

#### Center for Health Security

# Johns Hopkins Center for Health Security's Recommendations for Improving America's Readiness for the Next Pandemic

It is considerably harder to put effective systems in place to reduce health and economic impacts amid a large disease outbreak. As we continue to respond to COVID-19, and its lasting consequences, the next pandemic could appear at any time—we must be better prepared.

The <u>Johns Hopkins Center for Health Security</u> works to protect people's health from epidemics and disasters and ensure community resilience. For over 20 years, our Center has examined how innovations, policies, and programs can strengthen health security.

Below are crucial solutions that should be deployed to prepare the US effectively for the next pandemic, ensuring American lives and livelihoods are protected:

- Expedite Development of Medical Countermeasures for Unknown Viral Threats through a New "Virus 201" Program in the United States
- Establish a National Infectious Disease Forecasting Center
- Prioritize Funding for Development of At-Home Diagnostic Technology
- Modernize Public Health Data Infrastructure for 21st Century Disease Threats
- Create a National Center for Pandemic and Disaster Nursing Research
- Develop New Vaccine Delivery Platforms to Rapidly Immunize Millions in a Pandemic
- Develop a National Strategy to Battle Misinformation and Disinformation During Infectious Disease Outbreaks
- Create Deployable Research Response Teams in NDMS
- Adopt a Health Defense Operations Designation
- Create a Central Repository for Serosurveys and Public Health Observational Studies
- Develop a Community Engagement Infrastructure to Assess and Activate Public Sentiment and Support for Outbreak Management

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# **Expedite Development of Medical Countermeasures for Unknown** Viral Threats through a New "Virus 201" Program in the United States

**Problem:** As COVID-19 has demonstrated, new deadly viruses can spread quickly and easily around the globe, causing significant loss of life and economic downturn. With nearly 200 epidemics occurring each year, the next fast-moving, novel infectious disease pandemic—Virus 201—could be right around the corner. It still takes too long to develop novel antivirals, vaccines, and diagnostics through existing programs at HHS and DOD, which are primarily directed toward specific, known, high-priority health security threats.

A substantial proportion of pandemic and biological threat preparedness activities were and are focused on list-based approaches that are in part based on pandemic influenzas of the past, historical biological weapons development programs, or recent outbreaks of emerging infectious diseases. But a list-based approach by its nature fails to account for unknown pathogens or those without historical precedent. As has been seen in the COVID-19 pandemic, delays in medical countermeasures (MCMs) have catastrophic health and economic consequences. While it is not possible to identify exactly what virus may cause the next pandemic, there are certain overarching and known principles that can help make predictions that can in turn guide preparations for the development of MCMs.

**Solution:** The United States must set an ambitious national goal of rapidly developing MCMs for novel or unknown threats in months, not years. Innovative technologies, outside-the-box thinking, and game-changing science must be harnessed to meet this goal. A new dedicated Virus 201 strategy, program, and funding should be created to achieve this goal, and the US Department of Health and Human Services (HHS) Biomedical Advanced Research and Development Authority (BARDA) and the Department of Defense (DOD) Joint Program Executive Office for Chemical and Biological Defense (JPEO) are well poised to run these efforts. Rather than waiting for a specific viral threat to emerge, a Virus 201 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.

An unknown pathogen can affect both military personnel and the American public. DOD and HHS investment strategies should be coordinated through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), with DOD taking the lead on products targeted to protect young, healthy military personnel, and HHS leading on other products needed to protect the diverse American public, including children and other vulnerable populations.

A new congressional appropriation of \$1 billion, divided equally between HHS and DOD, should be provided to enable these agencies to initiate a robust and coordinated strategy to accomplish this goal before the next virus threatens the globe. Learn More.

### **Establish a National Infectious Disease Forecasting Center**

**Problem:** During rapidly evolving infectious disease outbreaks, early understanding of the potential spread and severity of the 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:** The Department of Health and Human Services (HHS) should establish a National Infectious Disease Forecasting Center to develop and apply the science of epidemic forecasting, thereby radically transforming responses to infectious disease outbreaks by guiding decision making, anticipating outbreak severity and trajectory, anticipating needs for key supplies, and helping decision maker choose appropriate interventions.

The Center would cement outbreak science as a critical component of modern outbreak management and function like the National Weather Center but instead with responsibility for developing and using outbreak science to support public health decision making.

The Center would function both during and between outbreaks, with these responsibilities:

- Collate and standardize outbreak data: the quality, quantity, and timeliness of data during outbreaks is often suboptimal to support outbreak modeling. The forecasting center would help establish a centralized location for data aggregation and analysis.
- Coordinate a network of both public and private surveillance systems deployed domestically and globally, providing continuous surveillance of key variables needed to understand, portray the state of, and predict epidemics.
- Encourage the development of data innovation, including improving the speed and quality of outbreak data.
- Develop new methodologies and approaches for outbreak science in the context of challenges facing outbreak response (e.g., data scarcity).
- Create deployable data science and technologists teams to support local outbreak responses.
- Establish a communication network for informing the public of imminent or expected threats.
- Create preparedness protocols for data sharing, model development, and forecast distribution in emergencies.
- Develop approaches for assessing potential intervention strategies during the early stages of an emergence event.
- Produce forecasts and analytics.
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# Prioritize Funding for Development of At-Home Diagnostic Technology

**Problem:** Before an infectious disease outbreak of any size can be addressed and before illness can be treated, it must first be identified through the diagnosis of disease and cases. Diagnostic testing is a mainstay of not only clinical medicine but also epidemiologic investigation. 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.

The funding, development, and review of such technologies by BARDA, FDA, CMS, and Congress should be prioritized. BARDA should be tasked with the specific aim of increasing the development and availability of direct-to-consumer home tests for infectious diseases. Additionally, 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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# Modernize Public Health Data Infrastructure for 21st Century Disease Threats

**Problem:** COVID-19 has exposed the inadequacy of US public health data systems to provide early warning and characterization of disease threats and to maintain situational awareness needed to support public health's response to them. Compared to other countries, which have maintained detailed dashboards that describe epidemiological trends and track the response to the pandemic, the US lags in its ability to access, analyze, and share publicly even the most basic epidemiological data. Across the US, public health agencies are receiving information from laboratories and health facilities about tests performed and treatment of cases. These data could be used to better understand and track disease trends at the local level and to identify factors that determine who is most likely to get sick, be hospitalized and die-essential information for understanding how best to protect people from becoming infected and to save lives. However, antiquated data systems and a lack of data scientists in public health agencies make it difficult for health agencies to analyze these data and to share it in a way that supports decision-making by responders and the general public. In addition, states may take different approaches to how they collect, analyze and share public health data, which hinders our abilities to gain a national picture of readiness and response. These data should be publicly available in a timely fashion to enable decision-makers at all levels—from the federal governments to individual members of the public-to be able gauge health threats and to make decisions about how best to protect health.

**Solution:** Congress should mandate a modernized information technology infrastructure for federal, state, and local health agencies. Federal, state and local public health agencies need to be better equipped to capture, analyze and display laboratory, clinical and other data in a timely manner. This will require having new data sharing agreements with and between government agencies, clinical and laboratory and other private sector data providers, stronger information technology systems to access and store data, and robust, inhouse data analytic capabilities. Congress should appropriate \$5 billion over 5 years to increase the data science workforce in all public health agencies, to support the acquisition of modern technologies for data analysis and visualization, and to foster partnerships with governmental and non-governmental data providers.

# **Create a National Center for Pandemic and Disaster Nursing Research**

**Problem:** The ongoing and evolving COVID-19 pandemic has resulted in thousands of infections and almost 600 deaths in healthcare workers—many nurses. Nurses play a pivotal role pandemic response, including supporting and informing epidemic surveillance and detection, dispensing live-saving medical countermeasures, implementing prevention and response interventions, providing direct care for patients, educating patients and the public to decrease risk of infection, providing health systems leadership, and counseling community members to allay fear and anxiety. Despite the many critical and unique roles of nurses, there are significant gaps in the education, training, workforce development and research needed to build, support and prepare the nursing workforce to respond to pandemics and other disasters.

**Solution:** The CDC should fund a National Center for Pandemic and Disaster Nursing Research to strengthen nursing workforce education, research, practice, and policy to:

#### Practice

- Create and train expert National Nurse Response Teams (NNRT) who can deploy during pandemics and disasters to support clinical care and nurse workforce training.
- Establish a cadre of senior pandemic and disaster nursing consultants who can act as subject matter experts during pandemics and disasters.
- Train a nursing workforce that is ready to support mass MCM dispensing efforts.

#### Education

- Establish a Disaster Nursing Certificate and courses on emergency preparedness, a capstone project, and field experiences.
- Develop a pandemic and disaster nursing fellowship to develop the next generation of nurse leaders to deepen expertise, expand their network, and build leadership skills.

#### Policy & Research

- Support career nurse scientists in developing best practices and strengthening the evidence base to improve the delivery of nursing care during pandemics and disasters.
- Expand the roles of advanced practice nurses and nurse midwives, to mitigate the disproportionate impacts that pandemics and disasters have on vulnerable populations and those living in rural communities.
- Support research efforts that focus on improving healthcare worker protections during pandemics and emergencies.
- Develop and support pandemic and disaster preparedness and response policies that are grounded in the experiences of frontline healthcare providers.

#### Learn More.

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

Controlling the next pandemic will pose significant challenges to future public health authorities. Chief among these will be the need to rapidly immunize large populations in very short timeframes. A novel, technologically driven public health strategy is needed to expedite that process.

**Problem:** Achieving control of infectious disease emergencies is typically only possible in the presence of a safe and effective medical countermeasure – usually a vaccine. This is certainly the case with the COVID-19 pandemic, where extraordinary efforts are being undertaken to rapidly develop, test and produce a vaccine. Following its development and large-scale manufacture, however, the challenge of rapid distribution and widespread vaccine administration to a sufficiently high percentage of the population remains.

Systematic bottlenecks during pandemic mass vaccination campaigns include 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.

However, the needle and syringe is not the only way to safely and effectively administer vaccines. A range of immunization delivery technologies have been developed and use. These technologies include microneedle patches and other intradermal approaches, liquid oral preparations, tablets and pills, sub-lingual gels, intranasal mists, plastic prefilled syringes, and others.

**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. BARDA should be empowered to support development of new delivery platforms for vaccines. This capability should be prioritized by and publicly articulated in public health preparedness plans and strategies including those promulgated by CDC, ASPR, PHEMCE, and other stakeholders. Funding or other incentives should be provided to enable the development of manufacturing infrastructure for particularly promising administration technologies. 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 action, guidance, and approval should be prompted to enable the use of this new class of vaccines.

# **Develop a National Strategy to Battle Misinformation and Disinformation During Infectious Disease Outbreaks**

**Problem:** Misinformation—information that contradicts the best expert evidence available at the time and can lead to false beliefs-and Disinformation-false information that is intended to mislead and is purposefully disseminated—have spread rapidly during the emergence of COVID-19. Misinformation and disinformation can undermine the effectiveness of a public health response, reduce trust in public health responders, and increase stigma. For example, misinformation spread during recent Ebola outbreaks contributed to violence against healthcare workers, social instability, and increased infections in the community. Rumors and conspiracy theories related to COVID-19 have also fostered distrust of governments when collaboration and cooperation are critical, led members of the public to embrace dangerous false cures, and reduced uptake of critical protective measures against the spread of the disease. The belief that COVID-19 is a hoax has divided the US public and led to increased social discord during a large-scale national emergency that requires collective action to successfully navigate. Although misinformation during epidemics has been observed with increasing international concern, there are a lack of proposals for effective and practical solutions grounded in evidence about the key drivers and impacts of misinformation.

**Solution:** Congress should require the development of a National Strategy for Combating Misinformation and Disinformation during infectious disease outbreaks. This strategy should be developed by the Department of Health and Human Services within 6 months of enactment of this legislation, and the strategy should be submitted to Congress and shared publicly.

The development of this strategy should include input from critical external stakeholders, including social media companies, news media organizations, public health practitioners, and education experts (the latter to represent processes for long term improvement in public information consumption). This strategy should include consideration of the following measures:

- The establishment of a program within CDC to develop specific and practice-based communication strategies and guidance for public health at the national and state level.
- Creation of a research agenda with funding to drive researchers toward the development of evidence-based solutions at a local and national level.
- Enhanced public-private partnerships between social media companies and federal public health agencies to improve efforts to respond to and manage misinformation and disinformation spreading over social media platforms.

### **Create Deployable Research Response Teams in NDMS**

**Problem:** Deployable rapid response teams for highly-skilled technical response are used in many aspects of emergency response. This includes the National Disaster Medical System (NDMS), which has several types of specialized technical 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 in the SARS-CoV-2 pandemic, the timeline for the identification, development, and evaluation of medical countermeasures 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. In the COVID19 pandemic, we have seen a need for de novo development of medical countermeasures in the face of a novel infectious agent. The disconnected national regulatory and operational landscape for the development and production of new therapeutics and vaccines 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 scientific researchers who could assist in rapid implementation of research protocols and could bring regulatory experience in order expedite the generation of data, specimens, enrollments, and other research outputs that support the development of MCMs, clinical and translational research, and operational policy.

A partnership should be formed under HHS between BARDA and ASPR to build this capacity within NDMS of medical research response in bio emergencies and disasters. Such teams could be deployed much like DMAT, DMORT, and DVET teams. This could leverage the existing training mechanisms of the NDMS system to ensure researchers are properly prepared for safely deploying in an emergency to rapidly implement human subjects research protocols. Teams could be deployed to high volume community hospitals, federal entities like field hospitals, the USNS Comfort and Mercy, or other environments where clinical research is not routinely conducted to implement human subjects research protocols. These protocols could include longitudinal cohort or natural history studies, first in human studies, randomized controlled trials, expanded access protocols, and specimen collection/biobanking studies to support future research and downstream laboratory analyses. Researchers with specialized training could be deployed to localized hot-spots with health systems that might not be otherwise able to readily implement emergency human subjects research. These teams could then facilitate rapid scale up of large, systematic, multi-site, clinical research studies to improve the validity and reliability of findings and speed up enrollments to improve time to completion of trials.

# Adopt a Health Defense Operations Designation to Ensure We Are Able to Prevent, Detect and Respond to Health Threats

**Problem:** The U.S. public health system has suffered from chronic underfunding, as such COVID-19 quickly and drastically required unprecedented supplemental funding to respond to the rapid outbreak in the country.

**Solution:** We must ensure that the investments made in our core public health infrastructure and health security programs are maintained and used to prevent the next pandemic. Future health and economic security can best be achieved by a permanent budget cap exemption for critical public health functions to prevent, detect and respond to health threats both globally and domestically. To ensure our long-term health security, Congress should adopt the creation of a Health Defense Operations designation for public health in line with the following:

- The HDO designation would only be applicable to core public health programs integral to health defense meaning those that prevent, detect or respond to public health threats domestically and globally.
  - Congress must specify which programs, projects and activities (PPA) are deemed HDO in the annual appropriations bill.
- PPAs designated as HDO:
  - Will be exempted from the Budget Control Act budget caps to ensure the entire public health defense infrastructure can receive the resources needed to keep us safe.
  - Will not be sequesterable for the length of the fiscal year to ensure health security.
  - Will be required to submit bypass professional judgment budgets ensuring there is an unvarnished look at preparedness needs.

#### Learn More.

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

**Problem:** Serosurveys (antibody studies) are important for public health decisionmaking, 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. Long-term questions regarding medical sequelae that may require specific interventions can also be addressed. 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, for example, 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 SARS-CoV-2, but also for public health research on emerging viruses in the future. 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, 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.

### Develop a Community Engagement Infrastructure to Assess and Activate Public Sentiment and Support for Outbreak Management

**Problem**: Prompt, effective control of an outbreak of a high-consequence infectious disease hinges on the public's willingness and ability to cooperate with efforts to interrupt the spread of contagion, ensure appropriate medical care for the sick, and mitigate cascading societal effects. The collective actions of millions of Americans – e.g., wearing masks, keeping physically distant, avoiding large gatherings, and helping their neighbors to do the same – have been critical to reducing the number of COVID-19-related infections, hospitalizations, and deaths. The public's sustained, positive sentiment and active support for outbreak management efforts, however, cannot be taken for granted. For instance, vaccine hesitancy – whether in the form of long-standing mistrust of health authorities due to past ethical lapses and present social bias or a recent mindset fostered by an organized domestic anti- vaccination movement or a foreign-led disinformation campaign – could thwart the potential success of Operation Warp Speed. Moreover, growing opposition to mask-wearing, an intervention that is scientifically proven to lower the risk of disease transmission, threatens the public health gains already made to date.

**Solution:** With sufficient resources from Congress the CDC should administer a sustained, 2-part initiative to develop a Community Engagement Infrastructure for the next pandemic, to include:

<u>Leading-edge social, behavioral, and communication research</u> that helps understand better the causes, instances, and impacts of public cooperation during outbreaks, as well as leads to the development of evidence-based "best practices" for generating the public's trust and help in a public health emergency. Technical and operational aspects of outbreak management (e.g., how quickly can a safe and effective vaccine be made, are hospital staff and equipment sufficient in number and protected from contagion, which nonpharmaceutical interventions can interrupt transmission) have largely overshadowed social, behavioral, and cultural matters perceived as intangible, less urgent, and/or harder to change in the short term (e.g., public trust, collective self-efficacy). Effective outbreak readiness, response, and recovery, however, depends on advancements in both bioscience and social science.

<u>Sustained partnerships and planning between grassroot stakeholders and state/local public health agencies</u>. Community engagement – i.e., dialogue, power-sharing, collaborative decision-making, and combined actions among a community and its leaders – can prepare the public for its role in outbreaks. Whether through the Public Health Emergency Preparedness (PHEP) grants program or a novel program to strengthen resilience to outbreaks from the bottom up, the initiative should provide technical and financial support to civic-minded groups for readiness, response, and recovery. Capacity-building resources should be targeted especially to nonprofits embedded in underserved minority populations, where cultural norms, language requirements, and social connections may not be well understood by mainstream institutions.