

A Canary in a COVID Coal Mine: Building Better Healthcare Biopreparedness Policy

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The SARS-CoV-2/COVID-19 pandemic has been devastating to the U.S. health-care system and sheds light on gaps in preparedness and response to biological threats. From limited personal protective equipment to staffing issues, hospitals are struggling to respond to the novel coronavirus outbreak. Unfortunately, hospital biopreparedness is a product of prioritization for hospital leadership and either exists or is neglected. Federal efforts to enhance health-care readiness have done little to drive true change across the U.S. health-care infrastructure. From optional efforts like the tiered hospital approach to special pathogens to the regulatory rule from the Centers for Medicare and Medicaid Services, federal efforts to build a resilient health-care infrastructure against biological threats are woefully inadequate and dependent upon hospital leadership priorities. The COVID-19 pandemic has revealed a need to implement regulatory requirements on health-care facilities to invest in continued preparedness for biological events.

KEY WORDS: biopreparedness, hospitals, regulatory oversight

In the middle of a pandemic, the United States has found itself with limited health-care response as a result of lackluster regulatory requirements and administrator interests. The novel coronavirus outbreak has led to over one million cases worldwide in roughly four months since it began. Sustained human-to-human transmission, gaps in testing capabilities, and delays in government efforts have slowed the U.S. response, resulting in further transmission and a skeptical public. As the world grapples with the SARS-CoV-2/COVID-19 outbreak, the United States is becoming increasingly aware of the vulnerabilities in not only pandemic preparedness and response, but also health-care biopreparedness. Unfortunately, the health-care aspect of COVID-19 response has been extremely challenged by those testing gaps, but also severely limited supplies of critical personal protective equipment (PPE). For many asking how it possibly got to this point, the truth is that the U.S. health-care system has been crippled with poor biopreparedness for years. Regulatory oversight and mandates to ensure hospitals are engaging in sustained preparedness for biological preparedness is weak at best. Moreover, hospital administrators have cited competing interests in efforts to maintain preparedness for special or emerging pathogens (U.S. Department of Health and Human Services Office of Inspector General, 2018). The painful truth is that there is a desperate need for mandated biopreparedness across the U.S. health-care infrastructure.

Dallas Ebola Cluster—A Red Flag

The first many Americans saw of the woefully inadequate health-care bio-preparedness in the United States was in 2014. As news spread of the first unexpected, important case of Ebola virus disease, so did the realization that hospitals across the United States were simply not ready. Soon after Thomas Duncan arrived at a Dallas hospital, two nurses were identified as having the disease through infection prevention failures (Chevalier et al., 2014). Hospitals around the United States raced to prepare for potential patients with Ebola (Morgan et al., 2015). The burden of preparedness for a high-consequence disease was not only costly, be deeply time- and resource-intensive (Smit et al., 2017). It quickly became apparent that such levels of readiness across the U.S. health-care system were deeply challenging and not sustainable (Popescu & Leach, 2019). For many, this was a red flag that the U.S. health-care system was woefully underprepared for emerging infectious diseases or high-consequence pathogens. Changing guidance on PPE and other infection control measures further complicated the situation, making the dissemination of information a continued problem for frontline facilities. Unfortunately, these gaps were not wholly unexpected, but rather a long-held fissure between health-care preparedness and biopreparedness.

Existing Strategies

Hospital preparation in the United States dramatically changed after the Dallas Ebola cluster. Not only was it apparent that the United States was not immune to emerging infectious diseases, but that this was an area that hospitals tended not to invest in. The Hospital Preparedness Program (HPP) through the Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response has provided funding through grants and cooperative agreements to help enhance general health-care system preparedness. Per their website, HPP is “the only source of federal funding for health care system readiness” and has provided awards to 62 health departments, localities, territories, etc. (Office of the Assistant Secretary for Preparedness and Response, 2018). Since 2002, HPP has invested \$5.9 billion in health-care preparedness (Office of the Assistant Secretary for Preparedness and Response, 2019). Sadly, a single unexpected case of Ebola virus disease brought the system to its knees.

To address this newly realized vulnerability to high-consequence diseases, funding was provided to enhance the U.S. health-care system's readiness through the HPP's Ebola Preparedness and Response Activities Funding Opportunity Announcement. The creation of the Regional Treatment Network approach would yield four tiers to management of patients with potentially high-consequence pathogens, like Ebola. The majority of hospitals (roughly 95 percent) fell into the lowest tier, the frontline hospitals, which required them to be able to identify, isolate, and inform of patients with possible Ebola, holding them for 12–24 hours (Office of the Assistant Secretary for Preparedness and Response, 2017). Next, was the creation of the now 217 assessment hospitals, 63 treatment centers, and 10 regional treatment centers. The higher on the tier, the more responsibilities, and

capabilities to manage patients with such special pathogens like Ebola and other viral hemorrhagic fever. Designation as one of the higher tiers was voluntary and involved assessment by the Centers for Disease Control and Prevention and the National Emerging Special Pathogens Training and Education Center. The costs of establishing these care capacities tended to be over \$1 million and were offset by funding through HPP (Herstein et al., 2016). The goal was simple—reduce the burden across the entire health-care infrastructure by creating specialized units that would carry the heavier burden in high-consequence disease preparedness and response. Unfortunately, funding for all but the 10 regional treatment centers expired in April 2020 (Popescu, 2020).

In addition to the tiered health-care approach and HPP grants, a mandatory requirement was set in place by the Centers for Medicare and Medicaid Services (CMS). Put into effect in 2017, hospitals were required to have their own set of emergency preparedness plans, policies/procedures, communication strategies, and training/testing efforts (CMS, 2019). Although all hospitals, for accreditation purposes, have to show policies related to emergency preparedness, the CMS Emergency Preparedness Rule required more proactive measures that forced hospitals to invest additional resources into emergency preparedness. This rule though is broad and encourages hospitals to invest in an all-hazards approach, which includes hazards like pandemic flu, hurricanes, fires, chemical spills, power outages, etc. More specifically, the hospital is required to develop and implement policies/procedures based on their own risk assessments using the all-hazards approach, meaning that if a hospital determines that pandemic flu is not a hazard or vulnerability, it can focus resources on other hazards. In short, this rule does not specify hospitals must invest in biopreparedness and response efforts.

A Way Forward

In the midst of the ongoing SARS-CoV-2/COVID-19 pandemic, with deaths and cases continuing to rise in the United States, the role of hospital biopreparedness has been highlighted more than ever (CDC, 2020). Dwindling personal protective equipment and critical medical supplies, a strained health-care workforce, and an overwhelmed health-care system have all plagued this pandemic for the United States. Despite lessons learned from previous coronavirus outbreaks, like 2002/2003 SARS-CoV in Toronto or 2015 MERS-CoV in South Korea, the threat of novel coronaviruses has done little to encourage biopreparedness within the U.S. health-care system (Ki, 2015; Low, 2004). Furthermore, efforts to enhance preparedness following the 2014 Dallas Ebola cluster require either voluntary efforts by hospitals or an all-hazards approach, which does little to ensure pandemic and high-consequence disease preparedness prioritization.

There is a desperate need for mandated biopreparedness across the U.S. health-care system. Hospital leaders have indicated that such heightened levels of preparedness following the 2014 Ebola cluster are no longer present, meaning that the United States must move past the voluntary biopreparedness and into a model that requires it of hospitals. It is critical that hospitals invest in preparedness efforts for

the range of biological threats, from natural to intentional. Tying these requirements to accreditation and reimbursement is one avenue to ensure compliance, but such mandates must specifically call out the need for biopreparedness rather than all-hazards. CMS regulations should move to establish a rule that requires hospitals to participate in annual risk assessments, education, training, and evaluation of efforts to maintain preparedness for biological events. Ties to financial reimbursement are not uncommon for driving change and associating biopreparedness with Medicare reimbursement or penalties has the potential to force hospitals to prioritize it. Emphasis on annual drills and the hospital's ability to "identify, isolate, and inform" could help ensure there is a baseline of biopreparedness.

Current requirements allow hospitals to determine levels of investment in preparedness for biological events, whether it be a bioterrorist attack or a pandemic like COVID-19. As this pandemic progresses, and the United States works through response efforts, it is critical to address the gaps in regulatory requirements that do little to encourage hospitals to invest in efforts often deemed unlikely.

Notes

Conflicts of interest: None declared.

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