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Special Report

Scope Cleaning Verification

By Kelly M. Pyrek

Current techniques used to clean endoscopes for reuse are still not consistently effective, according to a recent study published in the *American Journal of Infection Control* whose findings support the need for careful visual inspection and cleaning verification tests to ensure that all endoscopes are free of damage and debris before they are high-level disinfected or sterilized and used on another patient. This report summarizes some of the more significant issues relating to endoscope cleaning and disinfection and how studies indicate that not all steps in the decontamination process are being followed. Insufficient reprocessing leaves bioburden that can pose serious threats to patient safety by transmitting infectious pathogens.

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Scope Cleaning Verification

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Reprocessing endoscopes, particularly flexible endoscopes, requires numerous steps for proper cleaning and high-level disinfection. Studies have demonstrated that not all of these steps are followed by sterile processing personnel, leading to potential transmission of infectious organisms to patients during invasive procedures using contaminated scopes.

In a groundbreaking study, Alfa, et al. (1999) conducted a study to determine the type and amount of soil found in various types of flexible endoscopes before and after cleaning, in order to establish parameters for worst-case soil cleaning efficacy benchmarks. Suction channels from 10 each of bronchoscopes, duodenoscopes used for endoscopic retrograde cholangiopancreatography, and colonoscopes were assessed immediately after patient use for the levels of bilirubin, hemoglobin, protein, sodium ion, carbohydrate, endotoxin and viable bacteria. Another 10 suction channels of each type of endoscope were evaluated for the same components after routine cleaning but before processing by high-level disinfection or sterilization for subsequent clinical use. As the authors explain, "Recognizing that only soluble components could be quantified, the worst-case soil levels in the suction channels (the average surface area of these channels was 45.6 cm2, 149.8 cm,2 and 192.0 cm2 for bronchoscopes, duodenoscopes, and colonoscopes, respectively) were protein 115 µg/cm2, sodium ion 7.4 µmol/cm2, hemoglobin 85 µg/cm2, bilirubin 299 nmol/cm2, carbohydrate 29.1 µg/cm2, endotoxin 9852 endotoxin units/cm2, and bacteria 7.1 (log10) colony-forming units (CFU)/cm2. Colonoscopes had four to five times greater soiling on average compared with the other endoscope types. Routine cleaning reduced the levels of bilirubin to below the limits of detection for all endoscopes evaluated (limits of detection were

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<1 nmol/mL). After cleaning, residual hemoglobin was detectable in bronchoscopes only. After cleaning, the levels of protein, endotoxin, and sodium ion all were reduced fivefold to tenfold for all types of endoscopes. Carbohydrate was reduced to lower than the limit of detection for all endoscopes after cleaning, except the duodenoscopes. The average load of viable bacteria was reduced from 3 log10 to 5 log10 CFU/cm2 (which represents 5.9-9.5 log10 CFU/endoscope channel) after patient use to approximately 2 log10 CFU/cm2 (which represents 3.2-5.3 log10 CFU/endoscope channel) after cleaning."

The researchers concluded that, "These data demonstrated that cleaning effectively reduced or eliminated many components of soil, but a substantial amount of viable bacteria and protein remained. Hemoglobin levels in before samples indicated that blood was not present in high concentrations in the suction channels of the majority of flexible endoscope samples. Soil that mimics the worst-case composition from patient-used endoscopes would be ideal for simulated-use studies for such medical devices."

Fast-forward more than a decade, and current techniques used to clean endoscopes for reuse are still not consistently effective, according to a recent study published in the *American Journal of Infection Control* whose findings support the need for careful visual inspection and cleaning verification tests to ensure that all endoscopes are free of damage and debris before they are high-level disinfected or sterilized and used on another patient.

The Scope of the Problem

Currently, flexible endoscopes, including gastrointestinal, urological and respiratory endoscopes, are reused following cleaning and high-level disinfection. However, results from the new study conducted by Ofstead & Associates, Inc., suggest that even more rigorous reprocessing techniques of endoscopes are not consistently effective, and organic residues often remain.

"Understanding issues with the effectiveness of reprocessing techniques is critically important as institutions seek to improve the quality of endoscope cleaning and disinfection," says lead study author Cori L. Ofstead, MSPH, of Ofstead & Associates, Inc. "Even though top-notch methods were used, the endoscopes in this study had visible signs of damage and debris, and tests showed a high proportion were still contaminated."

Using a longitudinal study design, Ofstead, et al. performed three assessments of 20 endoscopes over a seven-month period. The assessments involved visual inspections with a tiny camera, microbial cultures, and biochemical tests to detect protein and adenosine triphosphate (ATP) – a marker that identifies organic matter. These assessments were used to identify endoscopes that required further cleaning and maintenance. During the final assessment, the researchers found that all 20 endoscopes examined had visual irregularities, such

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as fluid, discoloration and debris in channels. Furthermore, samples from 12 of 20 reprocessed endoscopes (60 percent) had microbial growth, indicating a failure of the disinfection process. Of note, endoscopes reprocessed using current recommended guidelines and those that were cleaned at least twice before high-level disinfection exhibited similar culture results.

Further results indicated that about 20 percent of endoscopes in each group exceeded post-cleaning benchmarks for ATP and protein residue. Moreover, ATP levels were higher for gastroscopes, which are used for upper GI procedures, than the endoscopes used for colonoscopy. "Since the same technicians used the same techniques to clean and disinfect these scopes, the findings and our visual observations suggest that something is happening to gastroscopes during procedures that changes the surfaces and causes reprocessing failures," says Ofstead.

This study comes on the heels of a 2015 report of Carbapenem-resistant Enterobacteriaceae (CRE) infections related to Endoscopic Retrograde Cholangio-Pancreatography (ERCP) duodenoscopes — devices that are threaded through the mouth, throat, and stomach into the top of the small intestine (duodenum) for examinations and treatment. No breaches in reprocessing were identified and yet infections related to the duodenoscopes were uncovered, raising concerns that current reprocessing techniques were ineffective, and illuminating the challenges in reprocessing of such intricate medical devices.

"The finding of residual fluid in 95 percent of endoscopes tested was significant because moisture fosters microbial growth and the development of biofilm—which can be difficult or impossible to remove," says Ofstead. "This confirms the importance of cleaning, disinfecting and drying to ensure patient safety."

One critical step in reprocessing is scope cleaning verification. The Centers for Disease Control and Prevention (CDC) advises "After manual cleaning, visually inspect the endoscope and its accessories. Visual inspection provides additional assurance that the endoscope and its accessories are clean and free of defects. Complex devices such as flexible endoscopes may require the use of lighted magnification or additional methods to assist with the inspection process."

On Sept. 11, 2015, the CDC issued an alert, "Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices," which addressed, in part, the need for a proper audit and feedback process. As the alert indicated, "Healthcare facilities should regularly audit (monitor and document) adherence to cleaning, disinfection, sterilization and device storage procedures. Audits should assess all reprocessing steps, including: Performing prompt cleaning after use, prior to disinfection or sterilization procedures; using disinfectants in accordance with manufacturers' instructions (e.g., dilution, contact time, storage, shelf-life); monitoring sterilizer performance (e.g., use of chemical and

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biological indicators, read-outs of sterilizer cycle parameters, appropriate record keeping); monitoring automated endoscope reprocessor performance (e.g., print-out of flow rate, time and temperature, use of chemical indicators for monitoring high-level disinfectant concentration). Audits should be conducted in all areas of the facility where reprocessing occurs. Healthcare facilities should provide feedback from audits to personnel regarding their adherence to cleaning, disinfection, and sterilization procedures."

Guidelines and Recommendations

While not foolproof, visual inspection can be supplemented with other methods developed by manufacturers of systems, including adenosime phosphate (ATP), designed to indicate residual bioburden not removed by manual cleaning or automated endoscope reprocessors (AERs). This kind of quality assurance (QA) was addressed in detail in a new standard issued in mid-2015 by the Association for the Advancement of Medical Instrumentation (AAMI). The standard, ANSI/AAMI ST91:2015, Comprehensive guide to flexible and semi-rigid endoscope processing in healthcare facilities," provides definitive guidance on precleaning, leak-testing, cleaning, packaging, storage, high-level disinfecting and sterilizing of flexible endoscopes used in a range of procedures.

ST91 recommends that hospitals develop and implement a QA program to ensure that sterile processing departments (SPDs) are adequately reprocessing endoscopes according to evidence-based best practices as part of an overall culture of safety and quality improvement. This QA program encompasses some documentable method of cleaning verification testing; in other words, SPDs must verify that the equipment used of mechanical cleaning if functioning properly and that manual cleaning efficacy is tested regularly — daily is preferable, but weekly is the minimum. Similar to the verification of other processes such as steam sterilization, cleaning verification is conducted following the manual cleaning of scopes to verify the effectiveness of the cleaning process. This is also when a visual inspection should be made.

As we have seen, visual inspection can be supplemented by the use of cleaning verification technologies which are designed to measure the levels of organic soil and other markers after cleaning. These technologies include flushing methods which test for residual protein, carbohydrate and hemoglobin, as well as swab testing for protein, hemoglobin and ATP. ST91 recommends the consideration of methods that detect organic residue.

Specifically, ST91 states, "Testing cleaning efficacy: The facility's onsite quality assurance program should include ways to verify that the cleaning equipment used for processing of medical devices is working. Testing the equipment upon installation, during routine use

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(daily) and on all cycles used, after repairs, and when changing to a new type of cleaning solution allows the user to verify its continued effectiveness... Manufacturers' written IFU should be consulted for recommendations of types and frequency of cleaning efficacy testing. The frequency of testing the efficacy of the manual cleaning step should occur on a regular basis, weekly or preferably daily (Drosnock 2014, Alfa 2014)."

ST91 explains that, "Meticulous manual cleaning is essential for the removal of organic contamination that can interfere with high-level disinfection. The manual cleaning step is prone to error… and therefore should be monitored on a basis at least as frequently as is recommended for the cleaning equipment (see ANSI/AAMI ST79). This testing should include at a minimum monitoring of the suction/biopsy channel (ANSI/AAMI ST58). While currently there is no universal consensus of the value of performing testing on endoscopes that have been through a high-level disinfection process, numerous studies have identified the nature of microbial contamination likely to be found in improperly reprocessed endoscopes and have demonstrated the value of surveillance testing." The standard continues, "AERs are designed to provide flow of solutions to internal channels. Quality testing devices are available for many of the AERs to ensure that the solutions are flowing. To help ensure function of this equipment, testing should be performed at least weekly, after major repairs, or whenever there is a concern about equipment function."

The Association of periOperative Registered Nurses (AORN) Guideline for Reprocessing Flexible Endoscopes (2017) notes that, "Efficacy of cleaning has traditionally been evaluated visually; however, visual inspection alone, even with magnification, is not sufficient to determine cleanliness of complex devices such as flexible endoscopes."

AAMI's ST91 is not the only guidance that addresses cleaning verification. The Association of periOperative Registered Nurses (AORN) Guideline for Reprocessing Flexible Endoscopes (2017) notes that, "Efficacy of cleaning has traditionally been evaluated visually; however, visual inspection alone, even with magnification, is not sufficient to determine cleanliness of complex devices such as flexible endoscopes. Visual inspection is subjective. Infectious microorganisms are not visible to the naked eye. It is also not possible to visually inspect the lumens of flexible endoscopes. Residual soil may remain and prevent effective subsequent high-level disinfection (HLD) or sterilization."

AORN's flexible endoscope guideline continues, "There is a need for rapid testing methods to detect residual soil and verify the adequacy of manual cleaning. Although no studies have been conducted linking clinical outcomes with using monitors for cleaning verification, auditing the manual cleaning of flexible endoscopes provides an objective method for verifying cleanliness and helps ensure that insufficiently cleaned flexible endoscopes are recleaned before HLD or sterilization."

The Society of Gastroenterology Nurses and Associates (SGNA), in its Standard of Infection Prevention in the Gastroenterology Setting, addresses what is considered to be "visibly clean," defined by Alfa, et al. (2012) and Rutala, et al. (2008) as a method routinely used to assess the adequacy of manual cleaning, by use of a magnifying glass to inspect for gross soil. As the AORN guideline alluded to, Alfa (2014) stated that

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visual inspection is insufficient to determine cleaning adequacy in narrow and internal channels of a scope and cannot detect microorganisms or bioburden. As the SGNA notes, "Rapid cleaning monitors are available. These monitors can provide documentation on cleaning efficacy but do not reflect microbial activity. Real-time testing of endoscope lumens/elevator channel should be done immediately after manual cleaning so that any improperly cleaned devices are re-cleaned prior to HLD. Facilities should consider the use of monitors to verify ongoing cleaning adequacy (Alfa, 2013)." Additionally, SGNA's Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes confirms that it is impossible to visualize internal channels.

Culturing endoscopes has also been proposed as a QA method. The CDC's Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes After Reprocessing, 2015, acknowledges that, "Although routine culturing of endoscopes is not part of current U.S. guidelines, recent outbreaks associated with duodenoscopes have led some facilities to consider regular monitoring to assess the adequacy of duodenoscope reprocessing." The CDC continues, "The optimal frequency of surveillance cultures has not been established. International guidelines have recommended intervals ranging from every four weeks to annually. facility choosing to perform surveillance cultures can consider performing post-reprocessing cultures periodically, e.g., monthly or after every 60 procedures for each duodenoscope. Some facilities could choose to perform duodenoscope cultures weekly (e.g., after procedures on Friday to allow cultures to incubate over the weekend). Alternatively, facilities can choose to perform cultures, after reprocessing, following each use. Cultures should be obtained after the duodenoscope has been reprocessed (after drying) and should include at least the instrument channel and the distal end of the duodenoscope (i.e., elevator mechanism and elevator recess for duodenoscopes with sealed elevator wire channel; and elevator mechanism, elevator recess, and elevator channel for duodenoscopes with unsealed elevator wire channels). (An interim sampling protocol developed by CDC that represents one approach to culturing of duodenoscopes is available by accessing the document, Interim Duodenoscope Sampling Method and Interim Duodenoscope Culture Method on the CDC's website.) Facilities may choose other sampling methods (e.g., flush-brush-flush method), or choose to sample additional channels beyond those specified in this approach. The sensitivity of the interim protocol has not been determined. A negative culture does not completely exclude the possibility of a contaminated duodenoscope. However, positive culture results should lead to some action…"

If successfully disinfected, culturing should not detect any high-concern organisms (i.e., organisms more often associated with disease), such as Gram-negative bacteria (e.g., Escherichia coli, Klebsiella pneumoniae or other Enterobacteriaceae, as well as Pseudomonas aeruginosa), Staphylococcus aureus, and Enterococcus.

According to the CDC, post-reprocessing cultures of duodenoscopes should be assessed for two types of microbial growth — high- and low-concern organisms: "If successfully disinfected, culturing should not detect any high-concern organisms (i.e., organisms more often associated with disease), such as Gram-negative bacteria (e.g., Escherichia coli, Klebsiella pneumoniae or other Enterobacteriaceae, as well as Pseudomonas aeruginosa), Staphylococcus aureus, and Enterococcus. Small numbers of low-concern organisms (i.e., organism less often associated with disease and potentially a result of contamination of cultures during collection) might occasionally be detected (e.g., coagulase-negative staphylococci excluding Staphylococcus lugdunensis, Bacillus species, diphtheroids). The levels of these low-concern contaminants on a duodenoscope can vary depending on the reprocessing, handling, and culturing practices in a facility; levels of such organisms detectable after reprocessing will therefore vary. Facilities can monitor the levels of these bacteria within the first month of surveillance testing to develop an expected baseline for those organisms. Typically, fewer than 10 colony forming units (CFUs) of low-concern microbes does not require intervention; interpretation of culture results with ≥10 CFUs of low-concern microbes should be considered in the context of typical culture results at the facility. Any quantity of high-concern organism (i.e., one colony or greater) warrants further remedial actions…"

Those remedial actions include holding duodenoscopes out of use while surveillance culture results are pending could be considered, especially if performing surveillance cultures after each use. As the CDC notes, any duodenoscope found to be contaminated should not be returned to use until remedial steps are taken: "Facilities should ensure that each endoscopic procedure is appropriately documented with regard to the specific endoscope used in order to allow identification of exposed patients should microbial growth be detected. Furthermore, results of postreprocessing duodenoscope cultures should be logged and tracked for each duodenoscope. Non-culture methods (e.g., adenosine triphosphate (ATP) bioluminescence assays) have been used to assess duodenoscope reprocessing by detecting residual organic material after cleaning. While individual facilities might choose to use such non-culture assays, more work is needed to interpret their results since non-culture methods lack consistent correlation to bacterial concentrations. They might, however, provide insight regarding the quality of duodenoscope reprocessing if systematically validated."

Studies from the Medical Literature

Let's examine a few studies from the literature related to cleaning verification:

Visrodia, et al. (2014) sought to evaluate contamination of clinically used endoscopes, using visual inspection and rapid indicator tests before and after manual cleaning, as well as determine which rapid indicator instruments and methods could be used for quality improvement initiatives in endoscope reprocessing. Researchers sampled endoscopes used for gastrointestinal procedures before and after manual cleaning. The external surfaces and one channel of each endoscope were visually inspected and tested with rapid indicators to measure protein, blood, and adenosine triphosphate (ATP) contamination levels. Multiple components were sampled during 37 encounters with 12 unique endoscopes. All bedside-cleaned endoscopes had high levels of ATP and detectable blood or protein, whether or not any residue was visible. Although there was no visible residue on any endoscopes after manual cleaning, 82 percent had at least one positive rapid indicator test. As the researchers concluded, "Relying solely on visual inspection of endoscopes prior to HLD is insufficient to ensure reprocessing effectiveness. For quality assurance initiatives, tests of different endoscope components using more than one indicator may be necessary. Additional research is needed to validate specific monitoring protocols."

Ofstead, et al. (2016) evaluated flexible endoscope damage and contamination levels at baseline and two months later. They found that post-cleaning test results exceeded benchmarks for all gastroscopes and no colonoscopes. Microbial growth was found in samples from 47 percent of fully reprocessed endoscopes at baseline and 60 percent at follow-up. Borescope examinations identified scratches, discoloration, debris, and fluid inside endoscopes. Importantly, internal damage and residual fluid may foster contamination and biofilm formation. Study evaluations allowed damaged and contaminated endoscopes to be identified and re-reprocessed or sent for repairs.

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Alfa, et al. (2014) sought to recommend sample collection method(s) based on relative soiling in patient-used gastrointestinal (GI) endoscopes and determine whether the published benchmarks for protein, bioburden and ATP remain relevant for pump-assisted manual cleaning. Patient-used gastroscopes, duodenoscopes, and colonoscopes were sampled before and after manual cleaning and assessed for protein, bioburden and ATP levels. The biopsy port (BP) to distal end (D) sample was collected using 20 mL of sterile reverse-osmosis water. After a 200-mL flush, the umbilical (UM) to BP portion was sampled by flushing 40 mL from the UM to the D. The BP to D portion of the suction biopsy channel contained 83 percent of ATP residuals. Despite cleaning with brushing and a flushing pump, 25 percent of gastroscopes exceeded the ATP benchmark of 200 relative light units (RLU), whereas all duodenoscopes and colonoscopes had <200 RLU after cleaning. The protein and bioburden residuals after pump-assisted cleaning were consistently lower than existing benchmarks.

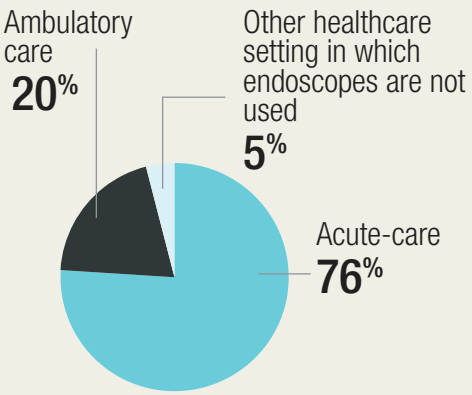
Alfa, et al. (2012) sought to validate the sample collection protocol and the Rapid Use Scope Test (RUST) and then assess its usefulness in clinical use. The benchmarks for adequate cleaning were protein <6.4 µg/cm(2), hemoglobin <2.2 µg/cm(2), and carbohydrate <1.2 µg/cm(2). Sample collection consisted of flushing 10 mL of sterile reverse osmosis water through the suction-biopsy port to the distal end. Validation of the RUST audit tool included simulated-use and in-use testing in 43 endoscopy clinics across Canada. The researchers found that simulated-use testing validated that improperly cleaned endoscopes that exceeded the cleaning benchmarks would be flagged by the RUST test. The clinical-use study indicated that 96.6 percent of 1,489 scope channels tested were RUST negative; however, 19 percent and 12 percent of elevator guide-wire channels and endoscopic retrograde colangiopancreatography channels, respectively, exceeded the benchmarks. The survey indicated that reprocessing personnel valued a rapid audit tool for assessing compliance with manual cleaning.

IPs Weigh in on Scope Cleaning Verification

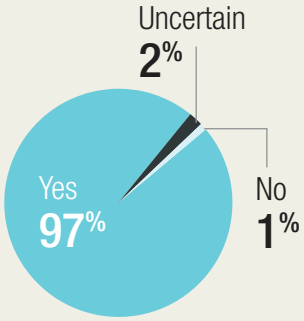
In late March, ICT conducted an online survey of infection preventionists to capture their perspectives on scope cleaning verification. Here's a look at the results of the survey:

Scope Cleaning Verification Survey

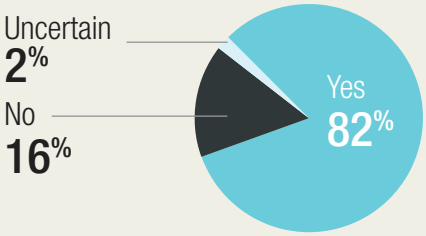
Do you work in:



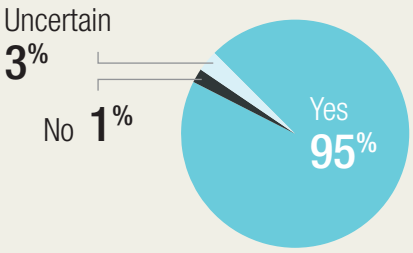
Are you aware of the outbreaks associated with improperly reprocessed endoscopes reported nationally?



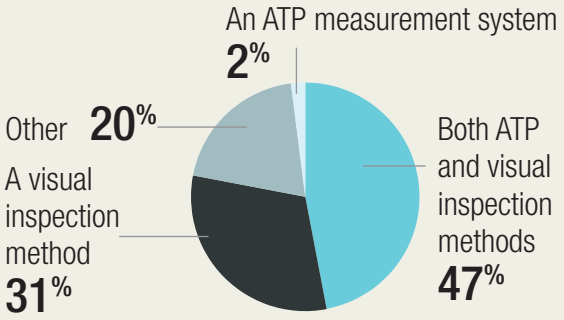
Does your healthcare institution perform scope cleaning verification as part of reprocessing?



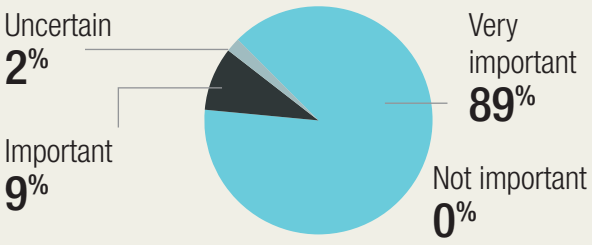
Do you work closely with your healthcare institution's sterile processing department personnel to ensure compliance with guidelines and evidence-based recommendations for reprocessing?



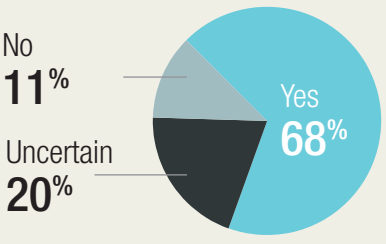
What kind of technology is used in your healthcare institution's SPD related to scope cleaning verification?



How important do you consider scope cleaning verification to be in terms of infection transmission prevention?



Do you believe there is adequate evidence to support the performance of scope cleaning verification?



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