



1275 K Street, NW, Suite 1000  
Washington, DC 20005-4006  
Phone: 202/789-1890  
Fax: 202/789-1899  
[apicinfo@apic.org](mailto:apicinfo@apic.org)  
[www.apic.org](http://www.apic.org)

February 5, 2015

Ms. Lisa M. Lee  
Executive Director  
Presidential Commission for the Study of Bioethical Issues  
1425 New York Avenue, N.W.  
Suite C-100  
Washington, D.C. 20005

Dear Ms. Lee:

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to provide input to the Commission on the ethical implications of public health emergency response with a focus on the current Ebola Virus Disease (EVD) epidemic. APIC is an international nonprofit, multidisciplinary organization whose mission is to create a safer world through prevention of infection. Our 15,000 members work as infection preventionists in healthcare facilities, academic institutions, public health and other settings to prevent the spread of healthcare-associated infections and educate healthcare personnel and the public about preventing the spread of infectious diseases.

#### **Ethical and scientific standards for public health emergency response**

APIC supports the recommendations of the Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC) characterizing the following most pertinent issues during emergency responses: harm reduction and benefit promotion; equal liberty and human rights; distributive justice; public accountability and transparency; community resiliency and empowerment; public health professionalism; and responsible civic response.<sup>1</sup>

To this end, we believe that public health emergency preparedness planning for Ebola must address the actions the general public needs to take to protect themselves and, by complying, to protect others using a community health and safety perspective.

APIC recommends that reliable information should be made public as soon as possible. All crisis plans should be public and when possible, go through a period of public commentary. Plans for distribution of resources such as personal protective equipment should be released to hospitals, emergency services and other frontline providers. APIC recognizes, especially in the early stages of an emergent situation, plans can change as new information becomes available. However, these changes should be shared, along with their rationale as soon as possible.

Healthcare providers demonstrate the balance between professional practice and personal risk every day. Policies and procedures should be based on the best evidence available to reduce risk to the provider and yet provide safe care to the patient. Professional societies, such as APIC, have the ability to help disseminate and translate crisis plans to their membership through established communication channels that include the opportunity for members to discuss, debate, and bring the information to the healthcare providers across the healthcare spectrum in rapid format. We encourage public health



agencies to partner with established professional societies as an additional source for rapid distribution of resources and content.

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

The use of quarantines and isolation are longstanding tools of public health and the State; however, such curtailment of personal liberty cannot be applied to the individual without evidence that a particular individual presents an active risk to the community.<sup>2</sup> All such persons are entitled to due process.<sup>3</sup>

We appreciate that the aim of quarantine or other movement restrictions during public health emergencies is to protect citizens from infectious diseases that are easily spread through human-to-human contact. We also appreciate that Ebola is included on the Revised List of Quarantinable Communicable Diseases which allows persons who are in the “qualifying stage” of disease to be evaluated for inspection and quarantine.<sup>4</sup> The challenge with the current situation is that there is no scientific basis to justify placing a person who had contact with an infectious patient, but is currently asymptomatic into quarantine. The greatest infectious risk for Ebola is when patients are symptomatic; that is, the patient has a fever, vomiting, diarrhea, and malaise. Prior to this time, transmission risk is viewed as exceedingly low.<sup>5,6</sup>

The experience of isolation during quarantine can be a traumatic experience for individuals, with serious financial and psychological hardships reported.<sup>7,8</sup> In the absence of scientific evidence of a public health benefit to quarantine, we believe the ethical consideration of curtailment of personal liberty must be the primary deciding factor.

### **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**

APIC believes that the impact of mandatory quarantine can have the negative effect of discouraging healthcare professionals from volunteering in epidemic areas

Considering that self-monitoring and voluntary quarantine is an option that could be exercised by persons returning from high-risk countries,<sup>9</sup> APIC advocates that this less intrusive option be considered when persons present for inspection. The Ebola outbreak in western Africa is at crisis levels, but at this time, in the United States, the risk continues to be low. Returning healthcare workers and military personnel could be made aware of their civic duty and would most likely be willing to sacrifice their freedom of movement voluntarily, if given the correct guidance and support from public health agencies.

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

Fear and anxiety increase when the general public lacks understanding of the science behind movement restrictions or quarantine recommendations. Educational efforts geared toward informing the public of behaviors that place individuals at risk for becoming infected or transmitting infection must accompany quarantine or movement restriction recommendations during a public health emergency.<sup>10</sup>

APIC recommends that quarantine and travel restrictions be consistent with CDC recommendations and discourages individual municipality or state recommendations which create confusion and anxiety.



**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**

The current Ebola epidemic was announced in March 2014<sup>11</sup> and has continued to the present time (Centers for Disease Control and Prevention, 2014). However, it could be argued that until the importation of Ebola to the U.S. and Europe, there was little significant U.S. government assistance to West Africa.

Once Ebola arrived in the U.S., it would appear there were not enough resources, infrastructure, and education regarding Ebola risks and transmission. Inconsistent recommendations from public health authorities, led to stockpiling and subsequent shortages of personal protective equipment both in the U.S. and abroad.

U.S. policy should consider local and global interests to ensure that resources are appropriately allocated in a timely and consistent manner. This includes identifying healthcare professionals, such as infection preventionists, who play a key role in public health emergency preparedness and response, and providing this group the support to act to the fullest extent of their licensure and abilities.

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

The Federal Policy for the Protection of Human Subjects, or the “Common Rule”,<sup>12</sup> published in 1991, was influenced largely by the 1979 Belmont Report on Ethical Principles and Guidelines for the Protection of Human Subjects of Research.<sup>13</sup> The report identifies three essential principles of ethical human research: respect for persons, beneficence, and justice. It noted that, even during emergent studies, participants must be provided with informed consent, receive the standard of care as part of any placebo arm, and be treated fairly. This includes minimizing harms and risks and maximizing benefits; respecting human dignity, privacy, and autonomy; taking special precautions with vulnerable populations; and striving to distribute the benefits and burdens of research equitably. APIC believes that these principles should guide ethical standards for clinical trials, even during public health emergencies.

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

In addition to the ethical research standards identified above, great care must be made regarding privacy and confidentiality regarding those persons who provide such specimens. Care must also be taken to ensure that biospecimens are shared and shipped according to international standards, and in a way that minimizes the threat to general population.

Thank you for allowing us to share our comments as the Commission as it considers the ethical landscape of U.S. public health emergency response to the EVD epidemic.

Sincerely,

A handwritten signature in black ink that reads "Mary Lou Manning". The signature is written in a cursive, flowing style.

Mary Lou Manning, PhD, CRNP, CIC, FAAN  
2015 APIC President

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<sup>1</sup> Jennings B, Arras J. Ethical guidance for public health emergency preparedness and response: highlighting ethics and values in a vital public health service. White paper prepared for the Ethics Subcommittee of the Advisory Committee of the Director, U.S. Centers for Disease Control and Prevention 2008. Available from [http://www.cdc.gov/od/science/integrity/phethics/docs/White\\_Paper\\_Final\\_for\\_Website\\_2012\\_4\\_6\\_12\\_final\\_for\\_web\\_508\\_compliant.pdf](http://www.cdc.gov/od/science/integrity/phethics/docs/White_Paper_Final_for_Website_2012_4_6_12_final_for_web_508_compliant.pdf). Accessed 1/29/15.

<sup>2</sup> Gostin, LO. *Public health law: Power, duty, restraint* (2nd ed.). Berkeley, CA: University of California Press 2008.

<sup>3</sup> *Ibid.*

<sup>4</sup> 42 USC 264(d), Ex. Ord. No. 13295, Apr. 4, 2003, 68 F.R. 17255, as amended by Ex. Ord. No. 13375, § 1, Apr. 1, 2005, 70 F.R. 17299. Available at <http://www.gpo.gov/fdsys/pkg/USCODE-2011-title42/pdf/USCODE-2011-title42-chap6A-subchapII-partG-sec264.pdf>. Accessed 1/29/15.

<sup>5</sup> Drazen JM, Kanapathipillai R, Campion EW, Rubin EJ, Hammer SJ, Morrissey S, Baden LR. Ebola and quarantine. *N Engl J Med* 2014; 371:2029-2030.

<sup>6</sup> Racaniello V. Nobel laureates and Ebola virus quarantine. Posted November 4, 2014. Available at <http://www.virology.ws/2014/11/04/nobel-laureates-and-ebola-virus-quarantine/>.

<sup>7</sup> Hawryluck L, Gold WL, Robinson S, Pogorski S, Galea S, Styra R. SARS control and psychological effects of quarantine. *Emerging Infectious Diseases*. 2004;10(7):1206–1212.

<sup>8</sup> Gilmartin HM, Grota PG, Sousa K. Isolation: A concept Analysis. *Nurs Forum* 2013;48:54-60.

<sup>9</sup> U.S. Institute of Medicine Forum on Microbial Threats. *Ethical and Legal Considerations in Mitigating Pandemic Disease: Workshop Summary*. Washington (DC): National Academies Press (US); 2007. 3, Strategies for Disease Containment. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK54163/>. Accessed 1/29/15.

<sup>10</sup> Soergel A. Ebola quarantine questioned. *U.S. News and World Report* October 27, 2014. Retrieved from: <http://www.usnews.com/>.

<sup>11</sup> U.S. Centers for Disease and Prevention. Previous updates: 2014 West Africa Outbreak. Retrieved January 17, 2015 from <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/previous-updates.html>.

<sup>12</sup> 45 CFR 46. Available at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>. Accessed 1/29/15.

<sup>13</sup> U.S. Department of Health, Education, and Welfare, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. April 18, 1979. Available at <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>. Accessed 1/29/15.