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In Defense of (Some) Altered Standards of Care for Ebola Infections in Developed Countries

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Abstract The current outbreak of Ebola virus infection in West Africa continues to spread. Several patients have now been treated in the United States and preparations are being made for more. Because of the strict isolation required for their care, questions have been raised about what diagnostic and therapeutic interventions should be available. I discuss the ethical challenges associated with caring for patients in strict isolation and personnel wearing bulky protective gear with reduced dexterity and flexibility, the limitations this may place on available treatments and the permissibility of consequent departures from the standards of care. Restricting access to some interventions such as surgery requiring an operating room, advanced imaging, etc. is reasonable due to concern for protecting other patients, visitors and staff. Cardiopulmonary resuscitation is a special case and the implications for withholding this intervention in situations where it may be desired is discussed, especially with respect to those patients who have suspected, but not proven, infection. These same restrictions are also considered under conditions where there are scarce resources and thus limited numbers of patients may receive care. While it is to be hoped that there is only limited and sporadic infection with Ebola virus in the US, careful thought must be given to the care of these patients under the unusual circumstances demanded by their isolation. I argue that an altered standard of care is reasonable and ethically acceptable under certain conditions.

Keywords Ebola · Altered standards · Healthcare crisis

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Introduction

While there have only been a relatively few patients to date who have been diagnosed with Ebola virus infection in the United States, most hospitals have been developing plans to care for anticipated patients with suspected disease under the guidance of the Centers for Disease Control (CDC). Smaller institutions will most likely seek to transfer their patients to large academic medical centers that may be better equipped to deliver the complex care coordination required for patients who have the potential for being both gravely ill and posing a substantial risk to those who care for them. Indeed, three of the US patients have been healthcare workers, although one—a physician—contracted the disease while in Liberia (Farrar and Piot 2014; Gostin et al. 2014; Klompas et al. 2014).

It has been reported both in the US and in the affected West African nations of Guinea, Liberia and Sierra Leone that people sick with Ebola can produce many liters of both diarrhea and vomitus per day, leading to both severe metabolic derangements that may be the primary cause of death in most patients. Such large volumes of infected fluids harboring high titers of viral particles have the potential to present a major hazard to any individuals participating in direct care of these patients. It is clear from the initial reports from Texas Health Presbyterian (the institution that cared for the first patient in the US who has died) that the requirements for effective patient isolation and containment can be cumbersome and formidable. The recommendations for personal protective equipment (PPE) for doctors, nurses and others who would be likely to have direct contact with infectious patients and their bodily fluids—the only demonstrable way to contract the infection—are both stringent and onerous and require significant training to don and doff correctly so as to not run the danger of inadvertent contamination. Moreover, experience with this apparatus (Biosafety Level 3) at my hospital has demonstrated that it can impede rapid movement and that manual dexterity is remarkably diminished, indicating that many standard tasks employed in the care of patients with dehydration and electrolyte abnormalities secondary to severe vomiting and voluminous diarrhea will be either difficult or even impossible to accomplish successfully.

As with the care of any possibly dangerous clinical situation, healthcare workers and the institutions in which they care for their patients are presented with an inescapable tension between the needs of the patient and maintaining their own safety and that of other patients, the staff, visitors and the durable equipment required for others. How these competing demands are negotiated requires balancing the duties and obligations of healthcare workers to the primacy of their patients' welfare and those to themselves, their families, their workplace and even society (Reid 2005; Ruderman et al. 2006). At the same time, hospitals have a reciprocal duty to provide an environment that offers the highest degree of personal security available that is compatible with reasonable patient care responsibilities. For example, it would be a gross violation of a healthcare facility's fiduciary duty to its staff to provide insufficient means to minimize their exposure to potential infectious or other pathogens by not purchasing enough disposable gloves or gowns or only having those of poor quality that did not furnish adequate barrier protection.

When these two duties clash, practical answers must be supplied to manage the conflict in a way that minimizes compromise in either safety or standards of care. In this way, healthcare workers can carry out their duties to care for their patients despite the possible dangers, armed with the knowledge that they are shielded as much as possible from harm by institutional policy. The unprecedented potential crisis presented by Ebola virus-infected patients in the US introduces a situation in which such decisions must be resolved, preferably beforehand so as to eliminate the risk of arbitrary, and hence possibly irresponsible, judgments. However, there is some past experience with developing plans to cope with novel medical disasters in the modern era, notably the large efforts involved in pandemic influenza preparation almost 10 years ago.

In the planning process for pandemic flu in 2006–2007, a considerable amount of time was devoted to discussing altered standards of care that might be needed to cope with what were expected to be huge numbers of very ill patients should the worse-case projections come true. Some of this debate merged with rationing decisions concerned with how certain limited resource technologies and medicines would be allocated to the anticipated deluge of patients. Reasonably detailed plans based on projected prognosis informed prioritization strategies for interventions such as ICU beds, mechanical ventilation and even extracorporeal membrane oxygenators (ECMO) (Patrone and Resnik 2011; Silva et al. 2012; Australia and Investigators 2009; Davies et al. 2009; Powell et al. 2008). Moreover, at least one published plan from New York State (and several unpublicized ones derived from this one) also factored in pre-existing conditions such as advanced, metastatic cancer, severe dementia, New York Class IV heart disease and others that would serve to limit the degree and amount of available treatments if they were in short supply (Health 2008). This recommendation was grounded on the belief that these kinds of patients would have a worse prognosis than others with severe influenza or whose other illnesses otherwise conferred a shortened lifespan and hence should not be eligible for intensive care. Obviously, these proposals represented significant departures from the usual standard of care in this country in which even patients with multiple incurable illnesses may be eligible for intensive care if they or their families insist. Under normal conditions, it is the rare patient who is refused an intervention due to lack of a realistic expectation of a positive outcome (Alpers and Lo 1999; Baily 2011; Courtwright 2012; Jox et al. 2012; Zier et al. 2009).

Consideration was also given to whether doctors and nurses, whose normal areas of practice did not include caring for patients with influenza and its complications, should be pressed into service if there were shortages of ICU staff, hospitalists, bedside nurses, pediatricians and the like. Under certain conditions it was deemed justified to permit less-than-formally qualified professionals (such as nurse administrators, dermatologists, etc.) to care for patients if they were willing and the circumstances warranted it, in an adaptation of "Good Samaritan" laws that exist in every state. Of course, taking such seemingly drastic steps would mean that these healthcare providers—assuming they were willing to serve in these capacities in this unique set of circumstances—would undertake responsibilities for which they were not necessarily trained. One issue that was never adequately addressed at the time (and, to my knowledge, since then) concerned how much allowance should be given

to physicians and nurses to practice outside their customary areas of expertise. While the situation could be desperate, would it have been so dire to justify permitting a pathologist (for example) to act as if she were an intensivist and care for patients receiving mechanical ventilation? It was assumed, but never clarified, that some departures from care standards would be so great and threaten such potential harm to patients that making do with the scarce, but more pertinent resources, including the possibility of only providing palliation (Rosoff 2010), would be better than having care provided by grossly unqualified personnel. Concordant with this judgment were efforts to obtain temporary relief from normally applicable laws and regulations that might make such practitioners and their institutions criminally or civilly liable for such departures from standard practice (Health 2008; Planning 2007).

Clearly, these guidelines represented significant departures from the customary norms by which very sick people—including those with severe seasonal influenza—are cared for under usual conditions. This deviation from standard practice was justified by the projections of severe shortages of supplies, equipment and healthcare workers compared to demand, necessitating rationing decisions based upon the best evidence available at the time. Standards of care can be dictated not only by what might be expected or by what is usual and accepted in a given location; they can also be determined by the specific circumstances of a given situation. For example, in Western Africa, the facilities and the resources available moderate the standards of care. However, in the United States, care of the EBV-infected patient would mandate a higher level of technological intervention. This would ordinarily be the case unless it could be demonstrated that circumstances were different enough. While the threat of an EBV pandemic in this country is likely far less than a pandemic of influenza, which have occurred at more or less regular intervals (Brundage 2006; Kilbourne 2006), the potential is real and most hospitals and healthcare providers are considerably better prepared to care for flu patients than they are for those sick with Ebola. Nevertheless, it is worthwhile considering what—if any—deviations from the usual standards of care would be acceptable if we were faced with significant numbers of these patients.

Healthcare Providers

In Toronto during the SARS epidemic in 2003 (and also during the initial years of the AIDS pandemic in the US), many hospitals were confronted with large numbers of nurses (and some physicians) who refused to come to work and face the prospect of having to care for patients with this disease, especially after several providers had died of SARS in Taiwan (Person et al. 2004; Reid 2005; Shiao et al. 2007). Subsequently, much attention was paid to what has been called the "duty to care", a position that medical professionals adopt when they accept the license granted them by society to practice (Reid 2005; Ruderman et al. 2006). However, this is not a unilateral compulsory obligation, and should be matched with a corresponding duty on the part of the places in which they work to provide them—to the extent that is feasible—with an environment that is safe. This could include furnishing personal and other protective equipment and facilities commensurate with the known or

likely dangers posed by patients. It remains an open question whether certain forms of coercion could be reasonable, such as making continued employment contingent upon working; to my knowledge this has only been used when it has been consistent with legal stipulations (like caring for patients with disabilities or HIV) or workplace requirements such as mandating annual influenza vaccination. To date, hospitals have been staffing their actual and anticipated EBV infection isolation units with volunteers, but it is worthwhile considering how institutions would cope if they failed to meet the demand with sufficient numbers of altruistic workers. It is highly unlikely that the threat of employment termination would be inadequate to change minds. Other added inducements, such as "hazard duty" payments, extra life insurance provided at no cost, etc., might be helpful. Finally, should the existing facilities and/or numbers of healthcare workers prove insufficient to meet demand, we would need to discuss whether it would be reasonable to consider using less-well-trained or experienced caregivers if they are willing to serve in these capacities. The challenges and risks of effectively caring for EBV patients may render this breach of usual practice so great that it may expose them to more harm than good. Thus not all novel measures adopted during a crisis of this sort can be defended; "something is better than nothing" is an adage that is not always true.

Boundaries on Care

Should the usual range of interventions continue to be available for use with patients sick with (or suspected of having) EBV infection? It should be noted that these patients will be isolated in a highly restrictive environment and cared for by nurses, doctors and technicians wearing bulky and uncomfortable complete PPE that can limit their movements, flexibility, dexterity and comfort. Current recommendations require two nurses per patient, one at the bedside and the other as an observer, with no more than 4 h of direct contact per individual (Healthcare 2014). Therefore, there will be practical limitations to what can be realistically done for these patients. Emory University Hospital, which has the most experience in this country with such patients, has published their guidelines, and they advocate confining the patients to the isolation unit, thus restricting access to advanced imaging (CT and MR), surgery requiring an operating room, and laboratory tests beyond those that can be performed by point-of-care equipment (Healthcare 2014). This already represents a significant departure from the standard of care for patients similarly sick and contagious, who are routinely brought to radiology suites and the operating room. It seems reasonable to restrict this sort of access because of the potential dangers to other patients, visitors, staff and the physical environment (from contamination) by moving infected patients throughout the hospital. There could be other modifications for those interventions that are portable and could be brought to the isolation unit. For example, use of mechanical ventilation and renal dialysis could be feasible; however, one would have to decide how much of the armamentarium of the iterations of these therapies should be available. While clinically important, they represent relatively modest alterations to customary intensive care.

Nevertheless, the restrictions on ordinary forms of available interventions imposed by the extraordinary precautions necessary to protect staff (and others) from possible contamination, forces other, perhaps more troubling, conclusions as well. The well-known ethical adage "ought implies can" is relevant to this discussion. One cannot require adherence to standards that a prudent individual, under conditions of rational and justifiable infectious precautions, cannot reasonably accomplish. If the protective gear that is necessary to shield healthcare workers from harm is found to be too bulky (for example) to effectively and safely deliver certain kinds of interventions, such as endotracheal intubation, insertion of particular sorts of intravascular catheters, etc., then it would be inappropriate to demand that the attempt be made. This does not imply that a priori decisions should be made about *all* complex, technologically sophisticated techniques. It simply means that we may need to adjust our expectations as we learn more about how to care for such patients in an environment in which these kinds of interventions are possible but not feasible.

More substantive, and no doubt more controversial, are questions concerning limits on circulatory support, especially whether or not cardiopulmonary resuscitation (CPR) should be performed. Dr. Joseph Fins has maintained that the main reason not to offer CPR is because of the increased danger it poses to medical staff (Fins 2014). However, these are patients who have massive and uncontrolled emesis and voluminous diarrhea, so it is difficult to imagine how much more a risk would be presented by chest compressions. It could be assumed that most—if not all—of the patients would already have intravenous access at the point of circulatory collapse (if they presented before they were *in extremis*), so it is unlikely that there would be need for additional vascular access. Moreover, the probability that patients needing CPR at this point in their illness trajectory would be salvageable would be remote. However, similarly ill patients (albeit without EBV) ordinarily receive CPR if the family insists, even if the chances of success are comparably unlikely. However, the fact that CPR can be routinely available to patients who could not benefit from it does not justify its use under the extraordinary circumstances of isolated EBV patients. Therefore, I would argue that patients who are receiving maximal support as defined by the limitations imposed by this form of isolation—such as vasopressors and mechanical ventilation—should have a "do not attempt resuscitation" order entered to prevent further escalation of fruitless interventions.

The biggest concern about a modified standard of care is that this might necessarily apply to patients suspected of having EBV infection in addition to those proven to have it. In all likelihood, patients who come to the hospital complaining of a fever and having been exposed to another infected patient would rapidly be isolated and assumed to have the virus until a definitive test proves them to be negative. Currently, the PCR technique can take 24–48 h to be complete, and during this time they must be presumed to have EBV. While it may be justifiable to limit access to certain interventions because of the reasons cited above, for these other patients it would because of suspicion of illness alone. Is this sufficient to warrant such departures from the usual standards?

Consider the consequences for patients who are suspected of being infected but who prove to be free of disease, who are also receiving mechanical ventilation and

vasoactive agents and who then suffer a cardiac arrest for whatever reason, perhaps after a myocardial infarction. Should these patients be treated differently from those with confirmed EBV? It can be assumed that some percentage of them will actually have the disease and thus they should receive the same treatment (or lack of it) as those with proven illness. On the other hand, it may not be futile to attempt resuscitation on patients who do not have EBV and are merely suspected of having it. Therefore treating them the same as patients with established EBV runs the risk of undertreating a patient who could potentially benefit from CPR (or surgery or advanced imaging, stenting of a coronary artery, etc., all of which would be unavailable as well). Since there would be no other mechanism at hand to care for patients who do not have verified EBV, we may have to accept the fact that some errors of this type could occur due to the unusual circumstances of this crisis.

Finally, we must consider whether there could be certain pre-existing conditions that would preclude attempts at curative supportive care (the only known effective therapy for this disease). As mentioned earlier, plans for pandemic influenza excluded patients with some co-morbidities from being considered for intensive care for two main reasons. First, their other disease(s) made the likelihood of surviving influenza-related respiratory illness much worse than others without such conditions, and second, when competing for limited resources, it seems reasonable to allocate scarce ICU beds and ventilators to those with the best chance of benefiting from them. We have little experience in treating EBV infection in people with other illnesses such as heart disease, cancer, obesity, diabetes and other disorders common in the US. Thus, there is no evidence to suggest that such patients would have worse outcomes than other patients. In a setting where there is no limitation in resources—meaning that there are available isolation beds—it is reasonable to offer these patients the same treatments available to others, unless of course they are already receiving palliative end-of-life care. However, if there must be an inescapable competition for scarce resources, then it would be acceptable to use an approach similar to that decided for pandemic influenza.

Conclusion

The current epidemic of Ebola virus in West Africa represents both a tragedy and a failure of poorly resourced public health systems in poverty-stricken countries. The inability to control the spread of the disease, as opposed to prior outbreaks, is of grave local and international concern. The belated Western response to the spreading disease may be effective in slowing its growth. It is unfortunate that efforts by wealthy industrialized countries to stem the flow of EBV out of the three most affected nations is based at least in part on the recognition that modern travel can easily facilitate dissemination of the infection well beyond the borders of Guinea, Liberia and Sierra Leone. Both repatriated Westerners, such as the first patients with EBV disease treated in the US, as well as those who enter having acquired the infection abroad, and healthcare workers infected during the treatment of patients, make real the possibility that significant numbers of patients could be hospitalized in American institutions. While the case fatality rate in Africa is at least

60 % (Dixon and Schafer 2014), it is certainly plausible that modern, advanced intensive care support could lower that number significantly.

However, this raises two issues. The first is concerned with conditions in which we have sufficient beds and personnel to care for patients adequately, albeit under the circumstances of strict isolation and the limitations to care—both inescapable and elective brought about by the situation. Should these patients be subject to a decreased standard of care, especially with respect to cardiopulmonary resuscitation, surgery and advanced imaging, *because* of EBV and mandatory isolation? The second becomes relevant when resources are limited, as would be the case if many more patients were identified with real or suspected EBV. Would certain co-morbidities become morally relevant to allocating scarce ICU isolation beds?

In this essay I have argued that altered standards of care can be justified under the specific and circumscribed conditions as I have described. CPR should be offered (when desired by the patient and/or family) to those patients—both with definitive and possible infection—who are not yet receiving maximal support such as vasopressor medications and mechanical ventilation. Contrary to others, I do not see this intervention as posing that much of an additional risk to those who already caring for the patient, assuming that their institutions are fulfilling their obligations to provide the maximal protective gear and environment that is available. Nevertheless, considering the physical restrictions imposed by isolation and the cumbersome protective gear worn by healthcare personnel, it also seems reasonable to not escalate life support beyond what is realistically feasible. This may very well entail not intensifying care further than blood pressure and possibly ventilatory support. However, when not all patients can be offered potentially life-saving therapy and rationing decisions must be made, treatment should be offered to those who could benefit the most from it, while the remainder should receive our compassion and symptom management as much as feasible. While troubling, these are the situations that Calabresi and Bobbitt described as forcing a "tragic choice" (1978). Needing to make choices of this kind is lamentable, but avoiding thinking about and preparing for their possibility would lead to preventable tragedy that can only add to the suffering imposed by this disease. In this way we can fulfill our duties to patients, staff and society.

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