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UPMC Center for Health Security Comments on Ethical Considerations and Implications of Public Health Emergency Response with a Focus on the Current Ebola Virus Disease Epidemic

The UPMC Center for Health Security is grateful for the opportunity to provide comments on the ethical issues related to public health emergency response that have arisen as a result of the Ebola Virus epidemic in West Africa. The following comments reflect the collective views of several staff members of our organization but do not necessarily represent the views of all our staff and do not necessarily represent the official views of UPMC. We address each of the 7 issues posed in the Request for Comment. <http://blog.bioethics.gov/2014/12/18/bioethics-commission-requests-comment-on-ethical-considerations-in-the-evd-response/>

1) Ethical and scientific standards for public health emergency response.

There is a set of ethical norms and procedural principles that should guide all preparedness and response actions in public health emergencies including the Ebola response. First among the norms is a commitment to **fairness**—policies and actions that:

- 1) Balance the potentially competing duties to care and steward resources (see below);
- 2) reflect the specific values and needs of the affected communities;
- 3) address the potentially differing viewpoints of patients, clinicians, government authorities and the general public;
- 4) are evidence-based (see below); and
- 5) are carefully considered and vetted in advance by a broad cross-section of relevant stakeholders.

Duty to Care- Clinicians have a well-recognized duty to provide medical care to the sick and injured especially when the needed care is urgent, such as in an epidemic like Ebola. This duty to care is complicated by the risk that is posed to care providers by the virus. The risk of exposure to the clinician must be weighed against the duty to care, and balancing the two is not easy. Clinicians should not be expected to take extraordinary risks for a patient with no chance of survival. On the other hand, patients should not be abandoned because of a fear of contagion.

Duty to Steward Resources- The duty to care is also complicated by the potentially competing need of the individual patient and the population. Clinicians, healthcare facilities, and public health organizations have a duty to steward limited resources in order to do the greatest good for the greatest number. In a crisis such as Ebola, health professionals and policy makers must constantly make difficult allocation decisions based a commitment to doing the most good.

Evidence-base- In crises like the Ebola epidemic, scientific certainty is hard to come by. Rigorous studies (e.g., epidemiologic, virologic, clinical and therapeutic) that might help answer critical clinical and public health questions have not been conducted in the past and likely are very difficult to conduct during the ongoing crisis. Nonetheless, clinicians, public health officials, and policy makers have a responsibility to make difficult decisions even in the absence of hard facts and therefore should do all that is possible to secure the best information possible, even if it is only a consensus of experts.

Among the process and procedural principles that should guide actions in preparing for and responding to a crisis are:

- 1) **Transparency**—in planning and decision-making
- 2) **Consistency**—in application among individuals and across populations
- 3) **Proportionality**—the actions taken must be commensurate with the scale of the emergency and degree of scarce resources
- 4) **Accountability**—of governments and policy makers for making reasonable and just policies and clinicians and healthcare facilities for implementing such policies in good faith with reasonable judgment.

2) *Ethical and scientific standards that guide the use of quarantine or other movement restrictions during public health emergencies.*

The use of quarantine and travel restrictions is premised on the assumption that they will reduce the likelihood of disease spread. If this were true, they maybe ethically permissible as a means of preventing harm to many even while imposing limited hardship on a limited number. The problem with this argument is that there is no evidence to support these assumptions. There is no data or historical evidence to shows that quarantine and travel restrictions significantly slow disease spread, and the hardship imposed maybe substantial and counterproductive. For example, in the Ebola outbreak, large scale quarantine contributed to areas of hunger and economic crisis in West Africa and made people fearful to report disease. For these reasons, we conclude that larger scale quarantines and travel restrictions are misguided policies that could worsen rather than improve outbreak control and are therefore both ethically and scientifically unsupportable. Limited forms of quarantine of specific individuals who have known high risk exposures to a highly contagious disease might be justifiable in certain circumstance but the degree of sequestration of the individual must be commensurate with the risk of exposure and the risk of subsequent transmission, scientifically sound, and the least restrictive possible.

Travel restrictions- The World Health Organization (WHO) and the US Centers for Disease Control and Prevention (CDC) have opposed imposing travel bans during the Ebola crisis because there is no scientific evidence that bans have ever been effective at limiting the spread of contagious diseases. At best, modeling studies of Ebola, influenza and other contagious diseases suggest that highly effective

travel restrictions (which are probably impossible in the real world) would delay cross-border disease spread by a matter of only 1 or 2 weeks. Unless there were a vaccine or other intervention that could suddenly be deployed in this short timeframe, this delay is insignificant. But it comes at substantial cost. It interrupts essential trade and causes significant damage to the economies of the affected countries. It also drives travel underground. If people cannot travel legally, they will travel illegally.

Geographic Quarantine- Geographic quarantine, what used to be called *cordon sanitaire*, involves sequestering a population who may (or may not) have been exposed to the contagious disease but who are not yet ill. Often this means confining people who are not infected along with those who are; thereby greatly increasing the risk of infection to the not-yet-infected. Furthermore, such geographic quarantine often leads to food and water shortages and cut off of basic medical care to the sequestered group. Such “collateral damage” might be ethically justifiable if these measures effectively reduced disease spread, but time and time again we see that many people escape quarantine or flee in anticipation of it and thus the imposition of quarantine promotes rather than hinders disease spread.

Limited individual “quarantine”- Some forms of limited quarantine (work/home quarantine) and other related forms of movement restriction or monitoring of specific individuals with known or suspected high risk exposures are ethically justifiable if they meet the tests of being scientifically sound, proportional, and consistent. Authorities must also ensure adequate support (e.g., medical, food, emotional, financial) to those whose movement is restricted. Authorities involved should be transparent in their decision-making and accountable. For many people and many diseases that are not transmissible until the onset of symptoms, self-monitoring and active public health surveillance are reasonable courses of action.

3) *The impact of quarantine or other movement restrictions on the availability or willingness of health workers to volunteer to contain the epidemic in disease-affected areas.*

The imposition of movement restriction on returning healthcare workers seems to have had a chilling effect on the willingness of volunteers to go to the affected countries. We have heard this from personal communication with healthcare workers considering volunteering and those who have returned and been subject to quarantine. We have also heard that the medical aid organization have reported a drop in volunteers due to these concerns. As stated above, such measures are justifiable only to the extent that they are scientifically sound, proportional, and consistent. In several well-publicized cases, returning healthcare volunteers were unnecessarily restricted.

4) *The impact of quarantine or other movement restrictions on public fear and anxiety about potential threats to public health.*

In many cases restrictions on movement as well as other measures such as decontaminating buildings and vehicles have been implemented “out of an abundance of caution” even though there was little or no scientific basis for the actions. Presumably these actions were taken to relieve public fear. However, we see no evidence that these actions mitigated fear. On the contrary, these actions appear to have reinforced and amplified unsubstantiated fears of contagion. Public fear seems to have been abated by

repeated evidence-based, clear, consistent messages that there was no public health risk and the lack of any community transmission. We believe that all actions taken “out of an abundance of caution” should be avoided as being not only unnecessary but counterproductive. These actions in the long term undermine the credibility of authorities.

5) *How U.S. public policy and public health response to the current EVD epidemic might or should affect public attitudes to, and further U.S. policy and public health response to, other current and future public health issues and emergencies.*

At this point it is not clear to us how the current response has affected public attitudes. Mostly it seems that the Ebola epidemic has disappeared from the public consciousness. To the extent that rational policies now in place (e.g., self-monitoring and self-reporting, a tiered –hospital response scheme) become understood as the norm, the better prepared we will be for the next event.

6) *Ethical and scientific standards for placebo-controlled trials during public health emergencies.*

We understand the ethical arguments made by either side on the debate about placebo controlled studies. One side argues that it is unethical to withhold a potentially life-saving treatment to a placebo control arm, while the other side argues that until we know if the treatments are safe and effective providing the treatment maybe unethical. Ultimately, in our minds, the issue boils down to the ethical principle of *first do no harm*. Are the treatments in question at least safe? For many of the experimental therapies being considered the answer is as yet unclear. Getting basic short term safety data in healthy subjects should not take too long if the treatments are in fact safe. Until short-term safety has been reasonably established, treatment trials do not seem justified in our view. The next question is whether all known safe and effective therapies (e.g., high quality supportive care) are being provided. Unfortunately, the answer for many patients is still no, but it appears that the situation is improving. There is anecdotal evidence that suggests that good quality supportive care can save many people without exposing them to a new risk from an experimental drug. If the treatments are in fact safe and good quality supportive care is being provided then experimental treatment trials are warranted. Because fatality rates appear to drop substantially with good supportive care, and patients enrolled in trials are more likely than not to get good quality care, it may be more difficult than imagined to determine if the investigational treatments are effective. The effect of the drug would have to be fairly dramatic. Placebo controlled trials may be the only true way to know for sure. Therefore, in our view, it is hard to justify therapeutic trials without placebo controls at this time.

7) *Ethical and scientific standards for collection, storage, and international sharing of biospecimens and associated data during public health emergencies.*

In our view the patients from whom the clinical specimens have been obtained and the countries that represent them have some legitimate ethical claims to the material and anything that derives from that material (e.g., patents or access to countermeasures). Understanding that research on a virus like Ebola requires high levels of biocontainment, biosafety and biosecurity, there are relatively few laboratories in

the world in which this research can be safely conducted. Therefore we believe that the viral specimens themselves should be tightly controlled in high biocontainment laboratories operating under strict regulation but the relevant research findings should be shared as much as possible (some data may require redaction for security reasons after careful prudence review). Furthermore, the countries from which the specimens have been obtained should receive some reasonable compensation for any products that derive from the specimens.