You're Not Doing What You Think: The Myth of Instrument-To-Patient Tracking

How do you know which surgical instruments were used on which patients? Why is that even important in the first place? Let’s just imagine that no regulatory guidelines or industry recommendations existed related to the tracking of surgical instrument to patients. What does transparency in the reprocessing life cycle of surgical instrumentation actually give us, why should we want to do it, and why do I think very few of us are actually doing what we think we are doing?

Good for Something
Although Creutzfeldt-Jakob disease (CJD), the universally fatal brain disorder believed to be caused by prions, was undoubtedly the impetus for industrywide acceptance that instrument-to-patient (ItP) tracking is a good thing, a number of other reasons exist for why this concept is critical to the future of our industry.

The broader need for inventory tracking and transparency that is tied to patient use relates to infection control practices in general. We have seen first hand that CJD is not the only danger lurking inside our instrumentation, and superbugs such as Carbapenem-resistant enterobacteriaceae were another reminder that this level of tracking is a non-negotiable.

The massive legal implications involved also are an ancillary part of this discussion. Healthcare facilities must prove that their infection control practices are taking all necessary precautions to protect patients and guard their processes against cross-contamination of surgical instruments.

A final impact of ItP tracking is the ability for hospitals to quickly and consistently identify trends in surgical instrument quality, product failures, and user noncompliance. Without the transparency of this process, instruments that were nonfunctional in one procedure could very well end up being used in another procedure.

The Old College Try
So, what kind of tracking actually is going on in the vast majority of our facilities (or at least the ones with some type of automated instrument tracking system in place)? The truth is, what many of us consider ItP tracking would be better described as "tracking of instruments to a general area where we intended the tray to be used but cannot be sure with any measurable range of confidence that they were used in that area."

Some readers may already be taking slight (professional) offense and retorting, “But, we scan to case carts! We scan to rooms! We even have surgery schedule integrations with our tracking systems!” And to that, I say, “More power to you.” Good work. But as good as those things may be (and they are really good), they are not true ItP tracking, or at the very least, they are not enough.

One Widget to Rule Them All
One of the central challenges to the existing conceptions of ItP tracking is the reality of instrument migration, both intentional and unintentional. Simply put, surgical instruments don’t stay put. Just because you sent a curved Kelly clamp upstairs in a major basic tray does not mean it will come back in the same tray—or even come back at all. In fact, just because you built a case cart for a particular physician/procedure/patient with all the related scanning does not ensure those instruments were not pillaged for a last-minute add-on procedure in another operating room (OR) suite, with another patient and procedure. It also does not mean that those were the only instruments used or that the case was not supplemented by additional untracked peel packs or emergency trays.

This leaves sterile processing with only one practical option for bona fide ItP tracking: Each surgical instrument must have its own, unique, traceable, surgical life cycle history—no exceptions. Yes, that means every instrument, from your number 3 knife handles to your $90,000 flexible...
endoscopes. In this context, not all 12-inch Mayo-Hegar needle holders would be created equal. Here’s an example, using three unique needle holders, of the granularity required by real ITP tracking:

   i) Patient occurrence 7/1/2018, case ID 435365
   ii) Patient occurrence 7/13/2018, case ID 808587
   iii) Patient occurrence 7/29/2018, case ID 983728

   i) Patient occurrence 7/4/2018, case ID 435322
   ii) Patient occurrence 7/17/2018, case ID 808537
   iii) Patient occurrence 7/30/2018, case ID 983799

3. 12-inch Mayo-Hegar needle holder (instrument no. 982897208954452386; purchased 7/12/2015, last repaired 5/17/2016).
   i) Patient occurrence 7/11/2018, case ID 435154
   ii) Patient occurrence 7/15/2018, case ID 808264
   iii) Patient occurrence 7/22/2018, case ID 983877

This type of information is necessary to make true ITP tracking possible, but even then, technologies must come into play to prepare the way.

**Tracked, Traced, and Tied**

To make all of this work, our industry will need to engage three primary concepts concurrently:

1. **The ability to identify and track unique instruments within surgical trays and as individual units.** Currently, this can be accomplished via data matrix barcoding or radio-frequency identification (RFID) technology placed upon individual surgical instruments.

2. **The ability to validate, and process of validating, all instruments used within a surgical procedure.** This would require point-of-use scanning of data matrix barcodes or RFID usage tracking within the OR suite.

3. **The ability to link/tie patient-specific surgical site infection (SSI) data with the patient occurrence data of surgical instruments.** This would be postoperative data that flowed back into our tracking systems to connect and trend occurrence of SSIs linked to unique surgical instruments.

The recent work toward instrument-level scanning in sterile processing is undoubtedly a huge step in the right direction for true ITP tracking, but it is still only a partial step. Both our technology and our processes must account for the invisible nature of intentional instrument migration (such as replacing missing/broken instruments during assembly or using instrument sets originally built for other cases or for emergency back-up purposes), as well as account for unintentional instrument migration (such as mixing up instruments in their trays after a surgical case or during the decontamination process).

These situational realities undercut how we use the vast majority of existing tracking solutions in the market today, and without access to pertinent SSI data, the current value of our tracking systems to proactively affect patient-specific care leaves much to be desired. Is our industry safer than it was yesterday? Absolutely. But will we be safer tomorrow? That is the question.