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February 5, 2015

Via [info@bioethics.gov](mailto:info@bioethics.gov)

Lisa M. Lee  
Executive Director  
Presidential Commission for the Study of Bioethical Issues  
1425 New York Ave, NW  
Suite C-100  
Washington, DC 20005

**RE: December 8, 2014 Federal Register Notice; Request for Comments on Ethical Considerations and Implications of Public Health Emergency Response with a Focus on the Current Ebola Virus Disease Epidemic**

Dear Dr. Lee,

The Society for Healthcare Epidemiology of America (SHEA) appreciates the opportunity to provide our response to the request for comments from the Presidential Commission for the Study of Bioethical Issues on ethical considerations and implications of public health emergency response with a focus on current Ebola Virus Disease (EVD) epidemic, as published in the December 8, 2014 *Federal Register*.

SHEA represents more than 2,000 physicians and other healthcare professionals globally with expertise in healthcare epidemiology and infection prevention. SHEA is dedicated to advancing the science and practice of healthcare epidemiology and preventing and controlling morbidity, mortality, and the cost of care linked to healthcare-associated infections (HAIs).

SHEA's response focuses on the Commission's first area of concern regarding U.S. public policies that restrict association or movement, such as quarantine, which have been proposed for healthcare personnel, military personnel, and other travelers returning from countries affected by EVD in west Africa. In consideration of ethical and scientific standards that guide the use of quarantine or other movement restrictions during public health emergencies, SHEA has been outspoken on its position opposing the imposition of mandatory quarantine for asymptomatic healthcare personnel or other individuals returning from EVD-stricken countries. SHEA supports standardized methods for monitoring healthcare personnel that are consistent with the most up to date Centers for Disease Control and Prevention (CDC)

Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure<sup>1</sup>. This guidance recommends active monitoring and reporting twice daily for fever and symptoms of EVD during the 21-day incubation period for all healthcare personnel who provide direct patient care to EVD patients and returning from EVD outbreak areas. As an important element of this monitoring program, healthcare personnel returning from EVD stricken areas must have the ability to be identified through exit and arrival screening.

Mandatory quarantine should only be implemented for those who fail to voluntarily adhere to monitoring and reporting standards set forth in the CDC guidance. Mandatory quarantine, and the resultant suspension of individual rights and liberties, should only occur if it is necessary in order to prevent significant risk to public health. In these rare cases, such decisions should be made by informed policymakers and based on sound medical and scientific evidence. The information gathered during an investigation and the rationale supporting the decision to quarantine healthcare personnel should be transparent to members of the public.

Going forward, policies on quarantine should be deliberated and promulgated in advance of a public health emergency but should also allow for revisions as necessary in response to new information. In agreement with comments submitted by the Infectious Diseases Society of America, SHEA believes quarantine policy decisions should (1) be based on the best available medical, scientific and epidemiological evidence; (2) be proportional to the risk; (3) balance the rights of individuals and the community; (4) consider public values and concerns (5) minimize unintended negative consequences; and (6) minimize unnecessary use of limited resources. In the case of EVD, it is well known that asymptomatic people pose no risk for Ebola transmission to others, particularly in public settings. Therefore, mandatory quarantine of asymptomatic individuals provides no benefit to the public.

In addition, using mandatory quarantine policies when they are not needed can cause significant harm. The inappropriate use of quarantine or movement restrictions for healthcare personnel providing direct patient care to patients with or suspected to have infectious diseases like EVD perpetuates fear in the public, misconceptions about how EVD is spread, and could cause these healthcare personnel to be stigmatized. In the case of previous infectious disease outbreaks where mandatory quarantine measures were employed as a matter of policy, such as during a SARS outbreak, there are data that demonstrate the adverse psychological impact of mandatory quarantine<sup>234</sup>. Those affected by the SARS quarantine policy exhibited symptoms such as Post Traumatic Stress

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<sup>1</sup> Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure. CDC, December 24, 2014. <http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html> . Accessed February 3, 2015.

<sup>2</sup> Reynolds DL: Understanding, compliance and psychological impact of the SARS quarantine experience. *Epidemiol Infect.* 2008 Jul;136(7):997-1007.

<sup>3</sup> Hawryluck L: SARS control and psychological effects of quarantine, Toronto, Canada. *Emerg Infect Dis.* 2004 Jul;10(7):1206-12.

<sup>4</sup> Lin EC1, Peng YC, Tsai JC: Lessons learned from the anti-SARS quarantine experience in a hospital-based fever screening station in Taiwan. *Am J Infect Control.* 2010 May;38(4):302-7.

Disorder and depression. Past mandatory quarantine policies levied on the public on a larger scale have also demonstrated the adverse consequences of quarantine, such as violent reactions from the public and mistrust in the government<sup>5</sup>.

Taken together, these phenomena could have the unintended consequence of dissuading healthcare personnel from voluntary service, leading to fewer volunteers and increased difficulty in assembling care teams in west Africa and in other countries, including the United States, preparing to care for EVD patients. Furthermore, mandatory quarantine and other policies designed to restrict the movement of healthcare personnel caring for EVD patients when applied unevenly and inconsistently among states and other localities may also erode the public's view of federal and state agencies responsible for setting standards and issuing risk-based guidance.

Healthcare personnel caring for EVD patients should have adequate access to appropriate Personal Protective Equipment (PPE) and other tools necessary to do their job safely. In consideration of ethical and scientific standards for public health emergency response, SHEA supports the current CDC guidance on PPE to be used by healthcare personnel caring for patients with EVD<sup>6</sup>. This guidance is consistent with the established science regarding how EVD is transmitted. Additionally, the local healthcare and infection prevention teams must have the ability to select the best specific items of PPE for their facility as long as the standards established by the CDC are maintained. Preference, availability, and competency for donning and doffing of PPE by nurses, physicians and other healthcare personnel are paramount as are considerations for familiarity, tolerability (e.g. discomfort, overheating), risk for self-contamination during doffing, and amenability to training which all require local input.

Mandating PPE that is excessive for the risk from a suspected or confirmed EVD patient results in unnecessary impediments to timely and effective clinical care. Further, excessive or unfamiliar PPE for healthcare personnel could increase the risk of contamination during donning or doffing. Unnecessarily narrow limitations on PPE types or application of PPE standards to providers or centers for where the risk of exposure is negligible will exacerbate already critical PPE shortages and limit the ability of U.S. hospitals to be prepared to care for those with known or suspected EVD. SHEA believes that the current CDC guidance, when practiced correctly and reinforced by adequate and continued training of healthcare personnel, protects them from EVD transmission.

The current EVD epidemic and lessons learned from the initial and current response can inform existing and new U.S. policies on both the current EVD public health crisis and future outbreaks and emergencies. SHEA supports the infection prevention guidance issued by CDC through multiple guidance documents and other resources available to the

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<sup>5</sup> Barbera J: Large-scale quarantine following biological terrorism in the United States: scientific examination, logistic and legal limits, and possible consequences. JAMA. 2001 Dec 5;286(21):2711-7.

<sup>6</sup> Guidance on Personal Protective Equipment To Be Used by Healthcare Workers During Management of Patients with Ebola Virus Disease in U.S. Hospitals, Including Procedures for Putting On (Donning) and Removing (Doffing). CDC, October 20, 2014. <http://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html> . Accessed February 3, 2015.

public through its web site. Many healthcare facilities across the country have made a commitment to train and prepare their teams for the care of patients with EVD based on the guidance provided by CDC. SHEA continues to support the rigorous application of evidence-based measures to prevent transmission of EVD and EVD-like diseases. A robust infection prevention program, led by a physician with advanced training in infectious diseases, is essential for patient safety.

SHEA believes that the current EVD epidemic illustrates the need for increased funding for hospital epidemiology and infection prevention programs worldwide. Increased resources for infection prevention programs will improve the response to not only EVD, but to countless other infectious diseases and HAIs that threaten our patients and healthcare personnel. Because EVD transmission risk is highest during severe illness, transmission of EVD to healthcare personnel and caregivers has been a major feature of most prior EVD outbreaks. The complexity of ensuring 100% adherence to infection control practices, particularly around PPE, points to the need for improved training of healthcare personnel across all practice settings. Dedicated funding at the hospital, state and national levels for infection prevention programs helps protect patients and healthcare personnel from both EVD and other HAIs.

SHEA thanks the Commission for soliciting public comment on bioethical issues related to the response to the EVD epidemic. We support all policy development initiatives that are based on the best scientifically sound and evidence-based medical information available. For future inquiries on this submission, please contact Lynne Batshon at 703-684-0761 or [lbatschon@shea-online.org](mailto:lbatschon@shea-online.org).

Sincerely,

A handwritten signature in black ink, appearing to read "A. Harris". The signature is fluid and cursive, with a large initial "A" and a long, sweeping underline.

Anthony D. Harris, MD, MPH, FSHEA, FIDSA, President, SHEA