Surgical Instrument Instructions for Use Challenges

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Those of us who have been working in Sterile Processing (SP) for multiple years understand the challenges associated with surgical instrument instructions for use (IFU). If you're like me, when you first started in SP, you were assigned a preceptor who was responsible for training you on where things were, how things work and how instruments are reprocessed. Also, if you were like me, you were likely amazed at how someone could retain so much information about everything in the department.

As you began working, you may have asked questions to your preceptor such as, "how do you decipher the reprocessing steps for one tray versus another?" And if you started in the SP world over a decade ago, you likely received an answer along the lines of, "That's just how we've always done it." Nowadays, you might receive an answer similar to, "Our steps are based on the manufacturer's instructions." Nevertheless, at some point, you began looking at IFU either when new instruments arrived or when you had a question about how an instrument should be sterilized. For me, this opened a whole new world of confusion as I began examining the reprocessing instructions for each instrument. I couldn't help but ask: how are SP technicians able to recall the exact reprocessing instructions for a single instrument or, more commonly, a group of instruments? I think back to the huge IFU binders we had, which eventually became online PDF versions on our department's computers. Where do they find the time during their shift to sit down with hundreds of IFU to encode, store the information on each IFU and then be able to accurately recall it?

In some instances, we would have a vendor representative come in and give an inservice on how to reprocess their instruments. More often than not, part of that inservice sounded something like this: "Just process it like you do everything else." However, when looking at the IFU, you might have realized there were differences (such as their instruments couldn't be placed in the ultrasonic or their instrument required a longer exposure time). In other instances, we would receive a quick inservice from the Materials person stating a new instrument "was being added to Doctor X's tray, so make sure not to remove it." As I became more experienced, these processes began to beg this question: *how can we say we're reprocessing instruments correctly if we're listening to reps' suggestion and processing instruments "like we've always done it"?*

Problem 1: Too many IFU

ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities,* states that the device manufacturer's current written IFU should be accessible, reviewed and followed. Per The Joint Commission (TJC), "It is important to understand that each patient care item has its own IFU for cleaning and disinfection, and the expectation is that the organization will follow those instructions. Failure to follow such instructions creates significant risk to safe, quality care."[1]

From a management perspective, when we think about the number of instruments in our departments and the number of IFU associated with those instruments, it can easily become overwhelming to come up with a process to ensure each and every person on our team is following the reprocessing instructions for each instrument in a tray. Consider this: in order to come close to being in compliance with each manufacturer's reprocessing instructions, we would need to pull the IFU for every instrument in a tray, analyze the reprocessing instructions for each instrument and come up with steps that ensure no instrument is improperly processed. Then we must transfer this information to each member of our team in a way that ensures no detail is overlooked. This process would need to be repeated for every unique tray in our department. A medium to large facility could easily have 500 unique trays for which this process would need to be repeated.

It's not uncommon to walk into a decontamination area and see a number of wall posters detailing the cleaning steps for a particular instrument (such as a drill or an endoscope). Obviously,

posting instructions on how to accurately clean each specific tray in your department is not feasible, which means the only other alternative is to either come up with a one-size-fits-all process or have technicians memorize the exact reprocessing details for each tray. But what happens when a surgeon wants to add a few more specialty instruments to the tray and remove other instruments? *Note: "Unique tray" refers to a type of tray and not the copies of those trays. For instance, if you have six copies (or indexes) of a Neuro Dissecting Tray, then this is considered as one unique tray.*

Problem 2: One-time inservicing

It is common practice for SP managers to get their teams together for an inservice that will either be conducted by a representative for the instrument manufacturer or a member of the department's education team. Many times, once the inservice is conducted with all team members, no additional inservices are performed on that instrument/tray until possibly a year later or when a problem arises that requires a reprocessing review with all team members.

The problem with infrequent inservices is that most people forget more than 40% of what was taught to them within the first hour following training and roughly 80% is forgotten by the first month following the training, according to the Forgetting Curve established by Hermann Ebbinghaus.[2] (See Figure 1) If your facility is one that houses more than 500 unique trays, then by the time you've completed reprocessing training on all 500 unique trays, the majority of your team will have forgotten most, if not all, of the detailed information you've taught them, depending on how long it takes to cover all trays in your inventory.

Now, for the good news: to combat the Forgetting Curve, Ebbinghaus discovered

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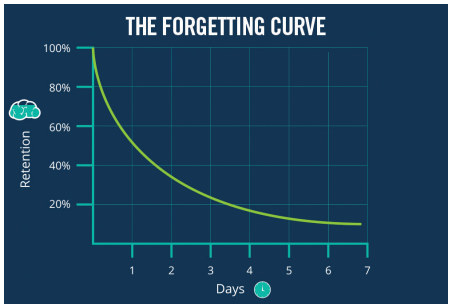

Figure 1

that information could be better retained through spaced repetition. That means that once training is completed, technicians will have a greater chance of storing the information in their long-term memory if the information is reviewed at certain intervals, beginning shortly after the initial training session. Figure 2 illustrates how if the training information is reviewed at the spaced intervals, then the amount of decline of the Forgetting Curve lessens. With this in mind, in order for an inservice to be effective (meaning your team remembers all of the details associated with that training) then it would be best to review the information covered in the training session multiple times at spaced intervals. But where do we find the time to do this?

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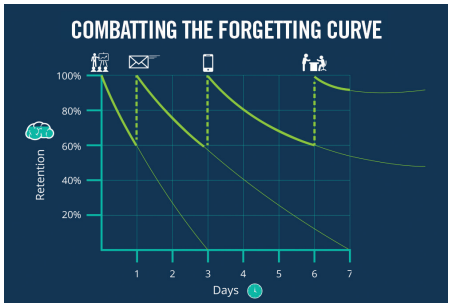

Figure 2

Problem 3: Employee turnover

In a world of competition, self-improvement and accountability, every department is bound to face some level of turnover. SP technicians leave for a number of different reasons, including being offered a higher salary by a competing facility or due to their completion of secondary education. No matter the reason, their departure now creates a position that must be filled – and with that, training on all of the processes in your facility must be performed once again. Now, in order to ensure compliance with the reprocessing instructions for all instruments in your department, this new team member must be trained on how to reprocess each of the unique trays in your facility. Per TJC, "Because of the complexities associated with use of equipment and devices, leadership is responsible to ensure that IFU are available and used by staff to ensure consistency among all staff involved in these processes. Compliance with IFU should also be an integral part of initial and ongoing staff education, policy/procedure development, and training/competency assessments."[3]

Problem 4: Too little time

Many SP professionals across the country can relate to the challenges associated with ensuring all surgical cases have what is needed for the current and following day's schedule. Add to that the occasional monkey wrench that is thrown in with equipment malfunctions, call-outs, missing instruments, and contaminated trays requiring quick turnover and it's easy to see how difficult it can be to find the necessary amount of time to devote to staff training and memorization of IFU.

Intelligence software as a solution

Think of all the things that have come along to make our lives easier over the past couple decades. Smartphones have eliminated the need for things like compact disk organizers and paper maps with the inclusion of iPods and Global Positioning Systems. Skype came

along and allowed us to see the person we're communicating with, regardless of distance. And with flash drives, we've gone from storing around 1.44MB of data to a floppy disk to storing up to 2TB of data on a device the size of a pinky finger.

Fortunately, recent technological advances, such as the development of decontamination intelligence software solutions, have made it so SP professionals no longer need to spend hours memorizing large amounts of extremely detailed information within IFU. Decontamination intelligence software eliminates the tedious task of looking up each and every instrument to put together a cleaning process and it also streamlines the training process. Lastly, it eliminates the need for wall posters and spaced repetition training. Having a system in place that takes care of the grunt work allows the technician to focus on their tasks and remain compliant with industry best practices, which in the end, provides the greatest benefit to the patient.

REFERENCES

1. The Joint Commission. Manufacturers' Instructions for Use - Expectations Regarding Access to IFU for Medical Instruments and Devices. Standards FAQs. Nov. 14, 2019.
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3. The Joint Commission. Manufacturers' Instructions for Use - Responsibility for Ensuring Availability. Standards FAQs. Nov. 22, 2019.

JEREMY CRISS, CBSPT, CSPM, serves as Chief Operating Officer for Petriss Sterilization Intelligence. Petriss offers the BLUEfin Sterilization Intelligence platform, which provides real-time IFU guidance for every tray, instrument and manufacturer, 24/7. BLUEfin calculates, communicates and documents all steps for all IFU to improve patient care and drive regulatory compliance.