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INSIDE

RELIAS MEDIA

Meeting the Challenge of Sterilizing Duodenoscopes

Reprocessed scopes still could be contaminated

By Gary Evans, Medical Writer

Infection preventionists and central sterile supply technicians must work together to protect patients from duodenoscopes that could remain contaminated after reprocessing. That is the take-home message from a comprehensive program that shows it can be done.

The intricate scopes are used to assess the pancreas and other organs in endoscopic retrograde cholangiopancreatography (ERCP). ERCPs using duodenoscopes are performed on some 500,000 patients annually in the United States. In a recent meeting with infection control advisors at the CDC, the FDA concluded that the standard protocol at many hospitals of reprocessing these scopes with high-level disinfection (HLD) leaves patients at risk of infections.

> THE FDA CONCLUDED THAT THE STANDARD PROTOCOL AT MANY HOSPITALS OF REPROCESSING THESE SCOPES WITH HIGH-LEVEL DISINFECTION LEAVES PATIENTS AT RISK OF INFECTIONS.

The failure to adequately disinfect the devices has been linked to outbreaks of carbapenem-resistant Enterobacteriaceae (CRE) and other pathogens. In response, some facilities have gone to more stringent reprocessing measures such as ethylene oxide (EtO) sterilization or use of liquid chemical sterilant reprocessing systems. However, some at the CDC meeting said the

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downside to these approaches includes prolonged reprocessing times and damage that shortens the "use life" of the scopes. Regardless of the reprocessing method, the scopes also can be damaged during ERCP procedures by, for example, sharp instruments. Currently. there are no disposable duodenoscopes on the market.

Patient safety advocates say the use of even a small percentage of potentially contaminated duodenoscopes is not an acceptable alternative, citing healthcare teams in hospitals that have committed to solving this problem. One such team includes infection preventionists and central sterile department experts at the Altru Health System in Grand Forks, ND.

Q&A

HIC asked **Jenni Gibbs**, BS, manager of the Central Sterile Department (CSD) at Altru, to describe her program in the following interview, which has been edited for length and clarity. As part of revamping and renovating the CSD several years ago, Gibbs and colleagues decided to transition away from EtO but continue their commitment to rigorously clean and sterilize duodenoscopes.

HIC: What method did you choose to sterilize duodenoscopes?

Gibbs: We went to a new product: a low-temp chemical sterilizer that uses hydrogen peroxide and ozone. We replaced an outdated hydrogen peroxide sterilizer and EtO with this new sterilizer. We knew that EtO wasn't going to be a viable long-term solution for sterilizing scopes because of the turnaround time and the needed volume of scopes we would have to have in inventory. It wasn't cost-effective.

The new hydrogen peroxide and ozone sterilizer has a 55- to 65-minute sterilization cycle, so it takes the same time to sterilize them as it does to high-level disinfect them in an automated endoscope reprocessor, but the scopes are terminally sterilized. We use event-related sterility, which means there isn't an expiration date on sterility. It is event-related — meaning, for example, if the wrapper or package integrity is compromised. This negates the hang-time expiration reprocessing guideline. This also has the benefit of reducing the amount of reprocessing cycles on less-often-used scopes and the associated costs.

HIC: While patient safety is the prime objective, you solved logistical problems related to the supply of scopes and shortening sterilization times. What about the problem of damage to scopes that has been cited as a downside to using EtO?

Gibbs: I will say, from the damage standpoint, hydrogen

As previously reported in Hospital Infection Control & Prevention, *the FDA has found that an estimated 3-5% of duodenoscopes remain contaminated with potentially infectious organisms after reprocessing. (See the July 2019 issue of HIC.) We continue our coverage in this issue with a profile of a hospital system that is successfully sterilizing the complex scopes. In a related story, the FDA is warning of potential shortages of critical equipment, as freestanding sterilization facilities using ethylene oxide (EtO) face shutdowns due to cancer concerns in surrounding communities.*

peroxide — just like EtO — causes wear and tear on the scopes. Most endoscopes that can be sterilized in hydrogen peroxide plasma have a cycle count, [indicating when] you need to send them to the manufacturer [for inspection and repair]. There is a level of wear and tear from high-level disinfectants and sterilants on the soft materials and adhesives that all endoscopes are made of, so there is a certain point where you are going to have to send them in. We have been sterilizing our duodenoscopes for a year with hydrogen peroxide and ozone technology.

For two years now, we have been inspecting every scope, every time, internally, in addition to an external inspection. We inspect the scope internally to look for damage in the channel. We are also doing ATP [adenosine triphosphate] testing, a residual protein test that we use for verification of the manual cleaning. We do that on every scope, every time.

The internal channel inspection and verification of the manual clean has had the biggest impact on the quality of our scopes and reducing our risk of contamination. If the scopes cannot pass that verification of the manual clean testing, it is cleaned again. If, after the second clean, it comes back [contaminated], we send it in for repair. Same with the damage inside the channels. There is damage and residual contamination identified routinely within the channels, so we are sending our scopes in more frequently for these repairs than for damage associated with sterilization. When we started looking at them we had an initial big uptick in our repairs.

HIC: The FDA estimated that 3-5% of duodenoscopes remain contaminated after reprocessing. Your program shows these scopes can be sterilized, but it certainly does not sound easy.

Gibbs: Giving what I am seeing in our daily work here, I think that [FDA estimate] is low. I think that is an underinflated number. There is a cost to doing it right, but no matter what, the patient deserves a sterile scope. In healthcare, we say we do no harm to patients. High-level disinfection is only a certain percentage of kill. It is not terminal sterilization. One patient harmed should be one too many. I believe the industry someday will go to all sterile or disposable scopes. We use disposable scopes when we can; for example, bronchoscopes. At the end of the day, if [a disposable] scope can provide the services and do what it needs it to do for that surgeon, that is your safest model for the patient. You eliminate all the manual reprocessing variables for failures. There is a significant cost to reprocess a scope correctly. But we need to eliminate high-level disinfection. Whatever percentage [of contamination] that is left, why is that risk acceptable for that patient?

Stopping the Line

HIC: Issues of informed consent were raised at the CDC meeting, with some saying it would be unacceptable to tell a surgical patient the scalpel used on them may not be completely sterilized.

Gibbs: Patients assume that these scopes are sterile, and I think some physicians assume that they are sterile. I don't think the physicians understand the time and skill [it takes] to clean these, and the risk of contamination that remains after high-level disinfection. I feel we are taking the steps to do it the absolute best we can.

We have centralized our reprocessing to a core team in the CSD. Only five CSD techs are validated to clean duodenoscopes. They have an extremely high level of competency. There is a lot of variation in levels of competency across the industry. There also is intense pressure to turn scopes around, and technicians do not always have the ability to stop the line.

Our technicians have the authority to say, "This has failed the test. This does not look right, this is not clean. I am pulling it out of service." They are the experts on that scope, and it is pulled if anything is in question. That is a luxury that a large portion of the reprocessing technicians in the U.S. do not have. There often is not an investment in them with the time, education, tools, technology, or authority to make sure that scope is clean.

HIC: So, the manual cleaning, testing, and inspection processes are just as important as the actual sterilization?

Gibbs: To me, that has been the biggest bang for our buck in making sure we have clean, safe scopes for our patients. We are inspecting them and making sure they are manually clean before we [reprocess].

You can't high-level disinfect or sterilize contaminates. If it is not clean, it is not going to be disinfected or sterile. We have to, as an industry, demand that technicians be given better resources for the current scope technology we have. Give them the tools, invest in inspection and sterilization technology, and then the leeway to do what they need to do to make sure that our patients are safe.

One sentinel event from a contaminated endoscope — I don't even know how you can justify that. I can't wrap my head around not doing it right.

I am blessed to be at an organization where I have the partnership with our infection prevention team and they are asking these questions. They introduced us to AAMI ST91[1] when I was new to my role. We have a partnership; we are together all the time. I know in some organizations IPs shy away from CSD. In others, they are the Big Brother watching over; it's an adversarial relationship. It has to be an interdisciplinary approach. It needs to be a partnership so IPs can help us advocate, along with quality, risk management, and compliance. Everything we are trying to do in the CSD is about risk mitigation. Lift us up to be experts, and partner to mitigate the risks. Help us so that the practitioners, nurses, and doctors have the tools they need in perfect working order that are safe to use for their patients. ■

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FDA: Hospitals Could Face Shortages of Sterile Supplies

Facility in Illinois shut down due to EtO cancer risk

The emission of ethylene oxide (EtO) from sterilization facilities into surrounding communities has raised cancer concerns, warnings, and closures that threaten the critical flow of sterile supplies in healthcare, the FDA reports.

Infection preventionists should keep communication channels open with central sterile supply and other key colleagues to ensure spot shortages of equipment do not pose a threat to patient safety.

"Regarding a potential for a shortage of any one type of medical device, we are frequently communicating with manufacturers, healthcare organizations, group purchasers, and trade organizations so we can keep our finger on the pulse of what is happening," said **Suzanne B. Schwartz**, MD, MBA, associate director for science and strategic partnerships at the FDA Center for Devices and Radiological Health.

Thus far, shortages of sterile equipment have been largely headed off, but a system already operating at capacity could be vulnerable to a cascade effect if stakeholders are not prepared for plant closures, she said at a CDC meeting.

"The nation is not seeing the spot shortages that we might otherwise be seeing," Schwartz said. "I want to underscore that once you start to have more of a domino effect, that is going to be significantly felt."

Classified as a carcinogen in certain doses, EtO is used to sterilize about half of new medical devices and equipment before they are packaged and shipped to hospitals. This includes terminally sterilized new products like surgical kits, sterile packs, stints, sutures, clamps, and tracheostomy tubes. Any disruption in the flow of these essential supplies must be balanced against the potential for raising the risk of cancer in the community, Schwartz told the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC).

"I want to emphasize that FDA recognizes and is very sensitive to the environmental concern for ethylene oxide emissions that are released into the air at unacceptable levels — levels that can present an increased risk to public health in surrounding communities" she said.

EtO is used widely in sterilization facilities because it is compatible with many of the materials used in construction of the equipment. Sterilization facilities may have limited options to go to other modalities that may damage or otherwise compromise safe use of the equipment on patients.

The FDA is looking for alternatives to EtO and different ways to use the sterilant; for example, reducing the quantity of EtO used in sterilization, which may reduce environmental exposures while preserving the safe use of the devices, she said.

Facility Shutdown

A critical moment in this unfolding situation occurred on Feb. 15, 2019, when the Illinois Environmental Protection Agency (EPA) issued a "seal order"[1] to stop Sterigenics in Willowbrook, IL, from further sterilizing medical products with EtO, Schwartz said.

In making the move, the EPA cited ambient air sampling and a report by the CDC's Agency for Toxic Substances and Disease Registry (ATSDR) that concluded, "If measured and modeled data represent typical ethylene oxide ambient concentrations in ambient air, an elevated cancer risk exists for residents and offsite workers in the Willowbrook community surrounding the Sterigenics facility. These elevated cancer risks present a public health hazard to these populations."[2]

The Illinois Department of Public Health conducted a separate epidemiologic study of cancer incidence near the facility over a 20-year period. Researchers found that cancer risk was elevated in general, but cited confounding variables that undermined a definitive conclusion. For example, interstate traffic adds to EtO emissions in the same area.

"The study's results, when taken as a whole, indicated that some cancers were elevated in populations living near the Sterigenics facility in Willowbrook," the state researchers concluded.[3] "Many apparent differences and inconsistences, however, existed between genders, across study areas, and among cancer sites."

On June 24, 2019, Sterigenics applied for renovations that would reduce emissions and comply with an Illinois state law passed in the wake of the closure. According to a statement by Sterigenics, "The application seeks permits to install new equipment which would establish a permanent total enclosure through the use of negative pressure, increase the number of emission control stages, and combine existing emissions stacks into one common stack at the facility. Sterigenics remains in compliance with legal obligations and is taking all appropriate legal actions to resume operations at Willowbrook."[4] Sterigenics has nine sites and approximately 150 contract sterilizers in the United States, Schwartz said.

Viant, a sterilization plant in Grand Rapids, MI, also announced it is shutting down at the end of 2019. In a letter[5] to local residents, Viant said a self-reported EtO leak by the plant in 2017 was cited as a violation by the Michigan Department of Environmental Quality. Viant said in the letter it was shutting down sterilization activities because it is not part of their core business.

The closures are a concerning trend, given that existing sterilization capacity is hard-pressed to meet demand.

"Contract sterilizers are working at close to maximum capacity in terms of devices coming in and going out," Schwartz said. "They are working 24/7. The impact of a closure of a single site can have significant consequences on the availability of medical devices that need to be delivered to supply chains, hospitals, and healthcare organizations."

The situation is in flux as both the EPA and the CDC are conducting surveillance of EtO emissions and health affects at other sterilization plants and the surrounding communities nationally. Congress is asking the FDA for updates on the situation, Schwartz said.

The FDA plans to form an advisory committee on the issues of EtO sterilization and sterile device supply in the fall, she said. The agency also is going to issue an "innovation challenge" in the coming months to solicit solutions that could help reduce EtO emissions and explore alternative sterilization technology. ■

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FDA Alert: Fatal Infection Following Fecal Transplant

C. diff patient dies of E. coli infection

Multidrug-resistant organisms (MDROs) are infecting new patients via transplantation, putting recipients at risk of infections and threatening to spur larger hospital outbreaks. Two recently reported incidents underscore the threat, with one described in an alert by the FDA about fecal microbiota transplantation (FMT) to treat *Clostridioides difficile* infections.

"Two immunocompromised adults who received investigational FMT developed invasive infections caused by extended-spectrum beta-lactamase [EBSL]-producing *Escherichia coli*. One of the individuals died," according to the FDA alert.[1]

C. diff kills some 15,000 patients annually, often emerging after antibiotics used for other infections disrupts the commensal bacteria in the gut. FMT is an option for patients with recurring *C. diff* infections.

In the case reported by the FDA, the fecal microbiota transplanted to the two patients came from the same donor. The donor stool and resulting FMT used in the patients were not tested for ESBL-producing, gram-negative organisms like *E. coli*.

"After these adverse events occurred, stored preparations of FMT from this stool donor were tested and found to be positive for ESBL-producing *E. coli* identical to the organisms isolated from the two patients," the FDA reported.

In light of the cases, the FDA recommended patients considering FMT for *C. diff* infections talk to providers and understand the potential risks associated with the procedure.

FDA Requirements

In addition, the FDA notified those physicians performing FMTs under Investigational New Drug (IND) provisions of new requirements, effective as of July 15, 2019[1]:

1. Donor screening must include questions that specifically address risk factors for colonization with MDROs, and individuals at higher risk of colonization must be excluded from donation. Examples of patients at higher risk include:
   - Healthcare workers;
   - Those recently hospitalized or discharged from long-term care facilities;
   - People who regularly attend outpatient medical or surgical clinics;
   - Those who recently participated in medical tourism.

2. FMT donor stool testing must include MDRO testing to exclude use of stool that tests positive for MDRO. The MDRO tests should, at minimum, include ESBL-producing Enterobacteriaceae, vancomycin-resistant enterococci (VRE), carbapenem-resistant Enterobacteriaceae (CRE), and methicillin-resistant *Staphylococcus aureus* (MRSA). Culture of nasal or peri-rectal swabs is an alternative to stool testing for MRSA only. Bookend testing (no more than 60 days apart) before and after multiple stool donations is acceptable if stool samples are quarantined until the post-donation MDRO tests are confirmed negative.

3. All FMT products currently in storage for which the donor has not undergone screening and stool testing for MDROs as described above must be placed in quarantine until the donor is confirmed to be not at increased risk of MDRO carriage, and the FMT products have been tested and found negative. In the case of FMT products manufactured using pooled donations from a single donor, stored samples of the individual donations prior to pooling must be tested before the FMT products can be administered.

4. The informed consent process for subjects being treated with FMT product under the IND should describe the risks of MDRO transmission and invasive infection, as well as the measures implemented for donor screening and stool testing.

MDRO Via Organ Transplant

Another case was recently reported at the CDC's annual Epidemic Intelligence Service conference.

The investigation began in August 2018, when the Connecticut Department of Health notified the CDC that a highly drug-resistant strain of *Acinetobacter baumannii* had been identified in a deceased organ donor.[2]

The isolate carried the OXA-23 gene, conferring resistance to carbapenems, last-line drugs against MDROs that are virtually untreatable. The donor had been admitted to a hospital with on ongoing outbreak

of OXA-23 carbapenem-resistant *A. baumannii* (CRAB) nine days prior the positive culture.

The lungs, liver, and kidneys from the donor were transplanted into four patients in three transplant facilities in Connecticut and Massachusetts. The facilities were not notified of the donor's MDRO status until 53 days after the transplants, said **Ana Bardossy**, MD, an EIS officer in the CDC Division of Healthcare Quality Promotion (DHQP).

"CRAB is not currently included in pathogens of special interest that are required to be reported for further investigation to the Organ Procurement and Transplantation Network, but this is now under consideration," she said.

Notifications of pathogens of special interest must occur within 24 hours. However, post-transplant cultures were obtained from the organ recipients as part of routine follow-up. CRAB was identified in the lung transplant recipient, but did not transmit to the other organ recipients. The lung transplant patient required prolonged antibiotic prophylaxis for CRAB colonization, but did not develop clinical infection.

Two CRAB isolates, one from the donor and one from the recipient, were resistant to 16 antibiotics. However, they remained susceptible to colistin and polymyxin b, she said.

"There was a second isolate from the recipient that was pan-resistant, including resistance to colistin and polymyxin b," Bardossy said.

The case shows the potential for transplants to spark an MDRO outbreak at an organ recipient facility.

"It important to note that OXA-23 CRAB has been linked to outbreaks in other cities across the country," Bardossy said. "MDROs have the potential to move through facilities through transplantation, [leading to] spread and transmission."

Once available, donor MDRO culture results should promptly be shared with transplant centers to trigger treatment and infection control response, she said.

"This highlights the importance of regional collaboration of public health authorities to detect resistance, protect patients, and prevent spread through MDROs," she said.

The question of whether organs from infected donors should be rejected by receiving facilities was raised at the EIS meeting. Bardossy put the risk in perspective with the critical shortage of organs.

"In 2017, 18 people a day died waiting for an organ transplant," she said. "In contrast, suspected infections happen to 1% to 2% of cases. From those suspected infections, less than 1% of the cases is transmission-confirmed, and mortality is low. Clinicians may evaluate whether they want to reject the organ or not. It is up to the facilities."

Moderating the EIS session was **Denise Cardo**, MD, director of the CDC DHQP.

"Sometimes, people say, 'Test all the donors to see if they have infections,'" Cardo said. "I think the most important piece here is the communication after detection, not only for the patient and the recipient to be treated, but also for avoiding further transmission. Patients move from one transmission center to another, and that can be a problem."

While initial communication is critical, another point to remember in preventing transmission is that recipients of organs with MDROs may remain colonized for prolonged periods as they go in and out of hospitals, Bardossy added. ■

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Infection Prevention: The Past Is Prelude

Carbapenem-resistant Enterobacteriaceae challenge will take collaboration

Looking to the past and the present, Association for Professionals in Infection Control and Epidemiology (APIC) President **Karen Hoffmann**, RN, MS, CIC, FSHEA, FAPIC, recently gave a keynote address in Philadelphia at the annual APIC conference. Hoffman also is an infection prevention consultant for the Survey and Certification Group at the Centers for Medicare & Medicaid Services (CMS) and a clinical instructor in the division of infectious diseases at the University of North Carolina School of Medicine.

Hospital Infection Control & Prevention asked Hoffmann to discuss some of the themes she raised in her address in the following interview, which has been edited for length and clarity.

HIC: Infection prevention has come a long way from its origins, but you stress the importance of the bedrock science.

Hoffmann: The foundations for our practices of hand hygiene, asepsis, and disinfection were really laid down by the early scientists of the mid-1800s, like John Snow, Pasteur, and Lister. I sometimes think we too easily put them to the side in considering why isolation precautions work, and the importance of hand hygiene. Asepsis and environmental cleaning are becoming more and more relevant as time moves on.

The 100 years from 1900 to 2000 was a period of learning but not a period of cooperation. It was a period of silos. We did have some significant things happen, like the first infection control nurse in 1968 as an outcome of *Staph* outbreaks. The first CDC Decennial meeting in 1970 was a major occurrence. Then, APIC was founded in 1972. That same year, the Joint Commission began requiring infection control programs.

HIC: Do you have personal experience with infection prevention operating in a silo?

> "WHAT WE HAVE LEARNED IS THAT THE MORE WE PARTNER, THE MORE SUCCESS WE HAVE — BECAUSE NOTHING CHANGES WHEN WE WORK IN ISOLATION."

Hoffmann: Yes. As someone who has done infection prevention for 35 years, who started in the field back in the 1980s, I began in infection control very much isolated. There was difficulty with implementation of policies and procedures, and working with facilities as a whole. We functioned in silos, which really did not have much impact. We wanted to be more impactful, so we started doing a lot of partnering within our facilities. The federal bloodborne pathogen rule, for example, created a partnership for prevention of needlestick injuries.

There have been several national partnerships with which infection prevention has become involved over the period from 2000 on. What we have learned is that the more we partner, the more success we have — because nothing changes when we work in isolation.

HIC: Now, we are in an era of more collaboration and opportunity for IPs. As you mentioned, there are programs at the federal level focused on reducing specific hospital-acquired infections (HAIs) and implementing antibiotic stewardship programs.

Hoffmann: We are looking at these national efforts that can support us at the local level. IPs can use these to demonstrate to their leadership the importance of infection prevention in terms of complying with regulatory bodies. We have made a major impact in the last 10 or so years for widespread practice change. We've seen from the CDC National Healthcare Safety Network [NHSN] data a reduction in HAIs. We are very concerned about patient safety and preventing HAIs, so that's the direction we want to keep going.

HIC: CMS "pay for performance" initiatives have helped make the business case for preventing HAI costs that may not be reimbursed.

Hoffmann: It has really gained leaderships attention, which from a financial business case aspect is important. I think IPs can use that to their advantage, even though it is an imperfect system. They need to use data to improve practices at their facility. I believe there are always practices that can be improved upon in every facility. It's up to the IP to use the data that is presented to them through these national systems like NHSN and Hospital Compare to their advantage and implement evidence-based practices. I think that

is the best use of this value-based purchasing that leadership is so concerned about.

HIC: We've seen a succession of emerging infections, from SARS to Ebola in this century alone. Do you see the next big challenge as containing multidrug-resistant organisms?

Hoffmann: Control of antibiotic-resistant bacteria is an area where we can use partnerships the most, because we have room for improvement. For example, CRE [carbapenem-resistant Enterobacteriaceae] is spreading into the wider world and becoming vastly more common. It is going to be harder to detect and harder to control.

The CDC does have evidence-based steps in their CRE toolkit that they really want all healthcare facilities to follow.[1] In their modeled data from their NHSN and emerging infections programs, they show that coordinated approaches to interrupt the spread of HAIs can have a big impact on increasing incidence of these infections — [as opposed] to independent efforts by facilities alone.[2] They projected, compared to independent facilities, that a coordinated and partnership response to CRE could result in a 74% reduction in five years in interconnected facilities. With that kind of collaboration, they projected that more than a half-million antibiotic resistant HAIs could be prevented over five years. That is really something to think about in terms of working within systems. This calls for infection prevention to be leaders in this area. ■

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Surgeons' Negative Attitudes Can Lead to Higher Infection Rates

Patients are at greater risk of complications and adverse outcomes if surgeons break team protocols or treat colleagues poorly, says **William O. Cooper**, MD, MPH, of the Center for Patient and Professional Advocacy at Vanderbilt University School of Medicine in Nashville.

"Patients whose surgeons had four or more co-worker concerns had an almost 50% increased risk of having a surgical site infection [SSI]," he says. "That is an important increase when you think about all of the work we do to decrease the risk of our patients having infections."

Cooper and colleagues hypothesized that patients of surgeons with a higher number of co-worker reports about unprofessional behavior could experience a higher rate of postoperative complications than patients whose surgeons have no such reports.

"Among 13,653 patients in this cohort study undergoing surgery performed by 202 surgeons, patients whose surgeons had a higher number of co-worker reports had a significantly increased risk of surgical and medical complications," the authors found. "Surgeons who model unprofessional behaviors may help to undermine a culture of safety, threaten teamwork, and thereby increase risk for medical errors and surgical complications."

The researchers assessed data from two academic medical centers in the National Surgical Quality Improvement Program. Both hospitals acted on reports from co-workers describing unprofessional behavior by surgeons.

The researchers went back three years preceding an operation in assessing reports of unprofessional behavior by the surgeon. The main outcomes assessed were postoperative surgical or medical complications within 30 days of the operation.

SSIs were significantly more likely among patients whose surgeons had more co-worker reports, with a rate of 5.3% in those with no reports, compared to 7.4% in surgeons with four or more reports of unprofessional behavior.

The researchers collected data on "many types of infections, including superficial SSIs, deep SSIs, catheter-associated bloodstream infections, and catheter-associated urinary tract infections," Cooper said. "We measured across all of those different types of infections and found, in general, an increased risk for patients whose surgeons had more than zero co-worker reports."

Among 13,653 patients who underwent operations performed by 202 surgeons, 1,583 experienced complications.

"Patients whose surgeons had more co-worker reports were significantly more likely to experience any complication," the researchers reported. "The adjusted complication rate was 14.3% higher for patients whose surgeons had one to three reports and 11.9% higher for patients whose surgeons had four or more reports, compared with patients whose surgeons had no co-worker reports."

Medical complications include pulmonary and renal problems, strokes, and pneumonia.

The researchers looked at several types of behaviors that generated reports by co-workers. One was failing to follow accepted care protocols, like handling a central line without using gloves, Cooper says. Others included unclear or confusing communications from the surgeon to colleagues.

"There were some that where just rude and disrespectful," he says. "Others were failing to follow through on professional responsibilities like signing verbal orders, or other things that are an important part of team function."

Clinicians working with volatile surgeons may be less likely to speak up if they see a break in protocol.

"You can see in a complex surgical operation how that would potentially impact things," he says. For, example, when a patient is not doing well, the surgeon may yell at an anesthetist.

"The next time they are paired together, that anesthetist may be distracted, waiting for the surgeon to blow, or be hesitant to speak up if the patient's blood pressure starts to drop or the patient is not doing well," Cooper says.

While this behavior can have a chilling effect on workers speaking out, there also are workers who express concerns during a procedure, he explains.

"In our work, we find that many times a nurse or another worker does speak up and reminds the surgeon, but he goes ahead and does it anyway," he says. "The clear majority of surgeons, like all physicians, perform in perfectly respectful ways and never have any problem at all. It is a very small proportion that account for a disproportionate share of these kind of behaviors."

The primary intervention for those with problems is to share the data with the surgeon, using a trained peer messenger, Cooper says.

"We find that 80% of the time that a surgeon or another physician is an outlier, they will self-correct and reduce the number of unprofessional behaviors they have," he says. "For the small number of individuals who don't respond to the peer intervention, we recommend that hospitals do a physical and mental health evaluation to see whether there could be burnout, mental illness, substance abuse, or other problems."

Ongoing research indicates that this general pattern could manifest in other healthcare clinicians and work groups. For example, in hospitals that employ nurse-driven Foley catheter removal protocols, physicians on the floor may be angry to find their patients' catheters removed, he says.

"We find that nurses are then reluctant to follow the protocols that we have worked so hard to put in place to protect our patients from infections," Cooper says. "We know the longer you have a catheter in place, the greater the risk for infection."

It is not all physicians, as continuing research by Cooper and colleagues suggests a similar pattern in advanced practice nurses.

"We are piloting some work looking at staff nurses, and we are seeing there is a non-random distribution that a small number of nurses account for a disproportionate share of unprofessional behaviors," he says. "As we look to extend this work to other types of clinicians in the non-surgical space, we do often find that the same behaviors are likely to affect important infection control practices."

The authors of an accompanying editorial[2] on the study said that surgeons may be at particular risk of these behavior problems.

"A hostile workplace is, unfortunately, not uncommon in academic surgery departments," they noted. "Surgeons experiencing hostility in the academic surgical environment may have fewer professional advancement opportunities, less satisfying clinical practice, and failed mentorship, and may be at greater risk for burnout or other psychological effects."

While these factors must be addressed, the study by Cooper and colleagues shows patient safety is at stake, the authors warned.

"As surgeons, we should have a zero-tolerance approach to unprofessional behavior in the workplace," they concluded in the editorial. ■

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CDC Drops Routine Annual Tuberculosis Testing of Healthcare Workers

As previously forecasted in *Hospital Infection Control & Prevention*, the CDC officially dropped routine annual tuberculosis testing of healthcare workers (HCWs) in recently published guidelines.[1] *(For more information, see the April 2019 issue of* HIC*.)*

The agency is dropping routine screening in favor of testing on hire, and after TB exposure or ongoing transmission. In updating 2005 TB guidelines, the CDC screening change was expected as the disease continues to decline nationally and healthcare workers appear to be at no greater risk of transmission than the general public.

"In addition, a recent retrospective cohort study of approximately 40,000 healthcare personnel at a tertiary U.S. medical center in a low TB-incidence state found an extremely low rate of TST [tuberculin skin test] conversion (0.3%) during 1998-2014, with a limited proportion attributable to occupational exposure," the CDC reported[1,2]

Routine annual screening in low-risk populations has little epidemiological value, and could trigger false positives and unnecessary anxiety in healthcare workers.

"The recommendation is a lot more strongly stated that we really don't need to be doing annual testing in almost every situation," says lead author **Lynn Sosa**, MD, TB/STD Control Programs Coordinator at the Connecticut Department of Public Health. "This will save time because now you are not focused on tracking down people to get them tested every year."

Oher CDC TB recommendations include:

- Screening with an individual risk assessment and symptom evaluation at baseline;
- Testing for TB using an interferon-gamma release assay (IGRA) or a tuberculin skin test (TST) for employees without prior TB or latent TB infection (LTBI);
- Encourage HCWs with untreated LTBI to seek treatment, unless treatment is contraindicated;
- Annual screening for HCWs with untreated LTBI;
- Annual TB education of all HCWs.[1]

There also is new emphasis on treating HCWs who test positive for LTBI. IPs played a large role in implementing TB infection control measures that made this possible. IPs must continue to emphasize rapid identification and isolation of TB patients.

"The 2005 recommendations[3] still stand in terms of the infection control and the environmental control recommendations," Sosa says. "Those are still really important. Just doing a test on healthcare workers does not prevent TB transmission."

As part of the preplacement TB test for healthcare workers, the CDC recommends an individual risk assessment. "Instead of looking at the risk of a particular facility, we are focused on the risk of the individual person working in the healthcare setting," Sosa says. "Because it really is important to understand what that individual's risk of TB is to interpret and better understand the test results."

HCWs should be considered at increased risk for TB if they answer yes to any one of the following statements:

- Temporary or permanent residence in a country with a high TB rate;
- Current or planned immunosuppression, including HIV, receipt of an organ transplant, treatment with a tumor necrosis factor-alpha antagonist, chronic steroids, or other immunosuppressive medication;
- Close contact with someone who has had infectious TB disease since the last TB test.[1] ■

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HOSPITAL INFECTION CONTROL & PREVENTION

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CME/CE QUESTIONS

1. **What percentage of duodenoscopes on the market are disposable?**

   a. 7%
   b. 5%
   c. 2%
   d. 0%

2. **Suzanne Schwartz, MD, of the FDA, says which sterilization method is used on approximately half of all new medical devices and supplies?**

   a. High-level disinfection
   b. Chemical sterilizer
   c. Ethylene oxide
   d. Hydrogen peroxide and ozone

3. **The FDA emphasized that donors for fecal microbiota transplantation may be colonized with multidrug-resistant organisms after a recipient was fatally infected with:**

   a. extended-spectrum beta-lactamase-producing *E. coli*.
   b. vancomycin-resistant enterococci.
   c. carbapenem-resistant Enterobacteriaceae.
   d. methicillin-resistant *Staphylococcus aureus*.

4. **In a study of surgeons that linked inappropriate behavior reported by co-workers and higher patient infection rates, what intervention worked in about 80% of surgeons?**

   a. Zero tolerance
   b. Meeting with a peer messenger
   c. Reduction in procedures
   d. Quarterly check-ins with chief of surgery

CME/CE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

1. Identify the clinical, legal, or educational issues encountered by infection preventionists and epidemiologists;
2. Describe the effect of infection control and prevention issues on nurses, hospitals, or the healthcare industry in general;
3. Cite solutions to the problems encountered by infection preventionists based on guidelines from the relevant regulatory authorities, and/or independent recommendations from clinicians at individual institutions.