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Innovations from Industry

Driving Innovation: A Transportation Methodology to Support the Transition of Orthopaedic Surgery from Acute to Ambulatory Care

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Using innovation to get instruments into the surgeons' hands efficiently and effectively is needed for future success in orthopaedics. As the United States healthcare delivery system trends toward provision of more-cost-effective care by moving from inpatient to ambulatory settings, it is fully expected that within the next five years we will see all musculoskeletal-related procedures and services be removed from the inpatient-only list, with corresponding support of outpatient funding in the outpatient setting when clinically appropriate ("Fact Sheet CY 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS-1736-FC)" 2020). In light of that projection, there are opportunities to invite innovation into the way we deliver surgery and improve the process for the manufacturer, the surgeon and ultimately the patient.

It is established that on many fronts this transition presents significant challenges specifically related to logistics and resources. Most critical in this process is a robust and coordinated sterile processing department. While sterile processing departments are an essential function within perioperative services, challenges of adequate space, stringent facility requirements, resources and capital constraints limit the ability of ambulatory surgery centers to support projected increased demand for surgery. As more surgeries move to the ambulatory setting, how do we support the increase safely, efficiently, and effectively? Accreditation surveys suggest that ambulatory surgery centers are challenged to meet standards and sterile processing guidelines, creating a potential for patient safety issues.

Logistics and resource challenges as highlighted in Figure 1 can be even more problematic within the orthopaedic specialties. In particular, stand-alone ambulatory surgery centers, unlike hospitals, are not open all hours of the day to accommodate implant and instrument deliveries before or after the normal workday. Surgery centers do not have the space to provide manufacturers a permanent on-site storage option, and in many cases, they don't even have the space to stage deliveries made two and three days ahead of surgery. A significant volume shift from inpatient to outpatient poses complex risks for the accordant demand upon sterile processing support services in ambulatory settings. These risks are exacerbated by this heightened need for high-value, complex orthopaedic loaner trays in the outpatient setting.

Loaner instruments are currently being shuttled at all hours between provider locations by implant manufacturer sales representatives, and at great personal expense. Because of these and other factors, we have seen a few health care systems embrace Western Europe's widespread use of a centrally located off-site sterile processing facility that serves multiple end points. From a business perspective, this approach makes sense.

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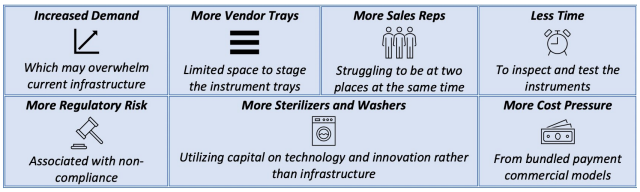

Figure 1.

The centralized approach delivers cost, energy and space savings through the sharing of capital equipment and the pooling of critical mass. In addition, cost and quality objectives are easiest to deliver by focusing operations management and highly trained staff on one location, rather than trying to reproduce that level of competency in multiple sites. That said, infection prevention and control continue to remain a concern, even with the move to a centralized sterile processing strategy.

While there are guidelines that provide a baseline for transporting soiled instruments to a sterile processing department within a hospital or healthcare facility, there is little or no clear regulatory guidance for the transportation of soiled or sterile instruments between organizations. Today there are three organizations who are working to advance guidance for transport of instruments: the Association for the Advancement of Medical Instrumentation (AAMI) ("Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, Standard ST79" 2017; Greene et al. 1987), the Association of periOperative Registered Nurses (AORN) ("Guideline for Cleaning and Care of Surgical Instruments" 2018), and the Occupational Safety and Health Administration (OSHA) (*Occupational Safety and Health Administration, Standards Interpretation: Transporting Contaminated Surgical Instruments for Cleaning* 2013).

This article explores the implementation and use of an innovative just-in-time transportation system that enables consistent and reliable processing and transportation of sterile as well as soiled instrumentation. This system minimizes last-minute tray processing under duress caused by equipment capacity constraints and the unavailability of vendor instruments. It allows the manufacturer's representative to get out of the delivery business and focus on the needs of the orthopaedic surgeon. Lastly, it enables sterility assurance during transport for the shared utility built to deliver the cost and quality needs of inpatient and outpatient points of care.

Current requirements exist for facility-based transport. We can expand on that knowledge to build a consistent, safe and reliable process that supports patient care. The care should be consistent regardless of the location. That same principle applies to sterile processing and the delivery and retrieval of both sterile and soiled instruments. While this article isn't intended to address the facility requirements, it is important to note that any instrument transport strategy should be comparable to the guidelines outlined in Figure 2.

The optimal mode of transportation requires a number of important considerations. First, there must be clear direction for the segregation of clean, sterile and soiled medical devices. Less obvious but equally significant is environmental monitoring during transport. When the internal environmental requirements issued by American Society of Heating, Refrigerator and Air Conditioning Engineers (ASHRAE) for sterile processing ("Ventilation of Healthcare Facilities" 2017) are reviewed, it appears that the environment can have a significant impact on the medical devices. Temperature and humidity may have an impact on the sterile instrument tray being transported. Consideration should be given to creating a similar environment for transport and monitoring to ensure that the environment it supports the protection of the sterile instrument trays. Using a risk-based approach allows for the identification of the potential environmental and other factors that may potentially compromise the integrity of the devices being transported.

Included in Figure 3: the primary considerations (*Occupational Safety and Health Administration, Standards Interpretation: Transporting Contaminated Surgical Instruments for Cleaning* 2013; "Guideline for Cleaning and Care of Surgical Instruments" 2018; "Ventilation of Healthcare Facilities" 2017; "Standards of Practice for the Decontamination of Surgical Instruments Standard of Practice" 2009; Greene et al. 1987; "Sterilizing Practices Guideline for Disinfection and Sterilization in Healthcare Facilities, Centers for Disease Control and Prevention" 2008; "Design and Handling of Surgical Instrument Transport Cases: A Guide on Health and Safety Standards 2018" 2018) for the design of a consistent, reliable, safe, and compliant transportation process. In order to protect the cargo and preserve the sterility assurance, care needs to be taken to assess each of these considerations in the modality of transport. It is important to assess and understand what is being transported (criticality), the radius of transportation (duration), and any factors that may impact safety, environmental control, stability, and infection prevention and control.

Given the income derived from surgical procedures, there are financial considerations for both the orthopaedic surgeon and the manufacturer as these high value elective surgeries often require the highest number of complex and expensive surgical instruments. Due to the expense, these show up to the ambulatory surgical center in the form of loaner instrument trays. Generally speaking, these trays are (a) transported by a manufacturer sales representative to each healthcare facility mostly clean but not sterile, (b) processed by the individual healthcare facility before and after surgery, but (c) not put back into circulation until the sales representative recovers them and is able to initiate the next cycle. In short, centralized processing of orthopaedic instruments currently depends on two sales representative transportation events not supported by the protocols being described in this article and not focused on optimizing the use of the instruments or the expertise of the sales representative.

This process poses delays on both ends, thereby limiting the number of times that a high value surgical tray can be put to use. Industry's reliance on a sales representative for transportation injects unproductive time losses which end up placing unwarranted time pressure on the technicians

Figure 2.

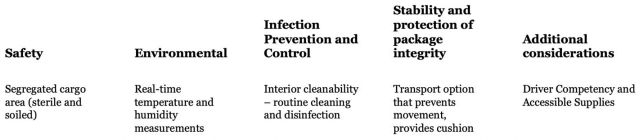

Figure 3.

who perform critical pre-sterilization instrument inspections. This time loss makes it even more difficult to make time for functional instrument tests and calibration procedures. Through the centralization of processing, forecasting and alignment of future orders, and just in time transportation of sterile instrument trays, paired with the timely retrieval of soiled instrument trays, the utilization of the instrument tray can be doubled if not tripled, yielding very sizeable cost reductions for the manufacturer. The increase in utilization of the surgical instrument trays will result in the ability to schedule additional surgeries which means additional revenue for the surgeon. While the cost savings and revenue generating opportunities are significant, there are also opportunities for improving sterile processing as well as the full surgical experience.

In order to get in front of the pivot from inpatient to the ambulatory setting, there is a definite need for innovation to ensure that cost-effective, quality care will continue to be a priority. As demonstrated in this article, the implementation and use of a consistent and reliable transportation methodology that allows for the preservation of the sterile status of the surgical instrumentation while supporting the needs of multiple inpatient and outpatient settings would address significant logistical and capacity issues that healthcare providers are facing today.

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