforce capacity shortfalls served to magnify already extreme levels of inequities, moral injury, and burnout.

Shortages have been experienced across all aspects of the health workforce, including among clinicians, emergency personnel, facility intake personnel, public health professionals, community health workers, social service workers, epidemiologists, laboratorians, data analysts, IT experts, supply personnel, public health workers, long-term care/nursing home staff and others. Alongside the shortages of personnel in certain categories, Black individuals have been disproportionally underrepresented in the clinician workforce as a whole, and especially so in backup and surge personnel. Enhanced workforce planning could have helped the health system to reduce fatalities by empowering it to fulfill all necessary pandemic response functions, effectively engage with communities that have been made vulnerable, prepare for surges, mitigate outbreaks in institutional care settings, and facilitate information sharing.

Another workforce challenge that has been growing over recent years (but experienced an acute increase during the pandemic) is burnout. In a survey of nearly 21,000 U.S. clinicians, nearly half of respondents reported experiencing burnout during the pandemic, exacerbating endemic patterns of occupational distress within the clinical workforce (Prasad et al., 2021). The health and well-being of the health care workforce was identified as an important need in many of the previous chapters in this Special Publication. The NAM's 2019 consensus study on the topic presents a systems approach to addressing clinician burnout and promoting professional well-being (NASEM, 2019b). There are numerous opportunities to act across the health care system and address this issue, from streamlining quality reporting to reducing the amount of time dedicated to "desktop medicine."

The ongoing pandemic experience exposes many priority areas for strengthening the workforce pipeline, including ensuring adequate numbers of critical care clinicians and long-term care personnel, as well as making coordinated investments in education and training across the health care and public health workforce. Meeting these shortfalls will require active collaboration to ensure high quality standards for staffing and adequate reimbursement for the workforce.

As is the case for each of the priority areas in this section, workforce investments should be deployed through the lens of equity, with a focus on correcting the longstanding gaps in representation at all levels of the profession, from trainees to senior leadership.

Box 10-6 presents considerations for investing in workforce capacity and readiness.

BOX 10-6

Investing in Workforce Capacity and Readiness

- Assess, build, and maintain the health workforce in the face of increasing dynamism, uncertainty related to emerging health threats, and increasing levels of burnout.
- Design, implement, and maintain continuous training and skill building for health workforce needs at national, state, and local levels.
- Ensure that regulatory and reimbursement strategies institute support and incentives for vigilance and progress on improving clinician well-being.
- Undertake regular re-assessment of the needs and strategies for maintaining the adequate numbers and skill levels of the health workforce.

Streamlining Innovation Pathways for Biomedical Science

While non-pharmaceutical interventions and prevention measures played an important role in slowing the spread of COVID-19, the rapid development of a portfolio of medical countermeasures—in particular, COVID-19 vaccines and therapeutics—has been critical to driving reductions in morbidity and mortality, especially in the U.S. The pandemic has shown the vital importance of a robust private and public research enterprise dedicated to the public's health. This enterprise has been supported during COVID-19 by a combination of substantial capital investment, innovative and often unprecedented public-private partnerships, and streamlined regulatory processes. Coordination across the health care system will enable this innovation ecosystem to be harnessed for both existing population health threats (e.g., chronic diseases) and future public health emergencies.

Biomedical advancements require investments in the fundamental science and scientific tools necessary to foster idea generation and innovative practice. This includes improved representation in clinical trials, including communities of color, low-income populations, and older individuals. As research begins to move downstream through clinical and regulatory processes, policymakers and product manufacturers must work together to ensure the careful translation of research findings for public release. The FDA's 2020 guidance document provides a valuable reference point for the field in ensuring appropriately health literate communications (FDA, 2020b).

COVID-19 has also highlighted the key role of regulation, reimbursement, and communication in advancing biomedical innovation. For example, concerns

around safety and study rigor and the consequences for public confidence illustrate the importance of robust processes for oversight, transparency, and ongoing communication during the R&D process. There are varying levels of public knowledge surrounding the values and processes of the scientific profession, so developing these policies effectively requires that communication and investments in public engagement and scientific education be appropriately tailored (Oreskes, 2019). Doing so can help to facilitate aligned analyses, communication, and expectations around evidence in advance of product development for public health emergencies.

Similarly, clear regulatory pathways for emerging technologies and partnerships between health care payers and health product manufacturers and innovators during emergencies can remove barriers to access. Aligned payment strategies and reimbursement approaches for emerging therapeutics and technologies, streamlined regulatory pathways, and clear communication on the processes will enhance both public confidence and biomedical innovation during future public health crises.

Collaboration across the health system will be critical to addressing each of these issues. For example, alignment between digital health, biomedical research, and health care payers can foster improvements in evidence generation practices to inform product development and future coverage and payment policies. Likewise, partnerships between leaders from patient and family advocacy, communities, care systems, and health product manufacturers and innovators can help identify and fill gaps in representation.

Box 10-7 presents considerations for streamlining pathways for biomedical science.

BOX 10-7

Streamlining Innovation Pathways for Biomedical Science

- Ensure sustainable funding for biomedical research, including incentives for the development of creative public-private and cross-institutional cooperative relationships in research activities.
- Develop and advance guidelines and standards for evidence generation and data sharing that promote collaborative models of research and development.
- Design and implement strategies for improved and more diverse representation at all stages of product development.
- Provide clarity on regulatory and reimbursement issues for emerging technologies, particularly for the development and use of such products in emergency situations.

Strengthening Stewardship of the Health Product Supply Chain

Collaboration to advance new innovations must be paired with partnerships to ensure equitable access to existing products both during inter-pandemic periods and during emergency situations. COVID-19 has exposed supply chain vulnerabilities that must be given high priority for correction. These vulnerabilities carry impacts across the health care system: PPE shortages impact the health care workforce and the American public, the availability of essential medications affects care systems' ability to serve their patients, and manufacturing capacity affects the global rollout of vaccines. As some of the supply chain shortfalls experienced so acutely in the early phases of the pandemic have begun to be corrected, others are now appearing. For example, the surge in demand for COVID-19 home test kits in response to the omicron variant has resulted in supply shortfalls in many areas.

A more resilient supply chain requires stewardship to identify and mitigate risks, sustainable funding to modernize manufacturing capacity, and informed regulatory elements that align with preparedness aims. Such improvements would benefit all sectors of the health system, improving both the efficiency of day-to-day operations and system-wide preparedness for future emergencies. While the U.S. possesses existing stockpiles and procurement procedures, it would be useful to extend oversight mechanisms to include critical medical products (e.g., devices, consumables) and encompass the entirety of the product life cycle. Collaboration across health system sectors and with policymakers can advance a generational restructuring of the national health care supply chain to ensure the availability of "ever warm" manufacturing capacity and stockpiling.

Modernization of the supply chain requires prioritizing resiliency through new investments in supplies, sourcing, manufacturing, and monitoring of supplies and technology. For example, the FDA has identified COVID-19 as a call to action to advance new manufacturing technologies, practices, and monitoring to improve preparedness for public health emergencies (Hahn and Shah, 2021). Federal leadership and funding can help replenish national stockpiles and incentivize the development of manufacturing capacity that stands prepared to respond and can be rapidly activated in the case of demand.

Box 10-8 presents considerations for enhancing stewardship of the health product supply chain.

Restructuring Health Care Payments to Focus on Outcomes and Population Health

COVID-19 has renewed the impetus to transition away from payment models based purely on volume of service, and move toward those that increasingly reward

BOX 10-8

Enhancing Stewardship of the Health Product Supply Chain

- Restructure, strengthen, and maintain the designations, tracking protocols, and decision rules needed to ensure the availability and distribution of health products for which unanticipated demand surges are most critical.
- Identify product categories most likely to require future iterations of improvements, and establish cooperative agreements with companies who are best positioned to undertake product development.
- Assess and streamline regulatory processes as needed for cross-sector and cross-national partnerships to replenish stockpile shortages and encourage innovations that promote supply chain resilience.
- Foster the development of international protocols and agreements to enhance the prospects for success in global responses in supply shortage circumstances.

the most impactful outcomes. However, the first decade of the value-based care movement has revealed that the sustainable transformation of payment and delivery systems requires collaboration, creativity, and determination across the health care system. With the pandemic experience as a guide, ineffective approaches to paying for health (such as traditional fee-for-service models) should be transformed to reflect non-traditional models (such as re-designed fee-for-service models and others) that improve the effectiveness, efficiency, and equitability of care. Ideally, these payment structures should incentivize the scaling of collaborative activities seen throughout the pandemic, including partnerships between decision-makers from digital health and quality, safety, and standards organizations to drive delivery innovation; and efforts by payers, clinicians, and professional societies to support the transition to new reimbursement arrangements. Continued progress toward value-based payment will require funding for new models, investments in value-based prospective payments, guidance from regulators about the long-term status of pandemic-era reimbursement flexibilities (e.g., telehealth, Hospital at Home), and leadership from payers on foundational questions related to benefit design and administrative processes (e.g., prior authorization).

The pandemic is also a reminder that payment reform is not an end in itself and cannot occur in isolation. Rather, the realignment of financial incentives provides opportunities to drive transformation across the health system. An era of future cross-sector development could include the use of payment reforms to advance public health functions, for example, developing incentive mechanisms for collective action during public health emergencies, changing

BOX 10-9

Restructuring Health Care Payments to Focus on Outcomes and Population Health

- Identify and translate to sustainable practices those pandemic-era reimbursement flexibilities most effective in accelerating care improvements.
- Identify the services and approaches that successfully use non-traditional fee-for-service models in improving the effectiveness, efficiency, and equitability of care.
- Accelerate design and emphasize implementation of alternative payment models oriented to broad movement from fee-for-service payment models to risk-adjusted prospective payment incentives.
- Design and foster locally based partnership strategies to marshal community resources so as to improve progress in public health, the social determinants of health, and health equity.

reimbursement to improve reporting of laboratory test results and syndromic surveillance, improving clinical trial recruitment, and incentivizing data sharing for research entities (Kadakia et al., 2021; McClellan et al., 2020). Likewise, payers can use the framework of value-based payment to build on pandemic-era pilots geared at addressing individuals' non-medical needs. As the Accountable Health Communities example demonstrates, these models exemplify the kinds of strategic partnerships envisioned by Public Health 3.0 and illustrate how cross-sector payment reforms can drive meaningful change (HHS OASH, 2016).

Box 10-9 presents considerations for restructuring health care payments to focus on outcomes and population health.

Fostering Communication and Collaboration Across Sectors and Stakeholders

For too long, health and health care in America has been characterized by fragmentation. Each of the opportunities identified above is intended to cut across the health care system, building on the new and collaborative ways of working together that were forged during the pandemic in order to advance system-wide transformation. Improving communication across the health system is intrinsic to this process. With so many sources of information about the dynamics in play, clear and close communication processes and patterns will accelerate the forging, reinforcement, and continual assessment of high priority public messages, allowing for effective messaging and increased trust between and among response partners.

A core lesson from COVID-19 has been that communication tools and strategies must reinforce clear and concise messages to the public, key stakeholders, and partners. To meet this need, communications should be tailored to target audiences. This can be achieved by co-designing messages and strategies by representative stakeholders and structuring communications so as to engage appropriate, targeted messaging strategies and language. Transparency is key–especially surrounding any limits to a message's contents or generalizability.

New scholarship and collaborative projects sponsored by federal agencies and private and voluntary organizations have sought to provide further guidance on the critical component of communication, especially as it relates to collaboration. As an example, the Public Health Reaching Across Sectors (PHRASES) project led by the de Beaumont Foundation is focused on improving public health's ability to communicate with other parts of the health care system to advance population health (Castrucci et al., 2020). The pandemic has required extensive communication between care systems and public health, public health and digital health, health payers and product manufacturers, biomedical research, and individuals, families, and communities; it has become evident that persistent and deliberate efforts are required to reduce the structural barriers to such open and continuous communication. Clear communication between partnerships must become the "new normal" in order for health system operations to emerge stronger from the COVID-19 pandemic, although this will not be easy to achieve.

Many aspects of the COVID-19 response, such as the organization of community testing sites and coordination of vaccination campaigns, have relied on collaboration with trusted messengers to reach different audiences. These types of partnerships cannot be transactional, one-off occurrences during emergency situations. Authentic relationships with trusted messengers require sustained engagement over time, and are one of the preconditions for centering the health system on individuals, families, and communities. To augment these strategies and further foster trust, the health system must develop inter-organizational approaches for communication that directly counter misinformation, and are transparent as to sources and resources. By investing in a shared commitment to improve communication and authentic collaboration, the entire health system can be better positioned to work together for transformational change. *Box 10-10* presents considerations for fostering communication and collaboration across sectors and stakeholders.

CONCLUSION

Reflecting on the 1918 influenza pandemic, the historian John Barry notes that "the disease has survived in memory more than in any literature." This is

BOX 10-10

Fostering Communication and Collaboration Across Sectors and Stakeholders

- Set in motion processes and communication patterns that will accelerate the forging, reinforcement, and continual assessment of key elements of high priority public messages.
- Without departing from key elements or transparency, design messages with the participation of targeted audiences and communities, and engage varied words, language, and messenger strategies most appropriate for the audiences and communities targeted.
- Ensure that an important conceptual component of any given message is transparency surrounding any limits to the message's contents or generalizability.
- Develop inter-organization agreement on approaches to directly counter misinformation, being transparent regarding sources and resources.

a shortcoming for future preparedness, for "memory dies with people" (Barry, 2004). To avoid repeating the generational amnesia surrounding the 1918 influenza pandemic, as leaders convened by the NAM from nine sectors of the health delivery system, we are committed to applying the lessons learned from our assessments of the impact of COVID-19, and to doing all we can to foster the actions necessary for health system transformation that enhances the health prospects for present and future generations.

As this chapter makes clear, two narrative threads define the pandemic: a recognition of remarkable responses and advances brought on by the urgency of COVID-19, tempered by the sobering reality of long-standing structural failings and inequities that the pandemic both exposed and exacerbated. The road forward sits at the intersection of these threads, and we must harness the momentum for change to build a more resilient health system. Each chapter of this NAM Special Publication has chronicled the experiences and opportunities relevant to individual health and varying health care sectors, but converting these aspirations into action will require strong collaboration across the system.

This summative chapter underscores the common themes from the individual impact assessments and illustrates the opportunities for partnership. Examples of leadership and change abound: the sacrifices and contributions of health care and public health workers, the development of innovative new biomedical products, the rise of unprecedented flexibilities for reimbursement and regulation, and collaborations across previously unbridgeable siloes to develop a rapid and successful pandemic response. Individual sectors, however, also continue to

encounter a number of common challenges, from issues with data sharing and system capacity to foundational gaps in trust, communication, and health equity. Taken together, these elements frame the opportunities for near- and long-term system-wide transformation. Moving forward, we must center health system incentives and accountability on the outcomes most important to individuals and populations, foster a health manufacturing and supply chain that is ever improving in preparedness and responsiveness, and advance progress toward eliminating health inequities.

The societally disruptive, intense, and too often tragic experiences with the pandemic offer an unprecedented opportunity to build coalitions, embrace aspirational goals, and implement lasting change. Through this Special Publication, its authors are pleased to answer the NAM's call. As health system leaders and stakeholders, we present an unvarnished picture of the U.S. health system's successes and failures—and, most importantly, its opportunities—revealed throughout the COVID-19 pandemic to date. We urge others throughout the nation to join with us in working toward the imperative that stands before us, as individuals and as leaders: to emerge stronger by applying what we have learned to build a system committed to the relentless pursuit of equity, efficiency, effectiveness, and continuous learning—and to achieve better health for all.

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CONFLICT OF INTEREST DISCLOSURES

Amy Abernethy discloses receiving personal fees from Flatiron Health (Roche Group), AthenaHealth, SignalPath, and CareDx no later than January 2019. **Jeffrey Balser** discloses that he receives compensation as a member of the board of Varian Medical Systems and is an unpaid member of the board for the Center for Medical Interoperability. **Mathai Mammen** discloses that his employer received funding from the US government to develop a COVID-19 vaccine; that his employer collaborated with BCG; that his employer's COVID-19 vaccine has received emergency use authorization in the US, European Union, and other countries;

and that Johnson & Johnson is a multi-faceted company that has pharmaceutical, consumer, and medical devices businesses. **Mark McClellan** discloses that he is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and receives fees for serving as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE. **Vasant Narasimhan** discloses that his employer is currently undertaking an internal drug discovery program toward a pan-Coronavirus Mpro inhibitor; that his employer has an option and license agreement to develop, manufacture and commercialize two Molecular Partners' anti-COVID-19 DARPin® candidates; and that his employer has initial agreements with Pfizer-BioNTech and CureVac to manufacture their COVID-19 vaccines, and with Roche for the production of the API for Actemra/RoActemra®. **Rahul Rajkumar** discloses that he is an advisor to Google Ventures and holds shares in OM1, Advantia Health, and PicassoMD.