Endo reprocessing lapses at the VA

Follow the published manufacturer’s instructions—that message is being hammered home once again following errors in the setup and reprocessing of endoscopy equipment at 3 Veterans Affairs (VA) facilities. The errors involved use of a wrong connector and failure to follow reprocessing instructions for tubing, according to the VA.

The incidents have messages for all GI labs, says James Bagian, MD, director of the VA’s National Center for Patient Safety.

“This is not just a problem for the VA,” he told OR Manager. “Manufacturers tell us as many as 9 out of 10 facilities they see are not reprocessing this equipment correctly.”

Testing offered

The VA has notified more than 10,500 veterans who may have been exposed to cross-contamination during endoscopy at VA facilities in Murfreesboro, Tennessee; Augusta, Georgia; and Miami during periods ranging from April 2003 to March 2009.

Dr Bagian says it’s not clear when the problems first arose, but the VA took a conservative approach in offering testing.

As of April 27, 2009, 6,687 veterans had received their test results, the Department of Veterans Affairs said. In all, 8 had tested positive for hepatitis B, 25 for hepatitis C, and 5 for HIV. Results do not necessarily indicate any relationship to the endoscopy procedures, the VA said. An epidemiologic investigation is being conducted to check for any such relationship.

The risk of hepatitis transmission through endoscopy is “extremely small,” the VA notes. HIV transmission through endoscopy has never been reported.

What happened?

The first error reported was use of a wrong connector to attach the auxiliary water tube to the endoscope’s irrigation source (illustration).

“Somebody apparently disassembled one tube and put the connector on another tube,” Dr Bagian says. He said the action shows “a lack of appreciation for the fact that medical devices should not be modified by clinical personnel without consultation with the appropriate authorities.”
The wrong connector has no valve. The correct connector has a 1-way valve that prevents fluid from flowing backward and contaminating the irrigation filter and tubing. Both connectors are green, but the incorrect connector has 1 wing, and the correct one has 2 wings.

Other errors surface
As other VA facilities reviewed their practices, more lapses surfaced:
• In some facilities, the auxiliary water tube wasn’t being reprocessed between patients, as the manufacturer recommends. The auxiliary water tube must be reprocessed each time it is used, according to alerts from the VA and Olympus, the endoscope manufacturer.
• The irrigation tube and its filter weren’t always being discarded at the end of the day, as instructed by the manufacturer.
• The auxiliary water tube was not always primed and flushed as directed.

These errors are described in a VA Patient Safety Alert (www.patientsafety.gov/alerts.html). The VA stresses that the alert applies to all flexible endoscopes and accessories, regardless of the manufacturer or model.

Many facilities thought they were doing the right thing but weren’t, Dr Bagian says. He emphasized the need to follow manufacturers’ written instructions explicitly for each component in the endoscopy setup.

Relying on diligence alone “is not enough,” he says. He advocates a quality control approach similar to that aviation employs for its mechanics, including detailed standard operating procedures, frequent training, testing, and accountability.

“The airlines understand if you don’t do a process meticulously, accidents happen, and people die,” he says.

His advice for GI labs:
• Make sure all procedures are consistent with manufacturers’ instructions. Locate instructions for all components and do a side-by-side comparison with your procedures.
• Develop standard operating procedures. Make sure the procedures are posted where they can be easily seen and are followed. “No one can accurately perform 48 reprocessing steps from memory every time,” he says.
• Instruct personnel to verify any advice given by company sales representatives. If a rep says, “Sure, you can do this,” require the rep to show where that instruction is written in the manual or to provide the instruction in writing, Dr Bagian advises.
• Test personnel on standard operating procedures.
• Conduct informal observations. Walk in and watch scopes being reprocessed. If some personnel aren’t capable of following directions consistently, “they need to be in different jobs,” he says.

Physicians and nurses share in the accountability, he adds. All clinicians should know the equipment and how to use it correctly. They should hold one another accountable. For example, if one clinician observes another is not flushing the endoscope when necessary before inserting it in the patient, “the clinician is obligated to speak up,” Dr Bagian says. “It’s just like telling someone to wash their hands or change gloves.” If the person doesn’t comply, a supervisor should be notified.

Standards for endoscope reprocessing are posted on the Society of Gastroenterology Nurses and Associates website at www.sgna.org