Emergency Preparedness in the U.S.: The Ebola Threat

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Is the U.S. prepared for a

potential virulent pandemic? This toolkit examines public health infrastructure, funding and policy levers that deal with these kinds of health crises in America.

Surveillance

According to the Centers for Disease Control

and Prevention (CDC), surveillance is the foundation of public health practice.¹ In the current climate of rapid exchange of information through advances in technology, timeliness of data and demands for population-specific and geographic-specific surveillance information are among the greatest challenges. In March 2014, the CDC launched a new surveillance strategy.² The improvements to the system are aimed at helping with detection and monitoring of any agent by providing more comprehensive, timelier, and higher quality data than were possible previously. One initiative involves modernizing the National Notifiable Diseases Surveillance System (NNDSS), the nation's system for monitoring and tracking disease. The information from this surveillance system assists Congress in developing appropriate responses. It also assists in timely public notification to increase awareness of preventive measures and to avert panic.

A Workforce at Risk

Nursing groups are voicing concern that they are not adequately trained, especially in procedures to avoid contamination with the virulent Ebola virus.³ Much of this concern grew out of the experience in Dallas, Texas in September 2014, where two nurses who treated an Ebola-infected patient later became ill with the virus.

Unlike the flu or a cold, which are airborn infections that can be spread by coughing and sneezing, Ebola is only spread by direct contact with bodily fluids, much like Hepatitis C and HIV.⁴ The risk to the average person is low, but the risk for health care workers treating infected persons with symptoms is much higher. Though nurses and physicians are the frontline workers, those who clean the exam rooms, the ICUs, laboratories, elevators and other hospital locations where a patient might have taken ill - and vomited, for example – are also at risk.

Health Care Facility Preparedness

In general, there are variable levels of hospital preparedness across the country, and there are Ebola treatment centers of excellence. The CDC has said that hospitals in this country are prepared to handle patients with Ebola.⁵ At the moment, however, there is no facility that could potentially hospitalize an epidemic-sized number of afflicted patients.

The two Dallas nurses were afflicted prior to a change in <u>CDC infection control guidelines</u>, and each was treated in yet another hospital, one at the National Institutes of Health (NIH), in the Washington, DC area and one at Emory University in Atlanta. The NIH facility has two hospital beds that meet the isolation requirement necessary for treating an Ebola patient.

Citing lessons learned from the Dallas experience, the CDC issued new infection control guidelines, as follows:⁶

 All health care workers involved in the care of Ebola patients must have received repeated training and have demonstrated competency in performing all Ebola-related infection control practices and procedures, and specifically in donning/doffing proper personal protection equipment (PPE).





- While working in PPE, health care workers caring for Ebola patients should have no skin exposed.
- Care must be overseen by an onsite manager at all times, and each step of every PPE donning/doffing procedure must be supervised by a trained observer to ensure proper completion of established PPE protocols.

The CDC has also issued guidance for laboratory personnel recommending the use of PPE.⁷

Drug Development

Currently no licensed vaccines or treatments exist for Ebola. Several experimental therapeutic agents have been used on a case-by-case basis, but these are available only in very limited quantities and none of them has been fully tested in controlled human clinical trials.

A World Health Organization (WHO) panel of experts recently convened to review and prioritize which Ebola drug candidates should be the first to be tested in human trials, and recommended four classes of drugs to start trials as soon as possible: favipiravir, brincidofivir, toremifine and interferons.⁸ Doctors without Borders (MSF) has agreed to host human trials of three of these drug candidates, which could begin as early as December 2014.⁹

Several other experimental drugs will take longer to make it into human trials but are worth noting. First, the Tekmira Pharmaceuticals Corp, a Canadian company, has begun limited manufacturing of an Ebola drug.¹⁰ The company estimates that limited quantities of the drug could be available by December 2014, but it is unclear how many doses will be available. It is also uncertain when the company will conduct human clinical trials to test for efficacy and safety.

Vaccine Development

There are no licensed vaccines for Ebola, but three candidate vaccines have already started (or are very close to starting) human trials after showing efficacy in earlier testing in primates. The three vaccine candidates include the GlaxoSmithKline ChAd3 vaccine,¹¹ the Public Health Agency of Canada/NewLink Genetics VSV vaccine, and Johnson & Johnson's two-shot vaccine.¹² Initial clinical trials of Ebola vaccines from GlaxoSmithKline and NewLink Genetics are under way,¹³ while human trials of the Johnson & Johnson vaccine are expected to begin in January. Testing in Lausanne, Switzerland

is the largest in the series, according to the WHO, which is coordinating the research. WHO is also coordinating a trial of a second experimental vaccine running concurrently at Geneva University Hospital.¹⁴

Diagnosing Ebola

According to the CDC, Ebola virus is detected in blood only after the onset of symptoms, most notably fever, which accompany the rise in circulating virus within the patient's body. It may take up to three days after symptoms start for the virus to reach detectable levels using traditional testing methods.¹⁵ This speaks to the need for more rapid diagnostic methods. Currently, a network of 14 public laboratories around the U.S., plus federal labs at the CDC and the U.S. Army Research Institute of Infectious Disease (USAMRIID), are ready to do traditional diagnostic testing for Ebola.¹⁶ The labs in the network include state facilities in Texas, Nebraska, Montana, Maryland, Florida, Minnesota, New York, Michigan, Virginia, North Carolina, Pennsylvania, and Washington, as well as local labs in New York City and Los Angeles County. This network may be expanded as the CDC further distributes the necessary assay test.

Under Emergency Use Authorization, the FDA has approved a device to screen for Ebola. The device was developed for environmental surveillance and has been used by military personnel in Africa.¹⁷ The machine can deliver results in about an hour with higher than 90 percent certainty, and, though not yet approved for use as a general screening device it may be able to detect the virus before symptoms appear. Emergency use authorization¹⁸ is good for a year (with the potential for renewal) or until circumstances no longer justify it. It requires special circumstances, including: a domestic emergency or a significant potential for a domestic emergency determined by the Secretary of the Department of Homeland Security; a military emergency determined by the Secretary of the Department of Defense; or a public health emergency under the Public Health Service (PHS) Act that affects, or has a significant potential to affect, national security as determined by the Secretary of Health.

Research

The National Biodefense Science Board, an advisory committee to the Department of Health and Human Services (HHS), issued a report in 2011 titled "Call to Action: Include Scientific Investigations as an Integral Component of Disaster Planning and Response." It recommended that HHS develop the requisite infrastructure for strengthening the research response to emergencies. As a result:¹⁹

- HHS is compiling, and will update regularly, rosters of national experts in key areas of concern.
- The CDC and the Agency for Toxic Substances and Disease Registry have constructed a Rapid Response Registry to enroll all people who are exposed, or potentially exposed, to emergencyrelated hazards.
- The Office of the Assistant Secretary for Preparedness and Response has provided funding to the U.S. Critical Illness and Injury Trials Group to develop a minimum data set that can be used to analyze clinical data in a public health emergency
- The Assistant Secretary for Health has established the Public Health Emergency Research Review Board for studies that require specialized expertise and are slated for conduct at multiple sites during public health emergencies.

Travel and Quarantine

Throughout history, questions about how far the government can and should go in requiring quarantine, property seizure, vaccination and other means of controlling infection have proven controversial. As Ebola came to the U.S., New York, New Jersey and Connecticut quickly put into place mandatory guarantine policies, but the CDC expressed concern that this approach might prompt health care workers returning from afflicted regions to conceal critical information, or deter them from volunteering in those areas at all. Three major medical associations, the American Hospital Association, the American Medical Association and the American Nurses Association announced their support for CDC guidelines, which they said strike the right balance between public health prevention policies based on science and individual rights.²⁰

The CDC guidelines, released in October 2014, called for 21 days of voluntary isolation and monitoring for travelers exposed to Ebola.²¹ Those who have had direct exposure to Ebola should stay off public transportation and airplanes; avoid "congregate settings" such as offices; and undergo active monitoring by a public health worker, such as checking temperatures twice daily. The guidelines establish four levels of risk and recommend restrictions and health monitoring for each category.²² The guidelines were updated in November.²³

State and local health departments make the final decision on whether to adopt federal guidelines. They are also the locus of enforcement as the CDC does not have enforcement authority.²⁴ An exception to voluntary adoption of CDC guidelines can arise if and when the president declares a national emergency or HHS issues a public-health emergency. That occurred in 2009 over the H1N1 flu virus.

The CDC, in its public education role, has been attempting to assure Americans of the low risk of contracting the disease. In the meantime, the U.S. is requiring all passengers from Liberia, Sierra Leone or Guinea to be routed through one of five airports: New York's John F. Kennedy, New Jersey's Newark, Washington's Dulles, Atlanta's Hartsfield-Jackson and Chicago's O'Hare.²⁵ In issuing the restriction, the Department of Homeland Security noted that those airports account for about 94 percent of travelers flying to the United States from the three most seriously-afflicted countries in West Africa. Several countries have imposed travel bans.

Policymakers in Washington, D.C. have had mixed reactions to the idea of a travel ban. Some have said that current restrictions don't go far enough. Others have said that the nation should be focused on the source of the outbreak, West Africa.

Public opinion is also mixed. Americans surveyed in a Reuters/Ipsos online poll, released October 21, favored by almost 75 percent a U.S. ban on civilian air travel in and out of Liberia, Sierra Leone and Guinea.²⁶

Funding

The Office of the Assistant Secretary for Preparedness and Response (ASPR) leads HHS in preparing the U.S. to respond to and recover from adverse health effects of emergencies. ASPR's Biomedical Advanced Research and Development Authority (BARDA) will provide approximately \$5.8 million in funding, in addition to subject matter expertise and technical assistance, to further develop an experimental Ebola vaccine.²⁷

The administration is considering various additional avenues of funding to support current emergency response efforts. One example is the reprogramming of \$1 billion in fiscal 2014 war funds. The defense department reports that "the money would be used in the next six months to construct isolation units, upgrade facilities, activate more than 3,000 members of the U.S. military, provide medical supplies and communications gear, and perhaps to handle sanitation and burial efforts designed to limit the spread of the disease."²⁸

The administration has requested \$6.2 billion in emergency funding to enhance the U.S response to Ebola domestically and abroad. It would cover a variety of activities, including building treatment centers in Liberia and elsewhere, enhancing screening at U.S. airports, providing more protective equipment for medical workers, and augmenting research and medical treatments in this country. Committees in both houses of Congress are holding hearings on the topic and are considering the request. Public health officials have expressed concern that automatic budget cuts – sequestration and other budget cuts in recent years have had a negative impact on their abilities to coordinate critical emergency efforts.²⁹

The IOM forum on medical and public health preparedness for catastrophic events has recommended that a high level of funding be sustained between emergencies so that the public health infrastructure can maintain preparedness for catastrophic emergencies. It has argued that funding should be "steady, predictable and robust" rather than suffer large fluctuations.³⁰ It asserts that steady funding is required for the level of cooperation and communication among public agencies that is needed to be adequately prepared to respond during emergencies.

Private individuals and foundations also are supporting the U.S. emergency response. Mark Zuckerberg, founder of Facebook, and his wife, Dr. Priscilla Chan, in October of 2014 announced a donation of \$25 million to CDC to help fight Ebola in West Africa.

Likewise, The Bill and Melinda Gates Foundation made a donation of \$50 million to the effort. The funds will be divided among the WHO, UNICEF and CDC. All of the recipient organizations are working in West Africa to stop the Ebola outbreak.³¹

Resources

Workforce

When Ebola Is a Workplace Issue

Wall Street Journal. R. Feintzeig, October 14, 2014; <u>http://goo.gl/nMxB6B</u>

A survey of 3,000 nurses found that 74 percent don't feel prepared to deal with an outbreak or patient.

Facilities

Fact Sheet: CDC Taking Active Steps Related to Hospital Preparedness for Ebola Treatment

Centers for Disease Control and Prevention. U.S. Department of Health and Human Services, October 2014;

http://goo.gl/mdOymh

This announcement describes the new protocol that CDC is implementing in regards to Ebola.

Hospitals Rising to the Challenge: The First Five Years of the U.S. Hospital Preparedness Program and Priorities Going Forward

Center for Biosecurity of UPMC, E. Toner, et al., March 2009;

http://goo.gl/kOOJhP

This report is an assessment of the impact of the Hospital Preparedness Program (HPP) on hospital preparedness from the time of the program's establishment in 2002 through mid-2007, as well as preliminary recommendations for improving the state of U.S. hospital preparedness going forward. It provides historical background on HPPs.

Ebola Raises Concerns Over Hospitals' Infection Controls

USA Today. P. Eisler, M. Hoyer, October 20, 2014; http://goo.gl/v6YOMT

According to this article, about one in every 25 patients gets an infection while being treated in a U.S. hospital, transmitted via contaminated equipment, rooms or caregivers. It continues to say that most hospitals have good infection control mechanisms in place, and the ones that don't must be identified.

Laboratories

CDC Laboratory Guidance on Ebola

Centers for Disease Control and Prevention. U.S. Department of Health and Human Services. T. Frieden, August 20, 2014;

http://goo.gl/RfHmzw

This blog post provides procedures for hospitals to follow if they receive patients with potential Ebola symptoms. It recommends that labs follow established Occupational Safety and Health Administration blood borne pathogens standards. It also recommends that hospital labs communicate with state and/or local health departments to determine the need for further lab testing.

Research

Research as a Part of Public Health Emergency Response

New England Journal of Medicine. N. Lurie, et al., March 28, 2013;

http://goo.gl/Cu4ZDq

According to the authors, recent events have illustrated gaps in planning for, and rapidly executing, scientific research in the context of disaster response. This article identifies challenges to the conduct of research in recent public health emergencies to identify critical elements of an effective research response.

Funding

Billionaires Are Stepping Forward To Fight Against Ebola.

Epidemiology Inside. Shawon, October 15, 2014; http://goo.gl/MtzYdz

This blog post focuses on private sector donations to support the fight against Ebola, and it also indicates how the public can contribute.

Investing in America's Health 2014: A State-by-State Look at Public Health Funding and Key Health Facts

Trust for America's Health. J. Levi, et al., May 2014; http://goo.gl/OZ8kj2

This report provides the public and policymakers with an analysis of the state of public health funding policies.

The 2013-2014 National Snapshot of Public Health Preparedness

Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, January 24, 2014;

http://goo.gl/utrxMy

This report notes that congressional appropriations for CDC's public health preparedness and response activities decreased by \$97 million from 2012 to 2013. It presents a snapshot of public health preparedness and response activities. It also provides good background on U.S. emergency preparedness infrastructure and jurisdiction of the various government agencies.

Analysis

The U.S. Government & Global Emerging Infectious Disease Preparedness and Response The Henry J. Kaiser Family Foundation. Oct 22, 2014;

http://goo.gl/C8Sycg

This report identifies governments, multilateral institutions, and other stakeholders engaged in the fight against Ebola and other illnesses that could lead to pandemic. It also addresses outbreak prevention, challenges, preparedness, detection and response strategies.

The Benefit of a Uniform Response to Ebola in the U.S.

Washington Wire, The Wall Street Journal. D. Altman, October 29, 2014;

http://goo.gl/xil1la

In this editorial, Drew Altman of the Kaiser Family Foundation calls for a uniform national strategy to fight Ebola. He cautions that the variation of local and state response plans (or quarantine) would cause greater fear.

Surveillance

CDC Surveillance Strategy: CSTE Surveillance Practice and Implementation

Centers for Disease Control & Prevention, U.S. Department of Health and Human Services, April 4, 2014;

http://goo.gl/Rhb8g4

This PowerPoint lays out goals, a timeline and overall strategy to improve the CDC surveillance system.

About Ebola

Ebola Then and Now

New England Journal of Medicine. J. Breman, October 30, 2014;

http://goo.gl/MukdQk This perspective piece explores the commonality between the 2013–2014 outbreak of Ebola virus disease (EVD) and the 1976 outbreak. It describes factors that helped successfully contain the first outbreak, including adequate staff for rigorous identification, surveillance, and care of patients and primary contacts; strict isolation of patients; good clinical care; and rapid, culturally-sensitive disposal of infectious cadavers.

Quarantine/Legal Authority

Ebola and U.S. Quarantines: Q&A with James Hodge and Kim Weidenaar of the Network for Public Health Law *New*PublicHealth, Robert Wood Johnson Foundation, October 28, 2014;

http://goo.gl/wnfkOh

Two attorneys answer legal questions about current federal laws, legal support and potential new laws that pertain to quarantine, as a result to guidelines that CDC released. Under the guidelines, people at high risk of Ebola exposure would be confined to their homes in voluntary isolation, while people carrying some risk would have their health and movements monitored by local officials.

Ebola Quarantines and State Powers

The Washington Post. E. Kontorovich, October 28, 2014;

http://goo.gl/sbK9MP

This editorial addresses due process and preemption challenges presented by state quarantine practices. The writer asserts that state laws triumphs unless the executive branch releases regulation.

The Flu, TB and Now Ebola: A Rare Legal Remedy Returns

New York Times. B. Weiser, J.D. Goodman, October 26, 2014;

http://goo.gl/2Ys8zn

The authors assert that the decisions by New York and New Jersey to quarantine some travelers returning from the Ebola zone in West Africa are forcing public officials into unfamiliar legal and medical territory. However, it explains that states have the power to impose quarantines, which derives from the general police power granted to states in the Constitution.

Legislation and Regulation

Pandemic and All-Hazards Preparedness Act (PAHPA)

http://goo.gl/oroJcF

The website explains that the 2006 Act establishes an Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Resources; provides new authorities for a number of programs, including the advanced development and acquisitions of medical countermeasures; and calls for the establishment of a quadrennial National Health Security Strategy.

CQ NEWS Exclusive Ebola: What Can Congress Do?

CQ Roll Call. October 14, 2014; <u>http://goo.gl/EbGvAg</u> This news article provides an overview of the current situation in the U.S. It identifies integral government agencies and the role they continue to play to contain Ebola.

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