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Close enough isn’t good enough for high-level disinfection: Part 1

Despite the danger to patients and repeated citations from CMS and other accreditors, many healthcare organizations still struggle to properly perform high-level disinfection (HLD) of medical equipment, says **Rachelle Babin, MBA, BSN, RN, CEC, CMMT,** certified executive coach and consultant at Rachelle Babin Leadership. Human error, missed cleaning steps, or unfollowed manufacturer’s instructions for use (IFU) can all lead to a patient having a contaminated medical device used on or inside them, causing infection and possibly death.

HLD is the complete elimination of all microorganisms except for a small number of bacterial spores, and is used on devices such as endoscopes and ultrasonic probes. Since these medical devices are reused on multiple patients, HLD is critical for preventing the spread of hospital-acquired infections and antimicrobial-resistant disease.

“The number one, top-cited standard in hospitals, ambulatory, critical access, and office-based surgeries is IC.02.02.01, related to high-level disinfection and sterilization practices. The number of citations tells us that this is an ongoing problem,” Babin says.

To understand the risk, one only needs to look back to 2015, when it was discovered that a mechanical flaw in duodenoscopes from multiple companies meant it was physically impossible to perform HLD or reprocess them. Manufacturers Olympus and Fujifilm covered up the problem for years, during which healthcare providers used scopes on patients that they believed had gone through HLD. This resulted in over 25 infection outbreaks, many involving Carbapenem-resistant *Enterobacteriaceae*.

We spoke with Babin about the challenges in performing HLD and best practices for ensuring the devices used on patients are disinfected. Tune in next week for Part 2 of this interview.

PSMJ: What is HLD, and what makes it different from sterilization?

Babin: If you're thinking about it from a regulatory perspective, HLD and sterilization fall within the same bucket in infection control. But they're two very different things.

It's important for folks to think about HLD as getting rid of as many microorganisms as possible, but it still leaves some bacteria—versus sterilization, [which] eliminates all of the bacteria. It has to do with temperature, the cleaning process, and how long it takes. They both follow two different trees. Both are vital, but they’re two very separate things.

HLD is a huge problem and so is sterilization, but sterilization is its own topic. They've ranked number one in findings for many, many years but for two very different reasons.

PSMJ: Can you elaborate on some of the trouble that healthcare organizations are having with HLD? Does a specific type of medical facility or device present the most issues with it?

Babin: Any manual process will have variation. It’s the job of organizations, leaders, and infection preventionists to decrease variations as much as possible, which can be done through streamlining processes, training, and education. If you’ve ever been to an endoscopy department or ENT clinic, they are bustling. Efficiency is of utmost importance without cutting corners. This is when we miss steps. I’ve been in different clinics and an HLD procedure is incomplete, [but] the staff must immediately go to another room to assist the doctor in another procedure. Now we have an item sitting and waiting for processing, which leads to organic debris drying.

I'm seeing it at a lot of hospitals. Take ambulatory surgery centers off the table, because they're a different animal and they don't have as many issues with this. But the hospitals, critical access hospitals, and even ambulatory care, those are where you see the findings come in. The number one finding of infection control, I think, is Joint Commission standard IC.02.02.01. You see it cited over and over and over again.

Here's where I see the biggest problems. There are manual processes that must occur, and it's in those processes where I see the most issues because they're people-dependent. Anytime there's a manual process, that means somebody's hands are having to touch something.

When you look at HLD and even sterilization, the first piece of the process is to wipe that instrument off. I like to use endoscopy scopes as an example. Once that procedure is done, immediately following that, you have to wipe that piece of equipment down. You've got to take debris off of that. Where people will get cited is because if I'm the nurse, the doctors finish this procedure, then I've got to go immediately to this next room or another procedure. Well, now I've got debris that is sitting on the scope or some piece of equipment and allowed to dry. That in and of itself is pretty significant if we don't want bacteria to proliferate. We don't want things to dry on the equipment. That first step is where I see a lot of people fall out, and it's a critical first step, so that's the big piece.

Once you get that wipe down, you must transport it to a room and there's still a big manual process that needs to happen. In that process, you have to fill the basin with water. You have to make sure there's the right ratio of disinfectant for a certain amount of time. But within that, you also need to brush out different lumens. I see folks getting cited for not brushing the lumens out, or they're not brushing them out long enough. They're not flushing the things they need to flush. That’s another area that's a really big deal.

Then you have the environment of care. When you are doing HLD, you start cleaning the equipment on the dirty side of your environment, then move over to your clean side after. Both those areas have to be separated. I've been in organizations where they built a whole new area in their facility, but they don't have separation of those two sides. And that's obviously very costly if you have a whole room that wasn't built up to spec and the right standards.

I was in a facility with a passthrough window, where you're passing these scopes from this dirty area to the clean area. Imagine a drive-through window that goes up and down. Well, the window didn't work, it didn't close all the way, so you had this constant cross-contamination.

Your environment of care also must be up to the regulations, which goes beyond the manual human piece of it.

There's a piece of equipment that does HLD of scopes: the automated endoscope reprocessor, which washes and circulates disinfectants in and around the scope, removing residues. That's great; we love to have automated processes. But we still need someone to run the machine; we still need someone to do quality checks and to make sure everything was loaded appropriately, went through the whole cycle, those types of things. Automated machines are awesome, but there's still human things that need to happen in there.

Once that's done, then we have a whole other process of drying and hanging. Then we need to store them correctly in a cabinet, with space between, HEPA filter, no dust, cleaning weekly or per IFU.

If you think of the Swiss cheese theory, there's so many potential holes to line up and so many steps that could be missed, forgotten corners that are cut. Once you introduce humans into something, it's not because they want to mess up. No one wakes up saying, “I think I'll harm somebody today or not do my job.” Usually something gets in the way of the process.

I’m saying a lot there, but I think that's part of the issue. It's because there's so many parts and pieces to it that there's a lot of potential failure points.