QUALITY COMMITTEE MEETING AGENDA

Wednesday, September 28, 2022
1:15 pm – 2:45 pm (ET)
Motif Room | Conrad Hotel, Washington, DC

https://us06web.zoom.us/j/87433075007?pwd=RC9RNm5XMXdvWGZmVjRyWUVDcVhhQT09

Meeting ID: 874 3307 5007 | Passcode: 766612 | Dial-in Number: 301-715-8592

I. WELCOME / ANTITRUST STATEMENT **TAB 1 pg. 7**

II. PRESIDENT'S REPORT

III. NEW STUDY **TAB 2 pg. 8**
A. Presentation Speakers
   1. Allen Dobson, Ph.D.
   2. Kimberly Rhodes, M.A.

IV. HOSPITAL ACQUIRED INFECTIONS DISCUSSION **TAB 3 pg. 10**
A. Lee Fleisher NEJM Articles
B. Impact of COVID-19 on HAI – SHEA/CDC 2021
C. SHEA Commentary

V. ANTIMICROBIAL RESISTANCE (AMR) DISCUSSION **TAB 4 pg. 41**
A. AMR Ecosystem Challenges Backgrounder / PhRMA
B. Background & Bill: PASTEUR Act of 2021

VI. CHAIR'S UPDATE **TAB 5 pg. 89**
A. Quality Payment and Initiatives
B. Health Equity
C. HIT and Cybersecurity
D. MA Managed Care

VII. MEDICARE ADVANTAGE (MA) / PRIOR AUTHORIZATION UPDATE **TAB 6 pg. 96**
A. MA Quality Measure One-Pager
B. FAH Level I Denials Upheld Rate Measure Concept

VIII. NQF UPDATE **TAB 7 pg. 99**
A. Hospital Association Virtual Roundtable Survey

IX. NEW BUSINESS

QUALITY COMMITTEE
2022-2023 BOARD OF GOVERNORS

Karen Johnson, Chair
SVP, Behavioral Health
Universal Health Services, Inc.
PO Box 61558, 367 S Gulph Rd
King Of Prussia, PA 19406
Karen.Johnson@uhsinc.com

Miguel Benet, MD
SVP, Clinical Services
Community Health Systems
4000 Meridian Blvd
Franklin, TN 37067
miguel_benet@chs.net

Sunny Bhatia
Corporate CMO & CEO Region I
Prime Healthcare Services
3480 E Guasti Road
Ontario, CA 91761
909-638-0595
sbhatia@primehealthcare.com

Kim Bodine
Sr. Director, Applied Clinical Inf.
Tenet Healthcare Corporation
14201 Dallas Parkway
Dallas, TX 75254
kim.bodine@tenethealth.com

Elisabeth Brisley
Senior Manager, Government Relations
Encompass Health Corporation
elisabeth.brisley@encompasshealth.com

FJ Campbell, MD, MBA
Chief Medical Officer
Ardent Health Services
One Burton Hills Boulevard, Suite 250
Nashville, TN 37215
615-296-3206
FJ.Campbell@ardenthealth.com

Cindy Chamness
VP, Quality and Safety Operations
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7521
cynthia.chamness@lpnt.net

Lisa Charbonneau, DO, MS
Chief Medical Officer
Encompass Health Corporation
3660 Grandview Parkway, Suite 200
Birmingham, AL 35243
205-970-5950
lisa.charbonneau@encompasshealth.com

Jeff Cohen
Senior Vice President, Government Relations
HCA Healthcare
1 Park Plaza, 1-4 West
Nashville, TN 37203
615-344-2092
jeff.cohen@hcahealthcare.com

David Critchlow
Senior Vice President, Government Relations
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7676
david.critchlow@lpnt.net

QUALITY COMMITTEE
2022-2023 BOARD OF GOVERNORS

Corey Davison
Vice President, Government Relations
Tenet Healthcare Corporation
14201 Dallas Parkway
Dallas, TX 75254
469-893-2293
corey.davison@tenethealth.com

Mary Ellen DeBardeleben, MBA, MPH
National Director, Quality
Encompass Health Corporation
3660 Grandview Parkway, Suite 200
Birmingham, AL 0
205-970-3420
mary.debardeleben@encompasshealth.com

David M. Dill
Chairman & CEO
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7986
david.dill@lpnt.net

Lisa Dolan
Vice President, Clinical Operations
Ardent Health Services
One Burton Hills Boulevard, Suite 250
Nashville, TN 37215
502-333-2468
Lisa.dolan@ardenthealth.com

Francie Ekengren, MD
Chief Medical Officer
HCA Healthcare
550 North Hillside Street
Wichita, KS 67214
316-962-2088
francie.ekengren@wesleymc.com

Dean French
Chief Medical Officer
ScionHealth
406-370-8315
dean.french@scionhealth.com

Gail Garrett
Vice President, Regulatory Compliance Support
HCA Healthcare
1 Park Plaza, Bldg 2 - 3W
Nashville, TN 0
615-344-6365
gail.garrett@hcahealthcare.com

Chuck Girard
Vice President, Government Relations
HCA Healthcare
One Park Plaza, Bldg. 1-2E
Nashville, TN 37203
615-344-4659
charles.girard@hcahealthcare.com

Michael Greer
AVP, Regulatory & Accreditation Quality
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-509-9523
michael.greer@lpnt.net

Ken Grubbs
AVP, Quality Standards
HCA Healthcare
2515 Park Plaza
Nashville, TN 37203
615-344-5865
Ken.Grubbs@hcahealthcare.com

QUALITY COMMITTEE
2022-2023 BOARD OF GOVERNORS

Joanne Hardin, RN, BSN, MBA
VP, Clinical Outcomes
Ardent Health Services
One Burton Hills Blvd, Ste 250
Nashville, TN 37215
615-296-3597
Joanne.Hardin@ardenthealth.com

Traci Holton
Vice President, Ancillary Service Optimization
Tenet Healthcare Corporation
14201 Dallas Parkway
Dallas, TX 75254
469-893-6654
traci1.holton@tenethealth.com

Carol Ann Hudson, RN-TN
Director, Quality Reporting
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7760
CarolAnn.Hudson@lpnt.net

Sandi Hyde, MSPS
AVP- Quality & Clinical Operations Data
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7531
Sandi.Hyde@LPNT.net

Ahmad Imran
VP, Quality & Value-Based Care
Prime Healthcare Services
3480 E Guasti Road
Ontario, CA 91761
909-638-0009
aimran@primehealthcare.com

Paige Kesman
Vice President, Assistant General Counsel
Tenet Healthcare Corporation
14201 Dallas Parkway
Dallas, TX 75254
469-893-6054
paige.kesman@tenethealth.com

Kacie Kleja, MBA, MS, CHDA
Vice President, Clinical Data & Analytics
HCA Healthcare
One Park Plaza
Nashville, TN 37203
615-344-5982
kacie.kleja@hcahealthcare.com

Karla Miller
AVP, Pharmacy Services & Clinical Therapeutics
HCA Healthcare
1 Park Plaza
Nashville, TN 37202
615-344-6518
karla.miller@hcahealthcare.com

Paryus Patel, MD
Corporate CMO
Prime Healthcare Services
3480 E Guasti Road
Ontario, CA 91761
310-680-4544
paryus.patel@primehealthcare.com

Brock Phillips
Director, Federal Affairs
Tenet Healthcare Corporation
1455 Pennsylvania Ave NW, Suite 400
Washington, DC 20004
202-465-0727
brock.phillips@tenethealth.com

QUALITY COMMITTEE
2022-2023 BOARD OF GOVERNORS

Jason Pinkall
Senior Counsel
Tenet Healthcare Corporation
14201 Dallas Parkway
Dallas, TX 75254
469-893-2514
jason.pinkall@tenethealth.com

Christopher Rehm
Senior Vice President and Chief Medical Officer
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7533
christopher.rehm@lpnt.net

Kenneth Sands
Chief Epidemiologist/ Chief Patient Safety Officer
HCA Healthcare
1 Park Plaza, Bldg 2-4W
Nashville, TN 37203
615-344-2791
Kenneth.sands@hcahealthcare.com

Lynn T Simon, MD, MBA
President, Clinical Operations and Chief Medical Officer
Community Health Systems
4000 Meridian Boulevard
Franklin, TN 0
615-465-7503
lynn_simon@chs.net

Paul Stefanacci
Chief Medical Officer
Universal Health Services
paul.stefanacci@uhsinc.com

Nathan Summar
Vice President, Revenue Management
Community Health Systems
4000 Meridian Blvd
Franklin, TN 37067
nathan_summar@chs.net

Warren Tardy
Government Relations Consultant
HCA Healthcare
warren.tardy@hcahealthcare.com

Kara Townsend
Director, Policy
HCA Healthcare
One Park Plaza, Bldg. 1-2E
Nashville, TN 37203
615-344-4942
kara.townsend@hcahealthcare.com

Harsha Upadhyay
CEO Region III
Prime Healthcare Services
3480 E Guasti Road
Ontario, CA 91761
hupadhyay@primehealthcare.com

FAH STAFF:

Don May
Senior Vice President, Policy
Federation of America Hospitals
750 9th St NW
Washington, DC 20001
202-624-1500
dmay@fah.org

QUALITY COMMITTEE
2022-2023 BOARD OF GOVERNORS

FAH STAFF:

Tilithia McBride
Vice President, Quality
Federation of America Hospitals
750 9th St NW
Washington, DC 20001
202-624-1500
tmcbride@fah.org

FAH STAFF:

Steve Speil
Executive Vice President, Policy
Federation of America Hospitals
750 9th St NW
Washington, DC 20001
202-624-1500
sspeil@fah.org

TAB 1

Antitrust Statement
Federation of American Hospitals

To Be Recited By Chairman

I would like to remind everyone that the Federation, its representatives, and its members, are committed to the continued existence of competitive health care delivery systems and markets, and ongoing compliance with all applicable federal and state antitrust laws.

As such, you are reminded that the Federation will not permit at this meeting, or in any other of its forums, any discussion or remarks that suggest or invite anti-competitive conduct among its member hospitals and/or health care systems.

Allen Dobson, Ph.D., is a health economist and President of Dobson | DaVanzo & Associates, LLC (Dobson | DaVanzo). Before he co-founded the firm in May 2007, Dr. Dobson spent eighteen years with The Lewin Group where he was Senior Vice President and directed the Health Care Finance Group. In this position, Dr. Dobson led numerous, large-scale studies for both Federal and private-sector clients. Prior to The Lewin Group, Dr. Dobson served as Director in the Office of Research at CMS (formerly the Health Care Financing Administration) when the Medicare Inpatient Prospective Payment System (PPS) and the Medicare Physician Fee Schedule (PFS) were being formulated and implemented.

Dr. Dobson has expertise evaluating Medicare's various PPS policies (e.g., acute care hospitals, long term care hospitals, skilled nursing facilities, inpatient rehabilitation facilities, home health agencies, and ambulatory surgery centers), and, over the last twenty-five years, has directed numerous efforts to model the economic impact of Medicare and Medicaid payment policies on providers using a variety of statistical and econometric methodologies. For 10 years, Dr. Dobson also advised CMS on the development of methodologies to determine physician practice expenses, and, more recently, on the calculation of Medicare Disproportionate Share Hospital (DSH) policy for CMS and Medicaid DSH policy for MACPAC.

Dr. Dobson currently co-leads Dobson | DaVanzo's research modeling activities for bundled payments, value-based purchasing, and alternative payment model (APM) systems. Here, Dobson | DaVanzo provides essential information to a number of stakeholders as they implement CMS' Bundled Payment for Care Improvement (BPCI) Initiative, and, more recently, CMS' Comprehensive Care for Joint Replacement (CJR) and Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Dr. Dobson also directs numerous private-sector research efforts on APM using linked Medicare research identifiable datasets through CMS-approved data use agreements (DUAs). Findings from many of these studies have been reported to CMS, the Medicare Payment Advisory Commission (MedPAC), the Medicaid and CHIP Payment and Access Commission (MACPAC), the Congressional Budget Office (CBO), and various other Congressional committees. Dr. Dobson also leads a series of efforts to assist clients' responses to CMS requests for public comment on rulemaking.

Dr. Dobson was selected as one of the nation's most influential health care policy leaders by Faulkner and Gray, selecting him in their first edition of "The Health Care 500." Dr. Dobson is a regular speaker at conferences and has testified before the Congress, MedPAC, and various state, federal, and presidential commissions on health care finance, provider payment, and health policy issues. Over the years, he has testified before Pennsylvania, Illinois, Mississippi, Maine, and Nevada state legislatures. His work has been widely published in peer-reviewed journals, such as *The New England Journal of Medicine, Journal of the American Medical Association, Inquiry, Journal of Managed Care, Health Affairs, Military Medicine (International Journal of the Association of Military Surgeons of the United States), Seminars in Dialysis, The Milbank Quarterly, and Health Care Financing Review.*

Dr. Dobson is a Phi Beta Kappa graduate from the University of Washington in Seattle, and earned his Ph.D. in Economics from Washington University in St. Louis, Missouri.

Kimberly Rhodes, M.A., a Senior Manager at Dobson | DaVanzo, joined the firm in 2016. She brings experience across a range of Medicare issues including post-acute care utilization and payment policy, the Part D program, hospital value-based programs and alternative payment models. Ms. Rhodes serves as the lead on two of the firm's Medicare Part D contracts to support the Centers for Medicare and Medicaid Services (CMS) in determining whether Part D formulary and benefit offerings are being administered appropriately and analyzing Part D policies and data as they relate to Medicare Parts A and B. Ms. Rhodes also contributes to several projects related to examining utilization and outcomes for Medicare fee-for-service and Medicare Advantage beneficiaries within pathways of care, analyzing the impacts of Accountable Care Organizations, and exploring the social determinants of health as they relate to CMS policy. In addition, Ms. Rhodes develops presentations for a broad range of audiences on the changing landscape of healthcare policy.

Prior to joining Dobson | DaVanzo, Ms. Rhodes was the Data Analyst at a home health agency that provides services to Medicare, Medicaid, and private pay individuals. During her time there, Ms. Rhodes conducted research and analysis using operational, financial, and clinical data. Ms. Rhodes' other professional experience includes working at the American Society for Nutrition (ASN) where she supported the publications process for three journals and facilitated the department's outreach and research efforts. Ms. Rhodes also worked at the World Bank Group where she provided legal reference and research services and contributed to her unit's information management initiatives.

Ms. Rhodes earned a Bachelor of Science in International Political Economy from Juniata College and a Master of Arts in Global Affairs with a concentration in Global Health from George Mason University.

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

FEBRUARY 17, 2022

Health Care Safety during the Pandemic and Beyond — Building a System That Ensures Resilience

Lee A. Fleisher, M.D., Michelle Schreiber, M.D., Denise Cardo, M.D., and Arjun Srinivasan, M.D.

For about two decades, the U.S. health care system was making strides in improving patient safety, as demonstrated by the reduction of health care–associated infections and other complications of care.[1] Though there was still room for improvement, the trends were certainly in the right direction. Since the Covid-19 pandemic began, however, many indicators make it clear that health care safety has declined. The public health emergency has put enormous stress on the health care system and disrupted many normal activities in hospitals and other facilities. Unfortunately, these stressors have caused safety problems for both patients and staff. Managing the competing priorities of providing care for large numbers of patients with Covid, as well as for the patients without Covid who need care every day, and of maintaining safety efforts such as robust infection-control practices is both difficult and essential.

The fact that the pandemic degraded patient safety so quickly and severely suggests that our health care system lacks a sufficiently resilient safety culture and infrastructure. We believe the pandemic and the breakdown it has caused present an opportunity and an obligation to reevaluate health care safety with an eye toward building a more resilient health care delivery system, capable not only of achieving safer routine care but also of maintaining high safety levels in times of crisis.

We have observed substantial deterioration on multiple patient-safety metrics since the beginning of the pandemic, despite decades of attention to complications of care.[2-4] Central-line–associated bloodstream infections in U.S. hospitals had decreased by 31% in the 5 years preceding the pandemic; this promising trend was almost totally reversed by a 28% increase in the second quarter of 2020 (as compared with the second quarter of 2019).[3] There were also increases in catheter-associated urinary tract infections, ventilator-associated events, and methicillin-resistant *Staphylococcus aureus* bacteremia. Safety has also worsened for patients receiving postacute care, according to data submitted to the Centers for Medicare and Medicaid Services (CMS) Quality Reporting Programs: during the second quarter of 2020, skilled nursing facilities saw rates of falls causing major injury increase by 17.4% and rates of pressure ulcers increase by 41.8%. The surges of

the delta and omicron variants of SARS-CoV-2 in late 2021 and early 2022 do not bode well for a return to prepandemic levels for any of these indicators.

There are multiple potential explanations for these increases in adverse events. The health care system has been challenged by repeated influxes of vast numbers of very ill patients, which have stretched staff and supplies. Health care personnel have responded with extraordinary effort and dedication, adapting with unprecedented speed and developing and modifying treatment protocols on the basis of data that have evolved by the week. They have done all these things while battling workforce-safety problems such as exhaustion and a dearth of personal protective equipment, at great risk to themselves and their loved ones. We have seen an increasing number of media reports about the rising incidence of staff burnout, which is causing health care workers to leave practice, retire, or move into other industries.

The strains on the system have also affected routine safety practices. Overworked clinicians have often had no time for safety rounds, safety audits, or error reporting. Supply-chain disruptions reduced access to personal protective equipment, putting both patients and health care workers at risk. Standard safeguards, such as checklists, quickly became inadequate. Moreover, the pandemic starkly highlighted health disparities, including inequities in the safety of patients and health care personnel.[5]

As Mary Dixon-Woods and colleagues argued in a 2011 article entitled "Explaining Michigan," contextual influences are important in solving safety problems. We therefore need to reevaluate whether the health care system has sufficiently invested in ensuring a deeply embedded safety culture and maintaining an unflagging commitment to safety. It is abundantly clear that the health care ecosystem cannot ask clinicians and staff to work harder, but must instead provide them with more tools and an environment built on a strong foundation of wellness and on instilling and rewarding a culture of safety. CMS must also use our oversight functions to ensure that emergency-preparedness and quality-improvement programs are more than plans on a shelf. Such a culture would ensure that patients and staff are protected from harm while rendering the system more resilient, especially during a crisis. So how do we bolster the health care ecosystem to avoid future threats to patient safety?

As we emerge from this public health emergency, we at CMS and the Centers for Disease Control and Prevention (CDC) are committed to a renewed focus on patient safety. We seek to join leaders from throughout the health care ecosystem in reviewing safety practices and seeking better and more deeply embedded solutions that also help to close health disparities, since there is no true health care quality and safety without equity. We are already working together to expand the collection and use of data on safety indicators in our programs, including data in such key areas as maternal health and mental health, and we will work with other government and nongovernmental organizations to further enhance patient safety. We are also developing safety metrics that draw on the rich clinical data captured digitally in electronic medical records, which incorporate information from all health care payers. Some electronic clinical quality measures are already being considered for inclusion in patient-safety monitoring in the CMS Quality Payment Program.

Over time, the U.S. health care sector has implemented various pieces of the safety-assessment-and-improvement puzzle, but it has not instituted a thorough system of safety that reaches from the boardroom to the front lines and that can be maintained during times of crisis. For example, it is important to have sufficient resources such as staff and personal protective equipment for times of stress. The United States deserves breakthrough thinking about systems built on foundational principles of safety, akin to those used in other industries in which safety is embedded in every step of a process, with clear metrics that are aggregated, assessed, and acted on. We also need renewed national goals of harm elimination throughout the health care system and a core safety strategy that includes promoting radical transparency, addressing workforce shortages, and continuing to strive for safety while being sensitive to such trade-offs as reporting burden and costs. This effort should extend across the continuum of care, beyond the traditional hospital-based safety indicators, and include attention to diagnostic errors and outpatient care.

The health care sector owes it to both patients and its own workforce to respond now to the pandemic-induced falloff in safety by redesigning our current processes

and developing new approaches that will permit the delivery of safe and equitable care across the health care continuum during both normal and extraordinary times. We cannot afford to wait until the pandemic ends.

An audio interview with Dr. Fleisher is available at NEJM.org

Disclosure forms provided by the authors are available at NEJM.org.

From the Center for Clinical Standards and Quality, Centers for Medicare and Medicaid Services, Baltimore (L.A.F., M.S.); and the Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, Atlanta (D.C., A.S.).

This article was published on February 12, 2022, at NEJM.org.

1. National Healthcare Quality and Disparities Report chartbook on patient safety. Rockville, MD: Agency for Healthcare Research and Quality, February 2021 (https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/chartbooks/patientsafety/2019qdr-patient-safety-chartbook.pdf).
2. Baker MA, Sands KE, Huang SS, et al. The impact of COVID-19 on healthcare-associated infections. Clin Infect Dis 2021 August 9 (Epub ahead of print).
3. Patel PR, Weiner-Lastinger LM, Dudeck MA, et al. Impact of COVID-19 pandemic on central-line-associated bloodstream infections during the early months of 2020, National Healthcare Safety Network. Infect Control Hosp Epidemiol 2021 March 15 (Epub ahead of print).
4. Patient safety and COVID-19: a qualitative analysis of concerns during the public health emergency. Rockville, MD: Agency for Healthcare Research and Quality, November 2021 (https://www.ahrq.gov/sites/default/files/wysiwyg/npsd/data/spotlights/spotlight-ptsafety-and-covid-19.pdf).
5. Rubin-Miller L, Alban C, Artiga S, Sullivan S. COVID-19 racial disparities in testing, infection, hospitalization, and death: analysis of Epic patient data. Kaiser Family Foundation. September 16, 2020 (https://www.kff.org/coronavirus-covid-19/issue-brief/covid-19-racial-disparities-testing-infection-hospitalization-death-analysis-epic-patient-data/).

DOI: 10.1056/NEJMp2118285

Inherited Patients Taking Opioids for Chronic Pain — Considerations for Primary Care

Phillip O. Coffin, M.D., and Antje M. Barreveld, M.D.

On May 19, 2021, a total of 28 Lags Medical Center pain-management clinics in California abruptly closed, leaving approximately 20,000 patients without pain management.[1] The patients who were on long-term opioid therapy received 30 days' worth of medications and instructions to contact their primary care clinicians or locate new ones. Many patients quickly found that their primary care clinicians were unwilling to prescribe opioids. Patients without a current clinician learned that almost none would prescribe opioids to new patients, and some would not prescribe opioids at all. Referrals to pain-management specialists would take as long as 6 months. Many of these patients have been going from emergency department to emergency department trying to obtain medications to avert opioid withdrawal. This crisis is ongoing and represents a blight on U.S. health care.

U.S. medical practice and policy with regard to opioids radically changed in the 1990s and again in the 2010s, swinging between extremes. First, a vast liberalization of opioid prescribing, in response to inadequate pain relief in end-of-life care, was shepherded by pharmaceutical companies, supported by many physician groups, and bolstered by welfare reform, the emergence of managed care organizations seeking low-cost ways to address pain, and the economic abandonment of swaths of the country.

After the Centers for Disease Control and Prevention (CDC) recognized the opioid overdose crisis in 2007, countervailing interventions began to emerge. Pain clinics that had dispensed enormous quantities of opioids were shuttered by the Drug Enforcement Administration. States developed controlled substance monitoring programs (CSMPs), which were often run by law-enforcement agencies rather than health care agencies. Pharmacists began to question or refuse to fill opioid prescriptions. Health plans instituted new rules regarding opioids or demands for confidential patient data and refused to cover some prescriptions. Clinic systems began requiring patient–provider agreements for opioid prescriptions, urine drug screening with consequences for unexpected results, and documentation that clinicians had checked the CSMP before prescribing opioids. Medical boards and other regulators began investigating opioid overdose deaths and bringing cases against clinicians. The opioid-prescribing guidelines issued by the CDC in 2016 (for which one of us was a core expert) led to steeper reductions in prescribing. Today, it is hard to find a clinician who will prescribe opioids for chronic pain — and nearly impossible if you are a patient receiving long-term

NEJM Catalyst

COMMENTARY

Learnings Regarding Emergency Preparedness During the Public Health Emergency: A Mixed-Methods Study of Hospitals and Long-Term Care Facilities

Sheila C. Blackstock, BSN, MSM, JD, Jean D. Moody-Williams, RN, MPP, Lee A. Fleisher, MD

DOI: 10.1056/CAT.22.0152

From May to September 2021, the U.S. Centers for Medicare & Mediaid Services (CMS) conducted a mixed-methods study to learn about hospital, critical access hospital, and nursing home experiences in responding to the Covid-19 pandemic. Through conversations with 30 providers across 10 states representing diverse experiences under the public health emergency (PHE), CMS identified seven key enablers and challenges to consider in preparing for future responses: (1) leadership, culture, and governance; (2) communications systems; (3) data reporting; (4) training and testing; (5) staff resilience; (6) infection prevention and control expertise; and (7) local planning and coordination. The enablers for implementation were leadership, culture, and governance; infection prevention and control expertise; and local planning and coordination. The four key challeges were planning for underserved and vulnerable populations; data reporting; technical assistance; and managing federal, state, tribal, local, and territorial guidance. Moving forward, CMS will use the information from this work to inform its policy approach on emergency preparedness including surveying and guiding its strategic use of Quality Improvement Organizations to prepare providers for future emergencies. Importantly, CMS will continue engaging with interested parties to ensure that the approach taken reflects the perspectives of all of the entities — federal, state, and local governments, and public and private organizations — that play a vital role in emergency preparedness.

The current public health emergency(PHE) related to coronavirus disease 2019 (Covid-19) has demonstrated the importance of the health care sector being prepared for a wide spectrum of emergencies. On January 31, 2020, the Secretary of the U.S. Department of Health and Human Services (HHS) declared a PHE under the Public Health Service Act because of the Covid-19 pandemic, effective as of January 27, 2020 (Appendix). While the onset and surge of SARS-CoV-2 infections was initially variable among different parts of the United States, the PHE quickly developed into an event of unprecedented scope and length for the entire nation. Entities including states and counties found themselves addressing issues locally and on their own, as opposed to previous PHEs, such as isolated weather events, when assistance was available from those in unaffected areas. For example, in its planning for the aftermath of a hurricane, a hospital may have planned to transfer its patients to a hospital outside its immediate local area, but because of the pandemic's national scope, the planned relief facility was unable to provide support. Additionally, central coordination of resources is nationally facilitated for only a subset of some provider or supplier types, like dialysis facilities, while coordination in other segments of the health care community lacks the same type of central coordination.

Given the importance of preparing for future emergencies, the U.S. Centers for Medicare & Mediaid Services (CMS) engaged in a mixed-methods study that included data analysis and discussions with leaders (including administrators, directors of nursing, chief medical officers, chief operating officers, and directors of emergency preparedness) at hospitals and long-term care facilities to determine how different local health care facilities prepared for and responded to the PHE for Covid-19 and their associated outcomes to understand different enablers (that is, the structural enabling systems/processes rather than invividuals) and challenges associated with pandemic response efforts. This study was not conducted for purposes of oversight, but instead to inform future efforts to promote greater provider preparedness and resilience.

Data and Methods

This study used a mixed-methods approach with a focus on hospitals and nursing homes, given the disproportionate impact on patients and residents affected by Covid-19 in these settings. The study working group was led by CMS staff, with input from HHS, including the Centers for Disease Control and Prevention (CDC) and the Office of the Assistant Secretary for Preparedness and Response (ASPR).

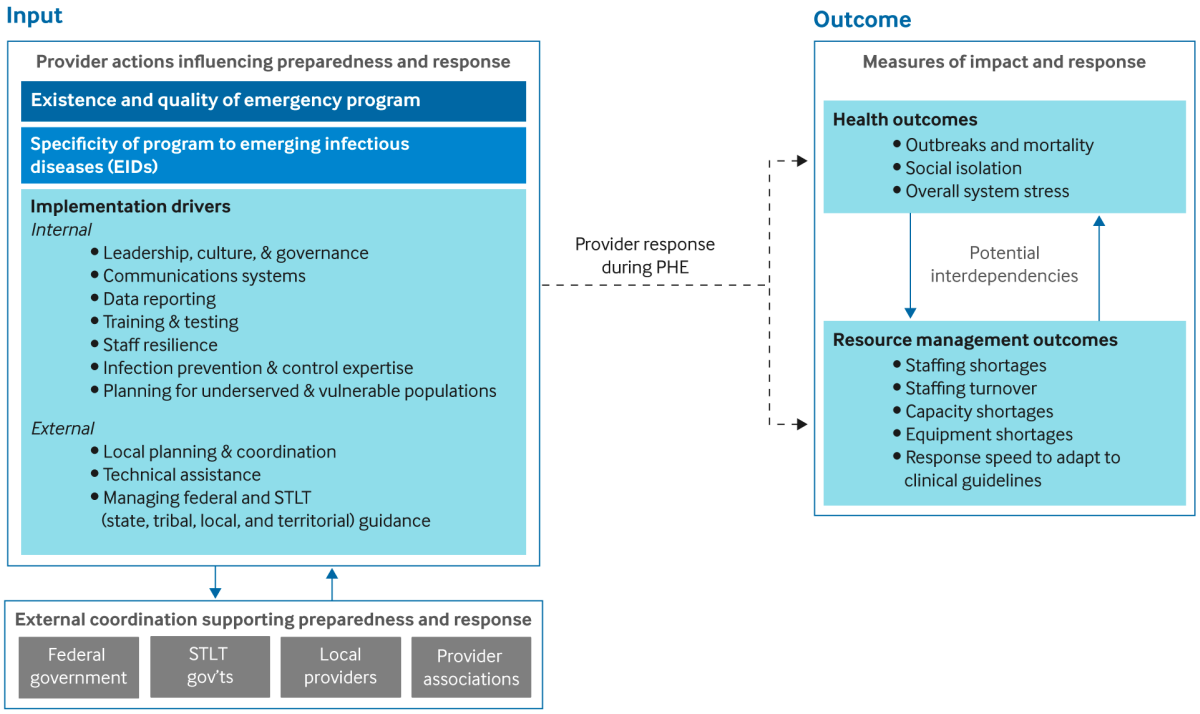
Conceptual Model and Approach to Assessing Emergency Preparedness Models

Prior to starting the discussions, CMS developed a conceptual framework to think about emergency preparedness (Figure 1).

FIGURE 1

Conceptual Model as Framework to Understand Influence of Provider Actions on Outcomes

The working group convened subject matter experts from across CMS and the Department of Health and Human Services (HHS) to collect input on the factors critical to provider emergency response and the outcomes influenced by their response. This was used as a guide for further discussion with the hospitals and nursing homes.



Abbreviation: PHE = public health emergency

Source: The authors

NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

This conceptual model provides a framework to understand the connection between factors that enable organizational resilience to emergencies and outcomes, with the goal of informing potential pathways to improve providers' ability to respond to emergencies.[1] To identify those input factors that enable resilience and influence outcomes, we considered internal drivers, such as leadership and training, with a particular focus on providers' approach to protecting vulnerable populations in their service area as part of their emergency preparedness plan (Panel A). We also considered external factors such as the local planning and coordination and available guidance. And, we considered two interrelated categories of outcomes (Panel B) to capture the effectiveness of providers' response to Covid-19: (1) patient and staff health outcomes, and (2) resource management outcomes. The latter set of outcomes is similar to the widely used *4S framework* for evaluating the essential components of a provider's pandemic response: space (capacity), staff, stuff (supplies), and systems.[1,2]

This framework for emergency preparedness and response was used as a basis for the evaluation, including selecting providers for conversations, defining the key questions examined throughout the evaluation, and analyzing responses.

Approach to Provider Selection

Through a combination of quantitative and qualitative measures, and to ensure the broadest spectrum of experiences, we selected providers that demonstrated wide variation in terms of their enabling factors and outcomes. In addition, CMS considered urban/rural status, size, system affiliation, pre-PHE compliance with emergency preparedness (EP) requirements, and relative impact of Covid-19 on provider operations based on self-reported data on management of staffing shortages, personal protective equipment (PPE) shortages, and — for hospitals — capacity shortages. The working group solicited additional input from representatives of state governments responsible for surveying the EP requirements and supporting provider preparedness and response.

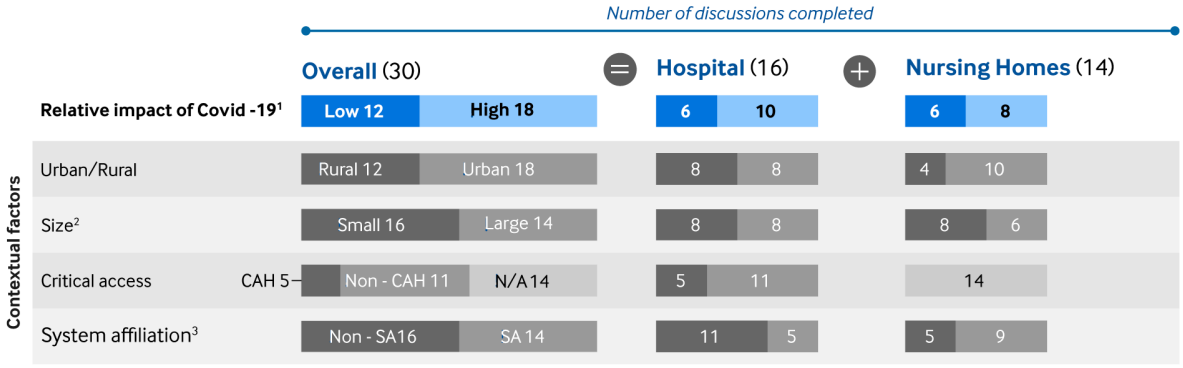
> *"This study was not conducted for purposes of oversight, but instead to inform future efforts to promote greater provider preparedness and resilience."*

The CMS working group met with a total of 30 providers across 10 States. The discussions included individuals selected by each facility to provide perspective on the facility experience with Covid-19, such as the Director of Nursing, Chief Medical Officer, Director of Critical Care, Chief Operating Officer, or Director of Emergency Preparedness. The conceptual model also provided the basis for guiding questions used during conversations with hospitals and nursing homes. Through nonstandard and informal conversations, the working group heard provider perspectives on how inputs, including existing emergency plans, influenced their approach to responding to Covid-19. While the nature of the conversations and the size of the sample may limit our ability to extrapolate these results, we believe that themes identified through these conversations are useful as we consider how to strengthen policies around emergency preparedness (Figure 2).

FIGURE 2

Discussions with 16 Hospitals and 14 Nursing Homes with Varying Impact of Covid-19 and Contextual Factors

This figure provides a description of the types of organizations that were involved in the study.



Notes:
1. Impact of Covid-19 on resource management outcomes, including staffing shortages, staffing turnover, capacity shortages, equipment shortages, speed to adapt clinical guidelines.
2. Size of facility is determined by bed count: Small hospitals <90 beds, small nursing homes <75 beds; Large hospitals >150 beds, large nursing homes >125 beds.
3. System affiliation refers to health system affiliation for hospitals and corporate chain ownership and/or health system affiliation for nursing homes in 2020, as stated in provider discussions.

Source: The authors

Coding and Analysis

Following each conversation, the working group analyzed and summarized providers' responses using the structure laid out by the conceptual model. Two types of coding were conducted: coding of binary or numeric data, such as whether a provider had an existing plan for emerging infectious diseases (EIDs), and descriptive data, such as the role an existing plan for EIDs played in providers' response.

The resulting analysis focused on three general areas:

- **Approach to preparedness pre-PHE:** Providers' baseline emergency preparedness prior to the PHE and its role in supporting the response to Covid-19, including existing emergency plans and the extent to which these specifically included threats from infectious diseases

- **Enablers and challenges during implementation:** Enablers and challenges influencing providers' ability to implement their response effectively, such as leadership, local planning and coordination, and technical assistance

- **Variation in response across provider contexts:** Role of contextual factors, such as system affiliation and rurality, in driving variation across the effectiveness of drivers

Results and Findings

We qualitatively assessed the relationship between existing emergency preparedness among providers and the outcomes experienced during the pandemic by this relatively small group of participating providers. Respondents described substantial variation across both emergency preparedness program quality and the degree to which plans addressed EIDs, both of which were significant to their ability to respond to the pandemic. We discuss our findings below.

Emergency Preparedness Program Quality

Providers with robust programs took more strategic steps during development of those programs. These providers often relied on experienced EP professionals to conduct detailed facility-specific assessments and develop scenario-specific plans to respond to multiple hazards. In contrast, providers with less robust programs often relied on off-the-shelf templates or external consultants. Programs developed in this manner were often less specific to providers' individual circumstances and, as a result, more challenging to implement during an emergency.

Consideration of EIDs

Notably, 40% of providers who participated in discussions (12 of 30) had not addressed EIDs in their plans, while 60% (18 of 30) had done so. Approximately half of providers with EID-specific plans (8 of 18) had considered at least one airborne EID (e.g., H1N1), while the other half (10 of 18) had only planned for non-airborne EIDs (e.g., Ebola), without including considerations for the specific PPE needs related to airborne EIDs. Only one provider had developed plans anticipating staffing and supply crises that could be caused by a national PHE.

While most providers felt unprepared to respond to Covid-19 to some extent, the majority of providers, 57% (17 of 30), described their emergency preparedness program as an effective tool to support their response. Similarly, 72% of providers that had planned for EIDs (13 of 18) felt these plans were beneficial when developing their approach to respond to Covid-19.

> *"A majority of providers,67% (20 of 30) described internal IPC expertise as critical for their response. Current regulations require that hospitals and long-term care facilities have a qualified infection preventionist, although they do not explicitly require it to be a full-time role."*

Role of Emergency Preparedness Program in Response

All of the providers we spoke with found their existing emergency preparedness programs supported their response to Covid-19, particularly if their programs were comprehensive. Existing programs supported providers' ability to anticipate necessary actions during an emergency and provided the foundational support for organizing a response, including existing infrastructure for

Table 1. Provider Discussions Highlighted Key Enablers and Challenges Influencing Implementation of Response

Key Enablers for Implementation	Key Challenges Faced during Implementation
1. Leadership, culture, and governance 2. Infection prevention and control expertise 3. Local planning and coordination	1 Planning for underserved and vulnerable populations 2. Data reportimg 3. Technical assistance 4. Managing federal, state, tribal, local, and territorial guidance

This table is informed by the conceptual model in Figure 1, which provided the basis for guiding questions used during conversations with hospitals and nursing homes. Through nonstandard and informal conversations, the working group heard provider perspectives on how inputs, including existing emergency plans, influenced their approach to responding to Covid-19 and identified the top enablers and challenges. Source: The authors

internal and external communications, such as an incident command system (ICS). Furthermore, providers had established relationships through their emergency preparedness programs that they leveraged when responding to Covid-19 (e.g., with local public health and emergency response systems).

Role of Preexisting Plans for EIDs

Providers that had considered EIDs described how this existing groundwork supported relatively rapid development of a response to Covid-19. This was particularly true for providers that had addressed airborne EIDs or aerosol transmission in their plans. For example, these providers described relying on a preexisting list of potential response activities to plan for Covid-19, including creation of negative-pressure rooms and additional PPE training.

Enablers and Challenges During Implementation

Throughout conversations with providers, the working group examined 11 internal and external implementation drivers that could influence providers' ability to respond to Covid-19. During these conversations, providers emphasized three drivers that were critical as enablers of an effective response and four drivers that posed significant challenges to their ability to respond (Table 1).

The three drivers highlighted as *critical enablers* by the providers were leadership, culture, and governance; infection prevention and control expertise; and local planning and coordination.

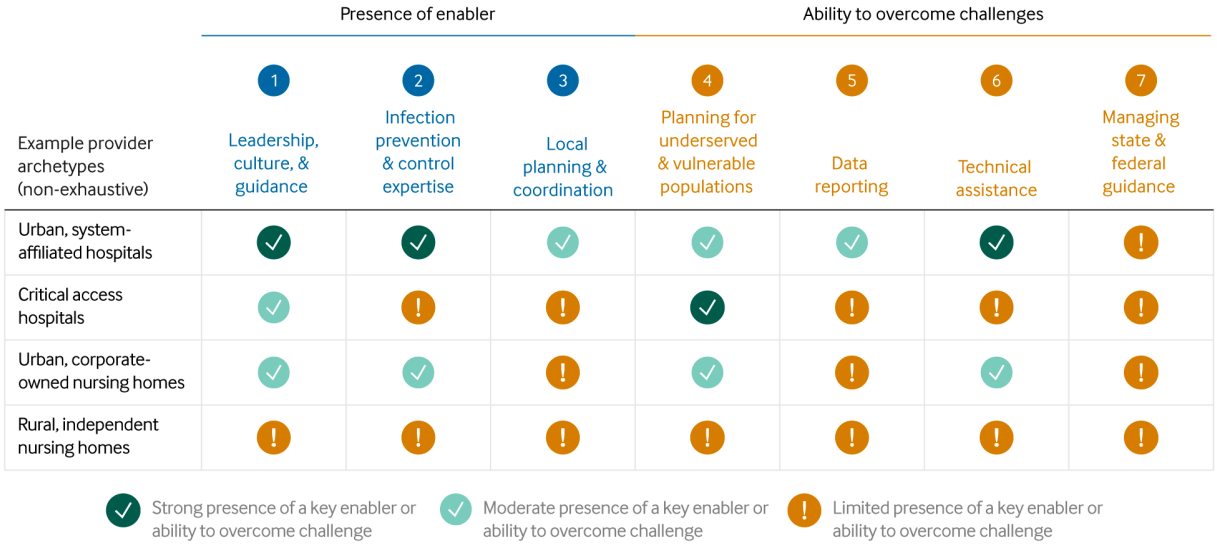
Leadership, Culture, and Governance

Nearly all providers, 93% (28 of 30) described this driver as important for their response, with three key themes across discussions. First, leadership that prioritized EP and engaged in pre-pandemic planning supported an effective response through investment in experienced staff and infrastructure. Second, providers with strong governance (e.g., through an ICS) found that it underpinned their ability to effectively organize their response and, as result, maintain staff resilience. Third, providers with an internal culture of cross-provider collaboration described relying on these relationships during the PHE to prevent supply shortages and manage space. Conversely, providers said that leadership turnover likely drove variation across providers. Those providers with leadership turnover reported facing challenges associated with lack of continuity in response, including complicating internal and external coordination. Nursing homes in particular described challenges when bringing on new leaders, for example, in familiarizing them with systems such as the National Healthcare Safety Network (NHSN) and in managing staff resilience (Figure 3).

FIGURE 3

Key Enablers and Gaps Highlighted During Provider Conversations

Following each conversation with a provider, the working group collaboratively determined which implementation drivers each provider described as most significant to their ability to respond to the pandemic overall or to manage resources. Providers highlighted seven drivers as most important for their response, including three that were critical as enablers and four that posed significant challenges to their ability to respond.



Note: Some providers may have leveraged additional drivers and/or described additional gaps while implementing response

Source: The authors

Internal Infection Prevention and Control (IPC) Expertise

A majority of providers, 67% (20 of 30) described internal IPC expertise as critical for their response. Current regulations require that hospitals and long-term care facilities have a qualified infection preventionist, although they do not explicitly require it to be a full-time role. The regulations instead focus on having programs that, for hospitals, reflect the scope and complexity of the hospital services provided, and for long-term care facilities, that are designed to provide a safe, sanitary, and comfortable environment, and to help prevent the development and transmission of communicable diseases and infections. Providers described having a dedicated, full-time infection preventionist as essential for monitoring and interpreting changing IPC guidelines, ensuring more consistent implementation of IPC practices, and adapting their facility's response when new cases were identified, particularly in nursing homes.

Local Planning and Coordination

Providers described local planning and coordination as a critical driver in their response to Covid-19. For example, 73% of providers (22 of 30) described the importance of local planning for accessing supplies. Other providers described relying on established connections to manage information and address medical surges. Providers also emphasized that local coordination during planning pre-PHE generally led to higher quality emergency preparedness programs. We note

that urban, system-affiliated hospitals were more likely to be integrated into local planning and coordinated efforts, compared to critical access hospitals (CAHs) and nursing homes, whether urban or rural. The four drivers described as posing the most significant challenges were planning for underserved and vulnerable populations; data reporting; technical assistance; and managing federal, state, tribal, local, and territorial guidance.

> *"We note that urban, system-affiliated hospitals were more likely to be integrated into local planning and coordinated efforts, compared to critical access hospitals and nursing homes, whether urban or rural."*

Planning for underserved and vulnerable populations: Providers widely described confronting challenges in continuing to meet the needs of specific populations during the PHE, although only one provider explicitly considered an underserved population in their pre-PHE emergency plans. Twelve providers (40%) described adapting their response to address needs that arose among underserved and vulnerable populations, and all 12 found these approaches critical for maintaining access to and quality of care. Providers that proactively adopted these practices broadly described preexisting engagement with underserved and vulnerable communities (e.g., existing planning protocols for serving non–English speaking pregnant population), even if not explicitly incorporated into EP plans.

Data reporting: All providers described significant challenges with the volume and logistics of data reporting, although challenges differed across provider types and between individual providers. While some providers struggled to manage disparate reporting systems, others described more fundamental challenges with data tracking. Many providers said that the time lines associated with reporting took time away from patient care, and that reporting did not benefit care delivery directly (e.g., through better infection control or the receipt of supplies). Data management practices differed substantially across states, which providers indicated could increase reporting burdens. Although most states maintained separate systems and definitions for Covid-19 data elements, some developed integrated state and federal platforms, and others used established emergency reporting requirements with which providers were already familiar.

Technical assistance: Only 25% of hospitals (4 of 16) described having received external technical assistance relevant to the PHE. Those that did primarily received it from their state departments of health or provider associations and relied on it for identifying better practices. A larger share of nursing homes received technical assistance (43%, or 6 of 14), including from Quality Improvement Organizations (QIOs), the state, or provider associations, and described mixed experiences. Differences in experiences were often driven by the relevance of topic (e.g., navigating conflicting regulations), timing (proactive versus retroactive), and effectiveness of the format (webinars versus one-on-one support).

Managing federal, state, tribal, local, and territorial (STLT) guidance: All providers described facing challenges continuously monitoring, interpreting, and applying guidance from federal or STLT officials. Given the frequency of changes and the time line for implementation,

providers described challenges with integrating guidance, particularly with respect to training staff on new IPC practices and communicating changes with patients and families.

Additional drivers of successful implementation of the facility's EP plan identified during discussions included communications, staff resilience, contingency planning, and training. Although these drivers were not identified as key enablers or key challenges, they remain important to consider for future planning.

Communications: Providers expressed that established centralized approaches for sharing information internally were helpful to ensure consistency in practices across their staff and maintain staff morale. They also found that defined channels for external communication (e.g., with the relevant department of health or community leaders) helped identify better practices and maintain community trust, although some providers struggled to implement these channels.

Staff resilience: Providers used a wide range of strategies to maintain staff resilience and agreed that these strategies were critical for supporting an effective response because they supported staff as fatigue and burnout increased.

Contingency planning: Most providers considered contingency planning as a critical element of their emergency response. Few had contingency plans specific to an EID, but those who had plans were better able to respond to changing resource needs. These providers described being able to respond more effectively to the changing situation because they had previously considered their facility's needs, likely shortages, and a process for decision-making.

Training: Few providers conducted testing exercises specifically to prepare for Covid-19, although those that did found them beneficial for identifying additional actions they should take. Few providers considered additional training specific to Covid-19 to be critical to their response and many voiced significant challenges with implementing just-in-time training for a variety of reasons, such as frequent changes in guidance and staff shortages.

Looking Ahead

The PHE and its national impact has exposed the wide variability in facilities' preparation for emergencies. While there have been frequent local emergencies including climate events and EIDs, they have been time-limited and regional in scope. With the emergence of the Covid-19 pandemic, we have experienced a national and sustained emergency that has exposed the fragility of many systems and their impact on the ability to respond to the challenges of the PHE.

> *"Providers widely described confronting challenges in continuing to meet the needs of specific populations during the PHE, although only one provider explicitly considered an underserved population in their pre-PHE emergency plans."*

Despite the advances made since CMS introduced EP requirements in 2016, providers — especially hospitals and nursing homes — face additional and new challenges to ensure they are prepared for future events. In particular, the absence of locally developed protocols has demonstrated that implementation of a customized emergency plan is critical including the training of the staff on that plan. Those providers in this study that purchased plans developed by consultants to meet the CMS Conditions of Participation (COP) requirements were not able to adapt to the unique circumstances of the current PHE. They also did not consider the unique needs of the populations they served and the connections with parts of the greater health system that had greater resources. Specifically, the plans may not be tailored to the unique facility as well as the facility may not have practiced nor knew how to implement the plan in the emergency situation. For example, providers described local planning and coordination as a critical driver in their response to Covid-19, although not all providers are included in local and regional planning, coordination, and implementation exercises or drills. Also, it will be important that local providers, such as nursing homes, be considered a critical partner in emergency planning efforts given the resource needs and roles in addressing surge capacity.

These conversations and the identified drivers and challenges also highlighted the importance of communication within the facilities, between facilities, at corporate levels, with states and federal agencies, and among federal agencies. During the PHE, we did observe that several states, health systems, and academic medical centers created collaboratives to share best practices including resources and education. It will be important for providers and state and local governments to determine how best to institutionalize such practice after the PHE ends. This should include the use of data to drive decision-making and the ability of the facility's data to be shared with local and national authorities; likewise, the ability to provide data back to the facility is crucial. It would also be important to ensure that best practices and expertise are shared within a given region, so that, for example, smaller and rural facilities could benefit from collaboration with larger hospitals in the region, including load-leveling of patients and residents in times of system stress. In addition, given the wide disparities in care exacerbated by the PHE, it has become apparent that facilities that care for specific populations need to incorporate the population's needs into their unique plan. Only one facility, a CAH, of the 30 we met with, considered that as a factor in their plan prior to the start of the PHE.

As we consider the learning from this study, we acknowledge that many entities — federal, state, and local governments, and public and private organizations — play a role in emergency preparedness. As we move forward, we will use the information from this work to inform our overall policy approach on emergency preparedness including how we survey as well as guide our strategic use of the Quality Improvement Organizations to prepare providers for future emergencies. Importantly, we will continue engaging with interested parties to ensure that the approach we take reflects the perspectives of all of the entities.

Sheila C. Blackstock, BSN, MSM, JD
Deputy Director of the Clinical Standards Group, U.S. Centers for Medicare & Medicaid Services, Baltimore, Maryland, USA

Jean D. Moody-Williams, RN, MPP
Deputy Director of the Center for Clinical Standards and Quality, U.S. Centers for Medicare & Medicaid Services, Baltimore, Maryland, USA

Lee A. Fleisher, MD
Chief Medical Officer and Director of the Center for Clinical Standards and Quality, U.S. Centers for Medicare & Medicaid Services, Baltimore Maryland, USA
Background on Federal Emergency Preparedness Regulations

Acknowledgments

The authors acknowledge the Boston Consulting Group who, under contract, developed the conceptual model and conducted the provider interviews for this study, and reviewed a prepublication draft of this article.

Disclosures: Sheila C. Blackstock, Jean D. Moody-Williams, and Lee A. Fleisher have nothing to disclose.

References

1. Barbash IJ, Kahn JM. Fostering hospital resilience — lessons from COVID-19. JAMA. 2021;326(6):693-4

2. Downar J, Seccareccia D. Palliating a pandemic: "all patients must be cared for". J Pain Symptom Manage. 2010;39(6):291-5

Infection Control & Hospital Epidemiology (2021), 1–14
doi:10.1017/ice.2021.362

Original Article

The impact of coronavirus disease 2019 (COVID-19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network

Lindsey M. Weiner-Lastinger MPH[1], Vaishnavi Pattabiraman MSc, MS, MPH[1,2], Rebecca Y. Konnor MPH[1,3], Prachi R. Patel MPH[1,3], Emily Wong MPH[1,2], Sunny Y. Xu MPH[1,3], Brittany Smith MPH[1,4], Jonathan R. Edwards MStat[1] and Margaret A. Dudeck MPH[1]

[1]Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, Atlanta, Georgia, [2]Leidos, Atlanta, Georgia, [3]CACI, Atlanta, Georgia and [4]Oak Ridge Institute of Science and Education, Oak Ridge, Tennessee

Abstract

Objectives: To determine the impact of the coronavirus disease 2019 (COVID-19) pandemic on healthcare-associated infection (HAI) incidence in US hospitals, national- and state-level standardized infection ratios (SIRs) were calculated for each quarter in 2020 and compared to those from 2019.

Methods: Central–line–associated bloodstream infections (CLABSIs), catheter-associated urinary tract infections (CAUTIs), ventilator-associated events (VAEs), select surgical site infections, and *Clostridioides difficile* and methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia laboratory-identified events reported to the National Healthcare Safety Network for 2019 and 2020 by acute-care hospitals were analyzed. SIRs were calculated for each HAI and quarter by dividing the number of reported infections by the number of predicted infections, calculated using 2015 national baseline data. Percentage changes between 2019 and 2020 SIRs were calculated. Supporting analyses, such as an assessment of device utilization in 2020 compared to 2019, were also performed.

Results: Significant increases in the national SIRs for CLABSI, CAUTI, VAE, and MRSA bacteremia were observed in 2020. Changes in the SIR varied by quarter and state. The largest increase was observed for CLABSI, and significant increases in VAE incidence and ventilator utilization were seen across all 4 quarters of 2020.

Conclusions: This report provides a national view of the increases in HAI incidence in 2020. These data highlight the need to return to conventional infection prevention and control practices and build resiliency in these programs to withstand future pandemics.

(Received 12 July 2021; accepted 15 July 2021)

As the coronavirus disease 2019 (COVID-19) pandemic swept through the United States, regions experienced peak cases and hospitalizations at various times in 2020.[1] The pandemic response placed burden on acute-care hospitals (ACHs), which may have altered staffing practices, increased critical care capacity, and modified use of personal protective equipment (PPE).[2,3] In the early stages of the pandemic, little was known about how COVID-19 hospitalizations would affect the incidence of healthcare-associated infections (HAIs). Single-site studies observed early signs of increases in select HAIs during the spring of 2020.[4–6] Others have studied the occurrence of secondary infections in COVID-19 patients.[7–9] Additionally, a report from the National Healthcare Safety Network (NHSN) found significant increases in central-line–associated bloodstream infections (CLABSIs) during the early months of the pandemic.[10]

The NHSN is the nation's largest HAI surveillance system and is used by nearly all US hospitals to fulfill local, state, or federal HAI reporting requirements. NHSN data are used to measure progress toward prevention goals; this progress is assessed using an observed-to-predicted ratio called the standardized infection ratio (SIR).[11] Nationally, from 2015 to 2019, there have been consistent, significant reductions in the SIRs for CLABSIs, catheter-associated urinary tract infections (CAUTIs), and *Clostridioides difficile* infection (CDI) laboratory-identified (LabID) events.[12–14] Some significant year-to-year decreases have also been observed in methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia LabID events since 2010.[12,13,15] Conversely, there has been minimal change in the occurrence of ventilator-associated events (VAEs).[12] Given the potential for COVID-19 response activities to impact HAI prevention and surveillance, the NHSN team analyzed national and state SIRs to identify potential changes in HAI incidence between 2019 and 2020.

Author for correspondence: Lindsey Lastinger, E-mail: LLastinger@cdc.gov
Cite this article: Weiner-Lastinger LM, *et al.* (2021). The impact of coronavirus disease 2019 (COVID-19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. *Infection Control & Hospital Epidemiology*, https://doi.org/10.1017/ice.2021.362

Methods

CLABSIs, CAUTIs, VAEs, select surgical site infections (SSIs), MRSA LabID, and CDI LabID events that occurred in ACHs between 2019 and 2020 and were reported to the NHSN Patient Safety Component as of April 1, 2021, were included in this report. Standard surveillance definitions and exclusion rules are described elsewhere for each HAI type.[16]

CLABSIs and CAUTIs included in this analysis were those in scope for the Centers for Medicare and Medicaid Services (CMS) Hospital-Acquired Conditions Reduction Program (HACRP).[17] The HACRP includes infections that occurred in adult and pediatric intensive care units (ICUs), neonatal ICUs (CLABSI only), and adult and pediatric medical, surgical, and medical–surgical wards. VAE data encompass all events classified as ventilator-associated condition (VAC), infection-related ventilator-associated condition (IVAC), and possible ventilator-associated pneumonia (PVAP). VAE surveillance is not included in the CMS HACRP, but events reported voluntarily or due to a state mandate from adult ICUs and adult wards were included.

The SSIs included were a subset of those required under the HACRP and classified as deep incisional or organ-space infections following adult inpatient colon or abdominal hysterectomy procedures, detected during the same admission as the procedure or readmission to the same hospital. LabID event surveillance for both organisms is conducted for facility-wide inpatient (FacWideIN) locations and is required for participation in the HACRP. Hospitals that reported no FacWideIN patient days or admissions for a quarter were excluded from the LabID analysis for that quarter.

Temporal comparisons in HAI incidence between 2019 and 2020 were analyzed using national and state SIRs, calculated for each calendar quarter by dividing the number of reported infections by the number of predicted infections, and they were represented by the relative change in magnitude. The number of predicted infections was obtained using regression models created from the 2015 national baseline data with appropriate risk adjustment for the respective HAI. The complete risk adjustment methodology and criteria used for SIR numerators are summarized in the NHSN SIR Guide.[11] SIRs below 1 indicate fewer infections observed than predicted, signaling reductions. Likewise, SIRs above 1 indicate more infections were observed than predicted, signaling increases.

The percentage change between pairs of 2019 and 2020 quarterly SIRs was calculated as follows:

$$\frac{\text{2020 SIR} - \text{2019 SIR}}{\text{2019 SIR}} \times 100$$

The 95% confidence intervals around the percentage change were calculated, and a 2-tailed $P \leq .05$ calculated by mid-P exact test was considered statistically significant. Percentile distributions of the 2020 SIRs were calculated using data from hospitals with at least 1 predicted HAI.

To reduce potential inclusion bias, SIR analyses were restricted to hospitals with complete surveillance data for both quarters in each pair of quarterly comparisons and for the same locations when applicable (ie, device-associated infections). Given the nature and impact of the pandemic on ACHs, the CMS issued an HAI reporting exception for 2020-Q1–2020-Q2, allowing hospitals to temporarily pause reporting to the NHSN.[18] The impact of this exception was assessed for each HAI type by calculating the percentage of hospitals in 2019-Q1–2019-Q2 that also reported HAI data for 2020-Q1–2020-Q2.

The CDC previously identified the states with a high number of hospitalized COVID-19 patients between April 1 and July 14, 2020.[1] To determine the impact of COVID-19 on HAI incidence in these states, the percentage change in state-level Q2 and Q3 SIRs were calculated for CLABSI, CAUTI, VAE, and MRSA bacteremia. For reference, supplemental data tables and interactive maps are provided on the NHSN website (https://www.cdc.gov/nhsn/datastat/index.html) that provide a comparison between 2019 and 2020 quarterly SIRs for all states and all applicable HAI types, as well as a comparison of location-stratified national SIRs for DA infections.

Additional supporting analyses were performed to help inform the changes in SIRs, including a review of the length-of-stay (from patient admission to discharge date), time to event (from device insertion to infection date), and device utilization measured by the standardized utilization ratio (SUR). SURs were calculated by dividing the number of reported device days by the number of predicted device days, based on 2015 national baseline data.[19] In addition, the inpatient and outpatient quarterly community-onset MRSA bacteremia prevalence rates were reviewed from 2019-Q1 to 2020-Q4.[16] The FacWideIN community-onset prevalence rate was calculated per 1,000 admissions, and the outpatient community-onset prevalence rate was calculated per 10,000 encounters in emergency departments and 24-hour observation units. Data were analyzed using SAS version 9.4 software (SAS Institute, Cary. NC).

Results

Most ACHs reporting 2019 HAI surveillance data continued to report data throughout 2020 (Table 1). Between 86% and 88% of hospitals that conducted surveillance for CLABSI, CAUTI, MRSA bacteremia, or CDI during 2019-Q1 or 2019-Q2 also reported surveillance data for 2020-Q1 or 2020-Q2. Larger declines in the number of reporting hospitals were seen for VAE (22 – 25% drop) and SSI (25%–36% drop) surveillance. Reporting levels during the second half of 2020 were close to those of the prepandemic period for most HAIs.

CLABSI

Despite an initial 12% decrease in the 2020-Q1 CLABSI SIR compared to 2019-Q1, the SIRs in 2020-Q2–2020-Q4 were significantly higher than those in 2019 (Tables 2–5). The largest year-to-year magnitudes of increase (46%–47%) occurred during Q3 and Q4, with the highest CLABSI SIR of 1.01 occurring during 2020-Q3. The increases in the CLABSI SIRs were driven by larger SIR numerators in 2020; for example, in 2020-Q3, there were 4,460 CLABSIs reported, representing a 53% increase compared to the 2,911 events reported from the same hospitals and locations in 2019-Q3. During the same time, the number of predicted CLABSIs increased by 5% (data not shown).

The change in CLABSI SIR varied by state and quarter (Table 6). Arizona's CLABSI SIR was 149% higher in 2020-Q2 than 2019-Q2, and the SIR for Massachusetts doubled in 2020-Q2. Louisiana and Michigan experienced statistically significant increases of >70% in their Q2 CLABSI SIRs. Although New Jersey and New York reported nonsignificant changes in their CLABSI SIRs in 2020-Q2, both states had a substantial decline (61% and 40%, respectively) in the number of reporting hospitals in 2020-Q2 compared to 2019.[12] The number of reporting

Table 1. Number of Hospitals Reporting Healthcare-Associated Infection (HAI) Data to NHSN for 2020 Q1 and 2020 Q2 When a Standard Exception Was in Place for the Centers for Medicare and Medicaid (CMS) Hospital-Acquired Conditions Reduction Program

	2020 Quarter 1			2020 Quarter 2		
HAI Type	No. of Hospitals Reporting in Both 2020 Q1 and 2019 Q1	Total Hospitals Reporting in 2019 Q1	Decrease in Reporting Hospitals, %[a]	No. of Hospitals Reporting in Both 2020 Q2 and 2019 Q2	Total Hospitals Reporting in 2019 Q2	Decrease in Reporting Hospitals, %[a]
CLABSI	3,130	3,567	−12.3	3,057	3,563	−14.2
CAUTI	3,129	3,566	−12.3	3,049	3,561	−14.4
VAE[b]	1,402	1,807	−22.4	1,332	1,783	−25.3
SSI, colon surgery	2,518	3,358	−25.0	2,443	3,351	−27.1
SSI, abdominal hysterectomy	2,269	3,345	−32.2	2,124	3,338	−36.4
Laboratory-identified MRSA bacteremia	3,176	3,626	−12.4	3,106	3,622	−14.2
Laboratory-identified CDI	3,190	3,631	−12.1	3,113	3,628	−14.2

Note: NHSN, National Healthcare Safety Network; CLABSI, central-line–associated bloodstream infection; CAUTI, catheter-associated urinary tract infection; VAE, ventilator-associated event; SSI, surgical site infection; MRSA, methicillin-resistant *Staphylococcus aureus*; CDI, *Clostridioides difficile* infection; CMS, Centers for Medicare and Medicaid Services.
[a]Calculated as follows: [(hospitals reporting in 2020 − hospitals reporting in 2019) ÷ hospitals reporting in 2019] × 100.
[b]VAE data are not included in the requirements for the CMS Hospital-Acquired Conditions Reduction Program.

hospitals returned to prepandemic levels in 2020-Q3 for both states, and New Jersey's 2020-Q3 CLABSI SIR (0.86) was 59% higher than the SIR from 2019-Q3 (0.54). Arizona, Georgia, and Florida observed substantial (97%–148%) increases in their 2020-Q3 state SIRs compared to 2019-Q3.

CAUTI

The national CAUTI SIR steadily increased from 2020-Q1 to 2020-Q4, ranging from 0.59 in Q1 to 0.82 in Q4 (Tables 2–5). Significant increases in the 2020 CAUTI SIR compared to 2019 were observed in Q3 and Q4, with the Q4 SIR increasing by 19%, from 0.69 in 2019 to 0.82 in 2020. The increase in the Q4 CAUTI SIR was driven by a 36% increase in the number of infections, from 3,142 in 2019-Q4 to 4,258 in 2020-Q4. The number of predicted CAUTIs increased by 15% during this period. At the state level, significant increases in the Q3 CAUTI SIR were reported by Arizona (69%) and California (24%) (Table 7). Georgia, Massachusetts, Michigan, and New Jersey each observed >20% increase in their state's CAUTI SIR for 2020-Q3 compared to 2019-Q3, although these increases were not statistically significant.

VAE

Between 1,332 and 1,496 hospitals reported VAE data to NHSN for each quarter in 2019 and 2020 (Tables 2–5). The 2020-Q2 and 2020-Q3 national VAE SIRs were 1.31 and 1.29. Preliminary Q4 data indicated an even higher SIR; 10,108 and 7,296 VAEs were reported and predicted respectively, resulting in a 2020-Q4 SIR of 1.39. Significant increases in the national VAE SIRs were observed in all 4 quarters of 2020 compared to 2019, with the largest increase of 45% occurring in Q4. Many states experienced significant increases in their VAE SIRs in 2020-Q2 and 2020-Q3, such as 88% and 91% increases in the Illinois and New York SIRs for Q2, and an 87% increase in the Georgia SIR for Q3 (Table 8). The median hospital-level VAE SIR for 2020-Q2, 2020-Q3, and 2020-Q4 were all above 1.0, with the highest median SIR of 1.30 occurring in Q4.

All Device-Associated infections

Overall, the national distributions of time to infection for CLABSI and CAUTI, or length-of-stay for patients with any device-associated infection were significantly different in 2020 compared to 2019 (not shown). The median time to infection for ICU CLABSIs increased from 8 days in 2019 to 10 days in 2020. The median length of stay for an ICU patient with a CAUTI increased from 17 days in 2019 to 20 days in 2020, and for ICU VAEs, it increased from 17 days in 2019 to 19 days in 2020.

Compared to 2019, central-line and urinary catheter usage were significantly higher in 2020-Q2–2020-Q4, and ventilator usage was significantly higher in all 4 quarters of 2020 (not shown). The central-line SUR increased by 7%, from 0.85 in 2019-Q2–2019-Q4 to 0.91 to 2020-Q2–2020-Q4. The urinary catheter SUR increased by 9%, from 0.81 in 2019-Q2–2019-Q4 to 0.88 in 2020-Q2–2020-Q4. The quarterly ventilator SURs were 25%–31% higher in 2020-Q2–2020-Q4, with the Q4 SUR increasing from 0.94 in 2019-Q4 to 1.23 in 2020-Q4.

MRSA bacteremia LabID

The national SIRs for MRSA bacteremia were significantly higher in 2020-Q2, 2020-Q3, and 2020-Q4 compared to 2019, with the 2020 SIRs ranging from 0.77 in Q1 to 1.07 in Q4 (Tables 2–5).

During 2020-Q2, there was a 15% (5 million) reduction in national FacWideIN patient days, an 18% (1.4 million) reduction in admissions, and a 34% (10 million) reduction in outpatient encounters (Appendix A1–A2 online). These decreases in denominators led to increases in the 2020-Q2 inpatient and outpatient community-onset MRSA bacteremia prevalence rates compared to 2019-Q2; there was a small increase in the inpatient community-onset prevalence rate (0.53 vs 0.59 events per 1,000 admissions) and a large increase in the outpatient community-onset prevalence rate (3.66 vs 5.47 events per 10,000 encounters).

The national MRSA bacteremia SIR was 0.92 in 2020-Q2, a 12% increase from 2019-Q2. This increase was largely driven by the decline in patient days in 2020-Q2, which contributed to a 10%

Table 2. National Healthcare-Associated Infection (HAI) Standardized Infection Ratios (SIRs) for Acute-Care Hospitals, January–March 2020 (Q1)

		2020 Q1			Q1 SIR				Percentile Distribution of 2020 Q1 Hospital-Level SIRs[e]					
HAI Type	No. of Hospitals[a]	No. of HAIs Reported	No. of HAIs Predicted	Device Days, Procedures, or Patient Days[b]	2020	2019	% Change in SIR[c]	95% CI Around SIR % Change	0%	25%	50%	75%	90%	100%
CLABSI[f]	3,130	2,236	3,738.12	3,725,983	0.60	0.68	−11.8[d]	(−17.2 to −7.3)	0.00	0.00	0.49	0.87	1.33	4.51
CAUTI[g]	3,129	2,449	4,152.83	3,562,137	0.59	0.75	−21.3[d]	(−33.2 to −20.0)	0.00	0.00	0.48	0.85	1.39	4.34
VAE[h]	1,402	5,642	5,239.51	756,925	1.08	0.97	11.3[d]	(6.5–14.9)	0.00	0.00	0.83	1.86	2.82	5.87
SSI, colon surgery[i]	2,518	1,437	1,802.05	71,170	0.80	0.88	−9.1[d]	(−15.5 to −2.6)	0.00	0.00	0.75	1.35	2.01	4.41
SSI, abdominal hysterectomy[i]	2,269	336	423.36	64,158	0.79	0.94	−16.0[d]	(−26.6 to −2.2)	0.00	0.00	0.69	0.91	1.90	3.75
Laboratory-identified MRSA bacteremia[j]	3,176	1,689	2,205.32	34,345,939	0.77	0.83	−7.2[d]	(−13.9 to −1.7)	0.00	0.00	0.69	1.11	1.75	6.59
Laboratory-identified CDI[k]	3,190	9,910	19,231.71	31,915,519	0.52	0.63	−17.5[d]	(−20.3 to −16.0)	0.00	0.17	0.43	0.73	1.09	3.77

Note. CI, confidence interval; CLABSI, central-line–associated bloodstream infection; CAUTI, catheter-associated urinary tract infection; VAE, ventilator-associated event; SSI, surgical site infection; MRSA, methicillin-resistant *Staphylococcus aureus*; CDI, *Clostridioides difficile* infection; NHSN, National Healthcare Safety Network; CMS, Centers for Medicare and Medicaid Services; ICU, intensive care unit.

[a]The number of acute-care hospitals that reported complete HAI surveillance data for both quarters in the comparison.

[b]Device days are shown for CLABSI, CAUTI, and VAE. Procedure counts are shown for SSI. Patient days are shown for laboratory-identified events.

[c]% change was calculated as follows: [(2020 SIR − 2019 SIR) ÷ 2019 SIR] × 100.

[d]Statistical significance based on 2-tailed $P \leq .05$, reflected in the relative % change in magnitude.

[e]Percentile distribution of hospital-level SIRs includes only those hospitals that had at least 1 predicted HAI.

[f]CLABSI SIRs were calculated using data from adult and pediatric ICUs, neonatal ICUs, and adult and pediatric medical, surgical, and medical–surgical wards.

[g]CAUTI SIRs were calculated using data from adult and pediatric ICUs, and adult and pediatric medical, surgical, and medical–surgical wards.

[h]VAE SIRs were calculated using data from adult ICUs and wards.

[i]SSIs included are those classified as deep incisional or organ-space infections following adult inpatient procedures that were detected during the same admission as the surgical procedure or upon readmission to the same hospital. The NHSN Complex Admission–Readmission model was used for SIR calculations.

[j]MRSA bacteremia SIRs were calculated using data from all inpatient locations in the hospital (facility-wide inpatient, or FacWideIN) except inpatient rehabilitation and inpatient psychiatric units certified by the CMS. Reported and predicted HAIs were limited to hospital-onset events that were identified in an inpatient location on the fourth day (or later) after admission to the facility.

[k]CDI SIRs were calculated using data from all inpatient locations in the hospital (FacWideIN) except neonatal ICUs, newborn nurseries, and inpatient rehabilitation and inpatient psychiatric units certified by the CMS. Reported and predicted HAIs were limited to hospital-onset incident events that were identified in an inpatient location on the fourth day (or later) after admission to the facility without a prior positive CDI specimen in the previous 56 days.

Table 3. National Healthcare-Associated Infection (HAI) Standardized Infection Ratios (SIRs) for Acute-Care Hospitals, April–June 2020 (Q2)

		2020 Q2			Q2 SIR				Percentile Distribution of 2020 Q2 Hospital-Level SIRs[e]					
HAI Type	No. of Hospitals[a]	No. of HAIs Reported	No. of HAIs Predicted	Device Days, Procedures, or Patient Days[b]	2020	2019	% Change[c] in SIR	95% CI Around SIR % Change	0%	25%	50%	75%	90%	100%
CLABSI[f]	3,057	2,963	3,394.90	3,358,039	0.87	0.68	27.9[d]	(21.5–35.2)	0.00	0.00	0.68	1.19	1.94	6.54
CAUTI[g]	3,049	2,590	3,831.88	3,266,836	0.68	0.71	−4.2	(−9.9 to 0.2)	0.00	0.00	0.58	0.97	1.60	4.86
VAE[h]	1,332	7,191	5,495.34	800,017	1.31	0.98	33.7[d]	(28.5–38.5)	0.00	0.00	1.18	2.33	3.59	12.55
SSI, colon surgery[i]	2,443	1,272	1,462.82	55,790	0.87	0.88	−1.1	(−8.1 to 6.4)	0.00	0.00	0.78	1.41	2.00	4.90
SSI, abdominal hysterectomy[i]	2,124	276	303.54	44,882	0.91	0.99	−8.1	(−20.6 to 6.9)	0.00	0.00	0.89	1.53	1.78	2.99
Laboratory-identified MRSA bacteremia[j]	3,106	1,729	1,881.91	28,488,801	0.92	0.82	12.2[d]	(5.0–20.0)	0.00	0.00	0.75	1.24	1.84	6.77
Laboratory-identified CDI[k]	3,113	8,141	15,701.11	26,107,710	0.52	0.58	−10.3[d]	(−13.8 to −8.7)	0.00	0.15	0.42	0.74	1.09	6.13

Note. CI, confidence interval; CLABSI, central-line–associated bloodstream infection; CAUTI, catheter-associated urinary tract infection; VAE, ventilator-associated event; SSI, surgical site infection; MRSA, methicillin-resistant *Staphylococcus aureus*; CDI, *Clostridioides difficile* infection. NHSN, National Healthcare Safety Network; CMS, Centers for Medicare and Medicaid Services; ICU, intensive care unit.

[a]The number of acute-care hospitals that reported complete HAI surveillance data for both quarters in the comparison.

[b]Device days are shown for CLABSI, CAUTI, and VAE. Procedure counts are shown for SSI. Patient days are shown for laboratory-identified events.

[c]% change was calculated as follows: [(2020 SIR − 2019 SIR) ÷ 2019 SIR] × 100.

[d]Statistical significance based on 2-tailed $P \leq .05$, reflected in the relative % change in magnitude.

[e]Percentile distribution of hospital-level SIRs includes only those hospitals that had at least 1 predicted HAI.

[f]CLABSI SIRs were calculated using data from adult and pediatric ICUs, neonatal ICUs, and adult and pediatric medical, surgical, and medical–surgical wards.

[g]CAUTI SIRs were calculated using data from adult and pediatric ICUs, and adult and pediatric medical, surgical, and medical–surgical wards.

[h]VAE SIRs were calculated using data from adult ICUs and wards.

[i]SSIs included are those classified as deep incisional or organ-space infections following adult inpatient procedures that were detected during the same admission as the surgical procedure or upon readmission to the same hospital. The NHSN Complex Admission–Readmission model was used for SIR calculations.

[j]MRSA bacteremia SIRs were calculated using data from all inpatient locations in the hospital (facility-wide inpatient, or FacWideIN) except inpatient rehabilitation and inpatient psychiatric units certified by the CMS. Reported and predicted HAIs were limited to hospital-onset events that were identified in an inpatient location on the fourth day (or later) after admission to the facility.

[k]CDI SIRs were calculated using data from all inpatient locations in the hospital (FacWideIN) except neonatal ICUs, newborn nurseries, and inpatient rehabilitation and inpatient psychiatric units certified by CMS. Reported and predicted HAIs were limited to hospital-onset incident events that were identified in an inpatient location on the fourth day (or later) after admission to the facility without a prior positive CDI specimen in the previous 56 days.

Table 4. National Healthcare-Associated Infection (HAI) Standardized Infection Ratios (SIRs) for Acute-Care Hospitals, July–September 2020 (Q3)

		2020 Q3			Q3 SIR				Percentile Distribution of 2020 Q3 Hospital-Level SIRs[e]					
HAI Type	No. of Hospitals[a]	No. of HAIs Reported	No. of HAIs Predicted	Device Days, Procedures, or Patient Days[b]	2020	2019	% Change[c] in SIR	95% CI Around SIR % Change	0%	25%	50%	75%	90%	100%
CLABSI[f]	3,451	4,460	4,415.75	4,388,693	1.01	0.69	46.4[d]	(39.4–53.1)	0.00	0.41	0.81	1.46	2.31	8.40
CAUTI[g]	3,448	4,034	5,025.69	4,263,776	0.80	0.71	12.7[d]	(7.9–18.4)	0.00	0.22	0.69	1.18	1.86	7.00
VAE[h]	1,496	8,521	6,604.97	954,394	1.29	1.00	29.0[d]	(24.8–33.8)	0.00	0.00	1.13	2.17	3.31	7.87
SSI, colon surgery[i]	2,769	1,729	2,127.12	80,372	0.81	0.87	−6.9[d]	(−12.6 to −0.3)	0.00	0.00	0.68	1.29	1.99	4.75
SSI, abdominal hysterectomy[i]	2,476	486	488.18	71,473	1.00	1.05	−4.8	(−16.2 to 6.7)	0.00	0.00	0.84	1.39	2.05	3.94
Laboratory-identified MRSA bacteremia[j]	3,512	2,482	2,539.42	38,333,911	0.98	0.80	22.5[d]	(14.6–29.0)	0.00	0.29	0.78	1.43	2.08	7.35
Laboratory-identified CDI[k]	3,511	10,875	21,087.49	35,313,701	0.52	0.57	−8.8[d]	(−11.4 to −6.8)	0.00	0.16	0.44	0.73	1.07	8.16

Note. CI, confidence interval; CLABSI, central-line–associated bloodstream infection; CAUTI, catheter-associated urinary tract infection; VAE, ventilator-associated event; SSI, surgical site infection; MRSA, methicillin-resistant *Staphylococcus aureus*; CDI, *Clostridioides difficile* infection; NHSN, National Healthcare Safety Network; CMS, Centers for Medicare and Medicaid Services; ICU, intensive care unit.

[a]The number of acute-care hospitals that reported complete HAI surveillance data for both quarters in the comparison.

[b]Device days are shown for CLABSI, CAUTI, and VAE. Procedure counts are shown for SSI. Patient days are shown for laboratory-identified events.

[c]% change was calculated as follows: [(2020 SIR − 2019 SIR) ÷ 2019 SIR] × 100.

[d]Statistical significance based on 2-tailed $P \leq .05$, reflected in the relative % change in magnitude.

[e]Percentile distribution of hospital-level SIRs includes only those hospitals that had at least 1 predicted HAI.

[f]CLABSI SIRs were calculated using data from adult and pediatric ICUs, neonatal ICUs, and adult and pediatric medical, surgical, and medical–surgical wards.

[g]CAUTI SIRs were calculated using data from adult and pediatric ICUs, and adult and pediatric medical, surgical, and medical–surgical wards.

[h]VAE SIRs were calculated using data from adult ICUs and wards.

[i]SSIs included are those classified as deep incisional or organ-space infections following adult inpatient procedures that were detected during the same admission as the surgical procedure or upon readmission to the same hospital. NHSN Complex Admission–Readmission model was used for SIR calculations.

[j]MRSA bacteremia SIRs were calculated using data from all inpatient locations in the hospital (facility-wide inpatient, or FacWideIN) except inpatient rehabilitation and inpatient psychiatric units certified by the CMS. Reported and predicted HAIs were limited to hospital-onset events that were identified in an inpatient location on the fourth day (or later) after admission to the facility.

[k]CDI SIRs were calculated using data from all inpatient locations in the hospital (FacWideIN) except neonatal ICUs, newborn nurseries, and inpatient rehabilitation and inpatient psychiatric units certified by CMS. Reported and predicted HAIs were limited to hospital-onset incident events that were identified in an inpatient location on the fourth day (or later) after admission to the facility without a prior positive CDI specimen in the previous 56 days.

Table 5. Preliminary National Healthcare-Associated Infection (HAI) Standardized Infection Ratios (SIRs) for Acute-Care Hospitals, October–December 2020 (Q4)

		2020 Q4			Q4 SIR				Percentile Distribution of 2020 Q4 Hospital-Level SIRs[e]					
HAI Type	No. of Hospitals[a]	No. of HAIs Reported	No. of HAIs Predicted	Device Days, Procedures, or Patient Days[b]	2020	2019	% Change[c] in SIR	95% CI Around SIR % Change	0%	25%	50%	75%	90%	100%
CLABSI[f]	3,259	4,371	4,498.95	4,476,688	0.97	0.66	47.0[d]	(39.5–53.6)	0.00	0.34	0.81	1.40	2.05	6.48
CAUTI[g]	3,256	4,258	5,205.82	4,424,667	0.82	0.69	18.8[d]	(12.9–23.8)	0.00	0.22	0.71	1.24	1.85	7.41
VAE[h]	1,438	10,108	7,296.11	1,061,907	1.39	0.96	44.8[d]	(38.9–48.7)	0.00	0.00	1.30	2.51	3.78	12.20
SSI, colon surgery[i]	2,594	1,469	1,899.78	72,700	0.77	0.84	−8.3[d]	(−13.6 to −0.6)	0.00	0.00	0.66	1.15	1.79	3.79
SSI, abdominal hysterectomy[i]	2,322	400	464.40	69,145	0.86	0.99	−13.1[d]	(−23.4 to −0.8)	0.00	0.00	0.74	0.96	1.58	7.04
Laboratory-identified MRSA bacteremia[j]	3,296	2,715	2,537.64	38,700,892	1.07	0.80	33.8[d]	(25.6–41.1)	0.00	0.39	0.80	1.47	2.28	7.82
Laboratory-identified CDI[k]	3,299	10,987	21,139.54	35,954,158	0.52	0.55	−5.5[d]	(−8.0 to −3.1)	0.00	0.16	0.43	0.72	1.07	9.25

Note. CI, confidence interval; CLABSI, central-line–associated bloodstream infection; CAUTI, catheter-associated urinary tract infection; VAE, ventilator-associated event; SSI, surgical site infection; MRSA, methicillin-resistant *Staphylococcus aureus*; CDI, *Clostridioides difficile* infection; ICU, intensive care unit; CMS, Centers for Medicare and Medicaid Services; NHSN, National Healthcare Safety Network.

[a]The number of acute-care hospitals that reported complete HAI surveillance data for both quarters in the comparison.

[b]Device days are shown for CLABSI, CAUTI, and VAE. Procedure counts are shown for SSI. Patient days are shown for laboratory-identified events.

[c]% change was calculated as follows: [(2020 SIR − 2019 SIR) ÷ 2019 SIR] × 100.

[d]Statistical significance based on 2-tailed $P \leq .05$, reflected in the relative % change in magnitude.

[e]Percentile distribution of hospital-level SIRs includes only those hospitals that had at least 1 predicted HAI.

[f]CLABSI SIRs were calculated using data from adult and pediatric ICUs, neonatal ICUs, and adult and pediatric medical, surgical, and medical–surgical wards.

[g]CAUTI SIRs were calculated using data from adult and pediatric ICUs, and adult and pediatric medical, surgical, and medical–surgical wards.

[h]VAE SIRs were calculated using data from adult ICUs and wards.

[i]SSIs included are those classified as deep incisional or organ-space infections following adult inpatient procedures that were detected during the same admission as the surgical procedure or upon readmission to the same hospital. The NHSN Complex Admission–Readmission model was used for SIR calculations.

[j]MRSA bacteremia SIRs were calculated using data from all inpatient locations in the hospital (facility-wide inpatient, or FacWideIN) except inpatient rehabilitation and inpatient psychiatric units certified by the CMS. Reported and predicted HAIs were limited to hospital-onset events that were identified in an inpatient location on the fourth day (or later) after admission to the facility.

[k]CDI SIRs were calculated using data from all inpatient locations in the hospital (FacWideIN) except neonatal ICUs, newborn nurseries, and inpatient rehabilitation and inpatient psychiatric units certified by the CMS. Reported and predicted HAIs were limited to hospital-onset incident events that were identified in an inpatient location on the fourth day (or later) after admission to the facility without a prior positive CDI specimen in the previous 56 days.

Table 6. 2020 Q2 and Q3 Central-Line–Associated Bloodstream Infection (CLABSI)[a] Standardized Infection Ratios (SIRs) for Acute-Care Hospitals Compared to 2019 for Select States

	2020 Q2 vs 2019 Q2							2020 Q3 vs 2019 Q3						
State[b]	No. of Hospitals[c]	2020 Q2 No. of CLABSIs	2020 Q2 No. of Predicted CLABSIs	2020 Q2 SIR	2019 Q2 SIR	% Change[d] in SIR	95% CI Around SIR % Change	No. of Hospitals[c]	2020 Q3 No. of CLABSIs	2020 Q3 No. of Predicted CLABSIs	2020 Q3 SIR	2019 Q3 SIR	% Change[d] in SIR	95% CI Around SIR % Change
Arizona	59	80	82.63	0.97	0.39	148.7[e]	(64.6–275.6)	59	105	92.20	1.14	0.46	147.8[e]	(72.5–269.2)
California	300	309	358.57	0.86	0.61	41.0[e]	(18.5–66.6)	323	536	436.18	1.23	0.70	75.7[e]	(51.9–102.8)
Florida	189	166	241.80	0.69	0.72	−4.2	(−22.0 to 18.1)	207	381	312.59	1.22	0.62	96.8[e]	(65.7–137.0)
Georgia	100	131	155.77	0.84	0.59	42.4[e]	(9.4–86.5)	103	238	172.12	1.38	0.68	102.9[e]	(61.7–156.6)
Illinois	111	129	126.73	1.02	0.69	47.8[e]	(12.4–91.9)	129	111	166.12	0.67	0.68	−1.5	(−23.9 to 28.7)
Louisiana	65	47	39.87	1.18	0.69	71.0[e]	(7.9–174.3)	85	101	69.75	1.45	0.89	62.9[e]	(18.4–125.6)
Massachusetts	59	109	87.77	1.24	0.62	100.0[e]	(45.1–181.7)	65	81	95.71	0.85	0.63	34.9	(−3.9 to 86.7)
Michigan	76	119	91.17	1.31	0.75	74.7[e]	(29.6–136.3)	94	111	130.22	0.85	0.64	32.8[e]	(0.1–77.2)
New Jersey	28	37	32.93	1.12	0.81	38.3	(−18.1 to 137.8)	67	76	88.38	0.86	0.54	59.3[e]	(10.7–127.9)
New York	100	73	121.75	0.60	0.61	−1.6	(−29.4 to 34.9)	168	249	285.50	0.87	0.77	13.0	(−5.3 to 35.6)
Pennsylvania	156	222	215.55	1.03	0.77	33.8[e]	(10.4–64.3)	155	197	234.26	0.84	0.80	5.0	(−13.7 to 29.2)
Texas	302	242	305.15	0.80	0.73	9.6	(−8.4 to 31.1)	322	487	395.20	1.23	0.73	68.5[e]	(45.8–97.8)

Note. CI, confidence interval; CDC, Centers for Disease Control and Prevention; NHSN, National Healthcare Safety Network; ICU, intensive care unit.
[a]SIRs were calculated using data from adult and pediatric ICUs, neonatal ICUs, and adult and pediatric medical, surgical, and medical–surgical wards.
[b]Quarterly CLABSI SIRs are available for all eligible states and quarters in the Supplementary Tables (online). The states shown in this table were identified by the CDC as having a high number of hospitalized COVID-19 patients between April 1, 2020, and July 14, 2020.[1]
[c]Hospitals reporting complete CLABSI surveillance data to the NHSN for the same location for both quarters in the comparison.
[d]% change was calculated as follows: [(2020 SIR − 2019 SIR) ÷ 2019 SIR] × 100.
[e]Statistical significance based on 2-tailed $P \leq .05$, reflected in the relative % change in magnitude.

Table 7. 2020 Q2 and Q3 Catheter-Associated Urinary Tract Infection (CAUTI)[a] Standardized Infection Ratios (SIRs) for Acute-Care Hospitals Compared to 2019 for Select States

	2020 Q2 vs 2019 Q2							2020 Q3 vs 2019 Q3						
State[b]	No. of Hospitals[c]	2020 Q2 No. of CAUTIs	2020 Q2 No. of Predicted CAUTIs	2020 Q2 SIR	2019 Q2 SIR	% Change[d] in SIR	95% CI Around SIR % Change	No. of Hospitals[c]	2020 Q3 No. of CAUTIs	2020 Q3 No. of Predicted CAUTIs	2020 Q3 SIR	2019 Q3 SIR	% Change[d] in SIR	95% CI Around SIR % Change
Arizona	61	50	81.37	0.61	0.37	64.9[e]	(4.9–161.2)	61	85	93.35	0.91	0.54	68.5[e]	(15.6–144.5)
California	294	339	388.79	0.87	0.87	0.0	(−13.4 to 16.8)	318	494	470.01	1.05	0.85	23.5[e]	(7.8–41.7)
Florida	188	123	265.60	0.46	0.62	−25.8[e]	(−40.7 to −6.3)	206	224	338.48	0.66	0.59	11.9	(−8.7 to 36.0)
Georgia	101	100	161.07	0.62	0.73	−15.1	(−35.4 to 10.9)	104	167	193.47	0.86	0.68	26.5	(−0.9 to 61.9)
Illinois	110	91	140.55	0.65	0.70	−7.1	(−30.6 to 23.6)	130	132	181.88	0.73	0.70	4.3	(−18.9 to 33.3)
Louisiana	64	44	50.37	0.87	0.84	3.6	(−31.7 to 57.7)	85	58	86.92	0.67	0.80	−16.3	(−41.5 to 19.5)
Massachusetts	59	105	101.67	1.03	0.99	4.0	(−21.6 to 38.7)	65	95	108.33	0.88	0.71	23.9	(−9.3 to 67.7)
Michigan	76	69	113.94	0.61	0.65	−6.2	(−32.6 to 30.2)	94	134	162.37	0.83	0.66	25.8	(−3.6 to 60.5)
New Jersey	29	23	41.40	0.56	0.99	−43.4[e]	(−67.8 to −4.0)	68	82	99.15	0.83	0.64	29.7	(−7.8 to 79.9)
New York	99	74	150.94	0.49	0.78	−37.2[e]	(−53.6 to −16.0)	167	255	342.35	0.74	0.85	−12.9	(−26.2 to 3.6)
Pennsylvania	156	211	263.25	0.80	0.66	21.2	(−0.3 to 49.0)	155	206	273.93	0.75	0.67	11.9	(−8.3 to 37.5)
Texas	299	180	298.04	0.60	0.59	1.7	(−17.0 to 25.0)	323	292	411.87	0.71	0.62	14.5	(−4.5 to 36.4)

Note. CI, confidence interval; CDC, Centers for Disease Control and Prevention; NHSN, National Healthcare Safety Network; ICU, intensive care unit.

[a]SIRs were calculated using data from adult and pediatric ICUs, and adult and pediatric medical, surgical, and medical–surgical wards.

[b]Quarterly CAUTI SIRs were available for all eligible states and quarters in the Supplementary Tables (online). The states shown in this table were identified by the CDC as having a high number of hospitalized COVID-19 patients between April 1, 2020, and July 14, 2020.[1]

[c]Hospitals reporting complete CAUTI surveillance data to the NHSN for the same location for both quarters in the comparison.

[d]% change was calculated as follows: [(2020 SIR − 2019 SIR) ÷ 2019 SIR] × 100.

[e]Statistical significance based on 2-tailed $P \leq .05$, reflected in the relative % change in magnitude.

Table 8. 2020 Q2 and Q3 Ventilator-Associated Event (VAE)[a] Standardized Infection Ratios (SIRs) for Acute-Care Hospitals Compared to 2019 for Select States

	2020 Q2 vs 2019 Q2							2020 Q3 vs 2019 Q3						
State[b]	No. of Hospitals[c]	2020 Q2 No. of VAEs	2020 Q2 No. of Predicted VAEs	2020 Q2 SIR	2019 Q2 SIR	% Change[d] in SIR	95% CI Around SIR % Change	No. of Hospitals[c]	2020 Q3 No. of VAEs	2020 Q3 No. of Predicted VAEs	2020 Q3 SIR	2019 Q3 SIR	% Change[d] in SIR	95% CI Around SIR % Change
Arizona	20	99	68.28	1.45	1.34	8.2	(−22.3 to 47.9)	17	83	90.53	0.92	0.91	1.1	(−26.2 to 46.3)
California	135	664	532.01	1.25	1.07	16.8[e]	(1.6–28.8)	156	878	709.83	1.24	1.04	19.2[e]	(4.2–29.5)
Florida	107	531	388.45	1.37	1.14	20.2[e]	(4.2–34.4)	112	956	552.00	1.73	1.07	61.7[e]	(39.4–76.3)
Georgia	52	457	370.17	1.24	0.78	59.0[e]	(31.3–80.7)	50	597	421.90	1.42	0.76	86.8[e]	(50.8–107.9)
Illinois	35	176	121.20	1.45	0.77	88.3[e]	(38.2–155.9)	44	105	118.60	0.89	0.78	14.1	(−16.8 to 50.1)
Louisiana	22	132	85.89	1.54	1.17	31.6	(−2.9 to 68.5)	26	128	104.95	1.22	0.86	41.9[e]	(0.0–83.7)
Massachusetts	15	146	77.64	1.88	1.27	48.0[e]	(5.9–87.1)	19	59	52.33	1.13	1.27	−11.0	(−36.9 to 28.5)
Michigan	37	342	207.62	1.65	1.32	25.0[e]	(1.0–41.2)	43	337	236.48	1.43	1.26	13.5	(−5.4 to 29.7)
New Jersey	21	86	77.39	1.11	0.82	35.4	(−14.4 to 109.9)	43	159	188.48	0.84	0.76	10.5	(−12.2 to 39.7)
New York	48	159	246.50	0.65	0.34	91.2[e]	(38.8–155.7)	97	341	482.43	0.71	0.64	10.9	(−5.3 to 28.6)
Pennsylvania	115	863	617.58	1.40	0.94	48.9[e]	(30.3–63.0)	111	648	556.45	1.17	1.03	13.6[e]	(0.9–27.4)
Texas	101	519	420.98	1.23	0.87	41.4[e]	(27.0–68.9)	103	903	553.69	1.63	0.96	69.8[e]	(46.8–89.5)

Note. CI, confidence interval; CDC, Centers for Disease Control and Prevention; NHSN, National Healthcare Safety Network; ICU, intensive care unit.
[a]SIRs were calculated using data from adult ICUs and adult wards.
[b]Quarterly VAE SIRs are available for all eligible states and quarters in the Supplementary Tables (online). The states shown in this table were identified by the CDC as having a high number of hospitalized COVID-19 patients between April 1, 2020, and July 14, 2020.[1]
[c]Hospitals reporting complete VAE surveillance data to the NHSN for the same location for both quarters in the comparison.
[d]% change was calculated as follows: [(2020 SIR − 2019 SIR) ÷ 2019 SIR] × 100.
[e]Statistical significance based on 2-tailed $P \leq .05$, reflected in the relative % change in magnitude.

Table 9. 2020 Q2 and Q3 Laboratory-Identified (LabID) Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia[a] Standardized Infection Ratios (SIRs) for Acute-Care Hospitals Compared to 2019 for Select States

	2020 Q2 vs 2019 Q2							2020 Q3 vs 2019 Q3						
State[b]	No. of Hospitals[c]	2020 Q2 No. of HO-MRSA Bacteremia[d]	2020 Q2 No. of Predicted HO-MRSA Bacteremia[d]	2020 Q2 SIR	2019 Q2 SIR	% Change[e] in SIR	95% CI Around SIR % Change	No. Hospitals[c]	2020 Q3 No. of HO-MRSA Bacteremia[d]	2020 Q3 No. of Predicted HO-MRSA Bacteremia[d]	2020 Q3 SIR	2019 Q3 SIR	% Change[e] in SIR	95% CI Around SIR % Change
Arizona	61	46	47.57	0.97	0.54	79.6[f]	(12.4–189.9)	63	50	54.89	0.91	0.66	37.9	(−12.5 to 122.3)
California	301	138	168.72	0.82	0.80	2.5	(−19.0 to 28.7)	325	162	204.71	0.79	0.61	29.5[f]	(2.8–64.6)
Florida	188	168	161.09	1.04	1.04	0.0	(−18.5 to 24.3)	208	260	207.15	1.26	1.11	13.5	(−5.6 to 35.9)
Georgia	98	87	72.57	1.20	0.79	51.9[f]	(10.3–110.9)	102	114	92.97	1.23	1.02	20.6	(−9.6 to 59.8)
Illinois	110	69	69.68	0.99	0.68	45.6[f]	(1.1–111.9)	128	69	83.86	0.82	0.65	26.2	(−10.9 to 82.2)
Louisiana	67	31	24.02	1.29	1.34	−3.7	(−41.5 to 58.5)	85	82	40.54	2.02	1.03	96.1[f]	(35.1–187.0)
Massachusetts	60	49	51.66	0.95	0.86	10.5	(−25.8 to 66.0)	66	43	60.94	0.71	0.70	1.4	(−34.5 to 56.9)
Michigan	81	64	50.35	1.27	0.98	29.6	(−9.6 to 85.2)	99	63	79.74	0.79	0.63	25.4	(−12.7 to 83.3)
New Jersey	31	34	22.23	1.53	0.77	98.7[f]	(13.0–259.1)	68	50	61.82	0.81	0.72	12.5	(−24.8 to 65.5)
New York	91	67	67.25	1.00	0.64	56.3[f]	(7.8–127.1)	169	134	170.41	0.79	0.88	−10.2	(−29.4 to 12.1)
Pennsylvania	164	96	102.89	0.93	0.62	50.0[f]	(11.1–104.2)	164	92	119.33	0.77	0.72	6.9	(−19.7 to 44.8)
Texas	307	138	159.74	0.86	0.83	3.6	(−17.6 to 30.9)	330	255	205.33	1.24	0.87	42.5[f]	(18.2–74.5)

Note. CI, confidence interval; HO, hospital-onset; MRSA, methicillin-resistant *Staphylococcus aureus*; CDC, Centers for Disease Control and Prevention; NHSN, National Healthcare Safety Network; CMS, Centers for Medicare and Medicaid Services.
[a]SIRs were calculated using data from all inpatient locations in the hospital (facility-wide inpatient, or FacWideIN) except inpatient rehabilitation and inpatient psychiatric units certified by the CMS.
[b]Quarterly MRSA bacteremia SIRs are available for all eligible states and quarters in the Supplementary Data Tables (online). The states shown in this table were identified by the CDC as having a high number of hospitalized COVID-19 patients between April 1, 2020, and July 14, 2020.[1]
[c]Hospitals reporting complete MRSA bacteremia LabID event surveillance data to the NHSN for both quarters in the comparison.
[d]Hospital-onset events are defined as those that were identified in an inpatient location on the fourth day (or later) after admission to the facility.
[e]% change was calculated as follows: [(2020 SIR − 2019 SIR) ÷ 2019 SIR] × 100.
[f]Statistical significance based on 2-tailed $P \leq .05$, reflected in the relative % change in magnitude.

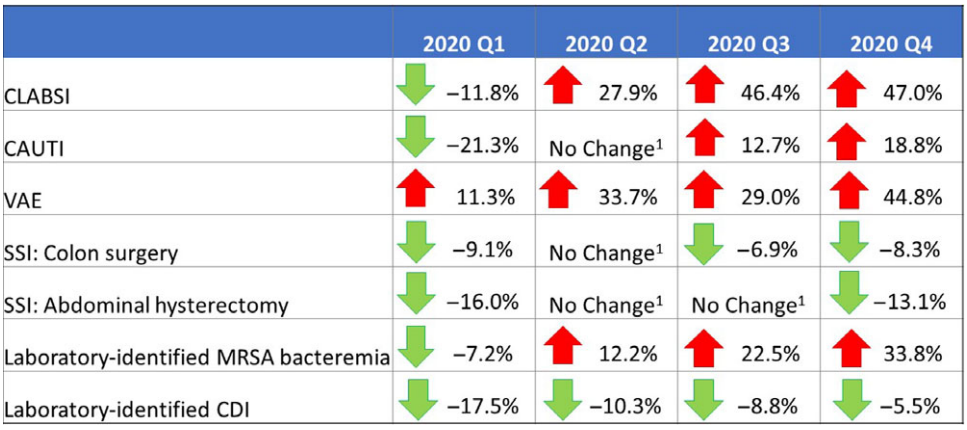


Fig. 1. Changes in the 2020 national healthcare-associated infection (HAI) standardized infection ratios (SIRs) for acute-care hospitals, compared to respective 2019 quarters. Note. CLABSI, central-line–associated bloodstream infection; CAUTI, catheter-associated urinary tract infection; VAE, ventilator-associated event; SSI, surgical site infection; MRSA, methicillin-resistant *Staphylococcus aureus*; CDI, *Clostridioides difficile* infection. Interpretation: Unless otherwise noted, the results of the significance tests comparing consecutive annual pairs of quarterly SIRs are based on a 2-tailed test $P \leq .05$; however, the directional percentage change is based on the relative change in magnitude. An arrow pointing down, and a negative percentage change value, indicate that the 2020 SIR is lower than the 2019 SIR for the same quarter. An arrow pointing up, and a positive percentage change value, indicate that the 2020 SIR is higher than the 2019 SIR for the same quarter. Note. 1. "No change" signifies that the change in SIR was not statistically significant.

decline in the number of predicted MRSA bacteremia events compared to the same quarter in 2019. A corresponding decline was not observed in the number of reported MRSA bacteremia events; the number of events reported for 2020-Q2 was 1% higher than that reported for 2019-Q2 (data not shown).

During 2020-Q3 and 2020-Q4, the national MRSA bacteremia SIRs were 23% and 34% higher than the 2019 values, resulting from a larger number of LabID events reported during these quarters in 2020 versus 2019. Several states reported significantly higher MRSA bacteremia SIRs in 2020-Q2 than 2019-Q2, such as Arizona with an 80% increase and New Jersey with a 99% increase (Table 9). Among select states in the Q3 comparison, Louisiana had the largest increase in their state SIR of 96%.

SSI and CDI LabID

We detected no significant increases in the national quarterly SIRs for SSI or CDI for any quarter in 2020 compared to 2019. The national CDI SIR steadily declined in 2019-Q1–2019-Q4 from 0.63 to 0.55 and remained stable at 0.52 for each quarter in 2020 (Tables 2–5). Decreases in the SSI SIRs compared to 2019 were reported throughout 2020 for both procedure categories, although some decreases were not statistically significant. Fewer inpatient colon and abdominal hysterectomy procedures were performed in each quarter of 2020 compared to 2019, with the greatest decreases of 23% and 39%, respectively, occurring during Q2 (data not shown).

Discussion

This report is the first to present national and select state-level quarterly SIRs for each HAI type in 2020, along with a comparison to 2019 SIRs. Due to reporting requirements for the CMS HACRP, NHSN data are representative of largely all ACHs in the country and provide a national picture of how patient safety, in particular HAI incidence, may have been affected by the COVID-19 pandemic.

Prior to the pandemic, widespread decrease in HAI incidence had been observed across US hospitals.[12] Except for VAE, the national 2020-Q1 SIR for each HAI was below 1 and significantly lower than that from 2019-Q1, indicating a continual decline in HAI incidence at the beginning of 2020. As hospitals began to respond to the COVID-19 pandemic in 2020-Q2, increases in national SIRs became apparent. Initial increases in the SIRs were observed early in the year for CLABSI and MRSA bacteremia (starting in 2020-Q2) and for VAE (starting in 2020-Q1). However, compared to 2019, 2020-Q3 and 2020-Q4 saw large and significant increases in the CLABSI, CAUTI, VAE, and MRSA bacteremia SIRs (Fig. 1).

The CLABSI SIR experienced the greatest increase among all HAI types; the heightened CLABSI incidence during the pandemic and the likely impacts of hospital COVID-19 prevention activities on central-line insertion and maintenance practices have been previously documented.[4–6,10] CAUTIs and VAEs were also reported more frequently in 2020 than 2019. A longer patient length-of-stay, additional comorbidities and higher patient acuity levels, and a longer duration of device use in 2020 could have contributed to an overall increased risk of a device-assoicated infection during the pandemic. In addition, some studies identified an increased risk of ventilator-associated conditions in critically ill COVID-19 patients.[5,20] The characteristic worsening of respiratory status in some patients with COVID-19 resulted in an increase in the number of hospitalized patients in 2020 that required ventilation, and an increase in patients' average duration of ventilation, both of which could have contributed to an increased risk of VAE. Almost all states previously identified by CDC with a high COVID-19 hospital admission burden observed increases in their 2020-Q2 CLABSI and VAE SIRs compared to 2019, most of which were statistically significant.[1]

Preliminary data for 2020-Q4 showed a large increase of 34% in the national MRSA bacteremia SIR compared to 2019-Q4. There were 2,715 MRSA bacteremia events reported for 2020-Q4, which is 41% higher than the number of events reported by the same set of hospitals in 2019-Q4. Further investigation is needed to identify the source of these additional events. A previous study found that device-associated infections, particularly those related to central-lines, are a common source of MRSA bacteremia; thus, the increase in MRSA bacteremia in 2020 is possibly a result of inadequate central-line insertion and maintenance practices.[4,6,21] However, preliminary NHSN data show no substantial changes in 2020, compared to 2019, in the proportion of CLABSIs caused by *S. aureus,* or in the proportion of *S. aureus* CLABSIs that are resistant

to methicillin (data not shown). *S. aureus* has been identified as a common cause of secondary bacterial infection in COVID-19 patients.[7,9] One meta-study found that >25% of all coinfections in COVID-19 patients were related to *S. aureus,* more than half of which were MRSA.[22] Whether some of the MRSA bacteremia events reported to NHSN in 2020 occurred as secondary infections in patients with COVID-19 remains unknown.

The increased focus on hand hygiene, environmental cleaning, patient isolation, and use of PPE during 2020, combined with continued inpatient antimicrobial stewardship programs and a marked decline in outpatient antibiotic prescribing, may have resulted in decreases in the CDI SIRs during 2020 compared to 2019.[5,23]

This analysis has several limitations. The 2020-Q4 data were analyzed prior to the CMS HACRP reporting deadline of May 17, 2021, and therefore may be incomplete. This analysis was restricted to hospitals that reported data for both 2019 and 2020; new hospitals and units that opened in 2020 were not included. Thus, this paper does not reflect all HAIs that occurred in the United States. Information on the voluntarily reported COVID-19 status of patients with HAIs was not explored. In addition, we focused solely on ACHs for this analysis, and did not address HAI incidence in other settings that may have cared for COVID-19 patients, such as critical access and long-term ACHs.

This is the first comprehensive look at the impact of COVID-19 on HAI incidence at the national and state levels. Substantial increases in CLABSIs, CAUTIs, VAEs, and MRSA bacteremia were observed. The year 2020 marked an unprecedented time for hospitals, many of which were faced with extraordinary circumstances of increased patient caseload, staffing challenges, and other operational changes that limited the implementation and effectiveness of standard infection prevention practices. A regular review of HAI surveillance data is critical for hospitals to identify gaps in prevention and address any observed increases in HAIs. Infection prevention staff should continue to reinforce infection prevention practices in their facilities, and consider the importance of building resiliency in their programs to withstand future public health emergencies.

Supplementary material. To view supplementary material for this article, please visit https://doi.org/10.1017/ice.2021.362

Acknowledgments. The authors express gratitude to all infection prevention staff in US healthcare facilities for their continued efforts in HAI surveillance and prevention, and for working tirelessly to keep all patients safe during an unprecedented public health emergency. We also thank the members of NHSN Protocol and Validation Team for their continued dedication to NHSN, patient safety, and for providing continued support to NHSN users in their HAI surveillance efforts during the COVID-19 pandemic: Katherine Allen-Bridson, Dominque Godfrey-Johnson, Cindy Gross, Denise Leaptrot, Nigel Lewis, Bonnie Norrick, Melissa Otis, LaTasha Powell, Victoria Russo, Henrietta Smith, Jennifer Watkins. The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the US Centers for Disease Control and Prevention.

Financial support. No financial support was provided relevant to this article.

Conflicts of interest. All authors report no conflicts of interest relevant to this article.

References

1. Sapiano MRP, Dudeck MA, Soe M, *et al.* Impact of coronavirus disease 2019 (COVID-19) on US hospitals and patients, April–July 2020. *Infect Control Hosp Epidemiol* 2021. doi: 10.1017/ice.2021.69.
2. Rebmann T, Alvino RT, Holdsworth JE. Availability and crisis standards of care for personal protective equipment during fall 2020 of the COVID-19 pandemic: a national study by the APIC COVID-19 task force. *Am J Infect Control* 2021;49:657–662.
3. Weiner-Lastinger LM, Dudeck MA, Allen-Bridson K, *et al.* Changes in the number of intensive care unit beds in US hospitals during the early months of the COVID-19 pandemic, as reported to the National Healthcare Safety Network's COVID-19 module. *Infect Control Hosp Epidemiol.* 2021. doi: 10.1017/ice.2021.266.
4. Fakih MG, Bufalino A, Sturm L, *et al.* Coronavirus disease 2019 (COVID-19) pandemic, central-line-associated bloodstream infection (CLABSI), and catheter-associated urinary tract infection (CAUTI): the urgent need to refocus on hardwiring prevention efforts. *Infect Control Hosp Epidemiol* 2021. https://doi.org/10.1017/ice.2021.70.
5. McMullen KM, Smith BA, Rebmann T. Impact of SARS-CoV-2 on hospital acquired infection rates in the United States: predictions and early results. *Am J Infect Control* 2020;48:1409–1411.
6. LeRose J, Sandhu A, Polistico J, *et al.* The impact of COVID-19 response on central-line–associated bloodstream infections and blood culture contamination rates at a tertiary-care center in greater Detroit area. *Infect Control Hosp Epidemiol* 2020. doi: 10.1017/ice.2020.1335.
7. Kumar G, Adams A, Hererra M, *et al.* Predictors and outcomes of healthcare-associated infections in COVID-19 patients. *Int J Infect Dis* 2020;104: 287–292.
8. Ripa M, Galli L, Poli A, *et al.* Secondary infections in patients hospitalized with COVID-19: incidence and predictive factors. *Clin Microbiol Infect* 2021;27:451–457.
9. Smith L, Karaba SM, Amoah J, *et al.* Hospital-acquired infections among adult patients admitted for coronavirus disease 2019 (COVID-19). *Infect Control Hosp Epidemiol* 2021. doi: 10.1017/ice.2021.148.
10. Patel P, Weiner-Lastinger LM, Dudeck MA, *et al.* Impact of COVID-19 pandemic on central-line–associated bloodstream infections during the early months of 2020, National Healthcare Safety Network. *Infect Control Hosp Epidemiol* 2021. doi: 10.1017/ice.2021.108.
11. The NHSN standardized infection ratio (SIR): a guide to the SIR. Centers for Disease Control and Prevention website. https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/nhsn-sir-guide.pdf. Updated February 2021. Accessed May 11, 2021.
12. 2019 National and State Healthcare-Associated Infections Progress Report. Centers for Disease Control and Prevention (CDC) website. https://www.cdc.gov/hai/data/portal/progress-report.html. Published December 2020. Accessed April 30, 2021.
13. Data Archive: National and State HAI Progress Reports or SIR Reports. Centers for Disease Control and Prevention (CDC) website. https://www.cdc.gov/hai/data/archive/archive.html. Accessed April 30, 2021.
14. Nkwata A, Soe M, Li Q, Godfrey-Johnson D, Edwards J, Dudeck M. Incidence trends of central-line–associated bloodstream infections in acute-care hospitals, NHSN, 2009–2018. *Infect Control Hosp Epidemiol* 2020;41 suppl 1:S294–S295.
15. Jones K, Mu Y, Li Q, *et al.* National reporting trend for HO-MRSA bacteremia LabID events, 2010–2018. *Infect Control Hosp Epidemiol* 2020;41 suppl 1:S68–S69.
16. National Healthcare Safety Network patient safety component manual. Centers for Disease Control and Prevention website. https://www.cdc.gov/nhsn/pdfs/pscmanual/pcsmanual_current.pdf. Updated January 2021. Accessed May 10, 2021.
17. FY 2021 IPPS final rule home page. Centers for Medicare and Medicaid Services website. https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipps-final-rule-home-page. Updated January 2021. Accessed May 10, 2021.
18. CMS announces relief for clinicians, providers, hospitals and facilities participating in quality reporting programs in response to COVID-19. Centers for Medicare and Medicaid Services website. https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting. Published March 22, 2020. Accessed June 3, 2021.
19. The NHSN standardized utilization ratio (SUR): a guide to the SUR. Centers for Disease Control and Prevention website. https://www.cdc.gov/nhsn/

pdfs/ps-analysis-resources/nhsn-sur-guide-508.pdf. Updated March 2021. Accessed May 19, 2021.
20. Maes M, Higginson E, Pereira-Dias J, *et al.* Ventilator-associated pneumonia in critically ill patients with COVID-19. *Crit Care* 2021;25:130.
21. Ham DC, See I, Novosad S, *et al.* Investigation of hospital-onset meticillin-resistant Staphylococcus aureus bloodstream infections at eight high-burden acute-care facilities in the USA, 2016. *J Hosp Infect* 2020;105:502–508.
22. Adeiza SS, Shuaibu AB, Shuaibu GM. Random effects meta-analysis of COVID-19/S. aureus partnership in coinfection. *GMS Hyg Infect Control* 2020. doi: 10.3205/dgkh000364.
23. The intersection of antibiotic resistance (AR), antibiotic use (AU), and COVID-19. Department of Health and Human Services website. https://www.hhs.gov/sites/default/files/antibiotic-resistance-antibiotic-use-covid-19-paccarb.pdf. Published February 10, 2021. Accessed June 28, 2021.

Infection Control & Hospital Epidemiology (2021), 1–2
doi:10.1017/ice.2021.377

Commentary

Healthcare-associated infections during the coronavirus disease 2019 (COVID-19) pandemic

Tara N. Palmore MD and David K. Henderson MD
National Institutes of Health Clinical Center, Bethesda, Maryland

In a coronavirus disease 2019 (COVID-19) ward in 2020, preventing a catheter-associated urinary tract infection was probably not always the foremost consideration for healthcare staff. Nurses and doctors were trying to save the lives of surges of critically ill infectious patients while juggling shortages of respirators and, at times, shortages of gowns, gloves, and disinfectant wipes as well. Infection control staff were working around the clock to ensure that their healthcare colleagues were wearing proper protective gear and that patients and visitors were screened for symptoms, were tested for severe acute respiratory coronavirus virus 2 (SARS-CoV-2), and were wearing masks. All available resources were directed at minimizing the risk of SARS-CoV-2 transmission in the hospital.

Sometimes these efforts went terribly wrong. Infection control practices in COVID-19 wards often adapted to shortages of personal protective equipment (PPE), responded to the fears of healthcare personnel, and did not always lend themselves to better infection prevention. Examples include reuse of PPE and use of double gowning or gloving. Some specific practices have been implicated in transmission of multidrug-resistant organisms.[1,2] Because of limited capacity and staffing shortages, some hospitals suspended their infection prevention activities altogether or redirected them entirely toward the prevention of SARS-CoV-2 transmission, which resulted in spikes in multidrug-resistant organism activity.[2] These focused views from the COVID-19 trenches provide clear insights into the challenges and complexities that have faced healthcare epidemiologists during the pandemic.

A broader view, however, contributes additional perspective. The COVID-19 pandemic has taken an enormous toll on our society. The health impact is obvious, with >615,000 lives lost in the United States alone. The economic impact has been severe: many businesses have closed, millions of people are out of work, and families are struggling to stay afloat. The mental health aspects of the pandemic cannot be overstated. Quarantine, self-isolation, physical distancing, separation from families and loved ones, stress, and uncertainty have been constant companions for most citizens. The concept of 'business as usual' has virtually disappeared. Perhaps no venue has been more affected than health care. Hospitals throughout the nation have dramatically altered their business and operational practices, precluding elective surgeries and admissions, barring visitors, and creating COVID-19 clinical and intensive care units. Some hospitals have struggled to remain solvent. Emergency rooms have been flooded with COVID-19 patients. During surges, acute-care hospitals have been overwhelmed to overflowing. Hospital staffs have been stressed, often to the breaking point, while trying to provide the best possible clinical and critical care to numerous patients, many of whom succumb to the disease in isolation with no family members present. The impact of this cataclysmic pandemic on traditional health care has been profound.

In this issue of *Infection Control and Hospital Epidemiology*, Weiner-Lastinger et al[3] from the CDC National Health Safety Network (NHSN) team in the Division of Healthcare Quality Promotion present data demonstrating the impact of COVID-19 on healthcare-associated infections in NHSN-reporting hospitals in 2020. Their results will not surprise hospital epidemiologists, many of whom (as did we in our own institution) observed an increase in several classes of HAIs. In their study, Weiner-Lastinger et al demonstrate that healthcare-associated infection rates in acute-care hospitals increased significantly in 2020 compared with 2019 in the hospitals for which they had data for both years. Their analysis shows that despite a lower number of admissions, the actual number of infections exceeded the expected number, resulting in higher standardized infection ratios (SIRs) for several key healthcare-associated infection categories: catheter-associated urinary tract infections (CAUTIs), central line-related bloodstream infections (CLABSIs), ventilator-associated events (VAEs), and MRSA bacteremia. The successes of the previous several years, with steady declines in rates of these nosocomial and device-related infections, further accentuate the upswings that occurred in 2020. Device-related infections in 2020 had a longer time to infection than in 2019.

The rates of surgical-site infections and CDI did not increase during 2020. Fewer hysterectomies and colon surgeries were performed in the hospitals described in this report, but a lower denominator does not explain the declines in SIRs. We hypothesize that surgical-site infection prevention relies on ingrained practices in antimicrobial stewardship, the preoperative arena, and the operating room, which were not as directly affected by the diversion of hospital infection control resources toward COVID-19. The considerable decrease in outpatient antimicrobial prescriptions[4] may have played a role in lowering the rate of CDI. Interestingly, the hospital factors that led to greater rates of other HAIs did not contribute to higher rates of CDI.

Several factors likely contributed to the increases in several categories of HAI, among them, the fact that hospital leadership and staff were laser-focused on the pandemic. Many institutions faced dramatic staff shortages, with large numbers of staff ill or quarantined. Staff who were able to work faced both an increased workload and a set of patients who had increased acuity of illness, with

Author for correspondence: David K. Henderson, E-mail: dhenderson@cc.nih.gov
Cite this article: Palmore TN and Henderson DK. (2021). Healthcare-associated infections during the coronavirus disease 2019 (COVID-19) pandemic. *Infection Control & Hospital Epidemiology*, https://doi.org/10.1017/ice.2021.377

more patients acutely or critically ill on admission. Staff were often asked to work in unfamiliar areas, sometimes in makeshift units, often with patients who had diagnoses with which they were unfamiliar and to perform care that they had previously not performed, such as use and care of central venous catheters. Staff were severely fatigued, and, unfortunately during surges, virtually exhausted.

One of the substantial negative effects of this nearly across-the-board increase in HAIs is the fact that hospital 'pay-for-performance' compensation from the Center for Medicare and Medicaid Services is tied to hitting SIR targets. Hospitals that are already struggling economically may suffer even more in the future. Interestingly, the Centers for Medicare and Medicaid Services excused hospitals from the obligation to report to NHSN in the first and second quarters of 2020. Although only 12% to 14% paused reporting of CLABSIs, ˜1 in 4 hospitals used the exception to omit VAE reporting, and an even higher proportion held off on reporting SSI for colon procedures and hysterectomies during those quarters.

Finally, hospital infection prevention staff also had to focus primarily on the pandemic. Infection prevention staff were inundated with COVID-19 problems and issues that simply had to be addressed emergently. For this reason, much of the effort typically given to traditional hospital infection prevention and control activities received less intense scrutiny than during nonpandemic times.

As a discipline, we need to develop strategies that can be effective in maintaining the highest possible quality of infection prevention and control activities while still supporting a pandemic response. Basic infection control practices must be hard-wired into practice so that they are less vulnerable when the healthcare system is stressed. Healthcare epidemiology teams need to be actively involved in pandemic preparedness planning. One approach might be to designate clinical staff to be added to the hospital epidemiology team to allow for rapid expansion of effort to support a pandemic response. As pointed out by Weiner-Lastinger et al, resiliency in the healthcare epidemiology team is essential. In the absence of additional resources, in similar circumstances, one might anticipate similar outcomes.

Acknowledgments.

Financial support. No financial support was provided relevant to this article.

Conflicts of interest. All authors report no conflicts of interest relevant to this article.

References

1. Perez S, Innes GK, Walters MS, *et al.* Increase in hospital-acquired carbapenem-resistant *Acinetobacter baumannii* infection and colonization in an acute care hospital during a surge in COVID-19 admissions—New Jersey, February–July 2020. *Morb Mortal Wkly Rep* 2020;69:1827–1831.
2. Prestel C, Anderson E, Forsberg K, *et al. Candida auris* outbreak in a COVID-19 specialty care unit—Florida, July–August 2020. *Morb Mortal Wkly Rep* 2021;70:56–57.
3. Weiner-Lastinger LM, Pattabiraman V, *et al.* The impact of COVID-19 on healthcare-associated infections in 2020: a summary of data reported to the National Healthcare Safety Network. *Infect Control Hosp Epidemiol* 2021. doi: 10.1017/ice.2021.108.
4. King LM, Lovegrove MC, Shehab N, *et al.* Trends in US outpatient antibiotic prescriptions during the coronavirus disease 2019 pandemic. *Clin Infect Dis* 2021;73:e652–e660.

The Role of the Innovation Ecosystem in Overcoming the Misaligned Incentives that Plague the Development of Medicines to Combat Antimicrobial Resistance

The world urgently needs new antimicrobials to help fight the rise of drug-resistant bacterial and fungal infections. Antimicrobial Resistance (AMR) is an ongoing public health crisis that affects at least 3 million Americans and results in 48,000 deaths annually.[1] The World Bank Group's 2017 report on drug-resistant infections estimates that unless action is taken, AMR could take 10 million lives annually by 2050, a higher death toll than from cancer.[2] If we fail to address the crisis, many modern medical advancements that depend on antibiotics—such as routine surgery, cancer therapy and treatment of chronic disease, may be jeopardized.

Unfortunately, current treatments were not developed to treat resistant strains and the pipeline of new antimicrobials needed to stem the tide of AMR has been on the decline. Nearly every antibiotic in use today is based on discoveries made more than 33 years ago.[3] Meanwhile, drug-resistant bacteria and fungi continue to evolve faster than new antimicrobial medicines can reach the market. Similarly, recent assessments of the pipeline of antibiotics targeting high-risk pathogens also report that though progress has been made, there are still too few potential medicines to meet current and anticipated needs.

Developing medicines is a long, complex and risky process that can take 10–15 years and on average $2.6 billion just to develop one new medicine. Among all medicines, just 12% entering clinical trials are ultimately successful in obtaining U.S. Food and Drug Administration (FDA) approval. Yet among antibiotics, this process is fraught by even more risk. Developing a single antimicrobial medicine can take anywhere from 10—20.5 years and $568-$700 million. And even among antibiotics in existing classes of antibiotics in preclinical development, just 1 in 15 will ultimately be approved and reach patients. And among new classes of antibiotics, just 1 in 30 are ultimately successful.[4]

The fundamental problem with developing new medicines to target antimicrobial resistance is, unlike most other medicines, the market is inherently limited by design. In order to slow and control continued antimicrobial resistance, newer medicines are frequently used only in a limited set of circumstances and in only the most necessary cases. This makes it challenging for biopharmaceutical research companies to recoup research and development costs in subsequent sales. Antibiotic stewardship programs are designed to limit the use of new antibiotics specifically for this reason and thus limit the commercial viability of new antimicrobials.

Unfortunately, our current reimbursement system also reinforces misguided incentives which discourage the appropriate use of new antimicrobials and favor older medicines that have been around for decades but may be less effective in meeting current AMR threats. That is because newer antimicrobial medicines are often more expensive than older medicines, and our bundled payment system creates financial disincentives for hospitals to prescribe these newer medicines, even when they may be more appropriate to treat drug-resistant infections. Ineffective or incomplete use of antimicrobials can also exacerbate AMR.

As a result of these challenges, in recent years several biotechnology companies have declared bankruptcy or exited this space, including those who had successfully developed new antimicrobials.[5] In fact, while 15 new antimicrobials were approved over the past decade, a third of the companies behind those medicines subsequently filed for bankruptcy or exited the field.[6]

Antibiotic Company Bankruptcies Underscore the Challenging Environment for Developing Medicines to Combat AMR

Recent reports of several high-profile bankruptcies highlight the funding challenges associated with developing these medicines and the lack of commercial sustainability in the market for novel antimicrobial medicines despite the tremendous public health need.

- One of the country's biggest antibiotic specialist companies, Melinta Therapeutics, filed for bankruptcy in 2019. The company cited slow sales growth and high costs. The bankruptcy occurred three weeks after failing to turn a profit on the four antibiotics that were available to treat patients. The filing sparked many companies to reconsider research in this space and prompted investors, executives and doctors to call for an overhaul in how these medicines are paid for.[7]

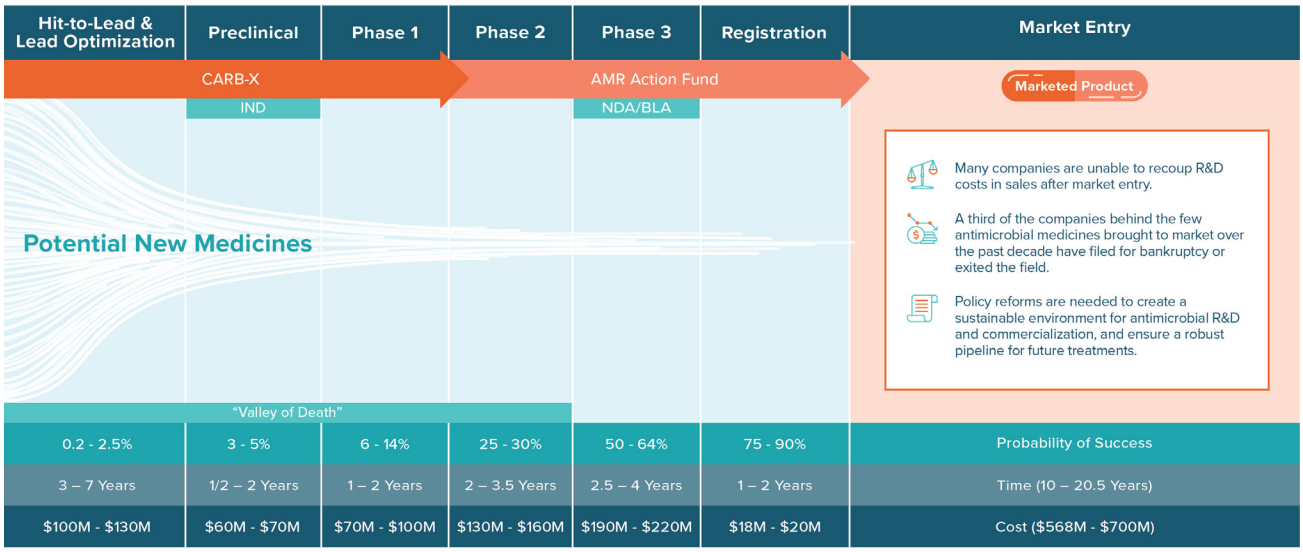
- Another manufacturer, Aradigm, had acquired and conducted research on a potential antibiotic that ultimately was not approved by the FDA. Aradigm subsequently filed for bankruptcy in 2018. The FDA asked the company to run an additional 2-year Phase 3 clinical trial before resubmitting for approval, a setback the company could not ultimately overcome given the lengthy time and resource requirements. The failure of the antibiotic candidate and resulting bankruptcy led to the sale of Aradigm's overall assets for $3.2 million to a former investor that had previously paid $26 million to the company just to acquire a stake in its inhaled antibiotics.[8]

- Achaogen, another antibiotic manufacturer, also declared bankruptcy just one year after it launched a new antibiotic for increasingly difficult-to-treat urinary-tract infections. The product was sold for about $16 million, a fraction of the hundreds of millions of dollars the company spent bringing the medicine to market over 15 years. Research and development for the antibiotic was also supported through a collaboration with the Biomedical Advanced Research and Development Authority (BARDA), aimed toward improving the government's preparedness for and ability to counter various threats to U.S. public health. The company was awarded $124.4 million in funding over the lifetime of the research and development program. The medicine became the first antibiotic designated as a breakthrough therapy and later it was added to the World Health Organization's (WHO) list of essential new medicines. According to one of the company's founders, microbiologist Ryan Cirz: "we got everything right, and it still didn't work."[9, 10]

A Unique Innovation Ecosystem has Evolved to Address the Challenges of AMR

In the 1980s, 18 major biopharmaceutical companies were researching and developing new antibiotics. Today, there is only a handful. About 90% of the companies currently developing antibiotics are small start-up biotechnology companies.[11] However, without a viable antibiotic market, these companies are often unable to find financing for early development phases. This means important antibiotics may never overcome the pre-clinical stages of development known as the "valley of death," where many projects are abandoned due to lack of funding and support. Even those who surpass this hurdle may struggle to find financing or broker acquisition by a larger pharmaceutical company offering the infrastructure necessary to complete costly late-stage clinical trials and the expertise needed to ultimately bring the drug to market.

To address the challenges of early- and late-stage clinical development and to overcome the market's failure to drive innovation for antimicrobials, innovative partnerships and initiatives within and between the public and private sectors have evolved.



Citation: *Adapted from CARB-X and Payne DJ et al., Drugs for bad bugs: confronting the challenges of antibacterial discovery. Nat Rev Drug Discov. 2007;6(1):29:40; Czaplewski L et al. Alternatives to antibiotics-a pipeline review. Lancet Infectious Dis. 2016(2): 239-51.*

Glossary: IND: Investigational New Drug Application NDA: New Drug Application BLA: Biologic Drug Application

Combatting Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X): CARB-X is a global non-profit partnership dedicated to advancing antimicrobial research to tackle the global rising threat of AMR by **accelerating preclinical candidates toward clinical development for dangerous bacteria identified by the WHO and CDC priority pathogen lists**. The ultimate goal of CARB-X is to support the early development of new antibiotics, vaccines, rapid diagnostics and other products so they can attract additional private and public investment. Between 2016 and 2022, the accelerator will fund up to $480 million to achieve this goal. CARB-X is led by Boston University, funded by U.S. BARDA, the Wellcome Trust, a global charity based in the U.K. working to improve health globally, Germany's Federal Ministry of Education and Research, the U.K. Government's Global Antimicrobial Resistance Innovation Fund, the Bill & Melinda Gates Foundation, the world's largest foundation dedicated to improving the quality of life for individuals around the world, and receives in-kind support from National Institute of Allergy and Infectious Diseases, part of the U.S. National Institutes of Health.

AMR Action Fund:[12] AMR Action Fund is a groundbreaking partnership that seeks to strengthen and accelerate the research and development of antibiotics through investment and provision of industry resources and expertise to biotechnology companies. With funding from over 20 leading biopharmaceutical companies, global foundations and development banks, the AMR Action Fund is the largest public-private partnership supporting the development of new antibiotics.

The AMR Action fund aims to bring 2-4 new antibiotics to patients by 2030 by investing more than $1 billion in smaller biotech companies and providing industry expertise to support the clinical development of novel antibiotics. The Fund provides a bridging solution to **help biotech companies take their discoveries over the finish line**. Without this type of support and investment in the more complex, expensive later stages of development, these compounds will wither on the vine. The broad alliance of industry and non-industry stakeholders also encourages governments to advance policies that will create market conditions that will encourage a sustainable pipeline of new antibiotics to fight the highest priority bacterial threats over the long term.

Antimicrobials Working Group (AWG): AWG is a coalition of emerging antimicrobials and diagnostics companies. AWG is committed to improving the regulatory, investment and commercial environment for antimicrobial drug and diagnostic device development.[13]

The Partnership to Fight Infectious Disease (PFID): PFID is a group of patients, providers, community organizations, academic researchers, business and labor groups and infectious disease experts working to raise awareness of threats posed by infectious disease. PFID will explore and advance solutions to address the need to enhance pandemic preparedness, address the growing threat of AMR and the need for new antimicrobial treatments and empower informed choice and confidence in COVID-19 vaccines.[14]

The Innovation Ecosystem Cannot Solve These Problems in Isolation, Comprehensive Policy Reforms are also Needed

While recent policy changes have enhanced the research ecosystem and provided support and incentives for researchers to develop new antimicrobials, additional policy reforms are needed to create a more sustainable environment for antimicrobial R&D and commercialization to ensure a robust pipeline for future treatments.

To safeguard our future from the global threat of AMR, congress and relevant government agencies should act by:

- Addressing the reimbursement barriers in the inpatient bundled payment system in Medicare by creating a separate payment mechanism;
- Advancing legislative and administrative policies that create a competitive return on investment after marketing approval to encourage a diverse pipeline of new medicines;
- Supporting policies that reduce barriers and speed the process of developing promising new ideas and investigational drugs into products that benefit patients;
- Advancing innovative payment mechanisms to maintain access while not driving overuse; and,
- Ensuring comprehensive stewardship programs and surveillance mechanisms to support appropriate use and public health management of medicines to address AMR.

Endnotes

1. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019. Available at: https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf

2. Jonas, Olga B.; Irwin, Alec; Berthe, Franck Cesar Jean; Le Gall, Francois G.; Marquez, Patricio V.. 2017. *Drug-resistant infections: a threat to our economic future (Vol. 2) : final report (English)*. HNP/Agriculture Global Antimicrobial Resistance Initiative. Washington, D.C. : World Bank Group. http://documents.worldbank.org/curated/en/323311493396993758/final-report

3. Pew, A Scientific Roadmap for Antibiotic Discovery, May 11, 2016, https://www.pewtrusts.org/en/research-and-analysis/reports/2016/05/a-scientific-roadmap-for-antibiotic-discovery; https://www.sciencedirect.com/science/article/pii/S1369527419300190

4. Wellcome Trust, Q&A, https://wellcome.org/news/why-is-it-so-hard-develop-new-antibiotics

5. AMR Industry Alliance, 2020 Progress Report, January 2020. https://www.amrindustryalliance.org/wp-content/uploads/2020/01/AMR-2020-Progress-Report.pdf

6. Andrew Jacobs, Drug Giants Create Fund to Bolster Struggling Antibiotic Start-Ups. July 9, 2020, https://www.nytimes.com/2020/07/09/health/antibiotics-pharma-drug-resistance.html

7. Denise Roland, Antibiotic Makers Struggle, Hurting War on Superbugs, January 5, 2020. https://www.wsj.com/articles/antibiotic-makers-find-rewards-for-tackling-superbugs-are-scarce-11578259557

8. Amber Tong, Bankrupt antibiotics maker Aradigm turns to old partner/investor for final $3M fire sale, February 21, 2020. https://endpts.com/bankrupt-antibiotics-maker-aradigm-turns-to-old-partner-investor-for-final-3m-fire-sale/

9. Andrew Jacobs, Crisis Looms in Antibiotics as Drugmakers Go Bankrupt. December 25, 2019. https://www.nytimes.com/2019/12/25/health/antibiotics-new-resistance.html

10. Global NewsWire, Achaogen Submits Response to ASPR/BARDA Request for Information (RFI) for Antimicrobial Resistance Project BioShield, February 14, 2019. https://www.globenewswire.com/news-release/2019/02/14/1725464/0/en/Achaogen-Submits-Response-to-ASPR-BARDA-Request-for-Information-RFI-for-Antimicrobial-Resistance-Project-BioShield.html

11. Denise Roland. Antibiotic Makers Struggle, Hurting War on Superbugs. January 5, 2020. https://www.wsj.com/articles/antibiotic-makers-find-rewards-for-tackling-superbugs-are-scarce-11578259557

12. AMR Action Fund: https://www.amractionfund.com/

13. The Antimicrobials Working Group: https://antimicrobialsworkinggroup.org/antimicrobial-resistance/

14. Partnership to Fight Infections Disease: https://www.fightinfectiousdisease.org/amr

ANTIMICROBIAL RESISTANCE:

A Growing Public Health Threat

Antimicrobial Resistance (AMR) is a natural process that occurs when microorganisms such as bacteria, viruses, fungi and parasites develop the ability to survive against the drugs designed to kill them. AMR is driven by the very use of the medicines needed to combat these organisms. The only way to slow down resistance is to preserve the effectiveness of existing antibiotics by using them under careful stewardship programs – however, even these measures can't stop resistance completely. A growing list of infections – including pneumonia, tuberculosis, blood poisoning, gonorrhea and foodborne diseases – are becoming harder and sometimes impossible to treat, as our current arsenal of medicines is not effective against resistant strains of the microorganisms that cause these infections.

Research published in *The Lancet* on the global impact of AMR found antibiotic-resistant infections are directly associated with at least 1.27 million deaths per year, making drug-resistant bacteria a leading cause of death globally, higher than HIV/AIDS and malaria.[i] In the U.S. alone, the Centers for Disease Control and Prevention (CDC) estimates resistant infections affect at least three million Americans and result in 48,000 U.S. deaths annually.[ii]

Unfortunately, a growing body of evidence indicates the COVID-19 pandemic has been exacerbating this growing crisis. As more patients are hospitalized due to severe COVID-19 infections, often due to worsening respiratory symptoms requiring ventilation, an increasing number of patients have been acquiring secondary bacterial infections that require treatment with antibiotics – thereby worsening current levels of resistance.[iii] A recent analysis found about quarter of hospitalized COVID-19 patients had a secondary infection. Among these patients, greater than 25% were co-infected with staph and more than half of those staph infections were antibiotic-resistant infections known as MRSA.[iv] CDC research also confirms that cases of resistant, hospital-acquired secondary infections are greater than pre-pandemic levels.[v] To make matters worse, not only have resistant infections become more common, but also they have become more deadly. Another study of hospitalized COVID-19 patients with secondary infections found these patients were associated with a higher risk of death.[vi]

Challenges in Researching, Developing and Commercializing New Medicines to Address AMR

Developing new medicines is a long, complex and risky process. Among antibiotics, this process is fraught by significant risk and can take anywhere from 10 to 20.5 years to develop a single new medicine. In fact, in existing classes of antibiotics in preclinical development, just one in 15 will ultimately be approved and reach patients. And among new classes of antibiotics, these odds are even slimmer, with just one in 30 ultimately obtaining FDA approval.[vii] In order to manage the growing threat that AMR presents, we need a robust and diverse pipeline of treatments. Experts believe it will be necessary to generate new chemical substances, as well as a better understanding of how to overcome the most difficult-to-treat infections in order to make progress on new research and development.

Unlike most other medicines, the market for antimicrobials is inherently limited by design. To slow and control continued antimicrobial resistance, public health experts have recommended stewardship programs to ensure that newer medicines are used

responsibly, only in a limited set of circumstances and in only the most necessary cases. This makes it challenging for biopharmaceutical research companies to recoup research and development costs in subsequent sales. Owing to these challenges, many biopharmaceutical research companies have declared bankruptcy in recent years or exited the field.

While policies such as the GAIN Act have enhanced the research ecosystem and have provided support and incentives for researchers to develop new antimicrobial medicines, additional policy reforms are still needed to create a more sustainable environment for antimicrobial R&D and commercialization and ensure a robust pipeline for future treatments.

Addressing AMR is Key to America's Future Preparedness

PhRMA and our members are committed to bolstering pandemic preparedness and health care resiliency to make sure our country and American patients are stronger, healthier and better prepared for the next public health emergency. Having a robust pipeline of medicines to address AMR is a key part of that preparedness. If we fail to address this growing crisis, many modern medical advances that depend on antibiotics – such as routine surgery, cancer therapy and treatment of chronic disease – may be jeopardized. Along with our government's commitment to addressing the COVID-19 pandemic, we can be prepared for the next public health emergency if we all work together to ensure a sustainable pipeline for new antimicrobials for this crisis and those in years to come.

A Path Forward

In the past decade, health policy experts have advanced new policy ideas aimed at incentivizing companies to continue to invest in, or return to, antimicrobial product development. One measure policymakers should consider is the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act, which would offer "subscription" contracts to manufacturers to provide full access to antimicrobial products for patients covered under federal programs. The subscription would de-link payment from volume for all U.S. government payers, with contracts offered ranging from $750 million to $3 billion based on the clinical characteristics of the drug. The intent of the policy is to incentivize companies to develop antimicrobial medicines for organisms, sites of infection and type of infections for which there is unmet medical need. Importantly, the PASTEUR Act also includes provisions to ensure appropriate stewardship by requiring companies to develop communications strategies for appropriate use of their drug, as well as submitting a plan for registering the drug in countries where unmet medical need exists and ensuring a reliable supply chain.

Payment reforms addressing misaligned incentives in the inpatient bundled payment system that encourage use of low-cost generics over antibiotics that might be more appropriate for patients in Medicare would also make a meaningful difference.

i. The Lancet. https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2902724-0. January 20, 2022.
ii. CDC's Antibiotic Resistance Threats in the United States, 2019
iii. Doctors Heavily Overprescribed Antibiotics early in Pandemic, New York Times, 6/4/2020.
iv. Adeiza SS, Shuaibu AB, Shuaibu GM. Random effects meta-analysis of COVID-19/S. aureus partnership in co-infection. GMS Hyg Infect Control. 2020;15:Doc29. https://www.egms.de/static/pdf/journals/dgkh/2020-15/dgkh000364.pdf
v. Weiner-Lastinger, L., Pattabiraman, V., Konnor, R., Patel, P., Wong, E., Xu, S., . . . Dudeck, M. (2022). The impact of coronavirus disease 2019 (COVID-19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. Infection Control & Hospital Epidemiology, 43(1), 12-25. doi:10.1017/ice.2021.362
vi. Shafran, N., Shafran, I., Ben-Zvi, H. *et al.* Secondary bacterial infection in COVID-19 patients is a stronger predictor for death compared to influenza patients. *Sci Rep* 11, 12703 (2021). https://doi.org/10.1038/s41598-021-92220-0
vii. Wellcome Trust, Q&A, https://wellcome.org/news/why-is-it-so-hard-develop-new-antibiotics

117TH CONGRESS
1ST SESSION

S. 2076

To establish a program to develop antimicrobial innovations targeting the most challenging pathogens and most threatening infections.

IN THE SENATE OF THE UNITED STATES

JUNE 16, 2021

Mr. BENNET (for himself and Mr. YOUNG) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

A BILL

To establish a program to develop antimicrobial innovations targeting the most challenging pathogens and most threatening infections.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pioneering Antimicrobial Subscriptions To End Up surging Resistance Act of 2021" or the "PASTEUR Act of 2021".

SEC. 2. DEVELOPING ANTIMICROBIAL INNOVATIONS.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

"PART W—DEVELOPING ANTIMICROBIAL INNOVATIONS

"SEC. 399OO. ESTABLISHMENT OF COMMITTEE; SUBSCRIPTION MODEL; ADVISORY GROUP.

"(a) IN GENERAL.—Not later than 60 days after the date of enactment of this part, the Secretary shall establish a Committee on Critical Need Antimicrobials and appoint members to the Committee.

"(b) MEMBERS.—

"(1) IN GENERAL.—The Committee shall consist of at least one representative from each of the National Institute of Allergy and Infectious Diseases, the Centers for Disease Control and Prevention, the Biomedical Advanced Research and Development Authority, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Veterans Health Administration, and the Department of Defense.

"(2) CHAIR.—The Secretary shall appoint one of the members of the Committee to serve as the Chair of the Committee.

"(c) DUTIES.—Not later than 1 year after the appointment of all initial members of the Committee, the Secretary, in collaboration with the Committee, and in consultation with the Critical Need Antimicrobials Advisory Group established under subsection (g), shall do the following:

"(1) Develop a list of infections for which new antimicrobial drug development is needed, taking into account organisms, sites of infection, and type of infections for which there is an unmet medical need, findings from the most recent report entitled 'Antibiotic Resistance Threats in the United States' issued by the Centers for Disease Control and Prevention, or an anticipated unmet medical need, including a potential global health security threat. For the list developed under this paragraph, the Secretary, in collaboration with the Committee, may use the infection list in such most recent report for up to 3 years following the date of enactment of this part and subsequently update the list under this paragraph in accordance with subsection (e).

"(2) Develop regulations, in accordance with subsection (d), outlining favored characteristics of critical need antimicrobial drugs, that are evidence based, clinically focused, and designed to treat the

infections described in paragraph (1), and establishing criteria for how each such characteristic will adjust the monetary value of a subscription contract awarded under subsection (f) or section 399QQ. The favored characteristics shall be weighed for purposes of such monetary value such that meeting certain characteristics, or meeting more than one such characteristic, increases the monetary value. Such favored characteristics of an antimicrobial drug shall include—

"(A) treating infections on the list under paragraph (1);

"(B) improving clinical outcomes for patients with multi-drug-resistant infections;

"(C) being a first-approved antimicrobial drug that has the potential to address unmet medical needs for the treatment of a serious or life-threatening infection, and, to a lesser extent, second and third drugs that treat such infections;

"(D) route of administration, especially through oral administration;

"(E)(i) containing no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any suc-

cessor regulations)) that has been approved in any other application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or intending to be the subject of a new original biologics license application under section 351(a);

"(ii) being a member of a new class of drugs with a novel target and novel mode of action that are distinctly different from the target or mode of any antimicrobial drug approved under section 505 of such Act or licensed under section 351, including reduced toxicity;

"(iii) not being affected by cross-resistance to any antimicrobial drug approved under such section 505 or licensed under such section 351;

"(F) addressing a multi-drug resistant infection through a novel chemical scaffold or mechanism of action;

"(G) having received a transitional subscription contract under subsection (f); and

"(H) any other characteristic the Secretary, in collaboration with the Committee, determines necessary.

"(d) REGULATIONS.—

"(1) IN GENERAL.—Not later than 1 year after the appointment of the initial members of the Committee, the Secretary shall issue proposed regulations which shall include—

"(A) a process by which the sponsors can apply for an antimicrobial drug to become a critical need antimicrobial drug under section 399PP;

"(B) how subscription contracts under such section shall be established and paid;

"(C) the favored characteristics under subsection (c)(2), how such characteristics will be weighed, and the minimum number and kind of favored characteristics needed for an antimicrobial drug to be designated a critical need antimicrobial drug; and

"(D) other elements of the subscription contract process, in accordance with this part.

"(2) DEVELOPMENT OF FINAL REGULATIONS.—Before finalizing the regulations under paragraph (1), the Secretary shall solicit public comment and hold public meetings for the period beginning on the date on which the proposed regulations are issued and ending on the date that is 120 days after such date of issuance. The Secretary shall fi-

nalize and publish such regulations not later than 120 days after the close of such period of public comment and meetings.

"(3) SUBSCRIPTION CONTRACT OFFICE.—Not later than 6 months after the date of enactment of this part, the Secretary shall propose an agency or office in the Department of Health and Human Services to manage the establishment and payment of subscription contracts awarded under section 399QQ, including eligibility, requirements, and contract amounts. The Secretary shall solicit public comment and finalize the agency or office no later than 45 days following the proposed agency or office. Such agency or office shall be referred to as the 'Subscription Contract Office'.

"(e) LIST OF INFECTIONS.—The Secretary, in collaboration with the Committee, shall update the list of infections under subsection (c)(1) at least every 2 years.

"(f) TRANSITIONAL SUBSCRIPTION CONTRACTS.—

"(1) IN GENERAL.—Not earlier than 30 days after the date of enactment of this part and ending on the date that the Secretary finalizes the subscription contract regulations under subsection (d), the Secretary may use up to $1,000,000,000 of the amount appropriated under section 399SS(a) to en-

gage in transitional subscription contracts of up to 3 years in length with antimicrobial developers, as determined by the Secretary, that have developed antimicrobial drugs treating infections listed in the most recent report entitled 'Antibiotic Resistance Threats in the United States' issued by the Centers for Disease Control and Prevention, and may include antimicrobial drugs that are qualified infectious disease products (as defined in section 505E(g) of the Federal Food, Drug, and Cosmetic Act), innovative biological products, or innovative drugs that achieve a clinical outcome through immunomodulation. Such a contract may authorize the contractor to use funds made available under the contract for completion of postmarketing clinical studies, manufacturing, and other preclinical and clinical efforts.

"(2) REQUIREMENTS.—

"(A) IN GENERAL.—The Secretary, through the office described in paragraph (4), may enter into a contract under paragraph (1)—

"(i) if the Secretary determines that the antimicrobial drug is intended to treat an infection for which there is an unmet

clinical need, an anticipated clinical need, or drug resistance;

"(ii) subject to terms including—

"(I) that the Secretary shall cease any payment installments under a transitional subscription contract if the sponsor does not—

"(aa) ensure commercial and Federal availability of the antimicrobial drug within 30 days of receiving first payment under the contract;

"(bb) identify, track, and publicly report drug resistance data and trends using available data related to the antimicrobial drug;

"(cc) develop and implement education and communications strategies, including communications for individuals with limited English proficiency and individuals with disabilities, for health care professionals and patients

about appropriate use of the antimicrobial drug;

"(dd) submit a plan for registering the antimicrobial drug in additional countries where an unmet medical need exists, which such plan may be consistent with the Stewardship and Access Plan (SAP) Development Guide (2021);

"(ee) subject to subparagraph (B), ensure a reliable drug supply chain, thus leading to an interruption of the supply of the antimicrobial drug in the United States for more than 60 days; or

"(ff) make meaningful progress toward completion of Food and Drug Administration-required postmarketing studies, including such studies that are evidence based; and

"(II) other terms as determined by the Secretary; and

"(iii) if—

"(I) a phase 3 clinical study has been initiated for the antimicrobial drug; or

"(II) the antimicrobial drug has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act or licensed under section 351(a).

"(B) WAIVER.—The requirement under subparagraph (A)(ii)(I)(ee) may be waived in the case that an emergency prohibits access to a reliable drug supply chain.

"(3) TRANSITIONAL GUIDANCE.—Not later than 120 days after the appointment of the initial members of the Committee, the Secretary shall issue, in consultation with the Committee, transitional guidance outlining the antimicrobial drugs that are eligible for transitional subscription contracts under paragraph (1), the requirements to enter into a transitional subscription contract under paragraph (2), and the process by which drug developers can enter into transitional subscription contracts with the Secretary under this subsection.

"(4) PAYMENT OFFICE AND MECHANISM.—Not later than 30 days after the date of enactment of

this part, the Secretary shall determine the agency or office in the Department of Health and Human Services that will manage the transitional subscription contracts, including eligibility, requirements, and contract amounts, during the period described in paragraph (1).

"(g) CRITICAL NEED ANTIMICROBIAL ADVISORY GROUP.—

"(1) IN GENERAL.—Not later than 30 days after the appointment of all initial members of the Committee, the Secretary, in collaboration with the Committee, shall establish a Critical Need Antimicrobial Advisory Group (referred to in this subsection as the 'Advisory Group') and appoint members to the Advisory Group.

"(2) MEMBERS.—The members of the Advisory Group shall include—

"(A) not fewer than 6 individuals who are—

"(i) infectious disease specialists; or

"(ii) other health experts with expertise in researching antimicrobial resistance, health economics, or commercializing antimicrobial drugs; and

"(B) not fewer than 5 patient advocates.

"(3) CHAIR.—The Secretary shall appoint one of the members of the Advisory Group to serve as the Chair.

"(4) CONFLICTS OF INTEREST.—In appointing members under paragraph (2), the Secretary shall ensure that no member receives compensation in any manner from a commercial or for-profit entity that develops antimicrobials or that might benefit from antimicrobial development.

"(5) APPLICABILITY OF FACA.—Except as otherwise provided in this subsection, the Federal Advisory Committee Act shall apply to the Advisory Group.

"SEC. 399PP. CRITICAL NEED ANTIMICROBIAL DRUG APPLICATION AND PAYMENT THROUGH SUBSCRIPTION CONTRACTS.

"(a) IN GENERAL.—

"(1) SUBMISSION OF REQUEST.—The sponsor of an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) for an antimicrobial drug may request that the Secretary designate the drug as a critical need antimicrobial. A request for such designation may be submitted after the Secretary grants for such drug an investigational new drug exemption under section

505(i) of the Federal Food, Drug, and Cosmetic Act or section 351(a)(3), and shall be submitted not later than 5 years after the date of approval under section 505(c) of the Federal Food, Drug, and Cosmetic Act or licensure under section 351(a).

"(2) CONTENT OF REQUEST.—A request under paragraph (1) shall include information, such as clinical, preclinical and postmarketing data, a list of the favorable characteristics described in section 399OO(c)(2), and any other material that the Secretary in consultation with the Committee requires.

"(3) REVIEW BY SECRETARY.—The Secretary shall promptly review all requests for designation submitted under this subsection, assess all required application components, and determine if the antimicrobial drug is likely to meet the favorable characteristics identified in the application upon the completion of clinical development. After review, the Secretary shall approve or deny each request for designation not later than 90 days after receiving a request. If the Secretary approves a request, it shall publish the value of the contract that the critical need antimicrobial developer would be eligible to receive if such developer successfully demonstrates

that the drug meets the maximum value of the favored characteristics listed in the application.

"(4) LENGTH OF DESIGNATION PERIOD.—A designation granted under this section shall be in effect for a period of 10 years after the date that the designation is approved, and shall remain in effect for such period even if the infection treated by such drug is later removed from the list of infections under section 399OO(c)(1).

"(5) SUBSEQUENT REVIEWS.—No sooner than 2 years after a designation approval or denial under subsection (3), the sponsor may request a subsequent review to re-evaluate the value of a contract to include any new information.

"(b) DEVELOPMENT OF DESIGNATED DRUGS.—If a critical need antimicrobial designation is granted during clinical development of an antimicrobial drug, the Secretary may work with the sponsor to maximize the opportunity for the sponsor to successfully demonstrate that the antimicrobial drug possesses the favored characteristics of high-monetary valued products identified under section 399OO(c)(2).

"(c) APPROPRIATE USE OF CRITICAL NEED ANTIMICROBIAL.—

"(1) IN GENERAL.—The sponsor of an antimicrobial drug that receives designation under subsection (a) shall within 90 days of such designation, submit to the Secretary a plan for appropriate use of diagnostics, in order for the Secretary and Committee to consider such plan in developing clinical guidelines. An appropriate use plan—

"(A) shall include—

"(i) the appropriate use of the drug; and

"(ii) the appropriate use of diagnostic tools, where available, such as diagnostic testing for biomarkers related to antimicrobial-resistant pathogens, or other targeted diagnostic approaches, to inform use of the drug; and

"(B) may be developed in partnership with the Secretary, infectious disease experts, diagnostic experts or developers, laboratory experts, or another entity.

"(2) CONSULTATION.—The Secretary shall consult with relevant professional societies and the Critical Need Antimicrobial Advisory Group established under section 399OO(g) to ensure that clinical guidelines issued by the Secretary under paragraph

(3), with respect to an antimicrobial drug designated under subsection (a), includes the use of appropriate diagnostic approaches, taking into consideration the diagnostic plan submitted by a sponsor under paragraph (1).

"(3) PUBLICATION OF CLINICAL GUIDELINES.—Not later than 1 year after the Secretary makes the first designation under subsection (a), and not less than every 3 years thereafter, the Secretary shall publish clinical guidelines in consultation with relevant professional societies with respect to each antimicrobial drug that has been approved or licensed as described in subsection (a)(1) and that has been designated under subsection (a), which guidelines shall set forth the evidence-based recommendations for prescribing the drug, in accordance with the submissions of the sponsor under paragraph (1) and after consultation under paragraph (2), as appropriate.

"SEC. 399QQ. SUBSCRIPTION CONTRACTS.

"(a) APPLICATION FOR A SUBSCRIPTION CONTRACT.—

"(1) SUBMISSION OF APPLICATIONS.—After approval under section 505(c) of the Federal Food, Drug, and Cosmetic Act or licensure under section 351(a), the sponsor of an antimicrobial drug des-

ignated as a critical need antimicrobial under section 399PP may submit an application for a subscription contract with the Secretary, under a procedure established by the Secretary.

"(2) REVIEW OF APPLICATIONS.—The Secretary shall, in consultation with the Committee—

"(A) review all applications for subscription contracts under paragraph (1) and assess all required application components;

"(B) determine the extent to which the critical need antimicrobial meets the favored characteristics identified under section 399OO(c)(2), and deny any application for a drug that meets none of such characteristics; and

"(C) assign a monetary value to the contract based on the regulations developed under section 399OO(d).

"(b) CRITERIA.—To qualify for a subscription contract under this section, the sponsor of an antimicrobial drug designated as a critical need antimicrobial shall agree to—

"(1) ensure commercial and Federal availability of the antimicrobial drug within 30 days of receiving

first payment under the contract, and sufficient supply for susceptibility device manufacturers;

"(2) identify, track, and publicly report drug resistance data and trends using available data related to the antimicrobial drug;

"(3) develop and implement education and communications strategies, including communications for individuals with limited English proficiency and individuals with disabilities, for health care professionals and patients about appropriate use of the antimicrobial drug;

"(4) submit an appropriate use assessment to the Secretary, Committee, Food and Drug Administration, and Centers for Disease Control and Prevention every 2 years regarding use of the antimicrobial drug, including how the drug is being marketed;

"(5) submit a plan for registering the drug in additional countries where an unmet medical need exists;

"(6) ensure a reliable drug supply chain, where any interruption to the supply chain will not last for more than 60 days in the United States;

"(7) complete any postmarketing studies required by the Food and Drug Administration in a timely manner;

"(8) produce the drug at a reasonable volume determined with the Secretary to ensure patient access to the drug;

"(9) price the drug at a price that is not lower than a comparable generic drug;

"(10) abide by the manufacturing and environmental best practices in the supply chain to ensure that there is no discharge into, or contamination of, the environment by antimicrobial agents or products as a result of the manufacturing process; and

"(11) abide by other terms as the Secretary may require.

"(c) AMOUNT AND TERMS OF CONTRACTS.—

"(1) AMOUNTS.—A subscription contract under this section shall be for the sale to the Secretary of any quantity of the antimicrobial drug needed over the term of the contract under paragraph (2), at an agreed upon price, for a total projected amount determined by the Secretary that is not less than $750,000,000 and not more than $3,000,000,000, adjusted for inflation, accounting for the favored characteristics of the drug, as determined by the

Secretary, in consultation with the Committee, under subsection (a)(2), and shall be allocated from the amount made available under section 399SS(a). Not later than 6 months after the subscription contract is granted under subsection (a), the Secretary shall provide payments for purchased drugs in installments established by the Secretary in consultation with the sponsor of the antimicrobial drug and in accordance with subsection (d)(3). Funds received by the sponsor shall be used to support criteria qualification under subsection (b), the completion of post-marketing clinical studies, manufacturing, other pre-clinical and clinical activities, or other activities agreed to by the Secretary and sponsor in the contract.

"(2) TERMS.—

"(A) INITIAL TERM.—The initial term of a contract under this subsection shall be no less than 5 years or greater than the greater of 10 years or the remaining period of time during which the sponsor has patent protections or a remaining exclusivity period with respect to the antimicrobial drug in the United States, as listed in the publication of the Food and Drug Administration entitled 'Approved Drug Products

with Therapeutic Equivalence Evaluations'. Payments may be in equal annual installments with the option to redeem 50 percent of the last year's reimbursement in year 1 of the contract in order to offset costs of establishing manufacturing capacity, or another subscription arrangement to which the Secretary and sponsor agree. Subscription contracts shall remain in effect for such period even if the infection treated by such antimicrobial drug is later removed from the list of infections under section 399OO(c)(1).

"(B) EXTENSION OF CONTRACTS.—The Secretary may extend a subscription contract with a sponsor under this subsection beyond the initial contract period. A single contract extension may be in effect not later than the date on which all periods of exclusivity granted by the Food and Drug Administration expire and shall be in an amount not to exceed $25,000,000 per year. All other terms of an extended contract shall be the same as the terms of the initial contract. The total amount of funding used on such contract extensions shall be no more than

$1,000,000,000, and shall be allocated from the amount made available under section 399SS.

"(C) MODIFICATION OF CONTRACTS.—The Secretary or sponsor, 1 year after the start of the contract period under this subsection and every 2 years thereafter, may request a modification of the amount of the contract based on information that adjusts favored characteristics in section 399OO(c)(2).

"(3) ADJUSTMENT.—In the case of an antimicrobial drug that received a transitional subscription contract under section 399OO(f), the amount of a subscription contract for such drug under this section shall be reduced by the amount of the transitional subscription contract under such section 399OO(f) for such drug.

"(4) CONTRACTS FOR GENERIC AND BIOSIMILAR VERSIONS.—Notwithstanding any other provision in this part, the Secretary may award a subscription contract under this section to a manufacturer of a generic or biosimilar version of an antimicrobial drug for which a subscription contract has been awarded under this section. Such contracts shall be awarded in accordance with a procedure, in-

cluding for determining the terms and amounts of such contracts, established by the Secretary.

"(d) ANNUAL ANTIMICROBIAL DRUG SPONSOR REVENUE LIMITATIONS.—

"(1) REPORTING REQUIREMENT.—

"(A) IN GENERAL.—Not later than a date determined appropriate by the Secretary following the end of each calendar year, and not earlier than 6 months after the end of each calendar year, the head (or a designee of such head) of each Federal agency carrying out a specified government program shall, in accordance with this paragraph, report to the Subscription Contract Office established under section 399OO(d)(3) the total prescription drug sales for each applicable antimicrobial drug under contract with respect to such program for such calendar year.

"(B) MEDICARE PART D PROGRAM.—For purposes of subparagraph (A), the Secretary shall report, for each applicable antimicrobial drug covered under part D of title XVIII of the Social Security Act, the product of—

"(i) the per-unit ingredient cost, as reported to the Secretary by prescription

drug plans and Medicare Advantage prescription drug plans, minus any per-unit rebate, discount, or other price concession provided by the sponsor of such applicable antimicrobial drug, as reported to the Secretary by the prescription drug plans and the Medicare Advantage prescription drug plans; and

"(ii) the number of units of such applicable antimicrobial drug paid for under such part D.

"(C) MEDICARE PART B PROGRAM.—

"(i) IN GENERAL.—For purposes of subparagraph (A), the Secretary shall report, for each applicable antimicrobial drug covered under part B of title XVIII of the Social Security Act, the product of—

"(I) the per-unit average sales price (as defined in section 1847A(c) of such Act) or the per-unit payment rate under such part B for a separately paid prescription drug without a reported average sales price; and

"(II) the number of units of such applicable antimicrobial drug paid for under such part B.

"(ii) UNITS AND ALLOCATED PRICES.—The Secretary shall establish a process for determining the units and the allocated price for purposes of this subparagraph for those applicable antimicrobial drugs that are not separately payable or for which National Drug Codes are not reported.

"(D) MEDICARE PART A PROGRAM.—

"(i) IN GENERAL.—For purposes of subparagraph (A), the Secretary shall report, for each applicable antimicrobial drug covered under part A of title XVIII of the Social Security Act, the product of—

"(I) the per-unit price under such part A for the antimicrobial drug; and

"(II) the number of units of such antimicrobial drug paid for under such part A.

"(ii) SPECIAL RULE.—For purposes of clause (i), the Secretary shall establish a

process for determining the units and the allocated price for those prescription drugs that are not separately payable or for which National Drug Codes are not reported in the diagnosis-related groups.

"(E) MEDICAID PROGRAM.—Under the authority of section 1902(a)(6) of the Social Security Act, the Secretary shall require each State that makes medical assistance available under the State plan under title XIX of such Act (or any waiver of such plan) for an applicable antimicrobial drug (including, if applicable, any such drug which is a covered outpatient drug under a rebate agreement entered into under section 1927 of such Act) to report, in a form consistent with a standard reporting format established by the Secretary, not later than the date determined under subparagraph (A)—

"(i) information on the total number of units of each dosage form and strength and package size of each applicable antimicrobial drug dispensed during the preceding calendar year under such State plan or waiver (including any such drugs dispensed to an individual enrolled with a

medicaid managed care organization or other specified entity (as such terms are defined in section 1903(m) of such Act)); and

"(ii) with respect to each dosage form and strength and package size of each such drug, the amount equal to—

"(I) the product of—

"(aa) the total number of units dispensed under the State plan or waiver during the preceding calendar year (as determined under clause (i)); and

"(bb) the per-unit ingredient cost paid by the State for each such unit; minus

"(II) any discounts or other price concessions provided and rebates paid to the State with respect to the dosage form and strength and package size of such drug and such calendar year (including rebates paid under a rebate agreement under section 1927 of such Act and any State supple-

mental rebates paid under a supplemental rebate agreement).

"(F) DEPARTMENT OF VETERANS AFFAIRS.—For purposes of subparagraph (A), the Secretary of Veterans Affairs shall report the total amount paid for each applicable antimicrobial drug procured by the Veterans Health Administration for individuals who receive health care from the Administration.

"(G) DEPARTMENT OF DEFENSE AND TRICARE PROGRAM.—For purposes of subparagraph (A), the Secretary of Defense shall report the sum of—

"(i) the total amount paid for each applicable antimicrobial drug procured by the Department of Defense for individuals who receive health care from the Department; and

"(ii) for each applicable antimicrobial drug dispensed under the TRICARE retail pharmacy program under section 1074g(a)(2)(E)(ii) of title 10, United States Code, the product of—

"(I) the per-unit ingredient cost, minus any per-unit rebate paid by the

sponsor of the applicable antimicrobial drug; and

"(II) the number of units of such applicable antimicrobial drug dispensed under such program.

"(H) DEPARTMENT OF HOMELAND SECURITY.—For purposes of subparagraph (A), the Secretary of Homeland Security shall report the total amount paid for each applicable antimicrobial drug procured by the Department of Homeland Security for individuals who receive health care through a program carried out by the Department.

"(I) BUREAU OF PRISONS.—For purposes of subparagraph (A), the Director of the Bureau of Prisons shall report the total amount paid for each applicable antimicrobial drug procured by the Bureau of Prisons for individuals who receive health care through the Bureau.

"(J) INDIAN HEALTH SERVICE.—For purposes of subparagraph (A), the Secretary, acting through the Indian Health Service, shall report the total amount paid for each applicable antimicrobial drug procured by the Service for

individuals who receive health care through the Service.

"(2) REGULATIONS.—Not later than 1 year after the date of enactment of this part, the Secretary, in consultation with the heads of Federal agencies carrying out specified government programs, shall issue regulations to assist such heads (or their designees) in carrying out the requirements under this section.

"(3) SUBSCRIPTION CONTRACT ADJUSTMENT.—Pursuant to the contract entered into under this section with respect to an applicable antimicrobial drug, for each year of the term of such contract, the Secretary shall, not earlier than 6 months after the end of each calendar year, subtract from the payment installments determined for such contract under subsection (c)(1) for such year the revenue of the sponsor of such drug from the previous year from sales of the applicable antimicrobial drug reported under paragraph (1) for specified government programs.

"(4) DEFINITIONS.—In this subsection:

"(A) APPLICABLE ANTIMICROBIAL DRUG.—The term 'applicable antimicrobial drug' means an antimicrobial drug for which

the sponsor of such drug receives a subscription contract under subsection (a).

"(B) SPECIFIED GOVERNMENT PROGRAM.—The term 'specified government program' means—

"(i) the Medicare part D program under part D of title XVIII of the Social Security Act;

"(ii) the Medicare Part B program under part B of such title XVIII;

"(iii) the Medicare Part A program under part A of such title XVIII;

"(iv) the Medicaid program established under title XIX of the Social Security Act and includes, with respect to a State, any waiver in effect with respect to such program;

"(v) any program under which prescription drugs are procured by the Department of Veterans Affairs;

"(vi) any program under which prescription drugs are procured by the Department of Defense;

"(vii) the TRICARE retail pharmacy program under section 1074g(a)(2)(E)(ii) of title 10, United States Code;

"(viii) any program under which prescription drugs are procured by the Department of Homeland Security;

"(ix) any program under which prescription drugs are procured by the Bureau of Prisons; or

"(x) any program under which prescription drugs are procured by the Indian Health Service.

"(e) FAILURE TO ADHERE TO TERMS.—The Secretary shall cease any payment installments under a contract under this section if—

"(1) the sponsor—

"(A) permanently withdraws the antimicrobial drug from the market in the United States;

"(B) fails to meet criteria under subsection (b); or

"(C) does not complete a postmarket study required by the Food and Drug Administration during the length of the term of the contract;

"(2) the annual international and private insurance market revenues with respect to an antimicrobial drug (not counting any subscription revenues from any source pursuant to a contract under this section or other international or private entities) exceed 5 times the average annual amount of the subscription contract paid by the Secretary as certified by the sponsor annually; or

"(3) if the total revenue of the sponsor from specified government programs, as defined in subsection (d)(4), for a year exceeds the amount of the subscription contract paid by the Secretary for that year.

"(f) PRIVATE PAYER AND INTERNATIONAL PAYER PARTICIPATION.—The Secretary shall make efforts to increase the participation of domestic private payors and international payors in subscription contracts or other types of value-based arrangements that are similar to the subscription contracts authorized under this section.

"SEC. 399RR. ENCOURAGING APPROPRIATE USE OF ANTIBIOTICS AND COMBATING RESISTANCE.

"(a) ESTABLISHMENT OF HOSPITAL GRANT PROGRAM.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this part, the Secretary and

the Director of the Centers for Disease Control and Prevention shall coordinate with the Administrator of the Health Resources and Services Administration, the Administrator of the Centers for Medicare & Medicaid Services, the National Coordinator for Health Information Technology, and other relevant agencies, to establish a grant program under the Centers for Disease Control and Prevention to support hospital and other inpatient facility efforts—

"(A) to judiciously use antimicrobial drugs, such as by establishing or implementing appropriate use programs, including infectious disease telehealth programs, using appropriate diagnostic tools, partnering with academic hospitals, increasing health care-associated infection reporting, and monitoring antimicrobial resistance; and

"(B) to participate in the National Healthcare Safety Network Antimicrobial Use and Resistance Module or the Emerging Infections Program Healthcare-Associated Infections Community Interface activity of the Centers for Disease Control and Prevention or a similar reporting program, as specified by the Secretary, relating to antimicrobial drugs.

"(2) PRIORITIZATION.—In awarding grants under paragraph (1), the Secretary shall prioritize hospitals without an existing program to judiciously use antimicrobial drugs, subsection (d) hospitals (as defined in subparagraph (B) of section 1886(d)(2) of the Social Security Act that are located in rural areas (as defined in subparagraph (D) of such section), critical access hospitals (as defined in section 1861(mm)(1) of such Act), hospitals serving Tribal-populations, and safety-net hospitals.

"(3) FUNDING.—Of the amounts appropriated under section 399SS, the Secretary shall reserve $500,000,000 to carry out this subsection.

"(b) SURVEILLANCE AND REPORTING OF ANTIBIOTIC USE AND RESISTANCE.—

"(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall use the National Healthcare Safety Network and other appropriate surveillance systems to assess—

"(A) appropriate conditions, outcomes, and measures causally related to antibacterial resistance, including types of infections, the causes for infections, and whether infections are acquired in a community or hospital setting, in-

creased lengths of hospital stay, increased costs, and rates of mortality; and

"(B) changes in bacterial resistance to antimicrobial drugs in relation to patient outcomes, including changes in percent resistance, prevalence of antibiotic-resistant infections, and other such changes.

"(2) ANTIBIOTIC USE DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall work with Federal agencies (including the Department of Veterans Affairs, the Department of Defense, the Department of Homeland Security, the Bureau of Prisons, the Indian Health Service, and the Centers for Medicare & Medicaid Services), private vendors, health care organizations, pharmacy benefit managers, and other entities as appropriate to obtain reliable and comparable human antibiotic drug consumption data (including, as available and appropriate, volume antibiotic distribution data and antibiotic use data, including prescription data) by State or metropolitan areas.

"(3) ANTIBIOTIC RESISTANCE TREND DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall in-

tensify and expand efforts to collect antibiotic resistance data and encourage adoption of the Antibiotic Use and Resistance Module within the National Healthcare Safety Network among all health care facilities across the continuum of care, including, as appropriate, acute care hospitals, dialysis facilities, nursing homes, ambulatory surgical centers, and other ambulatory health care settings in which antimicrobial drugs are routinely prescribed. The Secretary shall seek to collect such data from electronic medication administration reports and laboratory systems to produce the reports described in paragraph (4).

"(4) PUBLIC AVAILABILITY OF DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, for the purposes of improving the monitoring of important trends in patient outcomes in relation to antibacterial resistance—

"(A) make the data derived from surveillance under this subsection publicly available through reports issued on a regular basis that is not less than annually; and

"(B) examine opportunities to make such data available in near real time.

"SEC. 399SS. APPROPRIATIONS.

"(a) IN GENERAL.—To carry out this part, there are hereby appropriated to the Secretary, out of amounts in the Treasury not otherwise appropriated, $11,000,000,000, for fiscal year 2022, to remain available until expended.

"(b) EMERGENCY DESIGNATION.—

"(1) IN GENERAL.—The amounts provided by this section are designated as an emergency requirement pursuant to section 4(g) of the Statutory Pay-As-You-Go Act of 2010.

"(2) DESIGNATION IN SENATE.—In the Senate, this section is designated as an emergency requirement pursuant to section 4112(a) of H. Con. Res. 71 (115th Congress), the concurrent resolution on the budget for fiscal year 2018.

"SEC. 399TT. STUDIES AND REPORTS.

"(a) IN GENERAL.—Not later than 6 years after the date of enactment of this part, the Comptroller General of the United States shall complete a study on the effectiveness of this part in developing priority antimicrobial drugs. Such study shall examine the indications for, usage of, development of resistance with respect to, and private and societal value of critical need antimicrobial drugs, and the impact of the programs under this part on patients and markets of critical need antimicrobial drugs. The

Comptroller General shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the findings of such study.

"(b) ANTIBIOTIC USE IN THE UNITED STATES; ANNUAL REPORTS.—The Director of the Centers for Disease Control and Prevention shall, each year, update the report entitled 'Antibiotic Use in the United States' to include updated information on progress and opportunities with respect to data, programs, and resources for prescribers to promote appropriate use of antimicrobial drugs.

"(c) REPORT ON ANTIMICROBIAL PROPHYLACTICS.—Not later than 3 years after the date of enactment of this part, the Director of the Centers for Disease Control and Prevention shall publish a report on antimicrobial prophylactics.

"SEC. 399UU. DEFINITIONS.

"In this part—

"(1) the term 'antimicrobial drug'—

"(A) means, subject to subparagraph (B), a product that is—

"(i) a drug that directly inhibits replication of or kills bacteria or fungi relevant to the proposed indication at concentrations likely to be attainable in hu-

mans to achieve the intended therapeutic effect; or

"(ii) a biological product that acts directly on bacteria or fungi or on the substances produced by such bacteria or fungi; and

"(B) does not include—

"(i) a drug that achieves the effect described by subparagraph (A)(i) only at a concentration that cannot reasonably be studied in humans because of its anticipated toxicity; or

"(ii) a vaccine; and

"(2) the term 'Committee' means the Committee on Critical Need Antimicrobials established under section 399OO.".

○

Quality Payment and Initiatives Update

September 2022

Quality Reporting

- As the FAH recommended, CMS finalized its inpatient hospital policy to suppress several measures and payment reductions in the Hospital VBP and HAC Reduction Programs.
- The FAH continues to identify ways to improve CMS hospital quality programs. The FAH, with an outside consultancy, completed a study of the FY 2021 value-based, hospital programs (VBP, readmissions reduction program, and HAC program), including an analysis of certain equity-related variables that may impact hospital performance. The manuscript was accepted by Health Affairs, and we are hoping for publication later in 2022 or early 2023.

National Quality Forum (NQF)

- The FAH is seeking NQF funding and has endorsed legislation, the *Promoting Health Care Quality Act of 2022*, which would establish and increase funding for the NQF for next year, and we are positioning the legislation for inclusion in an end-of-year vehicle.
- The FAH, including through its leadership and engagement with the NQF, continues to pursue policies that ensure quality measures are fit-for-purpose across federal quality programs. This year, through Chip's co-leadership of the NQF's MAP Coordinating Committee, removal of additional measures from CMS quality programs was recommended to CMS, specifically five measures from the hospital outpatient quality reporting program. This was the second year of this effort, as we influenced the refinement of the process to include the full involvement of the technical workgroups, as well as the criteria used to examine each measure's suitability for continued use.

MA Managed Care Abuses and Unfair Practices

- As part of an overall strategy for CMS to exercise greater oversight and bring accountability to MA plans for patient access problems related to prior authorization practices, the FAH developed and submitted a novel quality measure for use in the MA Stars program.
    - This measure will show how often an MA plans upheld their own initial denial determinations for prior authorizations and payments denials (Level 1).
    - Next steps include identifying suitable collaborators to help field test the proposed quality measure and develop a strategy to satisfy CMS requirements for the measure to be successfully added to CMS quality programs.
    - While the measure was not expected to be adopted by CMS at this stage, the FAH is working with, and received enthusiastic support from other stakeholders (NCQA, AMA, other physician groups, and patient advocates) to advance the measure further and propose it for adoption in the next CMS measure adoption cycle.

Health Equity

September 2022

Administration Initiatives

In April 2022, the Department of Health and Human Services (HHS) released the HHS Equity Action Plan that focused on advancing equity as a central component of the HHS decision-making framework. Under this framework, HHS established the Office of Climate Change and Health Equity to lead initiatives that integrate environmental justice into the HHS mission.

- Additionally, CMS released their 2022-2023 Framework for Health Equity consisting of five priority areas to align with the HHS Equity Action Plan. The framework lays out HHS-wide strategies and approaches to embedding health equity across CMS including:
    - The HHS Rural Action Plan
    - The HHS Maternal Action Plan
    - The HHS National Standards for Culturally and Linguistically Appropriate Standards (CLAS) in Health and Health Care
    - The HHS National Quality Strategy
    - The HIS Strategic Plan.

- FAH supports CMS's efforts to drive health equity and quality through the development of new quality measures that address health equity, data reporting through existing measures, and the development of new health equity measures, especially in focus areas including maternal, rural, and mental health equity.

FAH Health Equity Task Force and Recommendations on FY 2023 IPPS

- In June 2022, FAH reconvened the Health Equity Task Force to provide comments on the FY 2023 Inpatient Prospective Payment System (IPPS) Proposed Rule. The FAH provided comments on various equity-focused Requests for Information (RFIs) related to measuring health equity and disparities of care.

- FAH recommendations to CMS in response to RFI questions related to guiding principles for selecting and prioritizing measures for disparities reporting include:
    - Measures for which CMS already has data sources containing potentially relevant demographic or social risk factors.
    - Measures for which self-reporting data are inherent within the measure (*e.g.*, experience-of-care surveys and patient-reported outcome performance measures (PRO-PM)).
    - Measures for which CMS can calculate performance results timely and provide feedback promptly to providers.

    - Expansion beyond clinical measures to resource-use measures, as providing equitable care to at-risk patients may necessitate increased resource use that may otherwise appear to be poor resource use performance.
    - Measures that are likely to align with collection and reporting requirements of other states and third-party payers as a means of minimizing provider burden.

- FAH was not supportive of the new measure concepts put forward by CMS related to health equity and the social determinants of health. Our comments centered around the lack of established evidence between health equity measures and improved health outcomes. We noted the performance gap among hospitals for the measure's five structural elements.

- FAH recommendations focused on opportunities to improve health equity through existing quality measures, specifically through additional stratification of data collection and reporting.
    - For example, the collection of race/ethnicity, payer, and gender have always been included in the electronic clinical quality measure (eCQM) specifications as supplemental data elements. CMS could choose to make the collection and reporting of these data required.
    - This change would allow hospitals to collect the data, use it for improvement purposes, and receive automatic credit through reporting of these data rather than require them to attest to it through a structural measure.

Health Information Technology and Cybersecurity

September 2022

Information Blocking (ONC)

- In March 2020, the Office of the National Coordinator for Health Information Technology (ONC) published the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule.
- In effect October 6, 2022, providers are required upon request to share all Electronic Health Information (EHI) in the Designated Record Set (DRS), including unstructured data, regardless of whether the group of records are used or maintained by or for a covered entity.
- In April 2020, the HHS Office of Inspector General (OIG) issued a proposed rule adding new information blocking civil monetary penalty (CMP) authorities for actors found in violation of the information blocking regulations. This rule has not yet been finalized, but is expected this Fall.
- ONC is on track to publish a proposed rule in the Fall with "enhancements" to the information blocking requirements and exceptions. This rule is currently under review at OMB titled, "ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing."

Cybersecurity

- The FAH continues to participate in the Health Sector Council Cyber Working Group.
- The FAH continues to work with HHS and Congress to improve the regulatory environment regarding cyber incidents, including pursuing HIPAA safe harbors and seeking revisions to the public posting of breaches of protected health information for providers who are victims of hacking or ransomware despite having appropriate cybersecurity safeguards.
- The *Strengthening American Cybersecurity Act*, signed into law in March 2022, requires critical infrastructure entities and civilian federal agencies to report any "substantial cyber incident" within 72 hours and any ransomware payment within 24 hours to the Department of Homeland Security's Cybersecurity and Infrastructure Agency (CISA).
- On September 12, 2022, CISA issued a 60-day RFI to receive input from the public as CISA develops proposed regulations required by the law. The FAH is working with members and the US Chamber in submitting comments on the RFI.

Legislative Activity on Privacy Legislation

- In July 2022, the *American Data Privacy and Protection Act* (ADPPA) reported favorably out of the House Energy and Commerce Committee (53-2 vote). The House has yet to vote on this legislation, and related measures have a long way to go before advancing in the Senate.

- The ADPPA would become a federal standard privacy law that:
    - Creates a "Duty of Loyalty," a subset of specific restrictions on the uses of certain types of data (e.g., social security numbers, precise geolocation information, etc.), enacts consumer data rights including individual data ownership and control rights, and adopts two new eCQMs to the Medicare Promoting Inoperability Program's eCQM measure set, among other provisions.

Digital Quality

- In the FY 2023 Inpatient Prospective Payment System (IPPS) Proposed Rule, CMS sought feedback for moving its entire quality enterprise to fully digital quality measurement by 2025. Special attention was given to refining the definition of digital quality measure (dQM), data standardization strategies and opportunities, and incorporating Fast Healthcare Interoperability Resources (FHIR®) into reporting existing electronic clinical quality measures (eCQM) to create dQMs.
- The FAH's comments included recommendations:
    - To utilize the Center for Medicare and Medicaid Innovation (CMMI), in trial design and rollout rather than collectively using IPPS hospitals as a test bed through HIQR Program and PIP eCQM requirements;
    - To ascertain from hospitals their actual state of readiness to incorporate FHIR-based API use as part of their quality measurement efforts in the very near term.
    - While the steps outlined above are underway, other related health IT initiatives should mature and their potential roles in a digital CMS quality enterprise can be assimilated.
- The FAH stands ready to partner with CMS in the important but pragmatic work that must be done.

Promoting Interoperability Program

- In the FY 2023 IPPS Proposed Rule, CMS proposed a number of changes to the Prescription Drug Monitoring Program (PDMP), the Public Health and Clinical Data Exchange Objective by adding an Antibiotic Use and Antibiotic Resistance (AUR) measure, the scoring methodology for the Medicare Promoting Interoperability Program beginning in CY 2023, and to institute public reporting of certain Medicare Promoting Interoperability Program data beginning with the CY 2023 EHR reporting period.
- To maintain eCQM alignment, CMS also proposed to add the same two eCQMs to the PIP that are being proposed for addition to the HIQR Program: Cesarean Birth eCQM and Severe Obstetric Complications eCQM. Both measures would be available for voluntary, self-selected reporting in the CY 2023 EHR reporting period followed by mandatory reporting starting with CY 2024.

Medicare Advantage / Managed Care

September 2022

- The FAH is engaged in a multi-faceted effort to highlight Medicare Advantage (MA) and managed care plan abuses and unfair payment and coverage practices. We continue to raise the issue with multiple policymakers and HHS and CMS leadership in every way we can.
- Our multipronged strategic effort to address MA and managed care abuses includes:
    - Creating metrics of accountability including the submission of a quality measure on Medicare Advantage denials.
    - Pushing for transparency, accountability, and increased oversight over MA plans and their practices.
    - Partnering on research with AHA to inform our advocacy efforts.
    - Educating and engaging policy stakeholders on MA abuses through earned and paid media campaigns.

Legislative Efforts

- On September 14, 2022, H.R. 3173, the *Improving Seniors' Timely Access to Care Act of 2022*, passed in the House. The bipartisan bill establishes several prohibitions, requirements, and streamlined standards relating to prior authorization processes under MA plans.
- The bill aims to:
    - Reduce delays in the prior authorization process by requiring insurers to make it electronic and by tasking HHS with creating a process that enables real-time decisions for routine items.
    - Directs plans to report prior authorization approval rates to CMS, and orders HHS to establish requirements that encourage plans to follow "evidence-based medical guidelines."
- The FAH participated in a large coalition of entities in support of the bill and its House passage. A Senate companion bill, S. 3018, has 43 cosponsors, and the goal is to move it for a Senate vote during the lame duck session of Congress at the end of this year.

HHS' OIG Report on MA Plan Abuses

- In April 2022, the HHS Office of the Inspector General (OIG) released a report finding that MA organizations (MAOs) are often shortchanging patients by denying millions of requests each year for medically necessary care. The report notes that "CMS annual audits of MAOs have highlighted widespread and persistent problems related to inappropriate denials of services and payment."
- In May 2022, the FAH wrote to CMS Administrator Chiquita Brooks-LaSure urging prompt implementation of the OIG's recommendations and further action to protect beneficiaries and address program abuses. The letter notes that the OIG's findings reflect a broader pattern of MAO practices that inappropriately deny, limit, modify, or delay the delivery of or access to services and care for MA beneficiaries.

- In August, CMS released a Request for Information (RFI) on MAO practices and access issues. The FAH submitted comments again urging CMS to make needed changes and to research the potential health disparities in care that may be resulting from MAO practices.

CMS Outreach and Regulatory Efforts

- As part of FAH efforts to hold MA plans accountable, the FAH submitted to CMS a prototype MA quality measure that would publish a plan's Level 1 denial upheld rate for inclusion in an MA plan's star rating. The measure would disincentivize the denial of services or payments that could not be easily supported upon provider or patient appeal.
- The FAH is currently in the early stages of the measurement development process and is engaging in outreach with potential partners to field test and certify the validity of the measure.

The Issue

FAH members routinely report delays and inconsistencies with prior authorization processes across Medicare Advantage Organization (MAO) plans that negatively impact patients' access to timely medically necessary services, as well as payments to providers for those services.

A recent Department of Health & Human Services (HHS) Office of Inspector General (OIG) report highlighted that Medicare Advantage organizations denied or delayed care and payments that met applicable coverage and billing rules.

- The report found that that among a sample of prior authorization requests reviewed, 13 percent met Medicare coverage rules.
- Similarly, 18 percent of denied payment requests met coverage and billing rules. A 2018 OIG report on MA service and payment denials noted that although MA plans overturn their own denials at high rates at various levels of the appeals process, only 1% of beneficiaries and providers appeal prior authorization and payment denials.
- The report stated, "MAOs may have an incentive to deny preauthorization of services for beneficiaries, and payments to providers, in order to increase profits."

The FAH believes that CMS should add a quality measure to the Medicare Part C & D Star Ratings Program.

Quality As a Lever of Influence

The FAH believes that the development of a quality measure is a key tactic to increase CMS's oversight of MA plans' denial of prior authorization and payments. Quality measures are central drivers of value-based healthcare and the Medicare Part C and D Star Rating methodology acts as a sharp tool for CMS oversight and drives improvements in MA plans.

The Star Rating program includes several indicators of the quality, patient safety, operations, and performance of MA plans, providing a direct avenue to address issues of transparency and access to care, including high rates of upheld Level 1 prior authorization and payment denials. The FAH's goal is to disincentivize MAOs from egregious operational activities.

Our Work

The FAH proposed a new quality measure to be considered by CMS for the 2023 MUC list: ***Level 1 Overall Denials Upheld Rate***.

- This measure will show how often an MAO upheld its own initial denial determinations for prior authorizations and payments (Level 1) submitted by the beneficiary, someone on behalf of the beneficiary, or the provider.
- The proposed quality measure would be added to the Part C & D appeals measures that have been in use in the Stars Rating Program since 2009. The FAH submitted the measure for proposal on May 20, 2022.

Next Steps

The FAH is now identifying suitable collaborators to help field test the proposed quality measure and develop a strategy to satisfy CMS requirements for the measure to be successfully added to the 2023 MUC list.

Technical Description of Specifications for New Level 1 Upheld Denial Rate Measure for MA Organizations

Measure Title	Level 1 Denial Upheld Rate
Measure Description	Percentage of prior authorizations and payment appeals submitted by the beneficiary, someone on behalf of the beneficiary, or the provider where a Medicare Advantage Organization (MAO) upheld its own initial denial determination at Level 1
CMS Program	Medicare: Part C & D Star Rating
Rationale	A new quality measure should be developed to rate and report on patient access problems related to Level 1 appeals and denial overturn rates for prior authorization, appeals and overturn rates for payment denials, network adequacy, and service delays. This will greatly improve transparency regarding MAO operations and help reduce patient access issues due inappropriate MAO initial determinations. • The OIG found that 13% of prior authorization denials met coverage rules, and 18% of denied payment requests met coverage and billing rules. • High numbers of overturned denials at Level 1 of the appeals process may indicate that some beneficiaries may not be receiving care that MAOs are required to provide, delaying necessary care, and increasing provider burden. • Each overturned denial represents a case in which beneficiaries or providers had to file an appeal to receive services or care normally covered by Medicare. • Measuring Level 1 denials of initial prior authorizations and payment requests, in addition to Level 2, aligns with CMS's Meaningful Measures 2.0, as well as its 2022 Quality Measure Strategy to prioritize patient access.
Numerator	Prior authorizations and payment denials made by the patient, a patient representative, or provider, submitted to the health plan where the initial denial decision was upheld in appeal by the health plan in the calendar year
Denominator	Total number of appeals (prior authorizations and payments) submitted to the health plan (upheld denial, overturned, and partially overturned) by the patient, a patient representative, or the provider that the MAO reviewed
Denominator Exclusions	Exclude appeals that failed one or both data validation checks (e.g., missing data in fields, missing documentation)
Stratification	Potential Categories: • Service / Item Requests • Medically Necessary Imaging • Transfers to Post-Acute Facilities • Injections • Inpatient Admissions • Payment Denials/Downgrades • Denials & Upheld Determinations by Race • Gender • Disability Status/SSI • Dual Eligibility • Provider Type
Analogous Measure	Measure C27 - *Reviewing Appeals Decisions:* The rate at which an independent review entity (IRE) found the health plan's decision to deny coverage to be reasonable at Level 2 of the appeals process

NATIONAL QUALITY FORUM
Driving measurable health improvements together

Survey of Hospital Association Virtual Roundtable Invitees

1. Performance measures are increasingly used for *accountability* purposes – including in value-based payment contracts, in publicly reported information for consumers, and in insurance product's provider network designs (*e.g.,* limited networks, tiered networks, center of excellence models). **Please rate the following measurement issues from 0-10 to indicate your members' level of concern about each issue.**

	0 - Not a Concern	1	2	3	4	5	6	7	8	9	10 - Significant Concern
Number/volume of measures used in any given payer's program	○	○	○	○	○	○	○	○	○	○	○

0 of 3 answered

	0 - Not a Concern	1	2	3	4	5	6	7	8	9	10 - Significant Concern
Adequacy of performance targets / benchmarks used to evaluate performance	○	○	○	○	○	○	○	○	○	○	○
Absence of measures addressing high priority areas of care (please specify which areas)	○	○	○	○	○	○	○	○	○	○	○
Lack of alignment among payers in the measures used	○	○	○	○	○	○	○	○	○	○	○
Adequacy of risk adjustment models	○	○	○	○	○	○	○	○	○	○	○
Burden associated with extracting data required to report measure results to payers	○	○	○	○	○	○	○	○	○	○	○

Other area of concern not listed (please specify along with degree of concern)

0 of 3 answered

2. The following are areas that are currently high priorities for measurement and improvement at many hospitals and delivery systems. **For which of these might your members find value in aligning with peer organizations on measurement methods? (check all that apply)**

- [ ] Patient care experiences
- [ ] Health equity
- [ ] Patient safety / avoidable harm
- [ ] Workforce well-being
- [ ] Other (please specify)

- [ ] None of the above

3. What is the single most important area of focus you would like NQF to have over the next 18 months?

DONE

Powered by

0 of 3 answered