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How COVID-19 is making the case for single-use bronchoscopes

he COVID-19 pandemic is ushering in a more infectionconscious era, with terms such as "personal protective equipment," "virus" and "infection" entering the common vernacular.

Pre-crisis, health systems were already striving for excellent outcomes. Fifty-three percent of hospital executives surveyed by Advisory Board in 2019 cited minimizing unwarranted clinical variation as an area of interest, making it the second-most cited area of interest in the survey. Improving ambulatory access, population health strategies and expense reduction rounded out the top five interests identified in the survey.

Now, these goals have taken on new importance. For some organizations, they may mean the difference between folding and staying afloat amid pandemic-related financial challenges. Infection control and sterilization processes are under heightened scrutiny, and the resulting long-term changes to healthcare delivery are in question.

Despite this uncertainty, one thing remains clear: physicians' obligation to do no harm. The question moving forward will be how, exactly, providers can fulfill that obligation – especially for patients who are already vulnerable.

A pressing safety concern

COVID-19 makes this question all-too pressing for pulmonary specialists such as D. Kyle Hogarth, MD, because the coronavirus specifically causes damage to the lungs – even leading to acute respiratory distress syndrome in the most severe cases. For Dr. Hogarth, a specialist with UChicago Medicine, continuing to do no harm means selecting bronchoscopes that won't increase a patient's infection risk.

The rate of cross-contamination with reusable bronchoscopes concerns him. "It's not zero – and it should be zero," he said in an interview with *Becker's Hospital Review*. "That should be filed as a never event."

Dr. Hogarth isn't alone in his concern. Researchers have evaluated contamination rates for reprocessed bronchoscopes. While some may find the results surprising, most should find them "disturbing," according to Cori Ofstead, an epidemiologist who spoke to *Becker's* about what she's learned in 25 years of studying hospital-based infections and outbreaks.

In 2018, an Ofstead & Associates study published in CHEST found that 58 percent of "patient-ready" reusable bronchoscopes in three major U.S. hospitals tested positive for bacteria or mold. The researchers observed major breaches of infection control standards in two of the institutions, even though all three of them were accredited by The Joint Commission. This suggests that more rigorous quality management strategies should be implemented to ensure patient safety.

Patients should always be able to expect that any device being used in their body is clean, whether a pandemic is ongoing or not, Dr. Hogarth said. But with new studies suggesting

that COVID-19 coinfections are linked to "significantly higher mortality rates," bronchoscope reprocessing issues cannot be ignored.

Reprocessing is arduous and resource-intensive

To get to the root of the issue, it's important to understand why Ms. Ofstead's team has been seeing high rates of improperly cleaned reusable bronchoscopes for years. To properly reprocess bronchoscopes for reuse, clinicians must follow a series of complex steps to a tee, she said.

Each step is critical to getting a bronchoscope fully disinfected, in part because it's impossible to see the inside of a bronchoscope with the naked eye – and therefore difficult to ensure it's been adequately cleaned. After procedural use, bronchoscopes must first be checked for leaks.

Reprocessing staff also need to conduct a visual inspection of the fragile devices. Every time a bronchoscope is used, there's a risk of scraping the inside, Dr. Hogarth explained. Putting instruments inside bronchoscopes to take biopsies or diagnose bleeding, for example, can cause scratching.

In most hospitals, Ms. Ofstead found, the reusable bronchoscopes are riddled with microfractures, cuts and grooves where biofilms, proteins and bacteria can easily escape cleansers.

"We see a lot of damage to these scopes after not that many uses," she said. "Whenever you have a damaged surface on a fragile device like a bronchoscope, bugs can go into the cracks and crevices, and you can't know if the scope is harboring soil and biofilm."

That's why guidelines advise technicians to swab and test bronchoscopes in addition to conducting leak checks and visual inspections. Reprocessing and related quality checks must be done using valuable personal protective equipment, which is in short supply as healthcare professionals scramble to protect themselves and patients from COVID-19.

This intricate high-level disinfection process is far from ideal, especially considering each arduous step must be repeated if the cleaning verification test comes out positive for organic soil residue.

It is possible to do the kind of high-end cleaning needed to get bronchoscopes properly cleaned, but Ms. Ofstead's research shows that critical steps are being missed far too often. Moreover, according to Dr. Hogarth, getting reusable bronchoscopes fully reprocessed after each and every procedure drives up costs and inefficiencies.

"Neither is very acceptable," Dr. Hogarth said. "That brings in – from an operational perspective – [the case for] single-use" bronchoscopes.

Cost and waste misconceptions

When Dr. Hogarth first heard about disposable bronchoscopes,

he didn't think it would make financial sense to pitch devices after every use. Dr. Hogarth eventually realized the cost benefit of single-use devices by observing a colleague and using them himself. His initial reaction, however, was one familiar to Jens Kemp, vice president of marketing at Ambu Inc., a provider of single-use devices.

In an interview with *Becker's*, Mr. Kemp said it's important to consider all the costs associated with reusable bronchoscopes.

"When you look at the cost of using reusable scopes – and all the steps you have to go through to reprocess the scopes, all the expensive capital that goes into buying the scopes and repairing the scopes – there's actually a great cost benefit to single use," he said.

For the same reasons, single-use bronchoscopes don't necessarily generate more waste than reusable bronchoscopes do. Reusable devices require heaps of reprocessing materials like brushes, sponges, towels, and PPE to be discarded, according to research from Ms. Ofstead's team.

Still, Ambu is being proactive about these concerns. The company plans to roll out a program in which it will collect discarded single-use scopes and ship them to recycling facilities that can sort broken parts from usable parts and convert the remaining medical waste to energy.

Quality and applications

Another misconception, according to Mr. Kemp, is that single-use bronchoscopes are poor-quality devices. He wants physicians under this impression to understand how rapidly technology is evolving – and how far it has already come.

"A typical reusable endoscope might have a life cycle of six to eight years before you see a new generation of scopes, whereas with single-use, the typical product life cycle is two to three years," he said. "There's much faster incorporation of new technologies into single-use scopes."

Rapid innovations are making single-use bronchoscopes viable for a growing number of procedures - and when physicians get these devices in their hands, they're impressed with the functionality, Mr. Kemp added.

Although more than 3,000 hospitals rely on Ambu's single-use bronchoscopes, some providers are still surprised at how well the product compares with features typically associated with reusable bronchoscopes, such as high image quality.

While single-use bronchoscopes are developing "better and better optics," as Dr. Hogarth put it, reusable bronchoscopes still have their time and place. He noted that certain situations – such as ones involving internal bleeding – may necessitate the highest quality optics available.

In general, though, single-use bronchoscopes offer unique advantages beyond lowering the risk of cross-contamination. Dr. Hogarth commended the fact that they come sterilized and ready for use. He also described scenarios in which getting a bronchoscope positioned properly may actually damage the scope, which would take a reusable scope out of rotation.

"If you're using an expensive, reprocessed scope, that's going to be a big problem," he said. "But if you damage my disposable scope, I don't care. You can be more aggressive in getting what's necessary, and you're not going to cause damage in a way that harms [future] patients."

The view from here

With the COVID-19 pandemic highlighting the dangers of contagion, the American Association for Bronchology and Interventional Pulmonology has issued guidelines asking physicians to use disposable bronchoscopes when bronchoscopy is warranted. The recommendations, which were based on CDC reports, say the use of disposable bronchoscopes that don't require reprocessing, maintenance or repair can "protect patients and staff."

Protecting healthcare workers warrants particular concern, Ms. Ofstead said. If staff members contract an infection – which is more likely if they're handling the device through various reprocessing stages – they can't be on the front lines helping to treat COVID-19 patients and provide other needed services.

"We could cripple ourselves by putting sterile processing or endoscopy lab workers in danger and cripple our ability to run hospitals by spreading germs in these areas," Ms. Ofstead said.

Not only do single-use scopes protect medical personnel, they also help conserve personal protective equipment.

When the pandemic subsides, there will be continued benefits to disposable bronchoscopes, according to Dr. Hogarth. Having single-use bronchoscopes waiting on shelves in the ICU eliminates the need to haul bronchoscope towers back and forth from central reprocessing locations, for instance.

More importantly, stocking shelves with single-use bronchoscopes means they're readily available for use in patients. They enable clinicians to diagnose pneumonia – and see the bacteria causing it – sooner than if they needed to wait for the bronchoscope to be reprocessed.

These advantages mean there's good reason to believe more hospitals will look to single-use bronchoscopes – and other kinds of single-use scopes – during the pandemic and beyond, according to Mr. Kemp.

"There's a heightened awareness around infections and contamination in hospitals," he said. "I also think there's heightened awareness of how cumbersome and intensive cleaning processes are in hospitals, and how many resources are required to ensure that hospitals are compliant with cleaning standards."

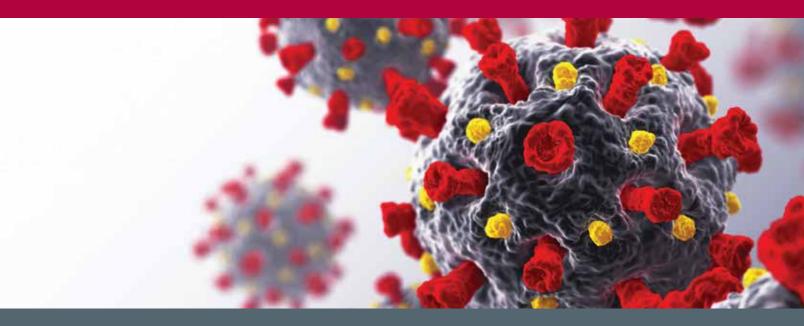
By underscoring these concerns, Ms. Ofstead said, the pandemic can bring much-needed change in bronchoscope selection.

"Every scope put into a vulnerable patient should be sterile," she said. "That's why I think single-use scopes are a good option. Every time, you know for sure that's a sterile scope going into the patient. But it's absolutely essential that there be strict adherence to quality assurance standards whenever reusable bronchoscopes are used."



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Cori Ofstead is the president and CEO of Ofstead & Associates, Inc., where she leads a multidisciplinary team that specializes in designing and conducting real-world studies to validate healthcare guidelines, treatments, and product claims. Since 1996, Ofstead – an epidemiologist with 25 years of research experience – has worked with healthcare providers, payers, employers, health & wellness program vendors, and medical products manufacturers to improve the quality of medical care.