Update on Infection Outbreak Investigation

**Background**

In late May 2014, an outbreak of an unusual bacterial surgical site infection was suspected at Greenville Memorial Hospital. This is the first time GHS has experienced an outbreak of surgical site infections involving mycobacterium. *Mycobacterium abscessus* is an environmental contaminant and can be found in water and dust. The environmental bacteria are considered widespread and part of the natural flora of potable water in the U.S. EPA regulations do not require that it be eradicated because the organism is not thought to be harmful to the general public under normal circumstances. There are no national standards of care regarding whether hospitals should screen for this bacterium or how they should treat incoming water.

It has been described as a cause of healthcare-associated infections. The bacterium is harmless in most circumstances but can result in infections if it comes into contact with surgical sites, especially in immuno-compromised individuals. Exposure pathways of potential concern also include inhalation and entry of organisms through abraded skin, according to the Environmental Protection Agency.

**Investigation**

Because of the organism’s long incubation period of an average of 79 days in the GHS patients, patients did not typically show signs of infection until as long as several months after their surgeries. The first-recognized patient tested positive in March 2014. Because of the strong surveillance system, we were able to identify the potential problem and take immediate and appropriate action. In May, when several patients developed similar infections with this same mycobacterium, our hospital epidemiologist identified this as a potential infection outbreak. GHS then began an aggressive sequential elimination of potential sources based on epidemiologic evidence. Water studies showed that some water samples inside Greenville Memorial Hospital tested positive for the bacterium.

Preliminary information focused the investigation on ice from a filtered-water ice machine used in the Operating Room during cardiac surgery. During cardiac surgery, cooling techniques are used to stop the heart without damaging the heart tissue. The equipment used for that cooling of the blood and heart uses ice. The ice never directly touches the patient. The ice machine was removed from use on May 21 as a precaution.
while the investigation continued. Subsequently, ice required for those surgeries was made using sterile water.

As an additional measure, equipment used for cardiopulmonary perfusion was removed from use on June 6 as part of the expanding investigation. That machine used a closed system in which cooled or heated water encased in tubes is run in close proximity to patient blood (also encased in tubes) as part of a heating/cooling procedure used in cardiac surgeries.

At that point, GHS also reached out to the S.C. Department of Health and Environmental Control (DHEC) and Centers for Disease Control and Prevention (CDC), as well as other authorities in atypical mycobacterium for additional expertise with the investigation.

**Current Status**

As the investigation progressed, we instituted numerous measures focused on reducing or eliminating the levels of mycobacterium within our facilities. Many of these processes were already in place but GHS is continuing or strengthening them. The control measures include:

1. Flushing scrub sinks in the OR for at least 10 minutes in the morning before first use.
2. Installing point-of-use bacteriologic filters in the operating room, including scrub sinks. The filters are able to screen the extremely small bacterium, which is only .2 microns in size and one of the smallest bacteria now known; in comparison, a single human red blood cell is about 5 microns across.
3. Increased frequency of the disinfection of the machine which actually utilized the ice from every two weeks to weekly. Completed a report to inform the U.S. Food and Drug Administration and the manufacturer about this outbreak.
4. Inspecting internal water systems to assess for unused plumbing branches and ensuring water flow is constant through the pipes, which would help discourage the organism. GHS engineers have completed this work within the operating room area.
5. Temporarily closing an operating suite associated with the cardiac cases as a precaution. That operating suite reopened July 16, after cultures of the environment were negative.
6. Instituting ultra-violet light disinfection throughout the operating rooms as part of a general disinfection schedule.
7. Ensuring that future installation of plumbing in the facility does not create unused branches in the plumbing system in order to prevent stagnation and microbial contamination of tap water.
8. Using an even stronger disinfecting process that is more effective against this specific organism. All operating rooms were previously disinfected by a standard EPA approved product; however, the product now being used is tuberculocidal.

9. Installing a point of use bacteriologic filter for the ice machine once it is returned to service. Continuing a cleaning disinfection schedule of the ice machine in accordance with manufacturer recommendations.

10. Requesting an independent analysis of the cardiopulmonary perfusion machine. The result of that analysis is that it is unlikely that the equipment allowed tap water to contact patients; nonetheless, the hospital will not return it to use.

11. Devising more stringent internal procedures for cleaning the operating room. For example, covering the OR table -- including preparation for emergency surgery - is done on the day of the surgery and assuring that no operating room bed coverings are present while cleaning is performed.

12. Eliminating use of tap water contact with medical equipment and supplies. GHS does adhere to evidence-based practice, recommendations of regulatory agencies, guidelines from professional societies, as well as manufacturer recommendations for equipment used in the operating room. Prior to this outbreak, and depending upon information from the above sources, the equipment and its purpose, non-sterile water may have come in contact with equipment in the OR when use of sterile water was not required. However, DHEC has advised GHS that exposure to M. abscessus may best be avoided by preventing any possible tap water contact with medical equipment and supplies.

13. Continuing to ensure that medications and flushes given during surgery are stored in areas that do not have a water source and, when utilized in the OR, preparation and handling should be done away from any source of tap water or ice.

14. Continuing to emphasize meticulous adherence to infection prevention methods by staff in the operating rooms for the prevention of surgical site infections.

GHS plans to continue working with experts including DHEC and CDC on this investigation. Clinical isolates are being submitted to CDC for molecular analysis and comparison of culture results. GHS plans to continue heightened surveillance for further cases for at least 4 months.

**Patient / Family Communication**

Communication with individual patients about the situation has been an ongoing process. Each time a GHS surgeon suspected a patient of developing an infection, it was communicated to the patient. The surgeon also discussed culture results and treatment. Physicians are prohibited from discussing a patient’s condition with other patients due to privacy laws. However, patients were informed of the infection outbreak, once that outbreak was confirmed. We personally reached out to each of the affected patients or families in order to share information regarding the situation, either by face-
to-face conversations or phone calls. Each patient / family we met with was given a card with the name and phone number for someone they could call to request additional information. Our staff continue to support and respond to patient needs.

In addition, although the investigation had not yet provided conclusions, it was decided, out of an abundance of caution, that GHS would notify patients who were believed to be at risk for developing this infection, based on the investigation at that time. A letter was written to make these patients aware of the situation and to ask them to notify their surgeon should they develop signs of infection. That letter was sent to close to 200 patients on whom specific cardiopulmonary surgical equipment had been used, via regular and certified mail.

Even though the overwhelming majority of surgical patients treated at Greenville Memorial have not been affected by this rare mycobacterial infection, because of our commitment to transparency we thought it was important to notify the community about the infection out of extreme precaution to ensure their safety and to alert them about possible symptoms.

We regret that any patient within our care could possibly be affected by this situation. Our thoughts are with those involved. Our ongoing priority is continued safe and effective care for the patients who allow us the privilege of caring for them.