FDA recommends the following:

**Action Needed:**

- Transmitting infection, but may not entirely eliminate it. FDA has received 75 reports involving 135 patients of possible microbial transmission from duodenoscopy reprocessing. These considerations, and possibly alternative solutions, will be presented with additional guidance in a future update alert.

*References:

1. ECRI Institute Perspectives:

Hospitals should heed FDA’s recommendations, but there is evidence that simply diligently following manufacturer and professional association instructions for cleaning and reprocessing duodenoscopes may be insufficient. Among the hospitals that have had outbreaks of CRE associated with the ERCP procedures, careful review of their reprocessing protocols found in some instances that the facilities were closely complying with the recommended procedures. This raises concerns that hospitals may still be at risk of a CRE outbreak even if reprocessing steps are meticulously followed.

To address this, ECRI Institute is investigating whether regular post-reprocessing sampling and culturing of duodenoscopes is warranted and practical. A significant concern is that it can reportedly take up to 48 hours for CRE cultures to grow out, meaning that hospitals would likely have to increase their duodenoscope inventory to accommodate the time scopes are quarantined waiting for culture results. Also, hospitals will need to carefully consider how they will respond if a scope cultures positive. These considerations, and possibly alternative solutions, will be presented with additional guidance in future ECRI Institute publications.

*References:

- Food and Drug Administration. Design of endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes may impede effective cleaning: FDA safety communication [online]. 2015 Feb 19 [cited 2015 Feb 20]. Available from Internet: [Click here](#).
- Food and Drug Administration. MedWatch. Endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes: FDA safety communication—design may impede effective cleaning [online]. 2015 Feb 19 [cited 2015 Feb 20]. Available from Internet: [Click here](#).
Comments:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert.

Source(s):

- 2015 Feb 20. FDA Safety Communication Download