WHITE PAPER
Single-use Flexible Bronchoscopes

FLEXIBLE BRONCHOSCOPES AND UPDATED RECOMMENDATIONS FOR REPROCESSING: FDA SAFETY COMMUNICATION

On Friday June 25th, 2021, the Food and Drug Administration (FDA) published a safety communication substantiating bronchoscope-associated cross-infections. To alleviate the cross-infection risk, FDA recommends introducing a sterilization step during reprocessing of reusable flexible bronchoscopes, and further that single-use bronchoscopes should be considered when there is an increased risk of spreading infection. The FDA gives five scenarios where there is an increased risk of spreading infection and where single-use bronchoscopes should be considered[1,2]:

1. **Multidrug resistant organisms (MDROs)**
2. **Immunocompromised patients**
3. **Patients with prion diseases**
4. **When there is no support for reprocessing**
5. **When treating patients with the coronavirus disease 2019**

WILL INTRODUCING STERILIZATION ELIMINATE CROSS-CONTAMINATION?

CURRENT PRACTICE AND UNMET NEEDS

Conventionally, reusable flexible bronchoscopes are cleaned via high-level disinfection (HLD). This includes seven separate steps and entails a significant financial and organizational burden. The steps involve: pre-cleaning, leak testing, manual cleaning, visual inspection, disinfection, storage, and documentation[3]. Reprocessing without the additional sterilization step has been found to cost $114-281 (2017 USD) per procedure[4].

Sterilization is intended to add a safety margin compared to the current reprocessing methodology[5]. However, recent evidence demonstrates major challenges associated with sterilization. A meta-analysis from 2020 found that a 15% risk of endoscope cross-contamination after HLD only dropped to 9% after adding a sterilization step. Even double HLD and sterilization failed to significantly diminish the contamination rate[6]. This clearly demonstrates that adding a sterilization step will likely not solve the issues of cross-contamination alone.

IMPLICATIONS OF STERILIZATION

There are multiple methods of sterilizing reusable flexible bronchoscopes. Each methodology represents different benefits and limitations. Since most reusable flexible bronchoscopes are heat-sensitive, the classic steam sterilization method via autoclave is not feasible to implement in current practice[7,8]. Other methods include ethylene oxide (EtO) sterilization and liquid chemical sterilization.

EtO sterilization is associated with a long turnaround time: it adds 150 minutes to the current 76 minutes of conventional HLD[4,9]. EtO sterilization has further been found to result in an additional per-procedure cost of $339 (2015 USD)[10].

In addition to the economic burden of EtO sterilization of $339 per procedure, there is a significant negative environmental and human health burden. Because of this, EtO sterilization is coming under increasing scrutiny and pressure from the FDA and the Environmental Protection Agency (EPA), which classifies EtO as a Hazardous Air Pollutant subject to tight restrictions within the Clean Air Act[11].

In July 2019, the FDA issued two "Innovation Challenges": to reduce EtO emissions, and to find alternatives to EtO sterilization. Last year, the U.S. faced an EtO capacity reduction after the EPA closed down an EtO sterilizer due to unacceptable levels of EtO in the air[12].

We expect both health systems and manufacturers to continue to be challenged by the FDA and the EPA to move away from EtO sterilization and towards solutions that are less harmful for the environment and for human health.

Alternatively, liquid sterilization adds an additional turnaround

time to conventional HLD of >23 mins[13]. This has been found to increase the cost per procedure by up to $221 (2019 USD), dependent on the procedure volume[14].
The gases and chemicals during sterilization are known to cause significant damage to the endoscopes. Accordingly, manufacturers acknowledge that general sterilization is harsher for the endoscopes than disinfection. Subsequently, sterilization will reduce endoscope availability due to increased repair rates leading to elevating repair costs.[8,10,15]

Since all additional sterilization methods result in a significant increase in the turnaround time and repair rates, this must be assumed to negatively affect current reusable flexible bronchoscope capacity. Hence, health care systems must expect additional costs associated with ensuring a bigger fleet of bronchoscopes to perform the same number of procedures; with establishing new reprocessing procedures; and with training the staff accordingly.

HIGH-RISK INFECTION SCENARIOS

FDA recommends that single-use bronchoscopes must be considered within scenarios with an increased risk of spreading infections.

MULTIDRUG RESISTANT ORGANISMS

The US Centers for Disease Control and Prevention (CDC) estimates that more than 2.8 million individuals annually become infected with multidrug resistant organisms (MDROs), resulting in more than 35,000 deaths per year[16].
Hospital stays with a diagnosis of bacterial infection account for 20.1% of all stays. Of these, 10.8-16.9% represent an infection with one or more MDROs. Accordingly, 2.2-3.4% of hospital stays are associated with an MDRO infection.[17]
The economic burden of treating MDROs doubled from 2002 to 2014, and accounted in 2019 for more than $4.6 billion annually.[16,18]
Dedicated prevention and infection control measures have reduced deaths by 18% overall, and by 30% in hospitals. However, more actions are needed to fully protect people from MDROs.[16]
From a payer perspective, an average hospital stay with a code of bacterial infection costs $19,000. Compared to this, the incremental cost of treating MDROs varies dependent on the type of MDRO infection; thus, MRSA, Clostridium difficile, other MDROs, and multiple MDRO infections result in an added cost of $1,700, $4,600, $2,300, and $3,600 (2017 USD), respectively.[17]
However, from a hospital perspective, the actual cost of treating MDROs has been found to be $18,600-29,000 (2008 USD) higher than treating an average hospital patient.[19]

IMMUNOCOMPROMISED PATIENTS

Within the US population, 2.7% of the adult population has been estimated to be immunocompromised.[20] It has further been argued that most intensive care (ICU) patients transiently develop features consistent with severe immunosuppression.[21]
Immunosuppressed patients belong to a subgroup of patients with a high risk of developing nosocomial pneumonia.[22] Among ICU patients, the most frequent nosocomial pneumonia is ventilated associated pneumonia (VAP), at a treatment cost of $25,100 (2005 USD).[23]

COVID-19

Aerosol-generating procedures such as bronchoscopy are considered high-risk for COVID-19 transmission. As a result, single-use devices should be used where feasible, and changing to single-use flexible bronchoscopes has been advised by multiple international clinical societies.[24-26] However, no published data are available on outbreaks associated with contaminated bronchoscopes infecting patients with COVID-19, although this likelihood has been presented.[27]

IS SINGLE-USE THE SOLUTION?

Since sterilization will not eliminate bronchoscope-associated cross-infections, and will result in increased turn-around time, increased repair rates, decreased capacity, and increased costs, implementation of single-use bronchoscopy is the solution. It should be introduced for all procedures within ICU, and further for all MDRO-positive patients, immunocompromised patients, COVID-19 patients, or prion-positive patients, and when there is no immediate support for reprocessing.
By implementing the use of single-use bronchoscopes for all MDRO-contaminated patients, the risk of bronchoscope-vectored cross-infection is reduced by 0.9% to 2.8%.[17,28] Accordingly, by diminishing the risk of MDRO infections, the cost saving amounts to $186-812 per bronchoscopy. Further, if all ICU patients are regarded as immunosuppressed, the cost saving by implementing single-use bronchoscopy for these patients will range between $227 and $703 per bronchoscopy.[23,28] To these costs there should be added $95, $93 and $66 (2019 USD), accounting for average capital, repair and reprocessing costs, respectively.[4,29-32]
In conclusion, single-use bronchoscopy is regarded as the preferred alternative to reusable flexible bronchoscopy, even when including HLD and sterilization. Single-use bronchoscopy offers a superior clinical outcome; it is cost-minimizing while retaining bronchoscopy capacity; and it offers attractive organizational benefits.

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