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We at Infection Control Today are pleased to announce dynamic changes to the way news and other information you depend on will be conveyed, all in the quest to bring you an improved experience.

In the coming days and weeks, you can expect to see a noticeable difference in the look and feel of the website, but still always providing industry-leading news, features and other educational materials. The new website will be designed with ease-of-navigation in mind, removing functions that impeded scrolling and making it more effortless to find and access what you are looking for. All the existing content will be preserved and available on the new site, which will also be completely mobile-responsive for smartphone and tablet screen sizes.

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We know you rely on our weekly e-newsletter for a fast and practical update on what’s happening in the infection prevention and control world, and that’s why we are also striving to improve your electronic news delivery as well. While it will look slightly different, it will continue to offer similar benefits. In any transition, it’s a work in progress, so we ask you to be patient with any potential broken links or any potential disruptions relating to the e-newsletter; we are changing email providers, so if for some reason you should stop receiving ICT’s e-newsletter, please be sure to search your spam folders, If you find it there, please label us as “Not Spam” or “Safe” to ensure future delivery.

But the biggest change of all is the new ownership of ICT. We have joined MultiMedia Healthcare, LLC, a division of MJH Associates, Inc., a leading independent full-service healthcare education, market research and multichannel medical communications company dedicated to engaging our valued audience in new and exciting ways and delivering high-quality content through print publications, multimedia platforms and live events. The new ownership means that ICT is now even better positioned in its dedication to remaining at the forefront of delivering trusted healthcare information now and into the future, and it continues its commitment to providing stakeholders — from providers to patients to caregivers — access to trusted and timely resources to help inform care and optimize outcomes.

ICT joins a division of more than 30 medical brands, spanning 17 markets to meet the information, education and marketing needs of the healthcare industry. MultiMedia Healthcare, LLC combines the reach and influence of its powerful portfolio of digital and print product lines, live events, educational programs, and market research with the customization capabilities of a boutique firm whose clients include world-leading pharmaceutical, medical device, diagnostic and biotech companies. With the power of this new association at its back, ICT is poised to bring you new and innovative content and programs designed to super-charge your professional performance. We’ll continue to update you about these exciting changes as they happen.

Until next month, bust those bugs!

Kelly M. Pyrek
Editor in Chief
kipyrekmjhgroup.com

ICT July/August 2019

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The More, the Merrier Within Our Clan

I'm a Gram-negative organism and part of a bacterial clan with many, many relatives, so you can just imagine how crazy our family reunions tend to get! We'll pitch a tent in the human intestines and party for days, weeks and longer, unless someone does something to kick us out. Most of us are relatively harmless and contribute to a healthy human intestinal tract. However, some of us are mean son-of-a-guns and are pathogenic, with one goal in life — causing the host as much misery as possible through illness and severe diarrhea. One of our brethren is even classified as a Category B bioterrorism agent, so you'd better take us seriously.

We are a diverse group, with the harmless members of our family keeping our distance from the pathogenic members of our family, which are classified into a number of pathotypes. Gee, how do you like that? I'm starting to sound like those folks in the clinical lab! The really bad actors produce a toxin — which shall remain nameless since that will give us away instantly — which triggers symptoms that vary for each person. This toxin can cause severe stomach cramps, diarrhea (often bloody), and vomiting, and some people may have a fever, which usually is not very high. Most people get better within five to seven days, but don't let that lull you into complacency about us; while some infections are very mild, others are critical or even life-threatening. Most people who have succumbed to our toxin will start feeling sick three to four days after ingesting something that we have contaminated, however, illnesses can start anywhere from one to 10 days after exposure.

We can create all kinds of havoc in the body, causing everything from urinary tract infections to septicemia, to five major gastrointestinal infections — I get dizzy just thinking about all of the delightful mayhem we can create. The thing is, people, we're most often transmitted by contact and — I know you hate to think about this — the fecal-oral route. That's right, take a good, hard look at those 10 digits of yours; I bet we're crawling around on your hands even as we speak!

We are responsible for many cases of food poisoning, and the folks who are at especially high risk of contracting the illness we cause — pregnant women, newborns, children, older adults, and those with weak immune systems — should take great care to practice proper hygiene, especially good handwashing. We shouldn't have to remind you, but here goes just in case: Wash your hands thoroughly after using the bathroom and changing diapers. Wash your hands thoroughly before and after preparing or eating food. If soap and water aren’t available, use an alcohol-based hand sanitizer with at least 60 percent alcohol (check the product label to be sure). These alcohol-based products can quickly reduce the number of us on hands in some situations, but they are not a substitute for washing with soap and running water.

You silly clinicians always want to prescribe a course of antibiotics, but actually, they are not recommended for patients with suspected infections caused by our toxin until complete diagnostic testing can be performed and infection by us and our toxin is ruled out. Until then, keep those hands washed and cook your food thoroughly.

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AH19-175
Ensuring Use of Appropriate PPE in the Decontamination Area of the SPD

Q: Our department was recently cited by surveyors for the personal protective equipment (PPE) we are using. Specifically, we use single-use isolation gowns, face masks and exam gloves. We were also told we were in non-compliance with OSHA standards. What are we doing wrong?

A: The Occupational Safety and Health Administration (OSHA)'s regulation on occupational exposure to bloodborne pathogens (29 CFR 1910.1030) requires employers to identify tasks that might put employees at risk for exposure to blood or other body fluids and to take appropriate measures to protect them from exposure. These measures include the development of an Exposure Control Plan that identifies (a) the tasks that could result in exposure to blood or other hazardous substances and (b) the means necessary to protect the employee. Employees should receive a copy of the Exposure Control Plan, and its contents should be covered during orientation and training. The Exposure Control Plan should change as new regulations are issued and better control or safety products become available.

The OSHA regulation includes requirements for appropriate PPE. The type of PPE might vary according to the tasks to be performed, but according to OSHA, the PPE selected must "not permit blood or other potentially infectious materials to pass through or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used." (29 CFR 1910.1030). Your isolation gowns probably do not meet this requirement. PPE must be worn whenever there is the potential for exposure to blood, body fluids or other infectious materials by spray, splatter or splash.

Sterile processing department (SPD) personnel should also wear PPE when working with chemicals (e.g., detergents, disinfectants). The chemical manufacturer's instructions for use (IFU) and safety data sheets (SDS) should be consulted for the recommended PPE, which might differ from the PPE used for protection from bloodborne pathogens. For example, personnel cleaning up spills of some of the chemicals used in disinfection might need to wear a respirator, and gloves worn during use of certain disinfection chemicals might be made of different materials than those worn during handling of contaminated items.

The use of PPE is not optional and is regulated by OSHA, which specifies the circumstances under which PPE is required. The Centers for Disease Control and Prevention (CDC) recommends when and what type of PPE is required and how the attire is to be used. It is the employer's responsibility to provide the appropriate PPE, ensure that it is used, and document and investigate failure to comply. All employees should be trained in the appropriate protective attire to be worn for the tasks they perform and in the potential health and disciplinary consequences if they fail to do so. This training should be documented and routinely verified as part of SPD competencies. Personal protective equipment must fit the individual user, and it is up to the employer to ensure that all PPE is available in sizes appropriate for the employees that must be protected.

Any visitors to the decontamination area are required to don PPE. (For this reason, the decontamination area should not be used as a shortcut, nor should anyone be in the decontamination area unless authorized.) At a minimum, visitors entering the decontamination area should wear an impervious jumpsuit or impervious gown, gloves, and shoe covers; a head cover should be worn to contain hair. It is the responsibility of SPD technicians assigned to the decontamination area to ensure that all visitors comply with the required PPE. Failure to comply should immediately be reported to the department supervisor or manager.

The PPE should be located as close as possible to the entrance to the decontamination area (unless there is a separate room for donning and removing PPE) so that personnel can avoid having to walk through the area without PPE. The PPE should be stored in a manner that prevents contamination of the PPE (e.g., in plastic tote bins or plastic bags).

Because of the potential for soaking of clothing, splashing, and the aerosolization of fluids and contaminants, and the consequent need to protect employees from exposure to both microorganisms and chemicals, appropriate attire and PPE in the decontamination area includes the following items:

- Surgical scrub attire that is laundered by the facility and changed daily or whenever it becomes wet or soiled

- A head covering that covers all head and facial hair (except for eyebrows and eyelashes) NOTE: A head covering is not considered PPE, but part of the required dress code. However, it does prevent contaminants from the head and hair from getting into trays and sets.

- Depending on the work being performed, either a Level 3 or Level 4 long-sleeved, impervious (fluid-proof) or fluid-resistant gown or jumpsuit (not an apron)

- Eye and face protection including, but not limited to, a full-face shield or goggles that prevent splashed fluids from entering from above, below, or the sides.

- A fluid-resistant mask. A fluid-resistant mask has been added as part of the required PPE for decontamination personnel because of the likelihood that, when personnel are performing typical activities, there is a real risk of exposure due to splash or splatter. This is in keeping with AAMI recommendations (ANSI/AAMI ST79).

- Fluid-resistant shoe covers with slip-proof bottoms

- Heavy-duty, powder-free protective gloves with long fitted cuffs that prevent fluid from entering the glove during use. The style of glove should protect the wearer from contact with contaminated water. (For example, a glove that is too short can permit water to enter the glove when the wearer is moving his or
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her arms up and down.) A cut-resistant glove liner may be used beneath the decontamination glove as additional protection. NOTE: On March 21, 2016, the Food and Drug Administration (FDA) published a proposed ban on the use of powdered gloves in the medical field because of the health risks associated with powder (FDA, 2016).

In summary, you should meet with your Infection Prevention department and discuss the recommended PPE for your department. Obtain samples from various vendors to ensure the PPE will accommodate all staff members, that they can work comfortable in the PPE, and it is cost effective. As noted, PPE is not optional, so it is the responsibility of the employer to ensure the correct PPE is provided and worn by the staff.

Nancy Chobin, RN, AAS, ACSP, CSPM, CEFR, is a sterile processing consultant and educator.

References:
Occupational Safety and Health Administration. Personal protective equipment standard. 29 CFR 1910.32.
Occupational Safety and Health Administration. Eye and face protection standard. 29 CFR 1910.33.
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Common sense dictates that limiting surgical patients’ exposure to any reservoir that could harbor pathogenic organisms could help prevent surgical site infections (SSIs). Wearing proper surgical attire is a cornerstone of SSI prevention, yet there has been strident disagreement on some of the finer points of surgical attire and its impact on SSI rates. Worse yet, a recent paper demonstrated that implementation of stringent operating room attire policies does not reduce SSI rates.

Farach, et al. (2018) describe how two teaching hospitals imposed strict regulations on operating room (OR) attire, including full coverage of ears and facial hair, with the researchers hypothesizing that this intervention would reduce superficial SSIs. They compared NSQIP data from all patients undergoing operations in the nine months before implementation (n = 3,077) to time-matched data nine months post-implementation (n = 3,440). The researchers report that, "Despite a shift toward more clean cases, there were more SSIs post-implementation (33 vs 30). There were no differences in length of stay, complications, or mortality between the two time periods. Overall, SSI increased with wound class: 0.6 percent, 0.9 percent, 2.3 percent, and 3.8 percent in clean, clean-contaminated, contaminated, and infected cases, respectively. Limiting the review to clean or clean-contaminated cases, incisional SSIs increased from 0.7 percent (20 of 2,754) to 0.8 percent (24 of 3,115) (p = 0.85). A multivariable analysis showed that implementation of these policies was not associated with decreased SSIs. The largest predictors of SSIs were preoperative infection, operative time >75th percentile, open wounds, and dirty/contaminated wounds. A hypothetical analysis revealed that a sample size of 485,154 patients would be required to demonstrate a 10 percent SSI reduction among patients with clean or clean-contaminated wounds."

Farach, et al. (2018) note that, "Although a number of SSI prevention recommendations were made about preoperative, intraoperative, and postoperative practices among these infection-control guideline statements, there were no recommendations specific to surgical attire until 2015, when the Association for Perioperative Registered Nurses (AORN) published their updated recommendations on operating room attire. These included stringent policies designed to minimize the exposed areas of skin and hair of operating room staff, stating that, 'personnel entering the semi-restricted and restricted areas should wear a clean surgical head cover or hood that confines all hair and completely covers the ears, scalp, skin, sideburns, and nape of the neck.' Since 2015, regulatory and accrediting bodies have enforced the AORN’s recommendations. However, these new attire policies have been met with much criticism, as there is no direct scientific evidence to support their recommendations. In fact, although these recommendations were made with the intent
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of reducing the risk and incidence of SSIs, the recent AORN-sponsored literature review of surgical head coverings repeatedly stated that there is ‘no conclusive evidence that hair covering prevents SSI,’ and in the original guideline statement, many of the recommendations are noted to be made based on pseudoscientific data.”

Chiming in on the issue are Kothari, et al. (2018), who observed, “The American College of Surgeons guidelines indicate that skull caps are acceptable, and the Association of periOperative Registered Nurses recommends bouffant caps. However, no scientific evidence has shown a significant advantage in SSI reduction with either cap.” The researchers sought to determine the influence of surgical cap choice on SSIs, and analyzed data from a previously published prospective randomized trial on the impact of hair clipping on SSIs. Patients were grouped by the attending surgeons’ preferred cap choice into either bouffant or skull cap groups.

Overall, 1,543 patients were included in the trial. Kothari, et al. (2018) found that, “Attending surgeons wore bouffant caps in 39 percent and skull caps in 61 percent of cases. Prevalence of diabetes and tobacco use were similar between the groups. Bouffant caps were used in 71 percent of colon/intestinal cases, 42 percent of hernia/other cases, 40 percent of biliary cases, and only 1 percent of foregut cases. Overall, SSIs occurred in 8 percent and 5 percent of cases with a bouffant and skull cap, respectively; with 6 percent vs. 4 percent classified as superficial, 0.8 percent vs. 0.2 percent classified as deep, and 1 percent vs. 0.9 percent classified as organ space; however, when adjusting for the type of operation, no significant differences in SSI rates were observed for skull caps vs. bouffant caps.” The researchers concluded that, “Attending surgeon preference for bouffant vs skull cap does not significantly impact SSI rates after accounting for surgical procedure type. Future guidelines should consider these clinical outcomes data and surgeon preference should dictate operating room headwear.”

As debate continues around the wearing of surgical caps or bouffants, AORN’s new guideline will reflect the latest study and recommend facilities determine the appropriate attire based on practice and specialty.

Lisa Spruce, DNP, RN, CNS-CP, CNOR, ACNS, ACNP, FAAN, director of evidence-based perioperative practice for AORN, recently reviewed the significant changes contained in the new surgical attire guideline, which will be available online July 1, 2019. Let’s review the most pertinent points.

Regarding laundering of surgical attire, Spruce pointed out that AORN maintains its stance on home laundering. “We are not approving home laundering because it is not monitored for quality, consistency or safety,” Spruce says. “Studies showed us that scrubs become contaminated throughout the work day and bacteria can be transmitted to the environment. Some of these organisms can survive home laundering, can cause biofilm formation in the home washing machine and can transfer that bacteria to other clothes washed in the home washing machine. What we don’t know is whether this scrubs contamination can contribute to healthcare-associated infections (HAIs), but it is a concern and we also know that the water in our home washing machines just doesn’t get hot enough to kill those microorganisms.”

Spruce adds, “We want you to wear clean surgical attire when you are entering semi-restricted and restricted areas, but after each daily use, we want you to launder your scrub attire.” If laundering at a healthcare-accredited laundry facility or at a healthcare institution’s laundry, then home-laundering will be necessary, but with a caveat. “If you are going to home-launder, you must provide guidance to your employees for home laundering,” Spruce says. “It is important to read the guideline; there are studies in it that will provide guidance. Even though we aren’t recommending home laundering, it will help you with that process.”

Spruce added that AORN recommends that surgical team personnel remove scrub attire before leaving the healthcare institution. “The benefits of removing surgical attire before leaving the facility outweighs the harms,” Spruce says. “Moderate-quality evidence here supports changing out of surgical attire into street clothes when leaving the building, to reduce the potential of healthcare workers to transport potentially pathogenic microorganisms from the facility into your home or community. A systemic review concluded that provider attire is a potential source of pathogenic material transmission; there is limited data on the role of attire in HAIs but the authors did recommend that healthcare workers wear clean clothes when returning and exiting the facility.”

Regarding personal clothing, Spruce says AORN does not offer any recommendation for clothes worn under scrub attire. “When you see these no-recommendation statements, you will need to establish and implement a process for managing personal clothing that may be worn under your scrub attire,” she advises. “That includes the type of fabrics, such as a non-linting fabric, the amount of fabric allowed, such as a turtleneck allowed under a V-neck, or a T-shirt that hangs down on the arms, as well as laundering frequency (for example, frequency and method of laundering). Any personal clothing that is worn that becomes contaminated with blood, body fluid or other potentially infectious material (OPIM), must remain at the healthcare facility for laundering; that is a regulatory requirement.”

Spruce continues, “Fabrics that are worn in the operating room should be tightly woven and low-linting, but we cannot make a recommendation for wearing surgical attire made of antimicrobial fabric, and this is a change to the guideline. Although the evidence regarding antimicrobial scrub attire was high-quality, there was a wide range of variability in the study results and several studies were performed in the laboratory setting. There is no research to determine the potential harm to the wearer, of wearing surgical attire made from antimicrobial fabric, so that is a gap we need more evidence on. If you want to consider this, you should follow your

“Studies showed us that scrubs become contaminated throughout the work day and bacteria can be transmitted to the environment.”

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We know that wearing a head covering may contain hair and bacteria that is shed by our team members, which may prevent contamination of the sterile field and reduce the patient risk for SSIs.

AORN recommends that if cover apparel is worn, it should be clean. Spruce reports that the evidence around cover apparel was of moderate quality, and it showed that lab coats worn as cover apparel can be contaminated with large numbers of pathogenic microorganisms. Researchers also found that cover apparel is not always discarded daily after use or laundered daily.

Regarding head coverings, the recommendation is to cover the scalp and hair when entering the semi-restricted or restricted areas of the OR. “This section is a big change from the previous guidelines and you will want to read this carefully,” Spruce advises. “We know that wearing a head covering may contain hair and bacteria that is shed by our team members, which may prevent contamination of the sterile field and reduce the patient risk for SSIs.”

But research has not demonstrated that covering the hair affects the multi-factorial outcome of SSI rates. There are case studies that demonstrated that human-to-human bacteria shed from the scalp and hair of operative team members has been directly attributed to SSI outbreaks; however, these case studies are old, there have been no recent case reports of this, so the recommendation is just cover your hair.

Spruce continues, “You must keep in mind that we have no recommendation for the type of head covers worn in semi-restricted or restricted areas. The evidence does not demonstrate any association between the type of head covering or extent of hair coverage in the outcome of SSI rates. You are going to need to form an interdisciplinary team, including members of the surgical team and infection preventionists, to determine the type of head covers will be worn at your organization. Please read the evidence before determining this. No recommendation can be made for covering the ears in semi-restricted or restricted areas. Moderate-quality evidence does suggest that ears are a potential reservoir for pathogens; however, research has not demonstrated any association between covering the ears and SSI rates. We also know that covering the ears may have potential harms such as causing impaired hearing, which could potentially interfere with important team communication, interfere with the use of stethoscope, and hinder the fit of protective eyewear. If you are going to allow the wearing of cloth head coverings, you must establish a process for the type of fabrics that you will allow in your setting, the laundering frequency, and the laundering method. Are you going to facility-launder them or have them home-laundered? Read the section on head coverings thoroughly to help you write any policies.”

Another change to the recommendations involves beards; AORN recommends covering beards in restricted areas and while preparing and packaging items in the clean assembly section of the sterile processing area.

Yet another change addresses shoes. “We want you to wear clean shoes when entering the semi-restricted or restricted area,” Spruce says. “Now, the definition of clean we have in our guideline is that it is the absence of visible dust, soil, debris or blood. There was a systematic review that found shoes have the ability to transfer infectious organisms to the floor and contribute to floor contamination. You’ll want to keep that in mind if you wear your shoes from the perioperative area to your home; you could be contaminating your home floor; you also want to wear protective footwear that meets your healthcare organization’s requirements.”

Regarding identification badges, Spruce notes, “They are part of your attire and you want to clean them with a low-level disinfectant when it becomes soiled with blood, body fluids or OPIM. There are quite a few studies with moderate-quality evidence supporting that ID badges may be contaminated with pathogens and need to be cleaned. You will need to determine the frequency of ID badge cleaning and disinfection; for example, daily, weekly and any time you see visible soil. You also want to clean your lanyards; the previous guideline said cloth lanyards should not be worn, but you can wear a lanyard if it can be cleaned with a low-level disinfectant when it becomes soiled with blood, body fluids or OPIM. Be sure you are cleaning those on a routine basis and they are made from a material that can be cleaned.”

Spruce continues, “Forever and ever we were not supposed to wear stethoscopes around our necks; however, that has been removed from the guideline; the recommendation is to clean stethoscopes before each patient use according to the manufacturer’s instructions for use. Moderate-quality evidence supports it, and it is also all about hand hygiene, which decreases the risk of transmitting pathogens to patients and environmental surfaces. Stethoscopes come in direct contact with patient skin and could be a mechanism for transmitting pathogens from that patient to other patients, from the patient to the healthcare worker, or from healthcare worker to patient. So, any time you use that stethoscope, you clean it before use.”

A conditional recommendation is to establish a process to prevent contamination of the semi-restricted and restricted areas of the OR through the introduction of personal items — such as purses, briefcases and backpacks, — into the operating theater. “This process may include cleaning them, or containing the item, or placing the item in a designated location,” Spruce explains. “These items that people bring into the OR can be difficult to clean, they also may harbor pathogens and cleaning them helps to decrease the transmission of potentially pathogenic microorganisms from external sources to perioperative surfaces and vice versa. You’re going to need to establish the process of how you are going to handle personal items, deciding what works best for your facility. Now, when we talk about cell phones, tablets and other personal communication electronic equipment and devices, this is a recommendation for you to clean those according to manufacturers’ instructions for use before you bring...”

healthcare organization’s process for the pre-purchase evaluation of products when considering purchasing antimicrobial scrubs.”

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Regarding head coverings, the recommendation is to cover the scalp and hair when entering the semi-restricted or restricted areas of the OR. “This section is a big change from the previous guidelines and you will want to read this carefully,” Spruce advises. “We know that wearing a head covering may contain hair and bacteria that is shed by our team members, which may prevent contamination of the sterile field and reduce the patient risk for SSIs.”

But research has not demonstrated that covering the hair affects the multi-factorial outcome of SSI rates. There are case studies that demonstrated that human-to-human bacteria shed from the scalp and hair of operative team members has been directly attributed to SSI outbreaks; however, these case studies are old, there have been no recent case reports of this, so the recommendation is just cover your hair.

Spruce continues, “You must keep in mind that we have no recommendation for the type of head covers worn in semi-restricted or restricted areas. The evidence does not demonstrate any association between the type of head covering or extent of hair coverage in the outcome of SSI rates. You are going to need to form an interdisciplinary team, including members of the surgical team and infection preventionists, to determine the type of head covers will be worn at your organization. Please read the evidence before determining this. No recommendation can be made for covering the ears in semi-restricted or restricted areas. Moderate-quality evidence does suggest that ears are a potential reservoir for pathogens; however, research has not demonstrated any association between covering the ears and SSI rates. We also know that covering the ears may have potential harms such as causing impaired hearing, which could potentially interfere with important team communication, interfere with the use of stethoscope, and hinder the fit of protective eyewear. If you are going to allow the wearing of cloth head coverings, you must establish a process for the type of fabrics that you will allow in your setting, the laundering frequency, and the laundering method. Are you going to facility-launder them or have them home-laundered? Read the section on head coverings thoroughly to help you write any policies.”

Another change to the recommendations involves beards; AORN recommends covering beards in restricted areas and while preparing and packaging items in the clean assembly section of the sterile processing area.

Yet another change addresses shoes. “We want you to wear clean shoes when entering the semi-restricted or restricted area,” Spruce says. “Now, the definition of clean we have in our guideline is that it is the absence of visible dust, soil, debris or blood. There was a systematic review that found shoes have the ability to transfer infectious organisms to the floor and contribute to floor contamination. You’ll want to keep that in mind if you wear your shoes from the perioperative area to your home; you could be contaminating your home floor; you also want to wear protective footwear that meets your healthcare organization’s requirements.”

Regarding identification badges, Spruce notes, “They are part of your attire and you want to clean them with a low-level disinfectant when it becomes soiled with blood, body fluids or OPIM. There are quite a few studies with moderate-quality evidence supporting that ID badges may be contaminated with pathogens and need to be cleaned. You will need to determine the frequency of ID badge cleaning and disinfection; for example, daily, weekly and any time you see visible soil. You also want to clean your lanyards; the previous guideline said cloth lanyards should not be worn, but you can wear a lanyard if it can be cleaned with a low-level disinfectant when it becomes soiled with blood, body fluids or OPIM. Be sure you are cleaning those on a routine basis and they are made from a material that can be cleaned.”

Spruce continues, “Forever and ever we were not supposed to wear stethoscopes around our necks; however, that has been removed from the guideline; the recommendation is to clean stethoscopes before each patient use according to the manufacturer’s instructions for use. Moderate-quality evidence supports it, and it is also all about hand hygiene, which decreases the risk of transmitting pathogens to patients and environmental surfaces. Stethoscopes come in direct contact with patient skin and could be a mechanism for transmitting pathogens from that patient to other patients, from the patient to the healthcare worker, or from healthcare worker to patient. So, any time you use that stethoscope, you clean it before use.”

A conditional recommendation is to establish a process to prevent contamination of the semi-restricted and restricted areas of the OR through the introduction of personal items — such as purses, briefcases and backpacks, — into the operating theater. “This process may include cleaning them, or containing the item, or placing the item in a designated location,” Spruce explains. “These items that people bring into the OR can be difficult to clean, they also may harbor pathogens and cleaning them helps to decrease the transmission of potentially pathogenic microorganisms from external sources to perioperative surfaces and vice versa. You’re going to need to establish the process of how you are going to handle personal items, deciding what works best for your facility. Now, when we talk about cell phones, tablets and other personal communication electronic equipment and devices, this is a recommendation for you to clean those according to manufacturers’ instructions for use before you bring...”
them into the operating room and perform hand hygiene. Moderate-quality evidence demonstrated that these items are highly, highly contaminated with microorganisms, some potentially pathogenic; you want to make sure you are cleaning them. It is critical to perform hand hygiene after any cleaning; those two things together are very important.”

This guideline is only available in AORN’s facility reference center on its website beginning July 1, 2019. This guideline will not be published in book form until January 2020.

Conflict Over Surgical Attire Guidance

Even as a nursing organization educates around its soon-to-be released updated guideline on surgical attire, a medical society calls its stance into question, causing practitioners to re-evaluate what they think they know about preventing surgical site infections (SSIs).

A paper by Elmously and Gray (2019) recently explored the effectiveness of surgical attire worn during operative and other invasive procedures as one of the mechanisms that may assist in preventing SSIs. However, AORN asserts that the paper misrepresented the AORN recommendation throughout the article. In a letter to Timothy J. Eberlein, editor-in-chief of the Journal of the American College of Surgeons, Lisa Spruce of AORN noted, “The authors state, ‘The guidelines ban the traditional surgeon skull cap, mandate the use of a bouffant cap...’ This is unequivocally incorrect. The guideline does not mention skull caps nor is there any mention of bouffant caps; AORN has neither urged the elimination of traditional surgical caps nor mandated the use of bouffant caps. AORN does not specify the type or style of head covering that should be worn. Recommendation III of the guideline states, ‘A clean surgical head cover or hood that confines all hair and completely covers the ears, scalp skin, sideburns, and nape of the neck should be worn.’ Additionally, it is standard practice that if the AORN guidelines are going to be discussed then the guideline itself should be cited and not secondary references.”

Spruce also points out that Elmously and Gray stated, “the main criticism (of the guideline) being that, although well intentioned, there is little evidence to support them, and they were promulgated without collaboration with the surgical community especially in light of multiple studies showing no relationship between headgear and SSIs.” In her letter, Spruce counters, “Again this is incorrect. The AORN guidelines are based on a comprehensive, systematic review of research and non-research evidence; the individual references are appraised and scored, and the recommendations are rated according to the strength and quality of the evidence supporting each recommendation. The guidelines are authored by AORN perioperative practice specialists and in collaboration with liaisons representing the American Association of Nurse Anesthetists, the American College of Surgeons, the American Society of Anesthesiologists, the Association for Professionals in Infection Control and Epidemiology, the International Association of Healthcare Central Service Materiel Management, and the Society for Healthcare Epidemiology of America. The recommendations in the Guideline for Surgical Attire include a benefits balanced with harms assessment to determine the risk/benefit of recommendations to patients. The recommendations are not based on a proven causal effect of a relationship between headgear and SSIs but a benefit to patients because hair and skin can harbor bacteria that can be dispersed into the environment and the purpose of covering them is to reduce the patient’s exposure to potentially pathogenic microorganisms from the perioperative team member’s head, hair, ears, and facial hair.”

Spruce added that in a table accompanying the Elmously and Gray article, the authors state that AORN recommends “Arms should be covered with long-sleeved jackets in semi-restricted areas” and that “Non-disposable head coverings should be covered with a disposable head cover.” Spruce says that neither is recommended by AORN and clarifies further, “For arm covering the guideline states that the arms should be covered during two activities only, in Recommendation I.c.1: ‘The perioperative team member should wear scrub attire that covers the arms while performing preoperative patient skin antisepsis.’ And in Recommendation I.c.2: ‘The perioperative or sterile processing team member should wear scrub attire that covers the arms while preparing and packaging items in the clean assembly section of the sterile processing area.’ AORN has never stated in the surgical attire guideline that non-disposable head covering should be covered with a disposable head cover. The foremost concern for all perioperative professionals should be for patient safety and for providing the cleanest surgical environment possible for all patients undergoing operative and other invasive procedures. Within a bundled approach for reducing risk of SSIs, covering and containing hair is a reasonable and prudent measure. There is no harm in doing so, but the benefit to all patients is a reduced risk of exposure to potentially pathogenic organisms that live on the hair, skin, and facial hair of perioperative team members.”

References:
The Clinical and Economic Case for Sterile, Disposable Instruments and Implants

By David M. Welker, MD, and Mark H. Hofbauer, DPM

Abstract

Contamination incidents related to cannulated endoscopes has caused more scrutiny of re-sterilization and re-use of orthopedic instruments. This article reviews instrument re-use vs. a trend in foot/ankle surgery toward sterile/disposable sets. We conducted a survey of operating room nurses to consider their current practices and the economics/efficiencies of in-hospital sterilization and disposable orthopedic instruments. Of the 100 respondents, 60 percent had been in the profession for more than 12 years, 20 percent for 8 to 11 years, and 20 percent for four to seven years. When asked how long it took to process and sterilize an instrument set at their facility, 83 percent of respondents said more than 61 minutes and 10 percent said 31 to 60 minutes. The most worrisome finding was that a majority had seen material residue on cannulated implants or instruments in the OR. Forty-seven percent of respondents estimated the per-case cost of instrument processing to be $600 to $1,000; with 30 percent estimating a lower cost and 23 percent a higher cost. By contrast, single-use disposable instruments can save more than $400 per case by reducing hospital labor and sterilization costs. Disposable instruments can also lower upfront and replacement cost, stand up to the rigors of surgery, help prevent expensive surgical site infections, and reduce liability risks.

Introduction

Recent news headlines reported two deaths and 179 exposures from contaminated surgical instruments used for endoscopic retrograde cholangiopancreatography (ERCP) at a university medical center in California.1 Similar infections also occurred in Washington, Illinois, and Pennsylvania. These events prompted the independent and highly respected ECRI Institute to add “Inadequate reprocessing of endoscopes and surgical instruments” to its Top 10 Patient Safety Concerns in 2014.2 These events also prompted the authors to examine instruments provided for foot and ankle surgery. Of particular interest is the common re-sterilization and re-use of cannulated instruments versus the trend toward sterile, disposable sets.

Cannulated instruments like endoscopes are especially hard to clean, yet Dr. Alex Kallen, an epidemiologist at the Centers for Disease Control and Prevention (CDC)’s Division of Healthcare Quality Promotion, noted that the agency has not found any breaches in recommended cleaning protocols at the affected re-processors or hospitals.3 In May 2015, a hearing held by the Food and Drug Administration (FDA) concluded that the CDC’s subsequent guidance for surveillance of bacterial contamination of reusable instruments could not be considered a best practice.4 Similar conclusions emerged from a recent survey of member of the Association of periOperative Registered Nurses (AORN). A majority of respondents said they had seen material residue on cannulated instruments or implants. Likewise, a majority reported having seen material residue or puddling in a sterilization tray, and 67 percent had seen material residue on a cutting instrument.

Given these findings, the use of disposable surgical instruments for foot and ankle procedures seems to be feasible and prudent. Sterile disposable packs are already the norm for many surgical procedures. This trend is driven by safety concerns, ease of use, lower upfront and replacement cost, and sterile-pack off-the-shelf convenience.3 This article considers the regulatory actions, current practices, and economics associated with re-sterilization/reuse vs. sterile, disposable instruments.

U.S. Regulatory Actions and Trends

The CDC’s Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, included evidence-based recommendations on preferred methods for cleaning, disinfecting and sterilizing patient-care devices.6 Unfortunately, recent exposures and infections occurred despite following manufacturer, CDC, and FDA requirements. The guideline noted that many factors affect the efficacy of disinfection and sterilization, including the number and location of microorganisms, innate resistance of microorganisms, concentration and potency of disinfectants, physical and chemical factors, organic and inorganic matter, duration of exposure, and biofilms.

The FDA is currently phasing in a unique device identification (UDI) system for medical devices.7 The UDI system allows individual devices to be tracked through distribution and use. Traceable instruments may well be next. Instrument-tracking systems are already considered a best practice for hospital central service (CS) departments. For foot and ankle procedures, several companies have begun to supply sterile, traceable implant and instrument sets (Figure 1).

Figure 1. Sterile, traceable screw
Partial protection is no protection at all.

Get full site protection with NEW PrevahexCHX™

PrevahexCHX is the first and only pure chlorhexidine dressing cleared by the FDA complete with antimicrobial protection throughout the transparent areas of the dressing.

**Rapid Onset:** PrevahexCHX demonstrates powerful and consistent antimicrobial efficacy from day 1 through day 7, unlike other antimicrobial dressings which can take up to several days to fully activate.

**Widespread Protection:** Rapid elimination of bacteria and yeasts, both underneath and several millimeters beyond the perimeter of the dressing sample.¹

**Broad Spectrum:** Effective against gram-positive bacteria, gram-negative bacteria, and yeasts commonly present at wound and catheter sites.

¹entrotech life sciences inc. study report no. 13-RP-1025
**Figure 2: SSI costs**

- The majority of AORN respondents (47 percent) estimated the per-case cost of instrument processing to be $600 to $1,000; 30 percent estimated the cost as lower than that (less than $600) and 23 percent as higher (more than $1,000). For orthopedic cases, facilities have long shifted the cost of large inventories to manufacturers, whose reps deliver implants and procedure sets for each case. Of course, the sets must still be sterilized on site, and manufacturers may simply pass the costs on to their customers. By contrast, single-use disposable instruments save more than $400 per case by reducing hospital labor and sterilization costs. Additional inventory savings may come from eliminating lost and obsoleted instruments, which amount to approximately 10 percent of the reusable instruments’ value annually.

The costs of reprocessing pale in comparison to the costs of treating a single SSI. We asked our respondents to estimate the cost (including longer length of stay, additional nursing care, antibiotic treatments, possible readmission and further surgery) for a superficial or deep SSI. Sixty-four percent of those who responded said that a superficial infection would likely cost $10,000 to $50,000, and 50 percent said that treating a deep SSI would cost $51,000 to more than $100,000 (Figure 2). Each year there are approximately 300,000 SSIs in American hospitals, imposing a total cost of approximately 10 billion dollars.15

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These estimates omit any costs arising from liability or lawsuits. Physician groups, such as the American College of Obstetricians and Gynecologists, are concerned about liability, and would like to see studies demonstrating safety, cost-effectiveness, and quality of reprocessed devices. The Association for Professionals in Infection Control and Epidemiology (APIC) warns, “Given the associated unnecessary morbidity and mortality that could be prevented, the suffering that could be eliminated, and the money that could be saved, no healthcare organization can risk ignoring the benefits of effective strategies aimed at preventing hospital-acquired infections.” The APIC guide to eliminating orthopedic SSIs, produced in association with AORN, specifically emphasizes the importance of teamwork in the surgical setting. It also notes that contamination of a sterile item is event-related, and the probability of contamination increases over time and with increased handling and longer storage.

The authors have personally experienced re-used instrument sets presented with incomplete and missing components when they reached the operating room (OR). These missing components cause delays in the surgical case and many times result in the need to open additional sterile sets to complete the original set. A missing instrument can totally disrupt OR efficiency. In the AORN survey, 70 percent estimated that pre-case processing of instruments costs greater than $600. A 2005 study of 100 U.S. hospitals placed average OR charges at $62/minute (range $22 to $133/minute).

The instrument sterilization process takes more than 61 minutes. Given this, a minimum re-sterilization “wait cost” for the OR would be $1,342 ($22 x 61 minutes) with an average minimum cost of $3,782 ($62 x 61 minutes). Instrument availability and reliability are essential to a well-run, cost-effective OR environment.

Sterile Disposable Orthopedic Instruments

Sterile, disposable procedure packs are commonplace for anesthesia, cardiac rhythm, and neuromodulation procedures, but reusable instruments and surgical trays remain the current standard for most orthopedic procedures. Single-use instruments were thought to be too frail to stand up to the heavy demands of orthopedic procedures, where torque set points can range from 0.112 to 11 Nm (more than 100 lb/in). Precision technology that mates surgical stainless steel to engineered polymers challenges that long-held belief. The technology has already proved robust, having been deployed in more than 25 million single-use, torque-limiting instrument sets designed for spine, cardiovascular, and neurological implants. These sets qualify for ISO 13485 standards, FDA approval, and CE mark certification. In the context of sterilization and infection control, single-use disposable orthopedic instruments could also tackle the problem of contaminated reusable instruments and associated hospital-acquired infections.

Global market demand for single-use disposable supplies and equipment expands by more than 6 percent annually. Lower upfront investment and replacement cost, along with procedure-specific orthopedic designs are certain to contribute to the growth of sterile disposable instrument sales. Sturdy construction combined with ergonomic design have resulted in high-quality instruments for extremity (foot/ankle and hand/wrist), spine, and trauma surgeries. Turn-key procedure kits are beginning to pair instruments and implants for even greater efficiency. As mentioned previously, off-the-shelf disposable procedure kits offer hundreds of dollars of savings per case by eliminating processing and re-sterilization costs, increasing OR efficiency through decreased turnaround time, helping to prevent expensive SSIs, and reducing liability risks.

**Conclusion**

Like other medical specialties, a trend is developing in foot and ankle surgery for sterile, traceable implants and instruments. This trend is driven by regulatory, liability, economic, safety and convenience factors. In today’s healthcare environment, safety and economic issues dominate. Manufacturing technology has improved enough to make sterile, disposable instruments a safe, economic benefit to hospital ORs. Sterile, disposable orthopedic instruments stand up to the rigors of surgery, save money by eliminating processing and sterilization costs, can help prevent expensive SSIs, and reduce liability risks.

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References:


“When endoscope damage occurs and repairs are required, you can further safeguard your endoscopes and patient safety by ensuring that repairs are performed by the OEM.”

Flexible endoscope reprocessing continues to be a major focus in infection prevention. To minimize, and ultimately prevent, infection risk, attention is placed on following essential standards and recommendations for flexible endoscope reprocessing: pre-cleaning, leak testing, manual cleaning, visual inspection, high-level disinfection or sterilization, storage and documentation. Beyond the standards for reprocessing procedures is an important factor that is often overlooked in the discussion of flexible endoscope reprocessing—the impact of non-OEM (third-party) repairs on the scopes. It is important to be aware: Once an endoscope is repaired by a third-party repair company, the OEM can no longer validate that the endoscope can be reprocessed as designed.

Reprocessing Validation

Medical device manufacturers validate the reprocessing instructions for their endoscopes in order to prove that, when followed, the instructions result in a device that has been effectively disinfected and is ready for use on subsequent patients. The validated reprocessing protocol typically includes cleaning, disinfection and/or sterilization in order to remove soils and inactivate microorganisms. The hazards of third-party repairs

If an endoscope is repaired by a third-party vendor, the OEM can no longer ensure that the reprocessing validation studies that were performed on the original device are still applicable, even when the instrument’s instructions for use (IFU) are followed precisely.

Here’s why:

♦ The use of after-market (non-OEM) parts and materials for endoscope repairs may affect the device’s material compatibility with reprocessing protocols and chemicals.

♦ An OEM has no oversight of third-party repairs (which are not regulated by the FDA) nor knowledge of the repair parts and materials used by various third-party vendors. Once a scope has been modified by a third-party vendor during the repair process, the OEM can no longer guarantee that the validated reprocessing instructions provided in the manual are still effective.

What to do:

♦ If you choose to use a third-party vendor for endoscope repairs, ask them directly for validation on the repaired device. You need to know if the device continues to be compatible with your facility’s reprocessing methods and chemicals based on the parts, materials and repair processes the vendor uses for repairs. This is the only way to ensure that your facility is following safe and validated reprocessing instructions.

♦ Likewise, contact your automated endoscope reprocessor (AER) manufacturer for usage instructions and reprocessing validation for scopes repaired by third-party companies.

The Case for OEM Repairs

Unlike third-party repair vendors, medical device manufacturers are regulated by the FDA. The FDA requires reprocessing validation data to be submitted by the OEM as part of the 510(k) premarket notification process, ensuring that a device is safe and effective for clinical use. When endoscope damage occurs and repairs are required, you can further safeguard your endoscopes and patient safety by ensuring that repairs are performed by the OEM. Repairs performed by the OEM return the device to its original factory specifications, ensuring the device is still validated for reprocessing.

Melinda Benedict, MS, CIC, CFER, is an industry expert in infection control and endoscope reprocessing. She is a frequent presenter on the importance of endoscope reprocessing training and best practices for preventing endoscope-associated infections. In her work, she liaises with professional societies to improve patient safety and works with endoscope reprocessor and sterilizer manufacturers on validation studies. She currently serves as the senior manager of infection control at Olympus Corporation of the Americas.
Addressing the Misconceptions About Using ISOs for Endoscope Repair

By David Anbari

There are many misconceptions about using independent service organizations (ISOs) for endoscope repair. Perhaps the one with wide-ranging implications is the misconception that using an ISO for service will invalidate the device’s 510K, instructions for use (IFU), or automated endoscope reprocessor (AER) validation.

According to the Food and Drug Administration (FDA)’s guidance, servicing a device without significantly changing its performance, safety or intended use does not require a new 510K. It follows that if the original 501K remains valid, then the device’s original IFU, reprocessing instructions, and AER validation are also unaffected by using an ISO for service. It should come as no surprise that ISOs can provide a high-quality repair. Many ISOs have already adopted and are audited to the internationally recognized ISO 13485 standard for quality manufacturing of medical devices. Although the FDA currently applies its Quality Systems Regulation (21 CFR 820) to original equipment manufacturers (OEMs), ISO 13485 is virtually identical to the FDA’s regulation and requires compliance with all applicable government regulations. In fact, the two standards are so well aligned that the FDA has indicated it will adopt ISO 13485.

Objective evidence proves that hundreds of thousands of flexible scopes are repaired by ISOs without incident. According to an ECRI study of medical device failure data reported to the FDA, less than 0.005 percent of all device failures associated with patient harm had any connection to servicing activity. So, if repairs do not impact reprocessing efficacy, then what factors do? The FDA has researched the factors affecting quality of reprocessing and has concluded that there are three factors unrelated to repairs that impact reprocessing quality: (1) device design; (2) re-processing methodology and (3) methods for validating the cleaning and high-level disinfection and sterilization instructions.

ISOs were born decades ago so healthcare providers had a high-quality alternative to expensive original equipment manufacturer (OEM) repairs. Over time, ISOs have evolved to offer much more than quality repairs at lower prices and faster turnaround time than OEMs. ISOs provide a superior customer experience because of local, focused representatives that can assist with loaners, education, repair prevention and face-to-face customer service. The FDA agrees stating “the continued availability of third-party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system.”

As a device owner, you have a right to service that device as you see fit and a responsibility to ensure that the service activity does not adversely impact the device. We encourage you to ask your ISO for information concerning the quality of their repairs. David Anbari

References:
1. Refer to the FDA’s guidance document titled Deciding When to Submit a 510(k) for a Change to an Existing Device Guidance for Industry and Food and Drug Administration Staff. Available online at: https://www.fda.gov/media/99812/download
2. Refer to the FDA’s document located at https://www.fda.gov/media/123488/download for the specific plans.
3. There are multiple references to the ECRI study’s conclusions in the FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices, which can be accessed at: https://www.fda.gov/media/113431/download
4. Refer to the FDA’s report titled “Factors Affecting Quality of Reprocessing,” which can be accessed at: https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/factors-affecting-quality-reprocessing
5. Refer to the FDA’s report to Congress titled “FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices,” which can be accessed at: https://www.fda.gov/media/113431/download
When it comes to the culture of a hospital, nothing is as important as the employees who work for it and aim to provide excellent patient care. When it comes to a hospital’s balance sheet, particularly the physical assets, nothing is as important as the actual hospital and other ancillary buildings.

Building a brand-new sterile processing department (SPD) is expensive, tedious, time consuming and in most cases, necessary. Central sterile processing departments are an essential piece of not only perioperative services, but the entire hospital. Most reasons for rebuilding or renovating an SPD is most likely because of an aging department, or the need to keep up with competitive market trends and to keep up with operating room (OR) demands. Most often, the reasons for expansion are to keep their facility modern and competitive, and to support a growth in OR case load. A lack of washer disinfectors, case cart washers, sterilizers and even prep and pack and storage locations can all become concerning areas for bottlenecking. SPD will not be able to meet OR demands if SPD does not have the equipment to match. This can possibly cause case delays and patient harm.

Raising Capital

Before hospitals can tackle a project as large as a new SPD, executives must know what capital and financing options that are available to them. Finding the capital is much harder than justifying the need for such a project. Market growth, healthcare insurance, and OR case load are often major factors when justifying capital needs. If OR case load has increased 10 percent over a 10-year span, and SPD hasn’t made any significant equipment or storage additions to its department, it might be time for a rebuild.

Team-Building

When tackling a project of such a large magnitude, selecting a strong project team is essential. A vast array of healthcare professionals and their expertise are needed. Infection control, environmental services, perioperative services, engineering, architects and others all play a tremendous role in assuring a positive outcome. When creating a new SPD, we should also be thinking of how we can improve operations and work-flow. A great way to start the PI process is to either hire a team of experienced healthcare professionals, preferably with a PI background. Or even better, create a team from the facility being rebuilt, including sterile processing techs, surgical techs, nurses, engineering staff, and environmental staff. Ideally, we want to be able to hear the opinions and perspectives of all different professions and departments, each department has a different and valuable outlook on operations.

Forecasting Needs for the Future

One of the more criticized aspects of building a new SPD comes in the form of a question. “How do we know you won’t need to expand more in the future?” When planning for a new SPD, you don’t just plan for the short term — you plan for the long road ahead. This can be accomplished by using forecasting modeling and by analyzing the demand of the future with financial consultants and other stakeholders. For example, identifying growing specialties (such as orthopedics), the demographics and population of the area, and what the competition is doing. Planning for a new SPD means analyzing statistical data for future predictions of demand for every one of the hospital’s provided services, ranging from the OR to the emergency department. This portion of the construction outline can be timely, but the project team must make sure what they are creating now will be relevant in no only the present, but in the future as well.

Central sterile processing departments are an essential piece of not only perioperative services, but the entire hospital.
and Middle East Respiratory Syndrome (MERS) in 2015 highlighted the vulnerabilities around use and supply shortages of disposable respirators. Commentators and industry experts are advising infection control teams to examine their PPE procedures and evaluate new re-useable respiratory protection devices in their preparations to protect staff and contain and manage an imminent public health crisis.

Authoritative.
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THE MANDATE TO MAINTAIN AND FOLLOW MANUFACTURERS’ MAINTENANCE DOCUMENTS AND SERVICE MANUALS

THE ONESOURCE SAFETY AND COMPLIANCE SOLUTION

Evolving Technologies for Decontaminating Healthcare Environments

ROBERT A. GARCIA, BS, MT(ASCP), CIC, FAPIC

SYNOPSIS
Serious geopolitical and social forces are converging to create the conditions, on a scale unique in history, for a major respiratory pandemic.

Recent experience of Severe Acute Respiratory Syndrome (SARS) in 2002 is overwhelming. Infection Control Today is excited to offer these whitepapers designed to help the infection control professional prepare for similar events.

Download and read these whitepapers
InfectionControlToday.com/media-assets
Equipment and Work Flow

Healthcare technology is ever-changing, so the need to stay up to date and current with SPD equipment is necessary. Instrument washer-disinfectors, automatic endoscope reprocessors (AERS), sterilizers, lighting, and assembly tables are all expensive and can vary in options. We need to give SPD staff the proper resources and tools to carry out their duties efficiently. Not only the OR, but the entire hospital relies on SPD to decontaminate, assemble, sterilize, store and deliver instruments and soft goods. Other areas need to be accommodated as well; the SPD is sometimes responsible for decontaminating and storing patient equipment, and restocking code carts and intubation boxes. This calls for even more storage and floor space. This all calls for proper planning and space. For example, a double-sided sterilizer and close-by storage areas are ideal ways of promoting an efficient work-flow. Sterilizers will be loaded from one end, and when the load is complete the other end of the sterilizer will open to the “cool-down” area, or storage area. This helps with decreasing foot traffic and minimizing exposure to dirty air. A one-way work flow from dirty to clean is an obvious must-have for a new SPD.

Staff Morale

The value of morale of staff in SPD is underestimated. When staff come to work in a brand-new facility with advanced technological equipment and machines, they feel better, they might even have an extra pep in their step. It’s a proud feeling that the people in the suits care and have an actual hand in our department. Quality of work can be directly correlated to staff morale and comradery.

There are always specific challenges in implementing a new central sterile processing department. The need for collaboration, coordination and communication involving all levels of stakeholders and is heavily stressed. Regular meetings amongst team members are important to keep the flow of communication and the schedule of completion as updated as possible. There is also a need for communication required so customers understand why a delay may occur.

There are two elements that are helpful to a project’s success.

The first point is that there be up to date references used, best practice standards, peers and experts who are experienced on the same process, and SPD employees including techs and management who know the ins and outs of the operation. Association for the Advancement of Medical Instrumentation (AAMI) ST79 and other standards/manuals from AAMI are designed to assist the design when building and planning. A new manual from AAMI can help healthcare facilities prepare for upcoming construction and renovation projects, as well as plan for equipment purchases, testing and implementation.

Secondly, there should be enough space available to accommodate the expansion of new equipment, which is one of the most important facets of the new construction. Space constraints are often a factor in new construction and is a frequent problem in remodeling projects. Before becoming fully operational, the new department must also pass department of health (DOH) inspections. These inspections can be tedious and long. Therefore, preparation and planning with the design teams are a crucial part of building a new SPD department. The last thing anyone wants is for the DOH inspection to come back with negative reports, or major revisions needed. The design team will most definitely miss some things, or maybe after the project is complete, wish they have done it another way, it won’t be perfect. There are too many moving parts and obstacles to create and build a perfect SPD, however we can sure get close. There are specific documents and forms that need to be submitted to the DOH before construction begins. A Certificate of Need preparation, Certification Letters, Plans Submittal and other documents are required prior to construction. Not only does the DOH visit after the project is complete, but they also visit when the project nears completion. This way, the DOH inspectors can become familiar with the project and become more acquainted with personnel. When the project is coming close to the final stages, a notification is sent to the DOH to request a DOH Sanitarian Inspection. This is to assure the project meets regulations and requirements, especially concerning work safety, but also including infection control, environmental codes and building codes.

When all is said and done, the main purpose for all renovations and rebuilds are to ensure the patients receive high quality care. OR staff and patients will also benefit from a new SPD. With new equipment, efficient storage and work flows, trays will be delivered to the OR faster, with fewer missing instruments and cleaner equipment — all have positive impacts for patient care and safety. That of course is everyone’s main goal.

Quality over quantity for patient care, one tray at a time.

William DeLuca, CRCST, CHL, CIS, is associate director of the sterile processing department at Mount Sinai West.
How do we clean an instrument has always been the question of the day in sterile processing departments all over the world; the answer is to come. The sad truth is, in some instances, the cleaning process was derived from someone in leadership making up a rule. The truth of truths is that those of us in the profession had not one clue as to how an instrument should be cleaned. Somebody taught somebody and that somebody passed it all along to others. Somehow instruments got clean enough for the sterilization process to kill the microbes.

The great news is that we, as a profession, have evolved with the help of guidance and research into our processes. We have learned that the Food and Drug Administration (FDA) has rules that guide manufacturers as to the information needed for our professionals to clean and reach the parameters of sterilization of instruments. Those guidelines are called instructions for use (IFUs) and every medical device has one that must be accessible to the end-users of the product.

The professionals of the sterile processing field must note that every medical device has its own IFUs. In the United States, medical devices cannot be sold until the validation testing required by the FDA shows that the medical device can be effectively cleaned, disinfected, or sterilized in healthcare facilities while following the IFU. The IFU allows sterile processing all over the world to do our job, which is to render the medical device/instrument safe for patient use.

With medical devices/instruments becoming more and more complex in design and the products used to make them require that they are processed according to the IFU. Sterile processing departments (SPDs) are not the manufacturer; therefore they must follow the guidelines as written. The importance of following these guidelines have made their way into the surveys being conducted in hospitals and outpatient centers all over the country. It is no longer acceptable to lean upon your own understanding when cleaning, disinfecting, or sterilizing a medical device/instrument. Surveyors are coming in and requesting that the sterile processing department members can demonstrate their knowledge of the instructions. It is also important that we in the profession understand that patient lives are impacted daily by medical devices/instruments being processed wrong only because the instructions are not followed.

IFUs being followed is a must, as medical devices/instruments are prepared for patient use in minor procedures and surgeries. It is most important that policies guide the use of IFUs in their facilities. Infection Control Prevent list must help the sterile processing department professionals by getting the importance of IFUs through all administrators. Everyone must be made aware that these instructions and the throughput are the keys to a successful hospital program.

Let’s examine a case study which illustrates why IFUs are critical to follow. The importance of an IFU covers all medical devices/instruments so, your robotic arms used every day in surgeries are part of the medical device family. There was a hospital group that used the robotic arms daily, conducting more than 300 cases a month. The IFU provided specific instructions on the cleaning process that was not being followed by any of the hospitals in the group. One main component to the cleaning process that was missing was the sonic machine. Not one of the hospitals had a sonic machine and the sonic process was the third step in the IFU document. Each department did its best to clean without the sonic machine. It was finally called into the corporate compliance office because the sterile processing team member could no longer go along with doing harm.

Everyone must be made aware that these instructions and the throughput are the keys to a successful hospital program.
All hospital programs have an organizational integrity program where they ask the employees to report things that are wrong. We in the profession of sterile processing must understand that we are to do the patient “no harm.” So, after many reports to the Joint Commission, surveyors made a visit to the hospital group and shut down all the hospital robotic case service. This was closed until they had installed sonic machines in the building and they were functioning properly. At the same time, doctors started complaining that their patients were coming in with infections. It was noted that the departments not following the IFUs had a large part to play in a contaminated product being presented to the doctors who performed surgery on the patients. Many of those robotic arms were still contaminated when used on the next patient.

IFU compliance is a must because we impact patients’ lives when the instruments used are contaminated. Patients come into the surgical suite with a medical problem that can be made better with surgery; the instruments used on that case must be processed following the IFU all in the name of patient safety.

It is also very important that the written IFU be accessible to all members of the sterile processing team. ANSI/AAMI ST79:2017 states that the current written IFU should be accessible, reviewed and followed. It is noted that if no specific written IFU is available, the manufacturer should be contacted and requested to provide a documented method of cleaning. [ANSI/AAMI ST79:2017 (7.3)]

As important as it is to follow the IFUs that come with medical devices/instruments, it is just as important the instructions be easily understood, with clear, concise directions at every step. I note that all IFUs are not created equal. Some IFUs are written for the engineers who design the medical devices. There are some that are not clear at all, with just a sentence that says, “clean meticulously.” Sterile processing professionals must decipher what is the right thing to do. This means SPD personnel must call the manufacturer’s technical support department to request the specific IFUs. It means that a medical device/instrument cannot be processed if you have no IFUs. We are called to be conscientious and trustworthy in everything we do, and our integrity should not and cannot be compromised. We can effectively impact a patient’s surgical outcome.

IFUs come in all shapes and sizes; some are well put together, and others are questionable. It is our responsibility to make sure we have these IFUs in hand or on a computer program so that they can be located and read for a clear understanding as to what is required for the medical device/instrument that is being processed. We must also regularly review the IFUs and institutional policies to be sure we are still practicing according to the rules.

For too long it was an accepted practice in the profession of sterilization that if the item was wrapped, and the tape turned black/brown, our job was complete. We now work under new rules and best practices. The item must be cleaned and processed according to the IFUs. We check the process by looking at the external and internal parameters, knowing that if any one of them is a fail, the medical device/instrument must be reprocessed. If a medical device/instrument is processed outside the realm of the IFUs, it should not be used on any patient. Remember, we are to do the patient no harm.

Sharon Greene-Golden, BA, CRCST, CER, SME, FCS, is a consultant for OneSource.

References:


Immediate need for healthcare facilities to review procedures for cleaning, disinfecting, and sterilizing reusable medical devices. Distributed via the CDC Health Alert, Sept. 11, 2015, CDCHAN-00382.

CleanSpace HALO

CleanSpace HALO is a revolution in powered respirator protection. CleanSpace HALO was designed by biomedical engineers for the healthcare sector providing all the protection of a PAPR without bulky belts and hoses. CleanSpace HALO weighs less than 1 pound (400g), runs up to nine hours, and recharges in under two hours. Unlike N95 or other disposables, CleanSpace HALO is completely reusable eliminating the need for stockpiling, making it more economical and environmentally friendly. CleanSpace HALO is NIOSH approved. https://tinyurl.com/cleanspacehalo

Peelaways

Peel Away Labs has created a disposable alternative to traditional laundered bedding offering patients soft, absorbent, multi-layered waterproof sheets, while helping healthcare facilities save money. Peelaways are both a fitted bed sheet and a waterproof mattress protector. Infection neutral, they do not transmit infectious material between layers. Peelaways nonwoven fibers are 32 percent softer and generate less friction than traditional bed sheets. Plus, a micropore waterproof membrane keeps patients cool while protecting the mattress. By simply pulling down the sheet from one corner, a soiled sheet is “peeled away” in seconds to reveal a fresh one underneath. Peelaways has multiple disposable layers. Cardinal Health and McKesson are currently distributing Peelaways sheets to hospitals and long-term care facilities. www.peelawayshealth.com

Glove Box Dispenser

Healthmark Industries Co., Inc. introduces the Glove Box Dispenser for Xtra Long Gloves (16 inches) to its personal protective equipment product line. Manufactured from clear PETG plastic/co-polyester resin, the Glove Box Dispenser is designed for boxed disposable glove storage, made to withstand heavy-duty applications and handling, as well as reduce losses due to breakage. The Glove Box Dispensers are offered in two different styles, a 0.8-pound single dispenser measuring 5.45 inches wide x 16.10 inches high x 2.95 Inches deep that accommodates one box of extended cuff gloves, and a 1.8-pound triple dispenser with dividers measuring 15.70 inches wide x 16.10 inches high x 2.70 inches deep that holds three boxes of extended cuff gloves. The clear design matches any décor and enables an unobstructed view of glove package information. The Glove Box Dispenser is equipped with keyholes for wall mounting, which saves counter space while keeping gloves within easy reach. www.hmark.com or (800) 521-6224

Blanket, Fluid and Combination Warming Cabinets

Getinge announces the launch of a new line of blanket, fluid and combination warming cabinet models, supporting the clinical benefits of intra-operative and post-operative warming to improve patient comfort, satisfaction and outcomes. Cabinets have optional locking doors, so they can be placed in locations convenient to staff while ensuring their contents are not compromised or used without authorization. Cabinet walls and shelves have patented intelligent, multi-zone heating technology that includes multiple foil panels to prevent blankets from overheating. Three independent heating systems and sensors monitor the cabinet temperature to provide evenly-balanced heat. If one heating source fails, the remaining panels compensate for any loss of heat to eliminate downtime while maintenance is scheduled. Additionally, to reduce costs and the need for repairs, the small, standalone blanket-warming cabinets do not incorporate lint-clogging fans or moving parts. The absence of air-circulating fans and lint traps also helps manage potential infection control issues. Each unit is completely enclosed in stainless steel to improve cleanability and help reduce the risk of hospital-acquired infections. All fluid warming units can operate as blanket warmers providing additional capacity if needed. The temperature range (90° to 150°) of the top chamber of Getinge’s combination blanket/ fluid warming cabinet can also be used to heat either blankets or injectable/irrigation fluids. In addition to the blanket, fluid and combination warming cabinets, Getinge has entered into a distribution agreement with Enthermics Medical Systems, for U.S. distribution of the ivNow Modular Fluid Warmer, designed to overcome shortcomings of traditional warming technology of intravenous solution bags. The ivNow Modular Fluid Warmer warms injection, intravenous and irrigation solutions in 30 minutes or less at the point of use. Hospital staff place the IV bag in the pod to activate the unit and automatically warm fluid up to 104°F (40°C). The adjustable temperature of every bag is tracked and recorded throughout the warming process to facilitate compliance with regulatory requirements and reduce waste. After 15 days of continuous warming (user adjustable from 7-60) days, the unit alerts staff to remove and discard the fluid bag. The ivNow Modular Fluid Warmer can be ordered in one, two or three pod configurations, and can be mounted on walls, booths, equipment places or placed on countertops. Each stackable pod operates independently to minimize disruption in the event of failure. www.getinge.com

ChloraPrep™ Skin Preparation with Sterile Solution

ChloraPrep™ skin preparation with sterile solution is the only fully sterile chlorhexidine gluconate (CHG) antiseptic skin preparation commercially available in the U.S. The 2% CHG and 70% IPA formulation is a rapid-acting, persistent, broad-spectrum antiseptic for a wide range of procedures that fights bacteria for at least 48 hours. ChloraPrep™ with sterile solution undergoes a proprietary and patented process to sterilize the antiseptic solution. It will include a mark to indicate that it is sterile. www.bd.com/ChloraPrepSterileSolution
Process Monitoring Toolkit

The Healthcare Laundry Accreditation Council (HLAC) introduces its new HLAC Laundry Process Monitoring Toolkit, which validates the effectiveness of a laundry’s processes by measuring the number of microorganisms found in a laundry on hard surfaces, in the air, on linen, in the water and on employee hands. HLAC is a nonprofit organization that inspects and accredits laundries processing textiles for hospitals, nursing homes and other healthcare facilities. According to HLAC, PMTK is vastly different in scale from anything else currently available in the industry. It employs an extraction technique designed to recover the most accurate representation of contamination on laundry media. With this data in hand, the laundry may adjust accordingly the effectiveness of its overall plant hygiene, wash and hand-hygiene processes.

www.hlacnet.org

EnSURE™ Touch Monitoring System

Hygiena introduces the new EnSURE™ Touch Monitoring System which collects, analyzes and reports data from multiple quality tests such as ATP, microorganisms, and enzymes, providing necessary data for audit and risk management. The EnSURE Touch features a responsive five-inch shatter-proof touch screen that works while wearing gloves; a re-designed user interface that functions like a smartphone and configures to fit any facility or network of facilities; Wi-Fi capabilities and wireless sync technology for secure data transfer to new cloud-based software; collection and storage of important testing data such as room number, line name, cleaner used, and more. The EnSURE Touch is designed with its users in mind. Incorporating key design features and customization options, it is easily setup for industries like food and beverage manufacturing, healthcare, food service, hospitality, and many more. The EnSURE Touch is accompanied by the latest version of Hygiena’s SureTrend Data Analysis Software, SureTrend Cloud. The updated software is available in cloud-based or desktop formats and enables users to monitor, track, and trend testing results across one or multiple facilities, schedule automatic reports, and easily configure one or hundreds of monitoring systems from a single SureTrend account.

www.hygiena.com

Testing for Leak Testers

Healthmark Industries introduces the Leak Tester Tester to its endoscopy product line. Testing your facility’s endoscope leak tester prior to use is a vital and necessary step to ensure leak testing demonstrates accurate results. Designed to validate the accuracy of air pressure provided by automated and handheld endoscope leakage testers, the Leak Tester Tester assists healthcare workers in the reprocessing areas their endoscope leak tester is working properly by testing the functionality of the pump and the connector for leaks prior to using. The Leak Tester Tester assists in reducing the potential for cross-contamination, damage and costly repairs that result from using an endoscope with leaks. Manufactured from stainless steel, the testers come in a package of four or can be purchased separately and are offered for the following leak testers: the Olympus automated leak tester, the Olympus handheld tester, the Pentax handheld tester and the Karl Storz handheld tester. Simply attach the desired leak tester tester to your facilities endoscope leak tester, turn it on or pressurize the bulb, and read the pressure on the gauge, which gives a quick and objective result of the amount of air being expelled from leak testers and air pumps.

www.hmark.com or (800) 521-6224

Micro-Kill Bleach Germicidal Bleach Wipes

For the first time, hospitals and clinics have a tool to combat Candida Auris (C. auris) a multidrug resistant fungus that can cause serious infections in hospitalized patients. Medline today announced the EPA has cleared its Micro-Kill Bleach Germicidal Bleach Wipes to be marketed as killing the fungus on hard, non-porous surfaces. The fungus, which has a mortality rate of 35%, has been shown to linger in healthcare facilities despite efforts to eradicate it with traditional disinfectants. Medline is the first to bring to market a product approved to kill C. auris due to the long-term planning of a team of professionals across different Medline divisions dedicated to improving healthcare infection prevention and minimizing the spread of infectious diseases. After years of development and rigorous testing, EVS associates can now begin using the wipes as part of infection prevention-informed room turnovers and nurses can use them on medical equipment and high-touch surfaces. Combining hand hygiene, decolonization and environmental cleaning with products like Micro-Kill Beach Germicidal Bleach Wipes, Medline helps hospitals, long-term care facilities and other clinics across the country keep their patients and caregivers safe. The ERASE Pathogens program combines all these elements into a holistic program that helps reduce costly and dangerous hospital-acquired and surgical-site infections.

https://www.medline.com/pages/clinical-expertise/infection-prevention/
ATP Complete Contamination Monitoring System

- Verify Cleaning
- Prevent HAI’s
- Enable Guideline Compliance
- Identify Training Opportunities
- Build Teamwork
- Track Cleaning Improvement

Test® InstruSponge for Endoscopes

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Pathogens include: Enterobacter aerogenes, Enterococcus faecalis, VRE (Vancomycin resistant enterococcus), Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus aureus (Methicillin Resistant) (MRSA).

You can’t be everywhere all the time. With the world’s first continuously active disinfectant, now, you can be.

Protect your patients and staff with a unique disinfectant that shields against epidemiologically important pathogens* for up to 24 hours. Just spray and walk away for peace of mind.

Together...We Got This!