The Importance of Bronchoscope Processing

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With the emergence of respiratory illnesses, such as the current COVID-19 pandemic, the effective processing of bronchoscopes has never been more critical for delivering safe patient care. With more than 500,000 procedures performed annually, bronchoscopes are valuable medical devices that enable minimally invasive diagnosis and therapeutic interventions that improve patient outcomes; however, patients undergoing bronchoscopy are often immunocompromised with significant disease (e.g., COPD, cancer, cystic fibrosis, pneumonia, tuberculosis), making them highly susceptible to acquiring infections. Societies that develop standards and guidelines are consistent in their recommendations, yet bronchoscope-related infections caused by inadequate processing or the use of damaged bronchoscopes are routinely documented. In response to recurring bronchoscope-related outbreaks, the US Food and Drug Administration (FDA) issued a Safety Communication to healthcare facilities regarding potential root causes of outbreaks and actions that can be taken to mitigate patient infection risk. There are several options as part of a comprehensive quality assurance (QA) program that can be implemented to improve the standard of care in bronchoscope processing, and improve safety for patients.

Objective 1: Review published recommendations and requirements for bronchoscope processing

There are several manufacturers and types of flexible bronchoscopes, including reusable fiberoptic bronchoscopes, video bronchoscopes, and endobronchial ultrasound scopes (EBUS), as well as single-use bronchoscopes. All bronchoscope types have the same basic configuration, including a control section, insertion tube, bending section, distal end, umbilical cord (video scopes only), and instrument/suction channel. With this common design, there is general consensus of processing recommendations for reusable flexible bronchoscopes. There are five major references for bronchoscope processing, including the American College of Chest
Bronchoscope processing, similar to all flexible endoscopes, starts with pre-cleaning at the point of use, transport to a designated processing room, leak testing, manual cleaning, inspection, high-level disinfection (HLD) or sterilization, drying, and storage. Although this sequence may seem simple and intuitive, there are more than 100 steps in processing of a typical bronchoscope.


A couple years after the multi-society guidelines were established for processing of gastrointestinal flexible endoscopes (2003), a joint guideline specific for processing bronchoscopes was published by ACCP/AAB (2005). Although the reported incidence of bronchoscope-related infections was rare (>800 cases), these cases included clinically significant infections and fatalities that may have been related to the procedure. In addition, the authors acknowledge that the incidence of bronchoscopy-related infections may be systematically under-reported, partially due to the subsequent infection being masked by the underlying condition of the patient. Another potential root cause for under-reporting may be explained by the procedure for sampling the lung, most often performed via a bronchoaveolar lavage, which leads to an inability to distinguish between a true patient infection and a positive result contributed by resident contamination in the bronchoscope.

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Although reusable endoscope types are processed according to these steps, there are notable differences that should not be overlooked. These include different diameter bronchoscopes that require cleaning brushes of different sizes, based upon the inner diameter of the instrument/suction channel. Using a brush of incorrect size may lead to ineffective cleaning and may also damage the bronchoscope. Another difference is the material compatibility of each bronchoscope. Some bronchoscopes are designed to be steam sterilized, while others may be sterilized using low-temperature sterilization modalities, such as hydrogen peroxide gas/vapor, with or without ozone, and ethylene oxide gas. Check with the bronchoscope manufacturer and sterilizer manufacturer for statements regarding compatibility.
Objective 2: Identify clinical evidence of documented bronchoscope-related infections

In 2015, the FDA issued a Safety Communication identifying bronchoscopes “as being part of a subset of devices that pose a greater likelihood of microbial transmission and represent a high risk of infection if they are not adequately reprocessed.” This safety communication was based upon 109 Medical Device Reports between January 2010 and June 2015. In a separate published report from a facility adhering to guidelines, 11 of 20 patients were culture positive as a result of using a damaged bronchoscope.9

In more recent years, clinical studies were conducted that directly demonstrated residual contamination recovered from “patient-ready” bronchoscopes. In one study, Ofstead et. al evaluated bronchoscopes and EBUS scopes at three tertiary care facilities and found residual protein and microbial contamination on 100% and 58% of patient-ready bronchoscopes (i.e., post processing), respectively. Furthermore, 100% of bronchoscopes evaluated in this study were found to contain visible defects or damage.10 Another study by Ofstead et. al revealed that 60% of “patient-ready” endoscopes contained residual microbial contamination.11

Beyond processing breaches and the use of damaged bronchoscopes, another major risk to patient safety is the emergence of multi-drug-resistant organisms (MDROs). Since 2012, there have been 12 reported cases linking bronchoscopes to infections of carbapenem-resistant Enterobacteriaceae (CRE) or a related MDRO.12 In CRE cases associated with duodenoscope processing, the mortality rate was up to 50%.13

Objective 3: Outline solutions for improving the standard of care in bronchoscope processing

There is no single cause for bronchoscope-related infections; therefore, a multifaceted approach is required to achieve effective reprocessing and minimize the risk of patient infection. All three systems (people, equipment, process) need to be addressed to improve the standard of care.

People are the most important of the three systems. People should receive adequate training on all bronchoscope models being utilized at the facility. This should be reinforced with annual competency assessments. Staff should also be enabled/encouraged to become certified in endoscope reprocessing.

Equipment should be visually inspected at every step in the process. Bronchoscopes are delicate instruments that routinely become damaged during handling, use and processing. There simply is no way to effectively process a damaged bronchoscope; therefore, identification of damage is paramount. The only way this can be achieved is with the use of lighted magnification and a borescope to inspect the internal channels. The most contaminated part of a bronchoscope, the instrument/suction channel, is also the most difficult to clean because it cannot be seen without the use of a borescope.

Equipment should be adequately dried prior to being stored in a clean, dry storage cabinet. Residual moisture is a breeding ground for bacteria; therefore, the best defense against microbial proliferation during storage is to eliminate the presence of water. Reusable bronchoscopes should be sterilized (or single-use, sterile bronchoscopes should be used). Most bronchoscopes can be sterilized and are compatible with low-temperature sterilization modalities commonly available at most healthcare facilities. Sterilization provides a significantly higher safety margin than HLD.

Processes are essential for improving the standard of care, and a comprehensive QA program should be implemented as part of bronchoscope processing. It is important to review current procedures and align with manufacturers’ instructions for use and guidelines. Quality checks should be implemented throughout the process and quality should be built into the process by design. For example, design elements should be incorporated to ensure the proper concentration of cleaning agent is being used. This could include a fill level on the sink, along with a cleaning...
agent dispenser that delivers the correct amount to achieve the manufacturer’s recommended dilution. A second example is to label or color code channel cleaning brushes, so the correct brush size is used for the correct bronchoscope.

Routine cleaning verification should also be performed. Cleaning is often identified as the most critical part of the process. If cleaning is inadequate, residual debris can protect microorganisms from subsequent HLD or sterilization, as well as provide the foundation for biofilm development. Cleaning verification is also a useful tool for staff competency assessments.

Testing should be performed to ensure the bronchoscopes are adequately dry and routine auditing of the process should also be implemented to ensure procedures are being followed.

**Conclusion**
The current standard of care in bronchoscopy must improve in order to provide safe healthcare for patients. Bronchoscopy patients are at an increased risk of infection for multiple reasons. First, these patients have underlying symptoms or disease, and many are immunocompromised. Second, the nature of the procedure is to bypass the body’s natural defense mechanisms that protect against pathogens colonizing the airways. Microorganisms from the upper airways are transported via the bronchoscope deeper into the lungs. The patients’ protective reflexes, such as a cough, are medically attenuated.

Finally, the mucosal barrier is often disrupted by sampling and biopsies, thereby enhancing the opportunity for microbial colonization. The sum of these risk factors is significant and presents an unacceptable risk profile for the patient. Implementing a comprehensive QA program, along with using sterile bronchoscope, directly minimizes these risks and provides a safer procedure for the patient.

**REFERENCES**
3. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST91: 2015; Flexible and semi-rigid endoscope processing in health care facilities.