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Thomas O. Forslund, M.P.A.
Director
Wyoming Department of Health
401 Hathaway Building
Cheyenne, WY 82002

Wendy Braund, M.D., M.P.H.
State Health Officer and Senior Administrator
Public Health Division
Wyoming Department of Health
6101 Yellowstone Road, Suite 420
Cheyenne, WY 82002

Dear Director Forslund and Dr. Braund:

Public Citizen's Health Research Group has learned, from an internal hospital memo (see Enclosure) and from other sources of information, that in November 2011, the Wyoming Department of Health (WDOH), responding to a complaint about dangers to surgical patients in the hospital, inspected the surgical services at Sheridan Memorial Hospital (SMH) in Sheridan, Wyoming, and discovered that, during the approximately eight previous months, SMH had ceased to properly sterilize or disinfect reusable laryngeal mask airways (LMAs) between each use in patients undergoing surgery (see enclosed memorandum). As a result, hundreds of patients were potentially exposed to a variety of infectious viral and bacterial agents because of the inadequacy of the substandard low-level disinfecting procedure the hospital had adopted. All microbes contaminating the LMAs from previous patient uses would have been killed had the proper sterilization procedure (which was employed prior to the aforementioned eight-month period) been maintained.

After its inspection, the WDOH apparently required that SMH take appropriate initial corrective action by immediately re-instituting standard steam sterilization procedures for LMAs between each patient use instead of the substandard interim low-level disinfecting procedure. However, we are unaware that SMH (a) notified all surgical patients unknowingly exposed to the inadequately disinfected LMAs about the potential risks of this exposure, (b) offered them screening for potential infections that may have resulted from such exposure, and (c) treated any patients found to have been infected. If our understanding is correct, we urge the WDOH to immediately require that SMH implement a plan for such patient notification, screening, and, if necessary, treatment. In the absence of such notification and screening, it is not possible to determine how many patients may have been infected by the inadequately sterilized LMAs, the nature of their infections, and whether proper treatment for these infections has been provided.

Furthermore, Public Citizen's Health Research Group also is concerned that SMH may have failed to (a) conduct a proper analysis to identify the root cause for this serious lapse in appropriate LMA sterilization procedures and (b) hold accountable hospital staff members responsible for this lapse. As a result, the risk for similar lapses may not have been minimized. Again, if such a root-cause analysis has not already been conducted by SMH, the WDOH should immediately require that one be conducted.

Requirement for at least high-level disinfection of LMAs between each patient use

LMAs are devices inserted into the pharynx (throat) of a patient in order to provide anesthesia and mechanical ventilation for elective surgery as well as in other clinical circumstances. The Centers for Disease Control and Prevention (CDC) guidelines for disinfection and sterilization in health care facilities categorize LMAs as "semicritical" medical devices, which are items that contact mucous membranes or non-intact skin of patients.[1] Under CDC guidelines, semicritical medical devices such as LMAs should be free from all microorganisms except small numbers of bacterial spores. These devices require ***high-level disinfection*** involving — for specific periods of time — either wet pasteurization or immersion in liquid chemical disinfectants, such as glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, and peracetic acid with hydrogen peroxide.

However, the manufacturer of the specific LMAs used by the surgical services at SMH, LMA North America, Inc., explicitly warns not to expose the devices to germicides, disinfectants, or any agents containing glutaraldehyde, phenol, iodine, or quaternary ammonium compounds because such substances are absorbed by the LMA materials, resulting in exposure of the patient to potentially serious tissue burns and possible deterioration of the LMA. Instead, the manufacturer indicates that steam autoclaving is the only recommended method of sterilization for its LMAs. The manufacturer's instructions for caring for the Reusable LMA Airways used at SMH state: "Steam autoclave according to the autoclave manufacturer's recommendations."[2] The LMA manufacturer's instructions further specify minimum steam-sterilization exposure times — based on the type of autoclave and whether the LMAs are wrapped or unwrapped — in order to ensure adequate sterilization.

Failure of SMH to steam-sterilize or perform high-level disinfection of LMAs

It has been alleged to Public Citizen's Health Research Group that approximately eight months prior to the November 2011 inspection by the WDOH, the SMH surgical service discontinued what had been the routine practice of steam sterilization of LMAs after every patient use. Subsequently, the LMAs allegedly underwent only manual brush washing, followed by washing and ***low-level disinfection*** using an automated spray washer that included sequential washings with an enzymatic cleaner and a neutral detergent, followed by rinsing with water and drying with forced air heat. These steps clearly fall well short of the ***high-level disinfection*** required under CDC guidelines for semicritical medical devices such as LMAs.

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[1] Centers for Disease Control and Prevention. Guidelines for disinfection and sterilization in healthcare facilities, 2008. Available at http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed March 7, 2012.
[2] LMA North America, Inc. Caring for your reusable LMA™ airway. Available at http://www.lmana.com/files/prosealcaring-for-reusable-airway.pdf. Accessed March 7, 2012.

The WDOH's requirement that SMH reinstate steam-sterilization procedures for LMAs following the agency's November 2011 inspection of the SMH surgical service affirms the agency's opinion, supported by current CDC guidelines, that the low-level disinfection machine washing procedure for the LMAs failed to provide sufficient disinfection or sterilization for such semicritical devices.

There are thus three lines of evidence pointing to the recklessness of the SMH decision to abandon proper sterilization of LMA devices and adopt a potentially dangerous, substandard method of disinfecting these devices between patient uses:

(1) SMH's temporarily adopted substandard cleaning and low-level disinfection method was in clear violation of the federal CDC guidelines for sterilization and disinfection of such semicritical medical devices.

(2) This cleaning and low-level disinfection method refuted the explicitly stated directions on the manufacturer's label for these LMA devices: "Steam autoclave according to the autoclave manufacturer's recommendations."

(3) When, following a complaint, the WDOH inspected SMH, the agency ordered the hospital to immediately abandon this substandard cleaning and low-level disinfection procedure and revert to the previously used steam-sterilization procedure.

Public Citizen's Health Research Group has been informed that approximately 100 patients undergo surgery using an LMA device monthly at SMH. If this estimate is accurate, several hundred or more patients at SMH may have been exposed to the inadequately sterilized LMAs during the time when steam sterilization of these devices was not performed.

Public Citizen's Health Research Group has also been informed that some staff on the SMH surgical services for months were allegedly aware of, and concerned about, the failure to steam-sterilize the LMAs. However, they purportedly refrained from bringing these concerns to the attention of hospital leadership because of fears of retaliation. If true, such an environment that generally stifles hospital staff from raising reasonable concerns about potential patient safety problems would more broadly represent a clear and present danger to patients at the hospital.

Recommended actions

(1) It is Public Citizen's Health Research Group's understanding that SMH has not (a) notified all surgical patients unknowingly exposed to the inadequately disinfected LMAs about the potential risks of this exposure, (b) offered them screening for potential infections that may have resulted from such exposure, and (c) treated any patients found to have been infected. If our understanding is correct, we urge the WDOH to immediately require that SMH implement a plan for such patient notification, screening, and, if necessary, treatment.

(2) The WDOH should also require that SMH conduct a proper analysis to identify the root cause for this serious lapse in appropriate LMA sterilization procedures and hold

accountable hospital staff members responsible for this lapse, if such action has not already occurred. Such action will help ensure that similar serious systemic lapses do not occur at SMH.

(3) The WDOH should urge SMH to implement policies and procedures that encourage all staff to bring concerns about potential patient safety problems to the attention of hospital management without fear of retaliation.

Thank you for your attention to this urgent matter. Please contact us if you have any questions or need additional information.

Sincerely,

Michael A. Carome, M.D.
Deputy Director
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group

Enclosure

cc: Mike McCafferty, Chief Executive Officer, SMH
Ron Mischke, Chairman, Board of Trustees, SMH
John Addlesperger, D.O., Chief of Staff, SMH