ICT | INFECTION CONTROL TODAY

MEDICAL DEVICE REPROCESSING: The Next Steps

The system-wide issues outlined in the seven clarion themes will require the whole healthcare community to work together as a team, AAMI emphasizes. AAMI president Mary Logan says that AAMI's Sterilization Standards Committee leadership is committed to sustaining the momentum from the summit with an action plan for addressing the priorities. At the November 2011 AAMI Sterilization Standards Committee meetings, three new technical information reports were discussed — endoscope reprocessing; standardized cleaning instructions for use; and human factors for device reprocessing — and work on these reports began at task group meetings held in February. AAMI also will convene a small group of stakeholders to review the clarion themes and determine which organizations will take the lead on various issues that cannot be addressed with standards alone.

AAMI'S SEVEN CLARION THEMES

❶ Gain consensus on "how clean is clean" and on adequate cleaning validation protocols for reprocessing reusable medical devices.

❷ Create standardized, clear instructions and repeatable steps for reprocessing whenever possible.

❸ Pay early, iterative, and comprehensive attention to reprocessing requirements throughout the device design process.

❹ Make human factors and work environment factors priorities when developing reprocessing requirements.

❺ Improve information collection and sharing to broaden the use of best practices in reprocessing.

❻ Improve reprocessing competencies by strengthening training, education and certification.

❼ Create a greater sense of urgency and understanding throughout the healthcare community about the consequences of inadequate reprocessing.

We asked individuals working in sterile processing and in the medical device industry to share their insights on these issues and present their insights to further spark dialogue within the infection prevention community.

Our roundtable participants are:

From sterile processing:

- Linda Condon, RN, MBA, CRCST, head, sterile processing department, Johns Hopkins Hospital
- Russell Gilbert, RN, CNOR, CRCST, perioperative/sterile processing educator, surgical services, CoxHealth
- Sue Klacik, CRCST, CHL, FCS, ACE, CSS manager, St. Elizabeth's Healthcare
- Rose Seavey, RN, BS, MBA, CNOR, CRCST, CSPDT, principal, Seavey Healthcare Consulting

From industry:

- Ralph Basile, vice president, Healthmark Industries
- Chuck Hughes, general manager, SPSmedical

ICT: What issues in the seven clarion themes that came out of the summit meeting are the easiest to tackle and the hardest to address, and why?

Ralph Basile: The easiest is to monitor the cleaning process. While there is no clear consensus as to "what is clean," in the real world "clean" means that contaminating soils are removed below the level of detection. There are various methods, including directly testing instruments for residual soils and challenge devices that provide feedback on the performance of cleaning equipment. The most difficult is designing devices that meet the competing masters — performance in use and simplicity in cleaning.

Linda Condon: Of the seven themes, No. 6 is the easiest to address: "Improve reprocessing competencies by strengthening training, education and certification." We are already geared with a lot of training, we just need to continue and make sure that we are capturing the right audience. Of the seven themes, No. 2 is the hardest to address: "Create standardized, clear instructions and repeatable steps for reprocessing whenever possible." Although AAMI has convened a working task group and is in the process of creating an IFU template, this will take a while to develop and spread the word. In addition, what do you do for IFUs that are already out there?

Russell Gilbert: Two of the themes should be relatively easy to tackle. Those are the ones for improvement of information collection and sharing, and the one for improvement of reprocessing competencies through training, education, and certification. It seems like most hospitals that I have communication with are trying to improve their information collection and sharing. They are doing this by increasing the technology that is available to the technicians doing the hands on processing of the instruments. If hospitals and even surgery centers do not have instrument tracking systems in place to help monitor their instruments then it seems that they have a plan in place to implement a system. Some of these instrument tracking systems have added features showing the cleaning instructions

from the IFUs provided by the manufacturer. Many facilities have available for the technicians websites that operate a data base for manufacturer IFUs. AAMI has started its Benchmarking Solutions web-based application which will allow hospitals to compare themselves with other similar hospitals. Improvement of reprocessing competencies are steps that each sterile processing department can accomplish, the technicians that do this job want to be professional. They do try to do things the correct way; it's just that in the past the correct instructions may not have been available to them to use. We as an industry are getting better at disseminating the correct education to our staff. Mandatory certification would be one of the biggest steps forward for instrument processing; I think we will eventually see this happen. Unfortunately it seems that it may end up being driven by bad press images on national TV instead of through the recognition of hard-working individuals. I believe that the hardest summit theme to address is to create standardized, clear instructions and repeatable steps for reprocessing. There are too many wheels in motion that can't be changed, meaning that, for the instruments that are already on the market, their IFUs won't change. Issues that technicians are currently dealing with will stay the same, but we can at this point and from here forward, work with manufacturers to standardize their IFUs.

Chuck Hughes: The easier to tackle of the seven clarion themes are 1, 3, 5, 6 and 7, as these primarily require staff education through sharing knowledge of reprocessing best practices. The other themes require a commitment to resources by medical device manufacturers and healthcare facilities which has long been needed. And while proper reprocessing of reusable medical devices has always been a patient safety issue, it appears that recent media attention has motivated our industry to a have a greater sense of urgency and understanding about the consequences of inadequate reprocessing.

Rose Seavey: None of these is going to be easy. There is no low-hanging fruit in these seven clarion themes, however, as an independent consultant the one that I think I can help tackle is No. 7: "Create a greater sense of urgency and understanding throughout the healthcare community about the consequences of inadequate reprocessing." As I meet, network and lecture to colleagues in the OR, GI, sterile processing, infection prevention, manufacturing, administration, etc. I emphasize that we all have a part in this and we need to get on board and make sure the resources are available and we need to keep reprocessing under the spotlight. The hardest in my opinion will be No. 2: "Create standardized, clear instructions and repeatable steps for reprocessing whenever possible." Right now reprocessing is all over the board, there is no standardized processes, training, education equipment etc. and not enough resources to provide it. We can create standardized policies and procedures, but it leadership in not holding people accountable for following it or if they do not provide enough resources (human and financial) than the policies are only as good as the paper they are written on. ICT

To read the rest of this roundtable, please consult the online version of this medical device reprocessing article when it is posted online at www.infectioncontroltoday.com in late April. A roundtable with responses from medical device manufacturers will also be available online.

Sterile Processing Certification ... DOES IT HAVE VALUE?

By Stephen Kovach

PEOPLE ACROSS THE UNITED STATES now know that hair dressers need some form of certification to do their jobs but if you are cleaning surgical instruments for surgery, unless you live in New Jersey, you are not required by law to have some basic knowledge to do the task at hand – cleaning and sterilizing medical devices in a medical facility.

Within 15 minutes of NBC's Today Show airing the segment, "Today Investigates: Dirty surgical instruments a growing problem in the OR" on Feb. 22, 2012, a close friend called me and asked if it was true that people cleaning instruments are not required to be certified. I said, "Yes it is true." He said, "Steve, that person cleaning the surgical instruments really isn't required by law to have special training?" "Yes that is correct," I told my friend again. He was shocked and said, "Is that what you have been talking about all these years?" and I also replied yes both to the certification and the issue of dirty instruments.

Soon after the call I sent out an alert to many of my fellow central sterile service department (CSSD) professionals to make sure they viewed this segment. My email was titled, "The Tipping Point for Certification is Now." The focus of The Today segment was about the difficulty CSSD staff had cleaning various items, but the end of the segment talked about the need for certification for the staff who works in the "bowels of the hospital." The responses I got back were unbelievable; here are a few of them:

"...I believe that the presidents from both the IAHCSMM and CBSPD need to somehow collectively get a message to the public that there are thousands of competent, educated and caring sterile processing personnel that perform complex processes everyday to assure that their surgical instruments are clean, sterile, and safe for use and that national certification would ensure these processes are always being done..." –Anna Grayson, MS, RN, CRCST, SPD manager

"...I certainly believe that all staff should be certified. However, being certified is only one step. We as managers need to make sure that our staff are competent in what they are doing as well as providing training, education and in-services regularly. I question my follow managers if they are doing that. Certification has to be more than a title..." – Al Spath, SPD manager

"....Management certification is just as important as technician certification. Managers are responsible for getting their staff pay raises. Managers develop competency programs for their staff and make sure they develop staff rather than just used competency programs as a human resource tool... the manager works with administration, OR managers and surgeons to identify and solve problems as well as marketing central service staff. I think without certified mangers we will have frustrated certified technicians...Technician certification is important. A certified technician understands the rational behind what they are doing. This helps them become a critical thinker. There are many situations in which the technician has to make a decision because no support staff is available. It's these situations an educated staff person can make the difference. I do some consulting in ambulatory care facilities now that I'm retired. I tell you from my experience that there is a significant difference in a certified technician from a non certified technician..." – Tony Monaco, healthcare consultant

"Certification allows for a means to standardize a baseline of core education and a basic knowledge base for those performing these complex tasks. It will require continued education.... in order to stay current in a ever changing and evolving field. Without certification, a means to measure a set knowledge base, training and the continuation of misinformation has a greater potential of reaping history over and over." – Michele DeMeo, retired SPD manager

I had felt the tipping point for certification was when Tony Monaco and the many CSSD professionals from New Jersey were successful in passing state certification back in August 2004. I truly believed that all the states would follow, but it has not happened.

So why do I now feel this is the possible "tipping point?" This news report has had an impact on the public that has never happened before. Public awareness usually generates interest of lawmakers. Allied healthcare professionals are discussing the merits of central certification. People across the nation are taking a positive position regarding central service certification. People in general think that certification in the healthcare environment has a purpose and that its purpose is to:

- Enhance quality patient care
- Promote personal satisfaction for those that are certified
- Recognize that CSSD are professionals who have met an accepted level of expertise and demonstrated a standard of knowledge specific to their profession
- Show accountability to the public

With certification comes accountability on the person certified. Their certification does reflect achievement beyond a basic level of knowledge and then demands continued skill and learning development to maintain certification.

Mary Velasco, manager of sterile processing, says, "We need to commit to certification and on-going education for our sterile processing staff. They need to have the knowledge and skills required to produce quality work and ensure that our customers receive clean, sterile and functioning instruments for their surgeries. We are the patients' advocate and we need to assure that they receive the best quality product possible by being educated in what we do."

Requiring certification is a must, but does certification guarantee no mistakes?

There is no certification program in any profession that could ever guarantee that. What certification will do is cut the odds of making a mistake and reduces risk of infection or injury from a reprocessed medical device. Education is the first step in prevention. As many of the comments have stated, certification is not just for the technicians it must be for the director/manager/supervisor of the department as well. The time is now to seize the moment and "get it done" as the saying goes. Why? Not because the public now knows our "dirty little secrets," but because proper patient care demands this level of professionalism.

It is time for all of us to say "I am certified." ICT

Stephen Kovach is director of education at Healthmark Industries.

BEST PRACTICES
to Keep Your Instruments Moist

By Matt Smith

There is nothing more challenging to effective cleaning than receiving instruments in the decontamination area that have dried blood on them. Reducing this concern has always been an issue.

Although it is recognized that contaminated surgical instruments should be cleaned immediately after use, it is observed that this is not always practical. However, dried blood does represent a great challenge to the cleaning of patient-used instruments (AAMI ST 79:2010 7.5.2). Many professional groups recommend that the processing of instruments take place within 30 minutes after the instruments are used in surgery to prevent organic soils from drying. Often device manufacturers instructions also recommend decontamination begin as soon as possible, not just to prevent drying of organics, but also to limit the chance for damage to the instrument.

Keeping instruments or equipment moist is only one of the issues. The other major issue is to safely transport the contaminated sharps. Both the 3rd edition of "The Basics of Sterile Processing" by Sterile Processing University and the "IAHCSMM 7th Edition Central Service Technical Manual" stress that items being transported in a covered, puncture-proof container that is clearly marked with a biohazard label according to OSHA guidelines.

So the issues are safely transporting instruments that are moist and processing them as quickly as possible after use. If you cannot quickly process the items at point of use, you must mark them as a biohazard and try to keep them as moist as possible until they can be properly decontaminated.

How long can an instrument wait after its final surgical use before the cleaning process begins? This wait period could be called decontamination holding time (DHT). The user of the instrument plays a key role in the condition of the instrument based upon how the instrument is sent back (i.e., gross soil still present). Failure to properly prep instruments (i.e., wiping off excess soil with a lint-free towel; taking measures to keep instruments moist during transport) will add time to the process. The fact that DHT could be minutes to hours and even days in some cases, is a concern.

Transporting and keeping instruments moist after use so they can be more easily cleaned involves four factors:

1. Where are instruments used and how are they taken care of at the site of use during and after usage
2. How the instruments are transported to the decontamination area for cleaning in a manor that protects all staff
3. The length of decontamination holding time
4. How the instruments are kept moist

Perkins states in his book, "The Principles and Methods of Sterilization in Health Science" (page 237), "...Instruments must be cleaned as soon as possible after use, to avoid rusting or pitting, and to remove soil before it can dry and harden in the serrations and crevices. If stainless steel instruments are permitted to lie around for several hours before cleaning they may acquire a tarnish, which is difficult to remove…therefore, immediately after use the instruments should be rinsed in cold water…." Staff should not use saline to keep instruments moist because saline can damage instruments. When in doubt about how to keep instruments moist, refer to the instructions for use (IFU) supplied by the manufacturer of the instruments.

There are three common ways to keep instruments moist:

1. Wet towel
2. Spray-on detergent
3. Self-seal pouch with absorbent layer

The placing of a wet cloth over instruments after surgery has been the traditional method of keeping instruments moist. It can be quite effective for relatively short periods of time (say, up to an hour).

Spray-on solutions are typically enzyme or some other protolytic formulations designed to break down blood soil and protein, as well as delay drying of organic soils. These solutions will keep instruments moist longer than the traditional wet towel method, providing moisture for a couple of hours. For the exact recommended duration, check with the solution manufacturer's IFUs. Some facilities have their OR staff spray the instruments before they leave the department for the sterile processing area.

Self-seal pouches with an absorbent layer are manufactured from a low-linting, highly absorbent material sandwiched between two layers of a transparent film. The transparent layers enable observation of the materials kept in the pouch. A specified amount of water is added to the absorbent material and soiled instruments are kept in the pouch, which is then sealed. This creates a humid environment where the instruments remain in a moist state until taken for cleaning. These devices are the optimal choice if an extended time (two or more hours) is needed before instruments can be reprocessed. Studies have demonstrated that instruments in these type of devices will remain moist for up to three days. Of course, the sooner decontamination begins the better and extended storage in a moist environment may not be well tolerated by some instruments. Be sure to consult with the device manufacturer.

Lisa Redfern, central sterile supply manager at Medical Center Hospital, implemented the use of self-seal pouches with an absorbent layer in her department. "By the time surgical instruments were getting to my department, the blood substance would be dry making them more difficult to clean. These specially designed pouches provided more time in order to keep the instruments moist and therefore easier to clean. It has worked out well for us, even other departments in the hospital are starting to use them."

All institutions are unique and follow different processes. For some medical facilities, decontamination holding time may not be an issue. For others, because of the number of surgeries and staffing issues, a longer time frame to begin the cleaning of surgical instruments is a common occurrence. When evaluating your facility's process, you may want to consider some of the options described in this article to improve the cleaning of surgical instruments. ICT

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