



Recommendations to Senators Murray and Burr to Improve the Nation's Public Health and Medical Preparedness Response Programs

The [Johns Hopkins Center for Health Security](#) works to protect people's health from epidemics and disasters and to ensure community resilience. For over 20 years, our Center has examined how innovations, policies, and programs can strengthen health security. Below are the Center for Health Security's suggested proposals that, if empowered through bipartisan legislation, would improve the nation's public health and increase medical preparedness and response programs.

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Expedite Development of Medical Countermeasures for Unknown Viral Threats

Problem: New deadly viruses can spread easily around the globe, causing significant loss of life and economic downturn. With epidemics occurring more frequently, the next fast-moving, novel virus could cause a pandemic within the next 10 years. It still takes too long to develop novel antivirals, vaccines, and diagnostics through existing programs at HHS and DOD, which are primarily directed toward known and listed threats.

A list-based approach to MCM development fails to account for unknown pathogens or those without historical precedent. While it is not possible to identify exactly which virus may cause the next pandemic, we know that certain viral families possess the attributes most likely to lead to large scale outbreaks, and we should use this knowledge to guide better preparations for rapid MCM development.

Solution: The United States must set an ambitious national goal of more rapidly developing MCMs for novel or unknown threats by leveraging platform technologies and other innovative approaches. Funding a new dedicated “Disease X” program can achieve this goal. Rather than waiting for a specific viral threat to emerge, a Disease X capability could, for example, design antiviral compounds that may have an effect against high-risk viral families. Such antivirals could be developed to target a specific pathway shared by all family members in designated viral families. These compounds could then form the basis of a more specific product once a threat materializes. In addition to viral family targeted approaches, multiple strategies exist to develop broadly applicable MCMs in advance of identifying the next pandemic pathogen; for example, host-side drug targets, advances in supportive care, inflammation controls, etc. A Disease-X strategy would ideally diversify its investments across many approaches.

BARDA within HHS and JPEO within DoD are well positioned to run these efforts, which could be coordinated through the Public Health Emergency Medical Countermeasures Enterprise. A new congressional appropriation should be provided to enable these agencies to initiate a robust and coordinated strategy before the next virus threatens the globe.

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Invest in Ongoing and Just-in-Time Social Science Research to Ensure Public Support for Outbreak Management

Problem: As we have seen during the COVID-19 pandemic, the public’s sustained and active support for outbreak management efforts, including vaccination, cannot be taken for granted. Regardless of the availability of improved data, response systems, and cutting edge MCMs, a hesitant public – whether in the form of long-standing mistrust of health authorities due to past ethical lapses and present social bias or a mindset fostered by an organized domestic anti-vaccination movement or foreign disinformation campaign – can thwart the potential success of pandemic response measures, as can social barriers that prevent the public from successfully engaging in personal protective actions. The collective of millions of Americans – e.g., masking, keeping physically distant, receiving the vaccine – have been critical to reducing the number of COVID-19 related infections, hospitalizations, and deaths. Nonetheless, the technical and operational aspects of outbreak management have largely overshadowed social behavioral, and cultural matters perceived as intangible, less urgent, and/or harder to change.

Solution: In close conjunction with investing in innovative technologies and MCMs, Congress should fund leading-edge social, behavioral, and communication research that advances understanding of the causes, instances, and impacts of public cooperation during outbreaks and leads to evidence-based “best practices” for generating the public’s trust and help during public health emergencies. The infrastructure and funding for high-impact research on the human factors of outbreak management should be able to support both applied research during rapid response to a health emergency as well as more methodical and sustained basic research. To that end, Congress should encourage NIH, NSF, and CDC to undertake an interagency effort to strengthen the nation’s capacity for ongoing and just-in-time social science research with the goal of improving outbreak management.

Authorize the National Center for Epidemic Forecasting and Outbreak Analytics

Problem: During rapidly evolving infectious disease outbreaks, early understanding of the potential spread and severity of an outbreak can enable public health decision makers to take decisive action, even when data are scarce. However, the current capabilities in the United States for using modeling for outbreak response suffers from a fundamental disconnect between epidemiological data, modelers, and public health decision makers. Currently, modeling capacity exists within informal teams at federal agencies and individual academic experts who volunteer their time and expertise during an outbreak response. There is no formalized modeling capacity to support public health decision making.

Solution: To combat this problem, the Biden-Harris administration announced in National Security Directive-1 an intention to create a National Center for Epidemic Forecasting and Outbreak Analytics. There is also \$500 million in the American Rescue Plan for the forecasting center and data modernization. However, in order to establish a permanent capability, Congress should include legislative language authorizing the Centers for Disease Control and Prevention to continue the work of the forecasting center as well as including annual appropriations to support its ongoing mission.

Prioritize Funding for Development of At-Home Diagnostic Technology

Problem: Limitations surrounding access to reliable diagnostic testing have dominated much of the response to COVID-19. As outbreaks emerged in countries around the world, the US was unable to quickly deploy reliable diagnostic testing tools. This critical gap, and the importance of diagnostic testing for all response activities, highlights the need to have more rapid, convenient, and equitable access to testing.

Solution: Through the increasing diffusion of health technology to consumers and patients, it is becoming more feasible for diagnostic testing to be placed in the hands of the patient. Such tests, when used to diagnose infectious disease and coupled to information technology, could have a transformative benefit for current and future pandemic response. Congressional funding, and the development and review of such technologies by BARDA, FDA, and CMS should be prioritized. BARDA should be tasked with increasing the development and availability of direct-to-consumer home tests for infectious diseases. FDA should have a complementary aim to expedite review and streamline regulatory pathways for such devices. CMS and private insurers should provide payment/reimbursement schedules for these at-home diagnostic tests to facilitate uptake.

At-home diagnostic technology already exists for HIV and is in advanced development being funded by BARDA for influenza. By accelerating the development, adapting existing at-home diagnostic technology for SARS-CoV2, and preparing the technology for future novel pathogens, we can be better prepared for future pandemics.

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Create a National Center for Pandemic and Disaster Nursing Research

Problem: The COVID-19 pandemic has exemplified the critical role that nurses play in emergency preparedness and response, including supporting and informing epidemic surveillance and detection, dispensing life-saving medical countermeasures, implementing public health interventions, providing direct care for patients, educating the public to decrease risk of infection, providing health systems leadership, and counseling community members to allay fear and anxiety. Despite this, there are significant gaps in the education, training, workforce development and research needed to prepare the nursing workforce to respond to pandemics and other disasters.

Solution: To help bridge this critical gap in preparing the nation's nursing workforce for pandemics, Congress should require CDC/HHS to establish a National Center for Pandemic and Disaster Nursing Research as a university affiliated research center. U.S. Schools of Public Health routinely generate research to inform practice on an ongoing basis, yet nothing similar exists for nursing. In a rapidly changing healthcare landscape with evolving technology, this Center could generate resources and technical assistance to support nurses across the U.S.

The National Center could address major gaps by creating an expert national nurse response team that could deploy to support clinical care and nurse workforce training; improving nursing education before public health emergencies, such as by establishing a Disaster Nursing Certificate and courses on public health emergency preparedness; and improving nursing policy and research for public health emergencies, such as by supporting research efforts that focus on improving health care worker protections.

A recent [NAS report](#), as well as a [Center for Health Security report](#) and an [American Nurses Foundation report](#) have all called for the establishment of such a Center.

Develop New Vaccine Delivery Platforms to Rapidly Immunize Millions in a Pandemic

Problem Controlling the next pandemic sooner will require more rapid immunization of large populations in very short timeframes. A major bottleneck during pandemic mass vaccination is the requirement for healthcare providers to physically administer vaccines, usually by intramuscular injection via needle and syringe, and the limited capacity to rapidly scale up domestic glass vial production, filling and finishing.

Solution: We should strive for a future where a substantial proportion of the US population can be immunized within days to weeks, rather than months. Such a capability may be possible if alternative and thermostable immunization delivery technologies such as microneedle patches, liquid oral preparations, tablets and pills, sublingual gels, or other technologies are integrated into public health practice. This capability should be prioritized by and publicly articulated in public health preparedness plans and strategies including those promulgated by CDC, ASPR, BARDA, the PHEMCE, DoD, and other stakeholders. Specifically, BARDA's 'Beyond the Needle' program, which aims to catalyze technology development in this space, should be prioritized and supported. Funding or other incentives should be provided to enable the development of manufacturing infrastructure for particularly promising administration technologies as part of a domestic public health supply chain initiative. CDC should undertake operational research and planning efforts to more fully elucidate how these products would be used during emergencies, what their functional characteristics should be, and to identify the most appropriate end-user. Finally, FDA's regulatory authority and guidance should enable the safe and effective use of this new class of vaccine delivery platforms.

Develop a National Strategy to Combat Health-Related Misinformation and Disinformation

Problem: A critical lesson from the COVID-19 pandemic is the dangerous influence of health-related misinformation and disinformation. False information, intentional or not, has had a myriad of effects in the past year, including reduced trust in public health responders, increased belief in false medical cures, and politicization of public health measures. The spread of these falsehoods has led to more infections, deaths, disruption, and disorganization of the effort to combat the pandemic. Confusing and conflicting messages also increased distrust and disrupted the public health communication environment. Both domestic and international actors have used false information during this public health emergency to further their own political and societal goals. Taken together, the spread and consequence of public health misinformation and disinformation can lead to national security threats.

Solution: The United States must address the problem of health-related misinformation and disinformation through a national strategy, both to ensure an effective response to the COVID-19 pandemic and to prepare for the challenges of future public health emergencies. Such a strategy should be organized around 4 main pillars of effort: (1) intervene against false and damaging content as well as the sources propagating it, (2) promote and ensure the abundant presence and dissemination of factual information, (3) increase the public's resilience to misinformation and disinformation, and (4) ensure a whole-of-nation response through multisector and multiagency collaboration. Solutions require shared responsibility from a range of actors, including, but not limited to, social media, news media, government, national security officials, public health officials, scientists, and the public. A national commission should be established to provide evidence-based guidelines and recommendations for nonpartisan oversight of this area.

Create Deployable Research Response Teams

Problem: Deployable teams are used in many aspects of emergency response. This includes the National Disaster Medical System (NDMS), which has several types of specialized medical response units, and the CDC Global Rapid Response Teams, which deploy public health experts. However, there is not currently a mechanism for the deployment of clinical research teams in outbreak scenarios.

As we have seen, the timeline for the identification, development, and evaluation of medical countermeasures and other therapeutic approaches can be protracted. The regulatory environment for human subjects research can be a challenging setting for any researcher to navigate, but in an emergency, the rapidly changing landscape can be near impossible to manage even for senior investigators. During the COVID-19 pandemic, we have seen a need for the development of MCMs in the face of a novel infectious agent. The disconnected national regulatory and operational landscape for the development and production of MCMs slows this process considerably.

Solution: Congress should establish a mechanism and infrastructure to enable organization and deployment during a public health emergency of medical research response teams. Teams would be comprised of pre-trained researchers who could assist in rapid implementation of research protocols and could expedite the generation of data, specimens, enrollments, and other research outputs that support the development of MCMs, clinical and translational research, and operational policy.

HHS should leverage the research and operational expertise within ASPR, BARDA, CDC, and NIH to build this capacity for use during public health emergencies. The teams could leverage existing NDMS training mechanisms to ensure researchers are properly prepared to safely deploy. These teams could rapidly implement research protocols including longitudinal cohort or natural history studies, first in human studies, randomized controlled trials, expanded access protocols, and specimen collection/biobanking studies. The proposed research teams could facilitate rapid scale up of large, systematic, multi-site clinical studies.

Support Innovation and Stockpile Strategies to Provide Better Respiratory Protective Devices

Problem: During the COVID-19 pandemic, there were shortages of respiratory protective devices for medical workers. Many of the face coverings used by essential workers and the public, while better than nothing, were far from optimal. Progress in development and manufacture of better respirators is currently stunted by factors including under-investment in research and development, poorly designed standards, industrial inertia, lack of competition, regulatory barriers, an uncertain market, and absent US government policy.

Solution: Better, reusable, easier to wear respirators are possible and cost-effective. This includes both disposable respirators like N95s and their reusable (“elastomeric”) counterparts. Widespread public use of effective easy to use respirators could help save hundreds of thousands of lives during the next pandemic and reduce the economic damage by trillions of dollars.

The Strategic National Stockpile should purchase reusable elastomeric respirators for healthcare workers and high-risk essential workers to use in a near-term public health emergency. It should select respirators for the stockpile using a recurring procurement process every two years. Each round of purchases should use a competitive process or impose increasingly demanding requirements to spur innovation and improvement. BARDA has already issued a Mask Innovation Challenge to leverage innovation in the private sector. It should also issue a next generation Respirator Innovation Challenge. Information from this challenge should inform the requirements for new respirator purchases for the SNS. The SNS should continue to replenish the supply of disposable N95s for healthcare workers who cannot wear an elastomeric respirator and for lower risk essential workers. ASPR should immediately commission scenario-driven modeling studies to determine the number of respirators needed in a severe pandemic.

Create a Central Repository for Serosurveys and Public Health and Observational Studies

Problem: Serosurveys (antibody studies) are important for public health decision-making, but the studies are generally not publicly announced until they are completed, preventing shared learning and planning.

Serosurveys, performed to determine the population which has been exposed to disease, have been an important feature in the SARS-CoV-2 public health response, and would likely be an important feature in future public health efforts. For SARS-CoV-2, estimating the prevalence of infection and recovery is important for decision makers and public health workers at national, state, and local levels to make sound decisions about allocation of personal protective equipment (PPE), mitigation efforts, and, ultimately, vaccine procurement and prioritization. The immediate effectiveness of various public health interventions in limiting virus spread can be assessed and compared, and the true case fatality rate of SARS-CoV-2 infections can be determined. While some details regarding ongoing serosurveys are available currently, most are announced when they are completed. Sometimes, only the results are announced without much methodological detail. Providing information in this way deprives opportunities for one state to learn from ongoing studies in another state. This can lead to overlapping studies that may be answering the same question or examining the same population. Such overlap wastes precious resources.

Solution: The US government should create a central repository for serosurveys, similar to clinicaltrials.gov, which would be useful for public health research on emerging viruses in the future. [ClinicalTrials.gov](https://clinicaltrials.gov) provides essential information about study design, recruitment, and organizations performing the research; a serosurveys.gov would be able to provide those same pieces of information, to the benefit of public health research and decision making. A systematic method of entering data on serosurveys would then allow studies to be easily compared and could also allow individuals to access serosurveys in their area. It could also identify research gaps, such as a lack of longitudinal studies in a particular region. This could inform local research decisions on study design. It may also provide federal funding sources, such as the NIH, a clear list of current research to enable decisions on grant distribution. Like [ClinicalTrials.gov](https://clinicaltrials.gov), such a repository could also be an international resource and could provide connections for others interested in initiating their own similar studies. The CDC or another HHS agency could host such a site.

Evaluate the Hospital Preparedness Program’s Effectiveness during the Pandemic

Problem: HHS/ASPR’s Hospital Preparedness Program (HPP) is the federal program that supports preparedness and response of hospitals and other healthcare entities for disasters and large-scale health emergencies. It primarily does this through cooperative agreements to states, territories, and several large cities. The foundation of HPP’s healthcare preparedness strategy is healthcare coalitions (HCC). The goal of HCCs is to foster collaboration and coordination among local hospitals, public health departments, emergency management agencies and emergency medical services. In recent years other healthcare facilities such as long-term care facilities and home care agencies have been encouraged to join the coalitions.

In the early years HCCs focused on preparedness but more recently there has been an emphasis on HCCs playing an active role in response activities. There is ample evidence that HCCs have played an important role in common disasters, but what role the HCCs played in the COVID-19 pandemic response is unclear and key questions must be answered. These include, to what extent did HCC preparedness activities such as joint planning, exercising, and purchasing improve the resilience of the local communities? To what extent did HCCs facilitate information sharing and communication among its members? To what extent did HCCs play a role in sharing resources or patient load balancing during periods of severe patient surge? Knowing the answers to these questions is essential to guiding future HPP strategy.

Solution: ASPR should commission a study of the role and effectiveness of HCCs during the COVID-19 pandemic as a prelude to future strategic decisions about HPP.

Enlist the Community Health Sector in Achieving Adequate Preparedness and Response for Vulnerable Populations

Problem: To date, health systems and health departments have been seen as the principal actors in the US public health preparedness and response system, and federal grants to state and local jurisdictions have privileged these institutions in terms of capacity building. Yet, as shown during the pandemic, these formal institutions have limits to their reach and influence, particularly among Black, Indigenous, and People (BIPOC) communities. Such groups have suffered COVID-19's physical, financial, and psychological effects disproportionately, and they have faced ingrained logistical and social barriers to care: e.g., clinics with hours outside the working day or locations hard to access by public transportation; present-day discrimination and historical trauma at the hands of medical and public health actors. Through the intervention of community-based organizations, faith-based organizations, and community health workers (CHWs) with deep roots in these communities, these underserved populations have had greater access to, and have placed greater trust in, COVID-19 health communication, testing, and vaccination.

Solution: Moving forward, federal investments in state and local readiness and response should flow directly, in a sustained manner, to three sectors: public health, health care, *and* community health. As a complement to PHEP and HPP programs, Congress should authorize and fund a federal grants program that enables the full integration of CHWs (and the community- and faith-based organizations that employ them) into the public health and medical and preparedness and response system, through sustained technical and financial support. CHWs function as trusted, culturally competent, and linguistically appropriate intermediaries between vulnerable communities and clinical, behavioral, and social service delivery systems.

Develop a Coherent Strategy and Substructure to Facilitate Comprehensive Recovery from an Infectious Disease Disaster

Problem: Once a major public health crisis resolves, collective attention tends to trail off, even though victims may continue to struggle with lingering mental and physical health needs; hospitals may confront worker burnout and interrupted revenue streams; the social fabric of a community torn by stigmatization may need mending; and businesses, local governments, and individual households may grapple with the lingering effects of economic shortfalls. By the time the crisis dissipates, response professionals are likely to feel drained, and no trained and resourced workforce currently exists to plan for, facilitate, and monitor recovery, especially over the long-term. There is an implicit bias in the country’s approach to disaster recovery toward incidents involving natural hazards rather than biological ones. As a result, the post-epidemic recovery process currently lacks a common vision, policy guidance, planning structures, and field “best practices.”

Solution: Congress should authorize the development of national guidance to support states and local jurisdictions in planning for a swift and comprehensive recovery from a major infectious disease outbreak. Such guidance should leverage the expertise of CDC in outbreak management and the expertise of FEMA in disaster recovery. The country requires a whole-of-government, whole-of-community approach to post-epidemic recovery that pulls together diverse sectors including public health, mental health, emergency management, public safety, primary care, social services, community health, and education, to plan for, and facilitate a return to holistic wellbeing.