

JANUARY 31, 2017

HEALTH UPDATE**Potential Contamination of Organ Preservation Solution,
United States Update**

The Centers for Disease Control and Prevention (CDC), Health Resources Services Administration (HRSA), and the Food and Drug Administration (FDA) continue to investigate bacterial contamination of SPS-1, an organ preservation solution distributed by Organ Recovery Systems (ORS).

This is an update regarding the potential bacterial contamination in SPS-1 lots PBR 0074-337, PBR-0060-386, PBR-0074-330, and PBR-0060-392.

FDA's investigation of potential contamination of several lots of SPS-1, manufactured by Organ Recovery Systems (ORS) is ongoing. We recommend that Organ Procurement Organizations (OPO) and transplant facilities consider transitioning to alternate, FDA-cleared organ preservation fluid products from other manufacturers.

Please take the following actions to report adverse events occurring on or after April 1, 2016, in patients who received organs or tissues from organ recovery procedures using SPS-1 from any manufacturing lot:

- Submit a report to the Organ Procurement and Transplantation Network in the Disease Transmissions section of the Improving Patient Safety portal in UNet at www.transplantpro.org.
- File a report with FDA's MedWatch Safety Information and Adverse Event Reporting Program either online (www.fda.gov), by regular mail or by FAX to 1-800-FDA-0178 if you suspect contaminated organ preservation products at your facility.
- Notify the North Dakota Department of Health by calling 1.800.472.2180 or 701.328.4549.

Categories of Health Alert messages:

- *Health Alert conveys the highest level of importance; warrants immediate action or attention.*
- *Health Advisory provides important information for a specific incident or situation; may not require immediate action.*
- *Health Update provides updated information regarding an incident or situation; no immediate action necessary.*
- *Health Information provides general information that is not necessarily considered to be of an emergent nature.*

This message is being sent to local public health units, clinics, hospitals, physicians, tribal health, North Dakota Nurses Association, North Dakota Long Term Care Association, North Dakota Healthcare Association, North Dakota Medical Association, North Dakota EMS Association and hospital public information officers.