

Monitoring the Cleaning Process for Flexible Endoscopes

“The device from hell,” the flexible endoscope as described by Martin Favero, PhD, Director of Scientific and Clinical Affairs for Advanced Sterilization Products when referring to cleaning and disinfecting this piece of medical equipment.¹

“A scope can be used anywhere from 300 to 1,200 times a year. The question is, can we be guaranteed that the scope has been processed appropriately each of those times?”²

“Based upon the AAMI standards that are in place today, the scale of measurement here after instruments are washed is visual inspection. I think most of us would agree that a method of visually inspecting the instruments is not a very good method.”³

Newspaper headlines echo these thoughts:

“Company blames bronchoscope infections on poor cleaning.”⁴

“Clear concerns amid murky debate--Patient documents raise questions in dispute on endoscope infection risk.”⁵

Headlines like these were the needle on the compass that guided us to write a paper on the cleaning of flexible endoscopes.

Did you realize that getting a clean, high level disinfected/sterilized flexible scope ready for patient use is like fitting puzzle pieces together? If one piece is missing, it is not complete.

Let us look at the different pieces of the puzzle that make up the process of ensuring a clean, sterilized/high-level disinfected scope ready for patient use.

Puzzle Piece # 1. Background Information

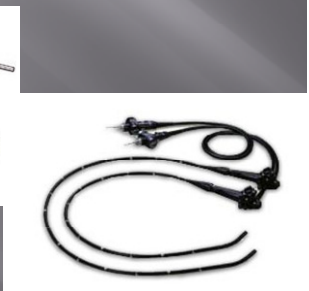
Three types of endoscopes are commonly used in hospitals: rigid, semi-rigid and flexible. This article will focus on flexible endoscopes (e.g., colonoscopes, duodenoscopes, gastroscopes, sigmoidoscopes), because concerns about cleaning these scopes appear more often in news headlines.

Flexible Endoscopes

- There are a variety of flexible endoscopes types with differing channel sizes and configurations.



Bronchoscopes



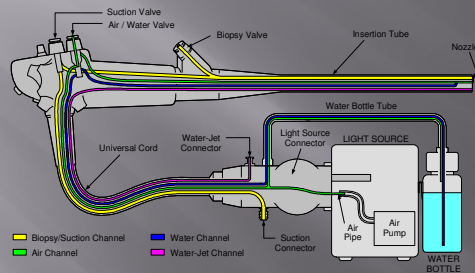
Colonoscopes



Intubation Scopes

Heightened concern about proper cleaning of flexible scopes is also reflected in the professional literature. A flexible endoscope may contain many internal channels, any of which can become contaminated.

Flexible Endoscopes



- Endoscopes are complex medical instruments having long and narrow working channels that are subjected to torque and angulation forces
- These forces require special materials and engineering
- Endoscopes have state of the art electronics, including fiber optics and imaging technology

It is estimated that in the U.S. alone 15 million flexible endoscope procedures are performed annually. Procedures are performed in a variety of settings, from a doctor's office to a hospital surgical suite. The methods employed to clean and disinfect these flexible endoscopes are also very diverse. A key concern, no matter where these procedures are done, is how clean these scopes are after reprocessing.

Puzzle Piece #2: Guidelines and Standards

Reviewing the most recent set of guidelines, literature, and products prepares an endoscopy facility to provide the best possible patient care.

Published in 2003 the Multi-Society (use the formal name) position paper states: **“Healthcare facilities should develop protocols to ensure that users can readily identify whether an endoscope is contaminated or is ready for patient use”** (*Gastrointestinal Endoscopy*, Volume 58 No.1; page 5). This document also details excellent general practices for any medical facility from start to finish of a flexible scope procedure.

AAMI ST 79 notes that the efficacy of any high-level disinfection/sterilization process, depends on a consistent system for lowering and limiting bio-burden before the high-level disinfection/sterilization stage. They also state:

- Staff qualifications, training, and continuing education are important: “.... Personnel should receive in-service training for all new instrumentation, devices, and equipment. All orientation, on-the-job, and in-service training should be documented....” (Section 4.3.1)
- Verification of the cleaning process is important: “...Sterile processing personnel are increasingly aware of the need to control and standardize the steps taken to ensure the sterility of devices for patient use. ***Because disinfection and sterilization cannot be assured unless the cleaning process is successful, professionals in the field ought to seek out whatever means are available and practical to verify this function.*** A quality system would call for monitoring and documenting decontamination processing parameters, whether the process is accomplished by hand or mechanically....” (Section 7.7.5)

Another AAMI document that calls for verification of the process is TIR 12; 2004. Some highlights of this document are:

- 4.3.5 Using scientifically valid methods, the manufacturer should show that the recommended cleaning process is effective in removing the simulated soil from all surfaces of the device that could come into contact with the patient or that are accessible to tissue, blood, body fluids, and other organic material. Testing should be adequate to ensure that the process can be successfully duplicated in the hospital environment.
- 4.3.5 If all surfaces of the device cannot be visually inspected (as in the case of some devices with lumens and some hinged instruments), manufacturers should provide users with rapid test methods that can be used as part of quality

assurance to ensure that the cleaning process has been effective. Such test methods may apply to automated cleaning equipment or to a specific medical device.

- 5.7 Efficacy of the process: Device manufacturers must show that recommended disinfection procedures ensure that all device surfaces (including internal channels) that will either come in direct contact with the patient or physician or be soiled with blood, body fluids, and other organic material will be in contact with the disinfectant solution.... Testing should be adequate to ensure that the process can be successfully duplicated in the hospital environment

Many of the products used for flexible endoscopy are regulated by the FDA. The manufacture must submit detailed information on cleaning and sterilization. Because many flexible scopes are processed by Automated Endoscope Reprocessors (AER) the manufacture must comply with strict FDA guidelines. Some of them are:

- Simulated-use testing should evaluate the performance of the medical washer-disinfector under “worst case conditions.” FDA defines “worst case conditions” as testing at the minimum parameters for the process variables in each cycle.⁶
- III.H.4. Simulated-Use and In-Use Tests: d. Simulated-use Testing 2) Incorporate other factors into the test that impede cleaning and germicide activity, e.g., a representative inorganic and organic challenge added to the inoculum. Include an organic challenge representative of the type of worst case organic load to which the device is exposed during actual use, such as serum, blood, and secretions, and may remain associated with the device following cleaning.⁷

JCAHO EC6.20 standard states that “**medical equipment is maintained, tested and inspected.**” This would apply to the AER type equipment used to process flexible scopes.

The American Society of Testing and Material (ASTM), has outlined test methods of interest for scopes⁸:

- E1837-96(2002) Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test)
- E1766-95(2002) *Standard Test Method for Determination of Effectiveness of Sterilization Processes for Reusable Medical Devices*
- E2314-03 *Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test)*
- D2775-Standard Guide for Blood Cleaning Efficiency of Detergents and Washer-Disinfectors
- F1518-00 *Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera*

Specific patent processes also apply to flexible scope some are:

- U.S. Patent 6428746 – Method for determining the efficacy of decontamination procedure⁹ was developed by Dr. Larry Muscarella is simple: raise public health standards, improve the standard of care, and reduce the risk of patient infection.
- U.S. patent 6447990 – Artificial Test Soil - This technology was developed by Dr. Michelle Alfa at the University of Manitoba involving using artificial test soil (ATS) for simulated-use testing and validation of cleaning protocols of medical devices. The soil was developed to mimic worst case conditions for simulated-use testing. (<http://www.artificialtestsoil.com>)

All of this information is used by the manufacture as they develop flexible scope products and validated methods for reprocessing to be used by a medical facility.

Puzzle Piece #3: Medical Publication

Medical publications have highlighted all kinds of issues with unclean instruments, poor training of staff and just bad practices:

- *57% of centers that process scopes were not in compliance with basic national standards.*¹⁰
- 53% of biopsy ports valves exhibited some form of debris or potential contamination after cleaning.¹¹
- *“Company blames bronchoscope infections on poor cleaning.”*¹²
- Endoscopes have been implicated in the transmission of disease (specifically nosocomial infections) when appropriate cleaning, disinfection or sterilization procedures were not employed. Of particular significance is the need to **thoroughly manually clean equipment prior to** any manual or automated disinfection or sterilization process.¹³
- “It is very clear that every documented case of patient infection linked to a contaminated scope is because of a breach of some of the reprocessing protocol. If you look back on the history, that is what it is – improper disinfection; you don’t dry the scope; inadequate cleaning; or somebody forgot to clean the biopsy channel. It has been more human error than anything else... Rules No.1, 2 and 3 are to educate the people who are cleaning the scopes -- how and what should be done. If I had it my way, I would have them take a test before letting them do the cleaning.”¹⁴
- In one case two colonoscopy patients were infected with hepatitis C (HCV) from an endoscope contaminated by an earlier patient. The investigation concluded that the biopsy channel had not been properly cleaned and the disinfection failed. Only two hours had elapsed between the first patient and the last, so even if samples had been taken immediately after the first patient, traditional

microbiology results would not have been available in time to prevent cross-infection.¹⁵

- 18% of the scope tested were still positive for blood residue after the first cleaning¹⁶
- A microbiologist at the University of Georgia; Mr. David Lewis has “calculated, just based on the amount of blood that can leak back out of the scope after it is manually cleaned, that the infection rate may be as high as several patients out of 100”.¹⁷

Puzzle Piece #4: Quality Talks

Medical facilities understand their relationship between quality and patient care. Just look at the banners on hospitals that make up the top 100. Those hospitals want everybody to know that they are “one of the best hospitals”.

Patients can now compare one hospital to another by way of a new process set up by CMS (Center for Medicare & Medicaid Services). This process is called Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS).

The objective of HCAHPS is to provide a standardized survey instrument and data collection methodology for measuring patient’s perspectives of hospital care.

The survey goals are:

- Increase the transparency of the quality of hospital care provided.
- Public reporting of the survey results is designed to create incentives for hospitals to improve quality of care.
- Produce comparable data on patients’ perspectives of care.

Today, patients can go online and compare hospital to hospital. Ask yourself this simple question: which hospital would you go to, one that scores 60% and below the national average or one that scores over 90%. For more on this unique process go to these web pages:

- http://www.cms.hhs.gov/HospitalQualityInits/30_HospitalHCAHPS.asp
- http://www.cms.hhs.gov/HospitalQualityInits/25_HospitalCompare.asp#TopOfPage

As recent as 8/27/07 the government released information that they will no longer pay for certain medial errors. “As of October 2008, Medicare will no longer reimburse hospitals for the additional cost of treatment for what it considers preventable errors. These include injuries and some infections acquired during a hospital stay, according to the [new rules](#) announced on Aug. 1. As of this writing, conditions not covered by Medicare if they are the result of a hospital visit”¹⁸ include: objects left during surgery, blood incompatibility, air embolism, falls, pressure ulcers and urinary tract infections associated with.

With scoping procedures being so numerous and in the headlines when something goes wrong you have to ask the question “***when will a scope related errors prevent a medical facility from being reimbursed for a procedure.***”

Patients are not limited to just the government information. Quality is also being pushed by groups such as RID (Reducing Hospital Deaths) whose mission is to inform the public about hospital acquired infections. Their web site is <http://www.hospitalinfection.org>

Puzzle Piece #5: Repair Information

This is a key piece in improving a medical facilities process. A repair company should be able to provide you with information and education that helps you reduce your repair costs.

For the endoscope quality process, sometimes this piece of the puzzle is the repair history. Data provides the opportunity to educate on relevant issues specific to the particular facility’s repair history. Working with a company that can provide electronic repair history reports can assist in analyzing equipment trends. For example, OnSiteSM Services of CareFusion can provide repair history on individual equipment reported down to the serial number using their online informatics tool, *Repair Manager*.). These reports can provide visibility of repairs based on a variety of factors such as manufacturer and type of scope as well as the service or department. OnSiteSM Services then utilizes this information in periodic business reviews to address specific educational needs. This can close the loop on repairs that potentially affect the repair budget, procedure efficiency, physician satisfaction and most important - patient safety.

Using the repair history is a great tool to begin education and training of staff on issues that relate to that particular facility. A repair company should begin with a thorough assessment of current hospital procedures for the handling and management of endoscopes. Assessment emphasis should include identification of process and logistic inefficiencies, regulatory or patient safety risks, and improper staff care and handling techniques.

Jon Fish, Director of Scope Operations for OnSiteSM Services, says that “Sometimes, techniques and processes are passed down from one technician to another. As processing staff move on to new positions, the training can sometimes become like a game of “Telephone.” Mary teaches Joe who teaches Sally who teaches George. The cumulative minor misinterpretations lead to inaccuracies of the processes.”

Having a trusted partner help you look at your process is very valuable. A repair company should be able to use their information to help you look at your process. During assessments it is not unusual to uncover processes that place undue risk on the medical staff or patients. According to Jon, OnSiteSM Services team has helped many customers with their process to reduce cost and improve patient and staff safety.

A good example and a problem that many facilities face is fluid invasion of the scope. While cleaning and high-level disinfection are essential to infection control, it is also the often the time when fluid invasion occurs. In fact, according to Jon, the most common source of avoidable damage is fluid invasion during reprocessing. Proper training and staff vigilance are key to preventing this expensive repair.

Flexible Endoscopes				
Reported Issue	Common Cause	Effects	Repair	Resolution
Flickering/distorted Image	Camera / CCD assembly damaged due to corrosion from fluid invasion	Delayed / cancelled procedure while alternative scope is made available Potential increase in anesthesia time for patient	Repair or replace camera	Educate staff on proper leak testing procedures and document in standard operating procedures.
Loose Controls	Stretched angulation cables/compressed insertion tube	Physician dissatisfaction, poor articulation and control response time	Adjust angulation cables/replace insertion tube and inner components	Preventative maintenance/ regular inspection cycle
Tight Controls	Previous fluid invasion/corrosion	Physician dissatisfaction and reduced articulation	Rebuild angulation system	Educate staff on proper leak testing procedures and document in standard operating procedures.
Video button not responding	Fluid invasion	Delayed / cancelled procedure while alternative scope is made available Potential increase in anesthesia time for patient	Replace video switch	Educate staff on proper leak testing procedures and document in standard operating procedures.

The benefits of implementing an endoscope management program with a trusted repair vendor are significant. But one must remember that, a repair vendor who will also provide an on-going relationship with actionable resolutions is the key difference

between education and implementation of key concepts. Knowing one's repairs and how to reduce and solve them is a key puzzle piece in improving the process.

Puzzle Piece # 6. Importance of Cleaning

"Without a doubt, flexible endoscopes are one of the most complex medical devices we process."¹⁹

Due to their complexity, flexible endoscopes generally cannot be steam sterilized. Low temperature, highly specialized devices or methods must be employed to clean, disinfect and sterilize these instruments. It is axiomatic: ***If a surgical instrument is not clean, it can't be rendered sterile.*** The cleaning process is critical to achieving disinfection and/or sterilization.

According to Lawrence Muscarella, PhD, chief of infection control for Custom Ultrasonics, Inc., the actual risk of infection is small provided scopes are adequately cleaned.

"It's just amazing how fragile these viruses are," says Muscarella. "The literature suggests that if you do cleaning properly you won't have transmission of HIV or hepatitis B or C — irrespective of any disinfection. In the cases where hepatitis has been transmitted, cleaning has been inadequate. So we have instances where cleaning is adequate, but the disinfection is either not being done, or being done inadequately, and we don't have disease transmission documented yet. That is why the risk of a bacterial infection is much higher. The risk of a viral infection remains fortunately very low, provided cleaning is done."²⁰

In January 1997 the publication *Q-Net Quiz* queried readers about the impact of cleaning on the sterilization/disinfection process. It asked, "*Which is likely to fail if cleaning is inadequate: (a) sterilization, (b) high-level disinfection (c) intermediate-level disinfection, (d) low-level disinfection, or (e) all of the above.*" The answer is (e). Sterilization and each level of disinfection are likely to fail if cleaning is inadequate.

Puzzle Piece # 7 . Understanding the Contamination of Flexible Endoscopes

General instruments used for surgical procedures are most commonly contaminated with blood. Likewise, flexible endoscopes are frequently contaminated with blood, particularly when a biopsy is taken. Flexible endoscopes are also exposed to other soils, which vary based upon the part of the body where the scope is use (i.e., fecal, protein, carbohydrates, matter in a colonoscope).

Research has shown that bioburden left on instruments interferes with the sterilization process and can render it ineffective. Making sure a scope is as clean as possible is thus paramount to preventing cross contamination of any patient undergoing a procedure. Ensuring cleanliness of scopes should be part of any hospital's infection control program. Cleaning should be monitored because it is directly correlated to

reducing hospital-acquired infections. A dirty scope, as the headlines point out, does not look good in the public eye.

The “sterile dirt” concept just doesn’t cut it; an instrument is either clean or not clean. Several publications cite examples of patient infections that resulted from failure to properly clean an endoscope.²¹

Endoscopes have been implicated in the transmission of disease (specifically nosocomial infections) **when appropriate cleaning, disinfection or sterilization procedures were not employed.** Of particular significance is the need to **thoroughly manually clean equipment prior to** any manual or automated disinfection or sterilization process.²²

With increasing frequency, studies are published focusing on the cleanliness of surgical instruments prior to sterilization or high-level disinfection. A recent study of instrument cleaning reported, *“In these studies, the lab has determined that if the instruments are not thoroughly cleaned of proteins and salts prior to sterilization, no method can be truly effective. In many instances, such as the narrow lumens employed in endoscopic surgery, it is extremely difficult to determine if the instrument is clean.”*²³

A 2003 position paper, *“Multi-society Guidelines for Reprocessing Flexible Gastrointestinal Endoscopes,”*²⁴ stressed the importance of staff training--not just initial training but an ongoing training process. Personnel assigned to clean scopes need to have competencies established for all steps of the process and all equipment. The paper states, *“Healthcare facilities should develop protocols to ensure that users can readily identify whether an endoscope is contaminated or is ready for patient use.”*²⁵

We know today that healthcare facilities rely on sterilizer manufacturers and makers of high-level disinfectants to design and validate products that deliver an “overkill” method for disinfection/sterilization. Such methods provide an additional safety factor for the process. Could this be a reason why people believe in “sterile dirt” and are not concerned with monitoring the cleaning process? We also know from monitoring our sterilization process that the biological indicator only informs us that the sterilizer has the ability to kill a live organism. If these organisms are killed we assume that the load is sterile. Similarly, we have methods for monitoring the solutions used for high-level disinfection. Should we not also monitor the cleaning process?

All healthcare facilities need a quality improvement program to reduce the number of flexible scopes that are “presumed clean” before sterilization. Such a program can play a key role in reducing hospital-acquired infections, which impacts public perception of the hospital within the community. *“Hospitals that eventually demonstrate a sustainable link between quality investments and better clinical outcomes will likely gain competitive advantage, thereby improving financial performance and possibly their bond ratings.”*²⁶

The quality improvement process should be multi-part. It must make sure that training is rigidly followed and documented.

A good example is that each scope must be leaked tested after every use. This has to be part of any quality process. Monitoring the cleaning of a scope is just as important.



An example of a scope that had a leak.

Because the healthcare field is a dynamic environment in which new products are constantly being introduced, hospitals must be willing to adapt to these new technologies and employ them when they can improve various processes within their facility. *".... Disinfection and sterilization cannot be ensured unless the cleaning process is successful... it is incumbent upon professionals in the field to seek out whatever means are available and practical to verify this function."*²⁷

We have heard all sorts of comments as to why hospitals do not monitor the cleaning process for flexible scopes, including *"It's not mandated," "We do not have to do it," "I know it is clean already, I don't need a test to tell me,"* or *"I do not have a simple, reliable product to test with."* These comments remind us of the ostrich with its head in the sand. *Are we putting our head in the sand when it comes to Quality Improvement for checking if our scope is clean? I hope not. Monitoring the cleaning process for flexible scopes should not have to be mandated; it should be part of our daily routine.*

Regarding performance measurement, The Joint Commission states, *"Performance measurement in healthcare represents what is done and how well it is done. The goal is to accurately understand the basis for current performance so that better results can be achieved through focused improvement actions."*²⁸

Puzzle Piece # 8. The Tools for Cleaning Flexible Scopes

" A problem analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The problem analysis should define and resolve the problem and the system should be monitored to ensure that the problem has been corrected..²⁹"

There has been a growing concern about the effectiveness of decontamination technique for reusable medical instrumentation in healthcare facilities. Studies have shown the ability of sterilization technologies, which under normal conditions achieve acceptable sterility assurance levels, to be greatly impaired by the presence of residual soil containing serum and salt³⁰. Residual organic debris on processed surgical instruments is a concern and visual inspection is not a 100% accurate.^{31,32} Items with lumens or channels pose one of the most difficult challenges in cleaning and inspecting.

Testing any channel / lumen item (instrument) especially flexible endoscopes is important. One cannot see down the channel / lumen. One issue of critical importance in the reprocessing of any reusable medical device is to ensure it is adequately cleaned such that it can be reliably disinfected / sterilized³³.

Compliance with accepted cleaning practices for flexible endoscopes has been shown to be less than optimal in many centers.³⁴

Healthcare professionals who process scopes need simple tools and quality improvement programs to help them ensure that the channels within the flexible scope are as free as possible from any residual, whether it be blood, other bodily soils, or chemicals found in the cleaning/disinfection/sterilization products used. Currently the standard for releasing surgical instruments after cleaning is based on visual inspection. But looking inside the channels of a flexible endoscope is an impossible task. Fortunately, simple tools for detecting residuals left in the channels of a flexible scope are now available.

One such product that is commercially available is the ChannelCheck.

The ChannelCheck™ is designed to allow in-house testing of any cleaned channel / lumen item (instrument) and allows you to verify that adequate cleaning has been achieved when looking at carbohydrates, protein, and blood as markers for cleaning.

Again as talked about earlier AAMI TIR 12 recommends that users be able to test and validate their cleaning process³⁵. The method is simple and fast.

ChannelCheck™ is the first product capable of testing for residual organic soils inside the various channels / lumens (such as a flexible endoscopes, suction tube,...) no matter the channel / lumen size.

ChannelCheck™ tests for three common organic soils at once: blood, protein and carbohydrates.

The ChannelCheck™ product was designed and based on research "...current data (Alfa, et al., 2002) indicate that for flexible endoscopes that have been cleaned after use on patients, the average levels of soil markers are as follows: protein, < 6.4 µg/cm²; carbohydrate, < 1.8 µg/cm²; hemoglobin, < 2.2 µg/cm²; ... in the biopsy/suction channel. "36

As noted channels / lumen items (instruments) provide a difficult challenge regardless if it is a suction tube or a flexible scope. A quality improvement system that allows you to monitor the inside of any channel / lumen is an important function of any Infection Control program. Testing channels / lumen instruments with the ChannelCheck™ and recording results in a log is one such system.³⁷

The ChannelCheck™ specifically reveals the presence of residues found within patient-used endoscopes, with low detection levels. Thus, the test can be used in-house for cleaning procedure verification. Carbohydrate, protein, and blood are the three soils that you monitor using the ChannelCheck™. No one tool will provide all the information but using the ChannelCheck™ is a step in the right direction.

The use of the ChannelCheck™ is an excellent tool to use for training of new employees as well as establishing a Quality Improvement Program for checking whether manual or automatic cleaning of these items is done properly. The frequency of testing of the various channel / lumen instruments (including flexible scopes) should be done at least weekly (preferable daily for flexible scopes).

Puzzle Piece #7: Testing & Training

This piece is vital to making sure quality is achieved and maintained. This comes from fitting the puzzle pieces together to complete the puzzle by each medical facility forming their own policy and procedures. This should include the following:

- Testing of the equipment (i.e., AER) that is used to process the scopes by independent methods;
- Following the manufacturer's preventative maintenance program;
- Testing the scope itself to determine its cleanliness (using the ChannelCheck™)
- Establishing a product review committee that meets on a regular basis as a means of staying current with changes in this always evolving technology;
- Competency of the staff
 - Ongoing training on equipment and practices;
- Certification of all staff
- Some type of review process to keep up with the latest articles and policy and procedures that deal with flexible endoscopy.

Remember, a well trained staff that understands why they are doing something is vital to the success of the procedure. The physician might have the skill but if the tool he uses is flawed, problems will occur over time.

Closing Comments

All of the puzzle pieces play a role in having the best practices. The information (puzzle pieces) is there for hospitals to improve and have better outcomes; because standards, guidelines, products all support better processes with better outcomes.

Ensuring that a medical facility is doing the best they can is important. JCAHO in their 2008 Patient Safety Goals make this bold statement “**Reduce the risk of healthcare-associated infections**”³⁸. This is what every medical facility should be doing. The question is what is your medical facility doing when it comes to best practices for flexible scope procedures? Everything they can? Or are they waiting to be part of the headlines reporting they had to recall patients because of poor quality. The following quote sums up the premise of this activity on monitoring the cleaning of flexible scopes; namely, that training and testing can only help in making sure a hospital reduces the number of patient infections that result from improperly cleaned scopes.

“...It is very clear that every documented case of patient infection linked to a contaminated scope is because of a breach of some of the reprocessing protocol. If you look back on the history, that is what it is – improper disinfection, you don’t dry the scope, inadequate cleaning, or somebody forgot to clean the biopsy channel. It has been more human error than anything else...rules No.1, 2 and 3 are to educate the people who are cleaning the scopes--how and what should be done. If I had it my way, I would have them take a test before letting them do the cleaning.”³⁹

Remember, it is in the patient’s best interest for a hospital to do the best it can each and every time. Testing scopes for cleanliness as part of a quality improvement program is part of that commitment to quality and to the patient.

Remember this “**Quality doesn’t cost. It pays. It pays in the long run**”⁴⁰

Questions

True or False

1. Carbohydrate, protein, and blood are the three soils that you monitor using the ChannelCheck™.
2. AAMI TIR 12 recommends that users be able to test and validate their cleaning process
3. Endoscopes have been implicated in the transmission of disease (specifically nosocomial infections) when appropriate cleaning, disinfection or sterilization procedures were not employed
4. The Joint Commission along with other organizations supports hospitals having quality improvement programs.
5. Three types of endoscopes are commonly used in hospitals: rigid, semi-rigid and flexible
6. Due to their complexity, flexible endoscopes generally cannot be steam sterilized.
7. The ChannelCheck™ can be used to test not only flexible scopes but any lumen / cannulated item.
8. After every use a flexible endoscopes must be leak tested.
9. Compliance with accepted cleaning practices for flexible endoscopes has been shown to be less than optimal in many centers
10. Research shows that if specific amounts of bioburden like blood, protein and carbohydrates are not cleaned from a scope it could hamper the high level / sterilization process.

¹ Pyrek K.M. .Nooks and crannies: The Breeding Grounds for bacteria. Infection control Today. June 2002,page 32

² <http://www.hpnonline.com/inside/june03/wr.html>; Michelle Alfa, Ph.D., assistant director for St. Boniface General Hospital, Winnipeg, Canada, on the difficulties inherent in properly cleaning endoscopes

³ page 35,Healthcare Purchasing News;1/2006;Sterile processing migrates towards electronic record-keeping

⁴ 3/7/02; http://www.hpnonline.com/dailyupdates/march_02.html

⁵ <http://www.myendosite.com/articles/bostonglobe.pdf>

⁶ <http://www.artificialtestsoil.com/FDAreferencePage.htm>

⁷ <http://www.artificialtestsoil.com/FDAreferencePage.htm>

⁸ <http://www.astm.org/cgi-bin/SoftCart.exe/index.shtml?E+mystore>

⁹ <http://www.customltrasonics.com/two.htm>

¹⁰ Infection Control and Hospital Epidemiology ; Volume 23 ; 2002

¹¹ Endonurse 12/6

¹² 3/7/02; http://www.hpnonline.com/dailyupdates/march_02.html

¹³ <http://www.gov.mb.ca/health/publichealth/cdc/fs/endoscopy.pdf>, page 1

¹⁴ page 16; New Technologies Require thorough reprocessing; EndoNurse; August/September 2005

¹⁵ *The New England Journal of Medicine* **337**, 237-240 (1997).

¹⁶ Humphries & Kovach; Infection Control Today ;Improving your Flexible Scope Cleaning Process;12/06

¹⁷ <http://www.infectioncontrolday.com/articles/412/77h1614361052726.html?cntwelcome=1>

¹⁸ Outpatient Eweekly update;8/27/7

¹⁹ Sue Klacik, Communique ,IAHCSMM January/February,2006;page 12

²⁰ <http://www.endonurse.com/articles/481feat4.html>

²¹ <http://www.hpnonline.com/inside/November%2005/0511Cover.html>

²² <http://www.gov.mb.ca/health/publichealth/cdc/fs/endoscopy.pdf>, page 1.

²³ <http://www.sbrc.ca/index.php?pid=12740>

²⁴ Volume 58,NO.1, 2003;pages 1-5; Gastrointestinal Endoscopy

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- ²⁵ Volume 58, NO.1; page 5;Gastrointestinal Endoscopy
- ²⁶<http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/Literature/ImprovingClinicalQualitySafetyImportanceofNotforProfitHospitals.htm>
- ²⁷ AAMI ST 35 – 2003; 7.4.4 Verification of the cleaning process
- ²⁸ <http://www.jcaho.org/pms/index.htm>
- ²⁹ ibid
- ³⁰ Alfa,M.,et al, Comparison of Ion Plasma, Vaporized Hydrogen Peroxide, and 100% Ethylene oxide Sterilization to the 12/88 Ethylene oxide gas Sterilizer, Infection Control and Hospital epidemiology, 1996; 17:92-100
- ³¹ AORR Journal; July 1995,Vol62, NO1;DesCoteaux, Poulin, Julien, Guidoin
- ³² AORN Journal; March 2007,Volume 85,#3;page 566
- ³³ Alfa MJ, Degagne P, Olsen N. Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning AJIC 1999
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