Oregon Association of Hospitals and Health Systems

To:	CEOs, Quality Directors, Nurse Executives, CMOs, Risk Managers, Infection Preventionists, Communications
From:	Diane Waldo, associate vice president of quality and clinical services Kennedy Soileau, associate director of communications
Date:	Oct. 12, 2016
Subject:	QUALITY ADVISORY: CDC links infections to potentially contaminated devices

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On Thursday, Oct. 13, the Centers for Disease Control and Prevention will publish an advisory regarding the **Sorin Stockert 3T heater-cooler device** manufactured by LivaNova PLC, which may have been contaminated with *Mycobacterium chimaera* in the manufacturing process, and that patients for whom these devices were used during cardiac surgery may be at risk of developing infections.

CDC is advising hospitals to alert patients who have had open-heart surgery involving the Sorin Stockert 3T heater-cooler device that they may be at risk for developing a life-threatening infection from *M. Chimaera*.

While this news is very concerning, the CDC estimates that less than 1 percent of the patients that may have been exposed will develop an infection. This is a slow-progressing bacteria and infections may take months to develop. This bacteria is common in soil and water, but rarely makes healthy people sick. Patients who are at higher risk include those with immune-compromised conditions.

This brand of device is used in 60 percent of hospitals nationwide. Even if your hospital does not use the Sorin Stockert 3T heater-cooler device, it is important to notify clinicians, including emergency department staff and those in the community, to help them identify the symptoms of M. Chimaera infections in patients who may have had surgery elsewhere so the proper course of treatment may be provided.

The Food and Drug Administration also plans to release a Safety Communication on Oct. 13 providing updated device-specific recommendations to help prevent the spread of infections related to the use of these devices.

Toolkit for hospitals

To assist hospitals in their outreach, the CDC has produced a **toolkit** (embargoed for media until 10 a.m. PT Thursday, Oct. 13), which outlines the issue and includes:

- Suggested next steps
- Embargoed advisory from the CDC
- Talking points for hospitals that have and have not used the device
- Sample patient notification letter
- Sample primary health care provider notification letter
- Sample letter to patients to take to their health care provider
- Contact information if you have further questions

Hospitals should review and determine how best to follow the recommendations in the CDC toolkit and the FDA safety communication that will be published tomorrow.

If you have any questions or need assistance, please contact me at diane.waldo@oahhs.org, (503) 479-6016. If the media contacts you about this issue, please contact Kennedy Soileau, associate director of communications, at ksoileau@oahhs.org or (503) 479-6019.