HEALTHCARE PURCHASING NEWS

August 2012

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Learning Objectives

1. ***Describe why flexible endoscopes are difficult to reprocess.***
2. ***Explain why the manual cleaning step is prone to error during reprocessing.***
3. ***Describe the different methods used to monitor the efficacy of manual endoscope cleaning.***
4. ***Discuss how a monitoring program can positively impact patient safety.***

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A risky undertaking

Manual cleaning of flexible endoscopes

by Grace Thornhill, Ph.D

"Every patient undergoing a medical procedure has a basic expectation that the environment and instruments of care will be safe and clean."[1] Consider that in the US, for GI endoscopies alone, over 20 million procedures are performed every year. Despite the fact that there are now well publicized guidelines for reprocessing, outbreaks of infection due to improperly processed endoscopes continue to occur with regular frequency. At a summit jointly convened by AAMI/FDA the issues and challenges for reprocessing reusable medical devices were debated as part of an ongoing effort to address the concerns of disease transmission due to improper reprocessing.[1]

When those who have the responsibility of reprocessing flexible endoscopes are asked "How do you know your scopes are clean?" the response is often – "I don't know." Nancy Chobin, RN sums up the concern in a statement to Biomedical Instrumentation & Technology, "The biggest problem is that we can't see inside these scopes. To put it bluntly, we're just taking a shot in the dark with reprocessing."[6] The fact that cross-contamination from flexible endoscopes has appeared on the ECRI Institute's list of the top ten technology hazards for the past three years is further evidence that the efficacy of endoscope reprocessing is a serious concern in the healthcare community.[7]

The good news is that reprocessing works and that cross-contamination and transmission of infection is preventable. "Endoscopes reprocessed appropriately in accordance with reprocessing and infection control guidelines pose virtually no risk of transmission of patient-borne or environmental microorganisms. In the absence of defective equipment, every reported case of hospital acquired infection associated with a contaminated GI endoscope have been linked to a breech or violation of at least one of several requisite reprocessing steps."[11] In other words, we just need to follow directions to ensure patient safety! That said, endoscope reprocessing has a very narrow margin of safety. "Any slight deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection."[3]

It has been difficult to establish that inadequate reprocessing is the actual cause of patient infections because it is often not included in the investigation when an HAI (Hospital Associated Infection) is diagnosed. "Providers may not know what to report, where to report, or when to report. So how often do lapses in reprocessing result in infection? Again, this is a question that we really don't know the answer to, and it likely depends on a number of factors."[10]

Why are endoscopes difficult to reprocess?

There are many contributing factors as to why flexible endoscopes are difficult to reprocess. First there is the complex design of the medical device itself. The long, narrow lumens are difficult to clean and, if using visual inspection techniques, virtually impossible to tell if the cleaning effort was successful. Complex device design is such a significant barrier to effective reprocessing that one of the top priorities coming out of the AAMI/FDA summit was a challenge to manufacturers. "Make effective reprocessing a priority from the very beginning of device design development and when possible, minimize features such as lumens, channels, articulated surfaces, and/or finishes and materials that are difficult to clean." It was also recommended that they "Take into account the reprocessing capacity of healthcare facilities and the reprocessing staff who will conduct reprocessing."[1]

A lack of time and resources to adequately perform all recommended reprocessing steps is another factor that adds significant risk to endoscope reprocessing. In a study published by Michelle Alfa in the *American Journal of Infection Control* it was shown that 25 minutes were required to clean a side-view duodenoscope when the manufacturer's instructions for use were followed. When actual practice was observed in a clinical setting, the time spent on these same scopes was 6.5 minutes.[3] The lack of consistent and effective training has also been cited as a significant risk factor for reprocessing reusable medical devices.[1]

Where do we focus our efforts?

Given all the risks inherent in endoscope reprocessing where is it best to focus improvement efforts so that patient safety can be improved? The MultiSociety Guideline on Reprocessing Flexible Endoscopes states that "Future efforts should be aimed at improving compliance with accepted guidelines in all centers where endoscopy is performed."[8] In other words make sure everyone is following directions.

There are six basic steps involved in reprocessing flexible endoscopes. Each of these steps also consists of a number of tasks and goals resulting in a complex process involving the endoscope and all of its component parts.

1. Pre-cleaning. This step is also referred to as the bedside flush.
2. Leak testing
3. Manual cleaning/Rinsing
4. High-level disinfection or Sterilization
5. Rinsing and Drying
6. Storage

It cannot be overstated that "Failure to adhere to established reprocessing guidelines accounts for most, if not all, of the reported cases of bacterial and viral transmissions."[4] Olfstead *et al* designed an observational study that evaluated the actual practices used to reprocess endoscopes. They discovered that, in general, recommended guidelines for reprocessing endoscopes were not followed. The manual cleaning step was shown to be especially prone to error. For example, it was found that the brushing of endoscope channels and components was adequately performed only 43% of the time. Along with a failure to clean all channels it has also been found that there were failures to assess if channels were blocked or leaking as well as failures to flush adequate fluid through channels.[3,9]

Manual cleaning – Why is it so important?

SGNA states that manual cleaning is "… the first and most important step in removing the microbial bioburden from an endoscope."[11] ASGE asserts the following: "The efficacy of cleaning and disinfection is personnel dependent, hence, training and quality control are critical for reliable infection control."[5] What is involved in the manual cleaning process? The following general steps are recommended by the Multi-society Guideline on Reprocessing Flexible GI Endoscopes.[8]

- Meticulously clean the entire endoscope
- Clean all valves, channels, connectors, all detachable parts using an enzymatic detergent solution
- Flush/brush all accessible channels to remove all organic and other residues
- Clean external surfaces
- Rinse

So… where is the risk? If manual cleaning is not effective, then retained debris may inactivate or interfere with the high-level disinfection or sterilization process creating a situation where microorganisms can survive and grow thus compromising patient safety. The very fact that cleaning is performed manually means that human factors come into play thus increasing the risk for making a mistake. These human factors may include human error, performing the cleaning steps in an inconsistent manner, attitude towards the job, lack of training and performing tasks in a stressful work environment.

Monitoring the endoscope for effective manual cleaning

Currently, visual inspection is used to ensure that the manual cleaning process is performed effectively. SGNA recommends the following: "Continue brushing until there is no debris visible on the brush."[11] The problem with visual inspection is that this process cannot tell us what we need to know. We cannot see up and into the long and narrow lumens to check that all debris has been removed. In fact, those things that we are most worried about, microorganisms and biofilms, are not even visible with the naked eye.

There are several ways to monitor the efficacy of manual cleaning. All monitoring methods use markers to assess the level of cleanliness. Examples of familiar visual markers include things like the presence of dust bunnies on the floor or a shiny finish on a surgical instrument. The absence of dust or a shiny surface indicates to us that a surface is visually clean. Because visual inspection is inadequate other types of markers should be used to assess the efficacy of manual cleaning.

Since the focus is on those soils that carry pathogens, we must look for biochemical markers that are present in those soils. These soils are composed of blood, cells, tissue, bone, microorganisms, human secretions and excretions just to name a few. A good biochemical cleanliness marker will be universally present in all these soil components. To date there are two universal biochemical markers that are commonly used to assess the cleanliness of medical devices including flexible endoscopes. They are adenosine triphosphate (ATP) and protein. These two markers are "universal" markers because they are both produced by living organisms and are both present in the types of soils found in flexible endoscopes. The big advantage of universal markers is that they are present everywhere. Paradoxically, this is also a disadvantage of universal markers. Because surfaces always have a certain level of protein and ATP present it remains to be defined what levels are clinically relevant. Both protein and ATP are listed as acceptable for use in AAMI ST79 Table D.1. User Verification of the Cleaning Process.[2]

Protein as a cleanliness marker

There are several commercialized, rapid protein tests that can be used to monitor the cleanliness of surgical instruments and medical devices. These tests are generally simple to use. The site of interest is sampled using a device such as a brush or swab or the surface can be flushed with water. The sample is then measured for protein levels using a colorimetric method. Colorimetric means the test solution changes color when protein is present. A limitation of the rapid colorimetric protein tests is that they are not quantitative and therefore cannot tell you how much protein is present making it difficult to tell just how dirty or clean the surface really is. Currently, a surface that has less than 6.4µg protein/cm^2 is considered clean.[2] Another disadvantage of some rapid protein tests are that they may not measure insoluble proteins left behind by reprocessing. Depending on the chemistry involved, a protein test can take from 5 to 45 minutes to perform.

Hemoglobin (Hg) is a protein marker that is also used to measure the efficacy of cleanliness. Hg is found only in blood and is therefore categorized as a "specific" marker because it only measures one specific protein out of all the proteins typically present in soils found in flexible endoscopes. Like the general protein test, the rapid Hg tests are colorimetric generating qualitative results. The level of Hg used to define "clean" is <1.8 µg/cm^2. [2]

ATP Bioluminescence

ATP Bioluminescence assays have been used to measure the efficacy of cleanliness in the Food Safety Industry for the past 30 years and are now being introduced into the healthcare industry. There are now commercialized ATP tests that can be used to measure levels of cleanliness of environmental surfaces as well as surgical instruments and medical devices. The surface of interest is either swabbed or flushed with sterile water. Using a specialized enzyme the ATP in the sample is converted to a light signal. The light signal (in relative light units

*See **SELF-STUDY SERIES** on page 42*

Self-Study Test Answers: 1. B, 2. A, 3. B, 4. A, 5. B, 6. A, 7. A, 8. B, 9. A, 10. A

or RLU) is measured using a luminometer. A dirty surface will generate a higher number of RLU's than a clean surface. The results from ATP tests are quantitative providing a numerical assessment of efficacy of cleaning in real time (less than 30 seconds). Pass/Fail benchmarks for ATP levels are typically set through a rigorous benchmarking process.

How can a monitoring program help improve the manual cleaning process for flexible endoscopes?

Monitoring the manual cleaning process allows one to assess if the manual cleaning process has been performed properly therefore it can identify and then help correct deficiencies. A monitoring program can be integrated into a quality control program that can be used to maintain and drive process improvement as well as enhance training and competency programs.[12]

Conclusion

Despite the ready availability of guidelines reprocessing personnel are facing significant obstacles that impact their ability to comply with recommended practices for reprocessing flexible endoscopes. The manual cleaning step is particularly prone to error putting at risk patient safety. By implementing a monitoring program the sterile processing staff and infection preventionists can ensure that proper reprocessing protocols are being followed and that staff is adequately trained. HPN

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A risky undertaking: Manual cleaning of flexible endoscopes

Circle the one correct answer:

1. **Cross-contamination of endoscopes due to improper processing is not a big concern because there is no real scientific evidence to support this idea.**
   a. True b. False
2. **Every reported case of hospital acquired infection associated with a contaminated GI endoscope has been linked to a breech or violation of at least one of several requisite reprocessing steps.**
   a. True b. False
3. **The long smooth outside surface of an endoscope makes it easy to clean.**
   a. True b. False
4. **Human factors, like a stressful job environment can lead to mistakes in reprocessing.**
   a. True b. False
5. **The manual cleaning step is not prone to error.**
   a. True b. False
6. **A common mistake made during manual cleaning is a failure to flush adequate fluid through the channels.**
   a. True b. False
7. **Cleaning efficacy can be assessed by measuring the levels of ATP inside the lumen of an endoscope.**
   a. True b. False
8. **Universal markers are present in only in blood residues.**
   a. True b. False
9. **A monitoring program can help in training reprocessing staff how to adequately clean an endoscope.**
   a. True b. False
10. **Protein tests are qualitative whereas ATP tests are quantitative.**
    a. True b. False

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