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# Ebola Virus Disease: Legal and Ethical Considerations for Indiana

The Ebola Virus Disease (EVD), formally known as Ebola hemorrhagic fever, is a virulent and often deadly infectious disease[1]. Fatality rates for the disease have reported to be as high as 90% following contraction[1]. As of October 14, 2014, a total of 8,914 probable, confirmed, and suspected cases of EVD and 4,447 deaths due to the disease, have been reported to the World Health Organization (WHO) by the nations of Liberia, Guinea, and Sierra Leone[2]. The WHO estimate by December 2014, the number of new EVD cases could rise ten-fold, to 10,000 per week, and the survival rate in these West African countries is now "30 percent at most"[2]. Based on the ongoing risk of spread of the highly deadly disease, the WHO declared the outbreak a public health emergency of international concern[3]. According to WHO Director-General Dr. Margaret Chan, the West African Ebola outbreak is "unquestionably the most severe acute public health emergency in modern times," and has become "a crisis for international peace and security"[3].


While health officials at the Centers for Disease Control and Prevention (CDC) do not believe EVD poses a serious risk to the general U.S. public, the recent EVD diagnosis and death of Liberian immigrant Thomas Eric Duncan in a Dallas, Texas, hospital, coupled with the subsequent infection of two nurses who treated him, have contributed to widespread concern by the public and policymakers, intensive media coverage, and surging public health preparation efforts domestically and abroad[4].

On October 9, 2014, the Indiana State Department of Health (ISDH) sponsored a webcast on Indiana's response to the emerging EVD threat[5]. During this webcast, Indiana Governor Mike Pence assured the public Indiana is "…prepared to effectively respond to the threat of Ebola should a case occur here…," and ISDH is working closely with the CDC and other national partners[5]. There are several legal and ethical challenges EVD presents for Indiana, as the disease is now a major public heath concern. The legal framework for Indiana's public health powers and possible reponse to an EVD outbreak are presented, along with several possible ethical issues from such a reponse.

**Ebola Virus Disease: Description, Transmission, Symptoms**

The Ebola Virus Disease (EVD) is not easy to contract due to the small set of circumstances under which it may be transmitted, however if an unprotected individual is exposed under the proper circumstances, transmission is highly likely. It is transmitted to humans through close contact with the blood, body fluids, or carcasses of infected animal hosts (e.g., fruit bats, nonhuman primates, bush animals)[1]. Human-to-human transmission occurs when a person who is not wearing personal protective equipment (PPE) has direct contact with body fluids (including, but not limited to, blood, saliva, vomit, sweat, breast milk, semen, stool, urine) or human remains of a person with EVD[6]. "Direct contact" is defined by the WHO as the virus entering the body via broken skin or mucous membranes in places such as the nose, eyes, or mouth[6]. EVD could also be transmitted through contact with contaminated objects, such as the soiled clothing, bed linen, or used syringes of a person with EVD[1].

Consequently, the populations at risk of exposure to EVD are very limited: those providing health care and comfort to EVD patients; those handling the remains or soiled belongings of EVD patients; people traveling to the outbreak-affected areas in West Africa; and family and friends in close contact with EVD patients. Ebola is not as easily transmitted as either measles or influenza, which are efficiently spread in the air and spread by infected people for 1-2 days before they develop symptoms. Ebola is not airborne or spread by water[6], and people infected with EVD are only contagious once they become symptomatic[7].

EVD symptoms typically appear in infected persons 8 to 10 days after exposure to the virus (the incubation period ranges from 2 to 21 days). Ebola symptoms include: fever of at least 100.4 degrees Fahrenheit, muscle aches, severe headache, vomiting, diarrhea, abdominal pain, and/or unexplained hemorrhage or organ failure (liver, kidneys)[1,7]. Early symptoms of EVD are similar to those of other infectious diseases prevalent in West Africa, such as malaria, cholera, typhoid fever, and pneumonia[7]. Clinicians should also consider whether the person was exposed to specific risk factors in

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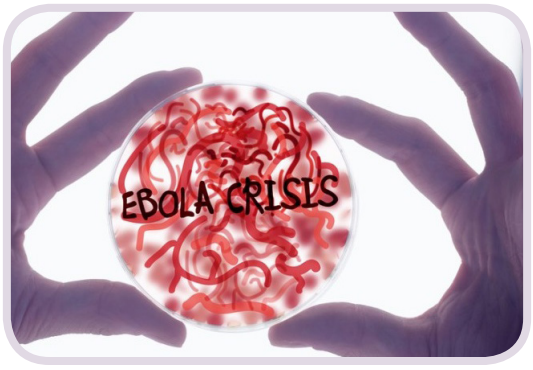
the three weeks prior to symptoms presenting, including: contact with the body fluids of a known or suspected EVD carrier; living or traveling in areas where EVD is present; attending a funeral or burial ritual of those who died from EVD; and/or direct handling bush animals (bats, primates, rodents) where EVD is present [7].

**Treatment for EVD**

Because EVD is only transmitted by symptomatic individuals and via direct contact with blood, body fluids, or human remains, the best way to prevent EVD infection is with strong infection control measures[7]. Additionally, patients require supportive care as soon as possible, including receiving intravenous fluids, pain control, balancing electrolyte, oxygen, and blood pressure levels, and tackling other infections that might arise[7].

There are no approved treatments or vaccines for EVD available for clinical use, although several experimental treatments are being tested[8,9,10]. The two American patients with confirmed EVD transferred from Liberia to Atlanta in early August (including Indiana University School of Medicine graduate Dr. Kent Brantley) consented to receive the experimental drug ZMapp under the Food and Drug Administration's (FDA)"compassionate use" program; both patients improved clinically[8,9]. A Spanish healthcare worker with EVD was also provided ZMapp, but did not survive.




The FDA approved a request from Liberia to have samples of ZMapp sent to treat two Liberian doctors with EVD[9]. ZMapp is still experimental and has not been fully tested in humans for safety or effectiveness[10]. Furthermore, ZMapp supplies have been exhausted, and will not be available again for several months. Another experimental treatment which has been recommended is the treatment of patients with *convalescent serum*, i.e., transfusions of the antibody rich serum or blood from Ebola infection survivors[11]. This treatment was used on Dr. Brantley, who, in turn, donated his blood for use in the treatment of at least three other Ebola patients in the United States with the same blood type[11]. The use of ZMapp and other experimental EVD drugs and therapies before they have been fully evaluated for safety and efficacy presents ethical issues on human experimentation, discussed in greater depth below.

**Current Federal Response to the EVD Outbreak**

The Ebola epidemic in West Africa presents a public health and humanitarian crisis. Controlling and ending the spread of the virus in West Africa can minimize the number of cases appearing in the United States. On September 16, 2014, President Obama announced a government response to the epidemic which included a request for significant additional funding for containment and relief efforts and authorization of the deployment of U.S. Military forces to West Africa to help facilitate public health and international relief efforts[12].

On July 31, 2014, in response to the West African EVD outbreak, the CDC issued a Level-3 Travel Warning (the highest level) advising against nonessential travel to the countries where Ebola is active; i.e., Liberia, Guinea, and Sierra Leone[13]. These three countries have airline passenger screening programs in place, and starting in mid-October, the CDC began enhanced-screening programs, requiring all passengers to enter through JFK International, Newark, Chicago-O'Hare, Washington-Dulles, and Atlanta airports, and be subjected to three weeks of monitoring[14]. However, suggestions to stop all travel between the United States and West Africa, while not ruled out as a future response measure, has been criticized by leading infectious disease and global health experts as an ineffective, and likely harmful, public health response, and a potentially politically and economically destabilizing act for the West African countries[15].

The CDC has activated its Emergency Operations Center to the highest response level, and is now working with WHO in a leadership capacity on the outbreak[16]. While a few cases of EVD have appeared in the United States, the CDC does not consider an EVD outbreak a serious risk to the U.S. public, and the agency is providing technical assistance with outbreak management to those locations domestically and abroad where cases have occurred or been suspected and have been preparing guidance for health departments, medical providers, and laboratories in the United States.

**Legal Framework for an EVD Response**

While federal law guides the U.S. national and international EVD response, most legal authority applicable to public health concerns such as local EVD cases, derives from state and local law[17,18]. The particular approaches used in EVD control efforts will be heavily influenced by the science-informed recommendations of federal, state, and local health authorities. The legal tools available to health authorities to advance such efforts, including restrictions on movement of EVD-infected and EVD-exposed individuals, are well-established and have been used and refined over numerous large and small public health infectious disease responses.

*Federal Authority*

Although the Preamble of the Constitution of The United States includes "to promote the general Welfare" as a guiding principle[18,19], the Constitution is largely silent on issues concerning public health. The Tenth Amendment to the Constitution provides that "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively,

or to the people" [20]. When the Preamble and Tenth Amendment are read in conjunction, it "indicates that the federal government's public health powers extend only to the boundaries permitted by its defense, interstate commerce, and tax powers"[17]. Therefore, individual states "…bear the primary responsibility for preventing and responding to threats to the public's health" [17,18].

*State Authority - Indiana's Power to Regulate Health*

The ISDH has a duty to "supervise the health and life of the citizens of Indiana and shall possess all powers necessary to fulfill the duties prescribed in the statutes and to bring action in the courts for the enforcement of health laws and health rules"[21]. State and local public health authorities should fulfill these responsibilities using the "least restrictive but medically necessary procedures to protect the public health"[22]. Therefore, if a public health goal can successfully be attained through gaining the consent of the affected party (such as getting an individual to voluntary quarantine themselves while their health status is monitored), that approach should be utilized before considering compelling action. Furthermore, all actions taken by state public health authorities should be guided by appropriate protections for the due process rights of the affected individuals.

ISDH is authorized by the Indiana General Assembly to inspect any public properties for sanitary conditions and to inspect the indoor air quality of all public buildings that are occupied by a state or local government agency[23]. ISDH may also, after due notice, inspect private property for the "presence of cases of infectious and contagious diseases and the possible cause and source of diseases" [23]. In addition to ISDH, each county in Indiana has their own local health department established by the executive of the county[24].

ISDH has the power to take a number of steps to prevent and respond to a disease or epidemic:

- Ask a person for written informed consent to be examined to prevent the transmission of an infectious disease, if there are reasonable grounds to believe the person may be infectious[25]. Should the suspected infected individual refuse to be examined, the public health officer may seek a court order to compel cooperation, which may be granted upon a demonstration of clear and convincing evidence[25].
- Establish a quarantine, including what is reasonably necessary to prevent and suppress the disease[26].
- Impose large-scale social distancing measures to prevent or attempt to contain an epidemic, such as postponing athletic events, ordering schools and churches to close, and prohibiting other nonessential public gatherings [27].
- Issue an order condemning or abating disease-causing conditions[28].

Local county health boards may do the same actions as ISDH, but are limited to the jurisdiction of where the board (or health officer) serves[29,30].

If a public health authority in Indiana has reason to believe an individual has been exposed to, or infected with, a dangerous communicable disease, health officers have the right to conduct an investigation into the movements of the patient to determine whether others may potentially have been exposed to the infectious disease[29]. If that person is likely to infect another, the public health authority may petition a circuit or superior court for an order of isolation or quarantine for that individual[31]. The petition should be verified and include a description of the facts to support the public health authority belief that the person should be isolated or quarantined, and should include descriptions of any prior attempts to allow the person to be voluntarily isolated or quarantined[31]. If notice and an opportunity to be heard from the possibly infected person cannot be obtained, then the public health authority may petition the court for an emergency order stating isolation or quarantine should be imposed on the person and the person may expose an uninfected person to the communicable disease before the infected person could be provided with notice[31].

In Indiana, a disaster is defined as "an occurrence or imminent threat of widespread or severe damage, injury, or loss of life or property resulting from any natural phenomenon or human act," and can include an epidemic or public health emergency[33]. If a disaster or emergency is beyond local control, the Governor of Indiana "may assume direct operational control over all or any part of the emergency management functions within Indiana"[32]. This may include making, amending, or rescinding any necessary orders, rules, or regulations with due consideration of the plans of the federal government in regard to a disaster of emergency[32].

Given the stigma, isolation, and media attention which may be associated with an Ebola diagnosis, those exposed to EVD may be hesitant to present to health care providers or to adhere to public health recommendations following diagnosis[34]. Public health authorities may issue an immediate order for up to 72-hours imposing isolation or quarantine on an individual "if exigent circumstances, including the number of affected individuals, exist that make it impracticable for the public health authority to seek an order from a court, and obtaining the individual's voluntary compliance is or has proven impracticable or ineffective"[31]. High-profile violations have been reported of quarantine orders (e.g., Dr. Nancy Snyderman[35]) and voluntary social distancing requests (e.g., Amber Vinson, the Dallas nurse who flew on a commercial airline the day before becoming symptomatic[36]), raising concerns about both the public's willingness to subject itself to public health control measures and the ability of local authorities to effectively monitor and enforce such measures.

**Ethical Considerations in an EVD Response**

*Access to Experimental Drugs and Treatments*

As noted above, several different treatments are currently being studied and used in limited circumstances in treating patients infected with EVD. To date, no drugs or vaccines have fulfilled the

effectiveness and safety testing standards for human subjects required to gain FDA approval. Therefore, any use of these proposed treatments is considered "experimental" under U.S. law, and subject to very strict distribution rules. Following the September 11, 2001, terrorist attacks, a new FDA policy, known as the "Animal Rule," was adopted to speed up the approval process when faced with a deadly pathogen (such as an emerging virus or a chemical or biological threat), and is determined to be both unethical and unfeasible to conduct field trials to determine the effectiveness of the treatment in human subjects[37]. This rule allows the FDA to approve a drug after appropriate animal studies have shown the drug to be reasonably likely to be effective in treatment, and the drug, after being tested in humans for its safety, passes FDA's safety standards[37]. Several vaccines are currently undergoing these human safety trials. The FDA also supports expanded access, also known as "compassionate use," of investigational drugs for patients with a life-threatening disease and without any satisfactory alterative or comparable treatments[38]. Normally, as part of the oversight process, experimental treatments are reviewed by Institutional Review Boards (IRBs) to ensure the drug benefits reasonably outweigh the associated risks[38]. IRBs require that prior to administering such investigational treatments, those proposing to administer the treatment engage the patient in a robust informed consent process to ensure the patient (or their legal representative) understands the potential risks inherent in the treatment (including the possibility of unknown risks), and makes a determination the patient willingly consents to treatment[38].

The two American patients who returned to the United States in August 2014 after being infected with Ebola in Liberia both received the experimental drug ZMapp prior to leaving West Africa[8]. Both patients gave consent to take the experimental drug knowing the drug was untested[8]. In response to the distribution of these untested treatments, the WHO convened an ethics advisory panel to weigh the ethical considerations in using unapproved (and unproven) EVD treatments. The panel stated that, given the paucity of available treatment options, "it is ethical to offer unproven interventions with as yet unknown efficacy and adverse effects, as potential treatment or prevention" [39].

*Allocation of Scarce Resources: Drugs, Medical Treatment, and Patient Beds*

Should experimental medications become available, questions arise as to how to ethically ration out such resources should there be more demand than supply. Similarly, while symptomatic patients may present at any emergency department in the state, it is unrealistic to anticipate all facilities will equally be ready, willing, or able to provide the intensive care needed to treat EVD patients and ensure the safety of the health care providers and staff involved with delivering care. Drugs and beds will likely be limited, and policymakers must make difficult choices in setting priorities.

Guidance may be found in preparations undertaken in response to previous significant outbreaks. As part of its pandemic influenza planning process in 2008, the Altered Standards of Care Community Advisory Group developed a report on scarce resource allocation for the ISDH[40]. In considering such issues as the distribution of a limited number of ventilators and limited supplies of vaccine doses, the Advisory Group recommended rationing policies be guided by: duties to care (supporting those who may not receive priority in receipt of care); to steward resources (balancing the obligation to save as many people as possible against a responsibility to every patient, keeping in mind survival chances); to plan in advance for allocation of staff and resources (rather than make such decisions in the moment of need); to maintain a commitment to distribute the scarce resource in ways fair to all state residents and do not disproportionately worsen the situation for Indiana's most vulnerable populations; and to ensuring broad input in the development of the distribution system design process[40].

The Hastings Center also developed a background report on fair allocation of scarce life-saving resources for a flu pandemic, describing seven ethical options policymakers might weigh in developing its rationing plan: (1) prioritize preventing new infection; (2) prioritize essential medical and scientific personnel; (3) prioritize health and safety infrastructure; (4) prioritize those with the greatest medical needs; (5) prioritize based on life cycle; (6) prioritize the chronically underserved; and (7) prioritize globally early detection and response[41].

In April 2014, ISDH published a report written by the Crisis Standards of Care Community Advisory Group on standards for patient care for triage and ventilator allocation, with an eye toward Pandemic Influenza preparedness. These standards may be helpful in the development of protocols for allocation of resources in response to an EVD outbreak[42]. The guide stresses that even during times of scarce resources all patients should be evaluated using the same triage criteria[42]. Triage of patients should be done as early as possible, into three groups: infectious, non-infectious, and no evidence of the disease[42]. Triage should be performed as soon as possible outside of hospital or health care facilities (e.g., doctors' offices, neighborhood clinics, extended health care facilities, or other locations approved by local health care systems)[42]. Tailoring a response to EVD and early triage of patients will be critical, given that it is a highly infectious disease and public health concern. This would include immediately placing the patient in isolation if the patient is symptomatic of EVD, and immediately notifying the local Indiana county health department or ISDH [43].

The WHO advisory panel, convened to offer guidance on the ethics of using experimental treatments for EVD, came to similar conclusions about the guiding ethical principles for rationing scarce resources, including the responsibility to ensure fair distribution across populations, be transparent and inclusive, protect vulnerable populations (especially children and pregnant women), and maintain the duty to care[39]. Many of the panel members also believed health care workers should get priority access to treatments, based upon

the ethical principles of reciprocity (the health care providers' willingness to endanger their own lives to offer care to others) and social usefulness (their critical role in providing care to other affected populations and containing EVD's spread)[39].

The contraction of EVD by two Dallas nurses involved in the treatment of Liberian EVD patient Thomas Eric Duncan has raised significant questions about hospital EVD preparedness efforts. Expert opinions are divided over whether every hospital should be ready to provide intensive care for EVD patients in their facilities, as the CDC has recommended[44], or if specific hospitals should either designate itself, or be designated as, the Ebola hospital for a particular region[45]. For example, on October 16, 2014, the governor of New York announced that, as part of its statewide Ebola preparedness plan, eight hospitals in the state agreed to be designated to handle all EVD-diagnosed patients, and plans are in process to designate more hospitals in the future[46]. Under either structure, the number of beds that can reasonably be made available to treat Ebola cases will likely be limited, therefore similar rationing and triage plans will be necessary.

**Thoughts for Policymakers**

The current EVD outbreak is an international public health crisis[3]. The number of legal and ethical questions arising out of prevention, treatment, and public health response to EVD mirrors the complexity of the local, state, national and international network of clinical and public health actors engaged in EVD control efforts.

Indiana can help prevent or mitigate a possible Ebola outbreak in the state. Any plan must adhere to the state's public health response laws, and account for possible ethical issues from such a response. This plan may include the following recommendations[8,9,10,42,43,46,47]:

- Include a state-wide EVD plan that accounts for the highly infectious nature of the disease, including the resources to ensure successful containment of the disease (e.g., have special isolation units for patients that present EVD symptoms; provide adequate training and protective gear for medical personnel).
- Integrate ethical considerations into a state-wide EVD plan (e.g., access to experimental treatments; rationing of scarce resources).
- Ensure compliance with a state-wide EVD plan by county public health departments, officials, medical personnel, and the general public.
- Provide robust education on the nature of Ebola, its symptoms, and its transmission. Such education may help dispel fear, stigma, and discrimination against suspect and actual EVD patients from both the medical community and the general public.
- Provide adequate funding to advance research on EVD vaccines and medications for the purpose of eradication.

The success of the global and domestic response to the EVD outbreak ultimately relies upon the willingness of healthcare providers to assume significant, possibly fatal, personal risks to provide care to the sick. Similarly, those involved with the cleaning of the facilities, the transportation and processing of samples, disposal of waste, and removal and burial (or cremation) of remains also place themselves directly at risk. This raises important questions employers, contractors, and policymakers will need to address for workplace safety and training, adequacy of protective gear and staffing levels, worker's compensation and disability, and liability.

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