A Business Process Management Approach to Surgical Instrument/Device Reprocessing and Tracking

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Abstract

This study examines business process management practices applied to monitor, measure, and improve reusable surgical instrument/device reprocessing and instrument-to-patient tracking within the hospital environment. This paper identifies how dynamic technological activities of analysis, evaluation, and synthesis applied to internal and external organizational data can highlight complex relationships within integrated hospital processes to target opportunities for improvement and ultimately yield improved process capabilities. The identification of existing limitations, potential capabilities, and the subsequent contextual understanding are contributing factors that yield measured improvement within a hospital’s perioperative process. This case study investigates the impact of integrated information systems to identify, qualify, and quantify perioperative improvement within efficient and effective instrument/device reprocessing and tracking, based on a 142-month longitudinal study of a large, 1,046 registered-bed teaching hospital. The theoretical and practical implications and/or limitations of this study’s results are also discussed with respect to practitioners and researchers alike.

1. Introduction

A hospital’s perioperative process provides surgical care for outpatients and inpatients during preoperative, intra-operative, and post-operative activities. The perioperative process yields patient end-state goals: (1) a patient undergoes a surgical procedure; (2) minimal exacerbation of existing disorders; (3) avoidance of new morbidities; and (4) subsequent prompt procedure recovery [45]. Accordingly, the perioperative sub-processes (e.g. preoperative, intra-operative, and post-operative activities) are sequential where each activity sequence paces the efficiency and effectiveness of subsequent activities.

The perioperative process is tightly coupled to patient safety, patient quality of care, patient flow, and stakeholders’ satisfaction (i.e. patient, physician/surgeon, nurse, perioperative staff, and hospital administration). Consequently, the efficient and effective reprocessing (e.g. transportation, cleaning, disinfection, drying, inspection, wrapping, sterilizing, and storage) of modern re-usable medical devices and surgical instruments within perioperative sub-processes must support patient end-state goals and avoid healthcare-associated-infection (HAI) (e.g. nosocomial or surgical site infections). Unfortunately, incidents at regional and academic medical centers across the United States demonstrate perioperative HAI attributable to ineffective surgical instrument/device reprocessing. A few of the more recent incidents demonstrate contaminated instruments/devices used in non-invasive procedures [18], invasive procedures [15], as well as contaminated medical equipment (e.g. cardiopulmonary perfusion) due to the use of contaminated water [22].

The reprocessing of reusable surgical instruments/devices is a core perioperative sub-process that involves many steps and is driven by regulations, manufacturers’ instructions, standards, guidelines, and best practices [44]. Intricate modern instruments/devices have revolutionized non-invasive surgical procedures, but the innovations have proven difficult to clean and sterilize [19]. Ineffective instrument/device reprocessing can yield devastating consequences to patient safety.

This case study identifies complex dynamics within the perioperative process, nested in the hospital environment. This research investigates traditional business process management (BPM) practices applied to surgical instrument/device reprocessing. This study highlights re-useable surgical instrument/device workflow, reprocessing, and tracking. The investigation method covers a longitudinal study of an integrated clinical scheduling information system (CSIS) as well as an instrument/device tracking information system (ITIS) within an academic medical center. The implementation of agile, integrated information systems (IS) and subsequent contextual understanding of perioperative process data and its sub-processes prescribed opportunity for measured improvements. Specifically, managing surgical instrument/device workflow, reprocessing, inventory turns, and utilization, grounded in internal and external best-practices, provide the framework for targeting opportunities and evoking improvement. The assessment, development, and implementation of surgical instrument-to-patient tracking also provide change dynamics for evaluation and improvement to the overall perioperative process.
The following sections review previous literature on BPM, key performance indicators (KPIs), and instrument/device reprocessing guidance. Following the literature review, we present our methodology, case study background, observed effects and discussion. By identifying a holistic framework for analysis, evaluation, and synthesis of end-to-end process measures with established benchmarks, this paper prescribes an a priori environment to support effective and efficient surgical instrument/device reprocessing, instrument-to-patient tracking, and perioperative workflow improvement. The conclusion also addresses study implications and limitations.

2. Literature Review

Integrated information systems (IS) offer continuity through information sharing, synergy, and improvement [26]. Likewise, integrated IS and information technology (IT) provide measurement and subsequent accountability for healthcare quality and cost, creating a dichotomy (e.g., quality versus cost) that represents the foundation for healthcare improvement [11]. Within the perioperative process, patient end-state goals [45] are the focus of work. However, United States hospitals currently face increasing pressure to provide objective evidence of organizational quality, efficiency, and effectiveness [6, 27]. The American Recovery and Reinvestment Act of 2009, the Joint Commission on Accreditation of Healthcare Organizations (JTC), and Centers for Medicare & Medicaid Services (CMS) require performance reporting and clinical outcomes improvement. These performance challenges require leveraging IS and IT to meet these requirements, especially in academic medical centers [35]. To this end, a BPM approach [24, 32] borrowed from the manufacturing industry provides a framework to target and measure improvement.

Financially, the perioperative process is typically the primary source of hospital admissions, averaging between 55 to 65 percent of overall hospital margins [34]. Other research shows 49 percent of total hospital costs are variable, with the largest cost (e.g., 33%) being the perioperative process [28]. Similarly, perioperative supplies and equipment can account for more than 50 percent of a hospital’s inventory assets and costs, yet the healthcare industry only allocates approximately 21 percent of its total costs to supplies when compared to manufacturing that allocates 50 to 70 percent [10]. Managing and improving a cost effective perioperative process is a critical success factor (CSF) for any hospital [29]. Likewise, managing and improving effective instrument/device reprocessing is a perioperative CSF. To meet these demands, administrators and medical professionals must focus technology-enhanced practices that yield high quality of care and patient safety, coupled with increased efficiency and cost effectiveness. Measured utilization of these practices is not a result from any lack of research as an extensive body of knowledge exists concerning the application of these approaches in healthcare [2, 6, 9, 23, 30]. However, the literature suggests that such management practices and interventions can yield positive results with significant variations in implementation success.

2.1 Business Process Management (BPM)

Continuous process improvement (CPI) is a systematic approach toward understanding the process capability, the customer’s needs, and the source of observed variation. Tenner and DeToro [46] views CPI as an organizational response to an acute crisis, a chronic problem, and/or an internal driver. CPI encourages bottom-up communication at the day-to-day operations level and requires process data comparisons to control metrics. Incremental improvement gains occur via iterative cycles of analysis, evaluation, and synthesis or plan-do-study-act [49] to minimize observed variation. Doubt can exist as to: whether the incremental improvement addresses symptoms versus causes; whether the improvement effort is sustainable year after year; and/or whether management is in control of the process [24].

This study uses the BPM definition provided by Jeston and Nelis [24, p. 10] as “the achievement of an organization’s objectives through the improvement, management, and control of essential business processes.” The authors further elaborate that process management and analysis is integral to BPM, where there is no finish line for improvement. Hence, this study views BPM as an organizational commitment to consistent and iterative business process performance improvement that meets organizational objectives. Business analytics within BPM focus on the effective use of organizational data and information to drive positive business action [46]. The effective use of business analytics demands knowledge and skills from subject matter experts and knowledge workers. Similarly, Wears and Berg [51] concur that IS and/or IT only yield high-quality healthcare when the use patterns are tailored to knowledge workers and their environment.

2.2 Key Performance Indicators (KPIs)

Information about performance before and after intervention is an integral part of CPI. Likewise, performance metrics are essential requirements for CPI and purposeful BPM. Early in the IT literature, Ackoff [1] proposed IS design to include feedback control to avoid management misinformation. Consequently, organizations define data metrics as KPIs to assist
management in monitoring CSFs for organizational action (i.e. business processes) [31, 36, 55]. Doubt exists as to whether perioperative management can meet the demands for cost effectiveness [7], in part due to perioperative process complexity [20].

Operating room (OR) schedules are tightly coupled to an individual OR suite, patient, and surgeon. When preoperative tasks are incomplete or surgical supplies/instruments/devices are not readily available at time of surgery, the scheduled case is delayed as well as the subsequent scheduled cases in the particular OR suite or for the particular surgeon. Operational and tactical KPIs in managing and optimizing a hospital’s perioperative process include: (1) monitoring the percentage of surgical cases that start on-time (OTS), (2) OR turn-around time (TAT) between cases, (3) OR suite utilization (UTIL), and (4) labor hours per patient care hours or units-of-service (UOS) expended [23, 25, 34, 47, 53]. Tarantino [47] noted how OR TAT and a flexible work environment are CSFs for physician satisfaction, which in turn is a CSF for hospital margin.

Poor OR operational and tactical KPIs (i.e., OTS, TAT, UOS, or UTIL) affect strategic CSFs of patient safety, patient quality of care, surgeon/staff/patient satisfaction, and hospital margin [29, 34]. Inefficient and ineffective reprocessing of instruments/devices can also yield poor OR KPIs. In contrast, perioperative management can advance OR KPIs and maximize surgical instrument availability by having accurate knowledge of inventory, performing sufficient point of use cleaning, and effectively managing components that affect instrument/device transport and reprocessing workflow [14]. The BPM approach of this study examines instrument/device reprocessing workflow KPIs that reflect instrument/device volume, case cart reprocessing, terminal sterilized loads, and immediate use steam sterilization (IUSS) occurrences.

2.3 Instrument/device reprocessing guidance

Well-established healthcare industry sources provide guidance for instrument/device reprocessing. The guidance typically focuses on handling, transportation, cleaning, disinfecting, packaging, sterilizing, and storage. United States regulatory bodies offering guidance include: the Centers for Disease Control & Prevention (CDC) [42], Food & Drug Administration (FDA) [27], and TJC. Professional organizations like the Association of Operating Room Nurses (AORN) [5, 9, 7b, 21], the Association for the Advancement of Medical Instrumentation (AAMI) [3], and the International Association of Healthcare Central Service Material Management (IAHCSMM) [12] offer standards and best practices. Hospital administration can pursue compliance with guidance, standards, and best practices, but the main responsibility for reprocessing resides with the reprocessing personnel [44] and responsibility of sufficient instrument reprocessing personnel training (i.e. up to $20K per new employee) rests with hospital administration [8].

Regulatory bodies and professional organizations all agree the standard for instrument/device sterilization is “terminal sterilization” where instruments are sterilized within proper containers, wrappers, or primary packaging designed to maintain the instruments’ sterility during storage for later use [21]. Immediate use steam sterilization (IUSS) or “flash sterilization” was originally defined as sterilization of an unwrapped object at 132 °C (e.g. 270 °F) for three minutes at 27 lbs. to 28 lbs. of pressure in a gravity-displacement sterilizer [5]. In 2009, TJC revised its position statement on IUSS and emphasized that three critical steps of reprocessing must be followed to ensure sterility (i.e., cleaning and decontamination, sterilization, and aseptic transfer) and that complete documentation must be available for each IUSS cycle so that the instrument/device is traceable to the patient if problems arise [32]. Best practices recommend IUSS be limited to urgent situations and only be used under controlled conditions due to potential human variation in the critical three-step process [21].

The FDA classifies surgical instruments/devices as class II and class III medical devices [21] that require manufacturers’ to provide validated [27] instructions for use (IFU), which are critical during instrument/device reprocessing due to complex surgical instruments requiring more complex cleaning, disinfection, and sterilization procedures [13, 14, 15]. However, the FDA makes it medical device regulatory decisions based on reviews of studies and tests performed outside the FDA domain. Given that TJC and CMS emphasize compliance to reprocessing procedures in accordance with manufacturers’ validated IFUs, reprocessing procedures for untested IFUs should also consider accepted standards and best practices [27].

In 2013, the FDA also issued a final ruling that requires medical device manufacturers to provide barcode readable unique device identification (UID) labels and/or permanent mark on reusable surgical instruments/devices to be phased over 2014 to 2020 [19]. Instrument/device UID implementation is expected to facilitate TJC standards requiring traceability documentation of surgical implants to reside within the receiving patient’s medical history and CMS is considering UID data collection as part of meaningful use criteria [43].

3. Research Methodology

The objective of this study is to examine the adaptability of traditional BPM practices applied to surgical instrument/device reprocessing and tracking in order to provide a framework that targets and measures improvement. To this end, case research is particularly appropriate [17, 50]. An advantage of the positivist approach [54] to case research allows concentrating on a specific hospital service in a natural setting to analyze
the associated qualitative problems and environmental complexity. Hence, our study took an in-depth case research approach.

Our research site (University Hospital) is an academic medical center, licensed for 1,046 beds and located in the southeastern United States. University Hospital is a Level 1 Trauma Center, with a robotics program covering over eight surgical specialties as well as a Women’s/Infant facility. University Hospital’s recognition includes Magnet since 2002 and a Top 100 Hospital by U.S. News and World Report since 2005. Concentrating on one research site facilitated the research investigation and allowed collection of longitudinal data. This research spans activities from August 2003 through May 2015, with particular historical data since 1993. During the 142-month study, we conducted field research and collected data via multiple sources including interviews, field surveys, site observations, field notes, archival records, and document reviews.

4. Case Background

Perioperative Services (UHPS) is the University Hospital department designated to coordinate and manage perioperative patient care across Pre-admissions, Admissions, Central Sterile Supply (CSS), Surgical Preparations (PRE-OP), OR Surgery and Endoscopy, and Post Anesthesia Care Units (PACU). The workflow through CSS reprocessors all reusable surgical instruments/devices and all three OR campuses have a separate CSS facility. The following sections highlight tools, events, and outcomes that have shaped the BPM approach across UHPS.

4.1 ITIS and CSIS Implementation

UHPS implemented its current ITIS in 2001, maintaining software vendor support for version revisions. ITIS supports AAMI compliant processes and electronically updates manufacturers’ verified IFUs as needed. ITIS is integrated with the sterilization equipment and barcode scanning devices on each station. ITIS also supports distinguishing loaner [12] instrument sets from UHPS instrument inventory.

UHPS implemented a new CSIS in 2003, after using its prior CSIS for 10 years. The CSIS supports OLAP tools, a proprietary structured query language, and both operational and managerial data stores (i.e., operational data and a separate perioperative data mart). Flexible routing templates or surgical preference cards (SPC) allow standardization of surgical care data (i.e., particular supplies and instruments needed) or customization for specific surgeons and/or procedures. Since the CSIS implementation, over 7,750 generic and specific SPC configurations [39] facilitate the surgical specialty services (SSS) represented in Table-1.

<table>
<thead>
<tr>
<th>Surgical Specialty Service</th>
<th>SPCs</th>
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</thead>
<tbody>
<tr>
<td>BURN – Trauma burns</td>
<td>26</td>
</tr>
<tr>
<td>CARDIO – Cardiovascular &amp; Thoracic</td>
<td>946</td>
</tr>
<tr>
<td>ENT – Ear, Nose, &amp; Throat</td>
<td>1,030</td>
</tr>
<tr>
<td>GI – Gastro-intestinal</td>
<td>460</td>
</tr>
<tr>
<td>GYN – Obstetrics, oncology, incontinence</td>
<td>611</td>
</tr>
<tr>
<td>NEURO – Neurological</td>
<td>763</td>
</tr>
<tr>
<td>ORAL - Oral Maxil Facial</td>
<td>236</td>
</tr>
<tr>
<td>ORTHO – Orthopedic, joint/device</td>
<td>1,208</td>
</tr>
<tr>
<td>PLAS – Plastic surgery</td>
<td>681</td>
</tr>
<tr>
<td>SURG ONC – Surgical oncology</td>
<td>329</td>
</tr>
<tr>
<td>TX – Transplants (liver, renal)</td>
<td>194</td>
</tr>
<tr>
<td>TRAUMA – Trauma, MASH</td>
<td>203</td>
</tr>
<tr>
<td>URO – Urology</td>
<td>533</td>
</tr>
<tr>
<td>VASCULAR – arteries &amp; blood vessels</td>
<td>558</td>
</tr>
</tbody>
</table>

University Hospital built a new diagnostic and surgical facility that opened in November 2004, where UHPS relocated CSS onto its own floor (e.g. 3rd) and ORs on the two floors above it (e.g. 5th and 7th). A new case cart system started with the relocation, where a case cart is a mobile vehicle stocked in advanced with instrument sets, devices, and supplies from SPCs designated for a specific patient’s surgical procedure. Used items are reloaded onto the cart and sent back to CSS for disposal or reprocessing. Three elevators connect CSS to the ORs, one for cart returns to instrument disinfection and two for sterile supplies and carts from the storage area. The new CSS facility was equipped with an automated 7-stage instrument washer and case cart wash-room that physically separates instrument disinfection and cleaning areas from instrument drying, inspection, wrapping areas. Steam and hydrogen-peroxide terminal sterilization units physically separate instrument inspection and wrapping from instrument/supply storage. The two elevators for sterile transfer are located on opposite walls of the instrument/supply storage area.

The ITIS was implemented across the relocation, with multiple stations across each CSS area and each OR floor. The interface between the CSIS and ITIS is the surgical procedure case number that is unique and linked to a patient’s medical record. The instrument/device type used on the same patient over multiple surgical procedures is traceable via the ITIS and CSIS.

4.2 November 2004

The new surgical facility expanded UHPS to cover an additional floor and nine additional ORs (i.e., 33% capacity increase). The new facility housed 40 state-of-the-art OR suites, each having new standard as well as surgical specialty equipment. Within six weeks of occupying the new facility, a scheduling KPI reflected
chaos. Surgical case OTS plunged to 18% during December 2004. Within a highly competitive hospital industry, having only 18% OTS was unacceptable, as 82% of scheduled surgeries experienced delays and risked patient care and safety. University Hospital had failed to adjust its perioperative process to compensate for the introduction of radical innovation and existing processes were disparate in the new environment.

4.3 Perioperative Process Improvements

In January 2005, UHPS expressed concerns before a quickly convened meeting of the c-level officers and top representatives of surgeons and anesthesiology. The meeting yielded a hybrid management structure and governance in the formation of a multidisciplinary executive team, chartered and empowered to evolve change. The executive team consisted of perioperative stakeholders (i.e., surgeons, anesthesiologists, nurses, and UHPS). The executive team’s charter was to focus on patient care and safety, attack difficult questions, and remove inefficiencies. No issue was off-limits.

University Hospital’s executive team launched a process improvement effort in 2005 to address the perioperative crisis through soft innovations [37]. As a result, the executive team enlisted numerous task forces to address specific problems and/or opportunities, which was the foundation for their BPM approach. In 2009, UHPS expanded its management beyond the 33 general ORs (GENOR) and 8 cardio-vascular OR suites (CVOR) to the other University Hospital OR facilities covering 19 OR suites at the Highland campus (HHOR) and endoscopy labs at the TK Clinic campus. An additional OR was added to GENOR in 2012.

Since 2005, UHPS has focused data-driven analysis of KPIs [40] to gauge process variance, identify improvement opportunities from variances, and improve end-to-end workflow. Using this systematic BPM approach [40], improvement efforts have targeted specific areas of the perioperative process and more recently the CSS/OR supply workflow [39].

5. Observed Effects

For simplicity, the focus of sections 5 and 6 is the CSS facility servicing the 41 OR suites across GENOR and CVOR. Given the perioperative improvements identified since early 2005, the perioperative data comparisons cover FY2010 forward (e.g. October 2009 to May 2015). The following sub-sections cover observed effects from reprocessing workflow, ITS workflow monitoring, IUSS monitoring and feedback, and ITIS instrument-to-patient tracking.

5.1 Reprocessing Workflow

Across CSS, the instrument/device reprocessing occurs via sequential workflow steps that begin in the OR suite and progress across: (1) transportation to CSS, (2) cleaning, (3) disinfecting, (4) washing, (5) drying, (6) inspection, (7) wrapping, (8) sterilizing, (9) storage, and (10) case cart preparation. Individual cycle time for a particular instrument or device will depend on the manufacturer’s IFU, but the minimum cycle time for an instrument to progress through the workflow is 3 hours.

During OR suite turn around, OR staff identify unused instruments from used instruments by laying a sterile damp towel around used instruments to minimize drying of blood or tissue, before filling the tray set with all the instruments. For transportation back to CSS (1), all instrument tray sets, devices, and used supplies are placed back onto the case cart and OR staff returns the cart to the CSS via the return elevator.

CSS technicians, wearing proper protective apparel [13], move return carts into the cleaning area (2) from the return elevator and unload the cart contents one instrument/device tray set at a time. Each tray set or device has a barcode tag that the CSS technician scans into ITIS to move the tray set into the reprocessing workflow. The barcode scans also identify the CSS technician with the instrument/device tray set cleaned. The CSS technician uses the appropriate IFU to prepare and clean the instruments/device, which usually involves pre-soaking, point-of-use cleaning and/or manual cleaning, or ultra-sonic cleaning. Cleaning times vary per IFU and best practices, where Endoscopes require 90 minutes of point of use cleaning to remove bio-burden [13, 16] from the device.

If the IFU calls for disinfecting (3), the CSS technician will immerse the instrument in the appropriate disinfectant. If the instruments’ IFU allows automated washing (4) then the CSS technician will load the instruments and tray onto a washer rack and place the rack into the 7-stage automatic washer. All the water used in the CSS is either germicidal ultra-violet-C light filtered or sterile. Lastly, the CSS technician will move the case cart into the cart wash room for cleaning with high pressure, high temperature water and disinfectant.

The automatic washing cycle takes approximately 25 minutes to run through the 7-stages. When removing an instrument rack from the automatic washer, the retained heat is sufficient to vaporize any water left on the instrument. However, some IFUs require instruments to be placed in a warm or cool air drying (5) cabinet. CSS technicians also move the dry, cleaned case carts into the storage holding queue.

After instruments are dry, CSS technicians will begin inspecting (6) each instrument in a tray set to ensure functionality per IFU. During this reprocessing step, instruments can be pulled from use and replaced. Each CSS technician records the inspected instrument/device or instrument tray set and contents via the ITS, which also credits the inspection to the technician. The Lead Instrument Technician is responsible for ordering all replacement instruments to maintain sufficient inventory volume and targets annual...
instrument replacement cost/expense to hospital standards of $5,000 per OR suite [39].

After inspecting all instruments/devices in a tray set, any instruments/devices removed are replaced within a given tray set. Some instruments/devices are loose and require placement into peel packs as wrapping (7). Other instruments/devices require actual wrapping appropriate to the intended sterilization process. All tray sets, peel packs, and wrapped instruments are loaded into the appropriate sterilizing (8) machine rack per IFU. A biological indicator (BI) is placed with the loaded instruments, where the BI is the control element to ensure deactivation of germs and sterile instruments/devices. All items on the sterilizing rack are barcode scanned into the ITIS based on the respective sterilizer to employ per IFU. CSS has four terminal steam sterilizers as well as three hydrogen-peroxide sterilizers. The sterilization cycle takes approximately 90 minutes to process a load.

Failed BI readings require instrument/device sterilization to be repeated. Once the sterilizing process is successfully complete, given the BI is negative of germs and the instrument/devices have cooled down, then the CSS technician will move the sterile instrument/device or tray set to storage (9). CSS storage is maintained at a constant temperature and relative humidity to support sterile shelf-life.

For case cart preparation (10), CSS technicians use pick lists generated by CSIS SPCs associated with a specific surgical case procedure (e.g. patient). Instrument tray sets’ barcode labels and/or device barcode labels are scanned into ITIS for association with the specific procedure case number and traceability to the patient’s EMR. CSS technicians prepare case carts up to 8-hours in advance and carts are sealed. Specific role responsibilities in the case preparation step include the head lead nurse director (HLND) in CSS, CSS technicians, and OR Staff. The HLND reviews surgical schedules 2-3 days in advance to check on loaner [52] instrument trays and implants as needed, as well as contact specific vendor representatives. CSS technicians receive the next day’s OR schedule and corresponding SPCs from CSIS at 2pm daily with ‘add on cases’ pushed through from RN Schedulers as required. The OR Unit Secretary will call CSS technicians to push pick lists to CSS technicians after hours. CSS technicians pull supplies/instruments/devices from SPC pick lists to put on corresponding case carts from 2PM to 7AM and transport all stocked case carts to the OR Cores via elevators in the storage area. OR Staff requisition from CSS additional supplies/instruments/devices not found or incorrect on the SPC, notifying the OR Team Leader of the discrepancy.

5.2 ITIS Workflow Monitoring

Reprocessing data collected by the ITIS provides instrument/device management and control for each cleaning, inspection, sterilizing, and storage steps, as well as machine cycles for planning CSS equipment preventive maintenance. The sterilization load data also provides a log of who sterilized which instruments and the BI result to meet TJC requirements.

As a quality control measure, auditing of workflow steps and instruments/devices within each step is performed monthly by Lead Instrument Technicians from the two other CSS facilities. ITIS process data can focus auditing though productivity and proficiency measures as well as non-conforming incident reporting. Based on audit results, the HLND will recommend additional technician training as needed. The HLND also uses the ITIS to verify and log all loaner sets of instruments/devices into the reprocessed workflow upon receipt into CSS and on exit of the loaner instrumentation from CSS.

5.3 IUSS Monitoring in the ORs

![Figure-1 OR IUSS Uses January to May 2015](image)

Each OR floor has IUSS sterilizers and ITIS access to record when IUSS is performed for instruments/devices in a surgical procedure (e.g. patient). TJC requires logging all IUSS occurrences and which IUSS instrument was used for traceability to the patient, should the patient have HAI complications. The industry benchmark for IUSS is less than 2% of the surgical procedures performed to limit IUSS use due to patient safety risk associated with individual variations of the critical three-step process [21]. UHPS management uses the IUSS KPI from the ITIS to monitor who, what, why, and where of the occurrence, ensure terminal
sterilization in CSS is the primary method, and identify potential process issues.

Figure 1 on the prior page represents IUSS log data from January to May 2015 over two charts. Both charts represent the same data, where the first chart is sorted by a specific OR user and the second chart is sorted by time of day in military hours. These forms of data visualization allow IUSS task force members to focus on potential process problems that are preventing sterilization from occurring in CSS. Discussing the data with the top four or five OR users and monitoring during the noon hours where the OR sterilizations occur can help limit IUSS and in turn limit risks to patient safety.

5.4 ITIS Instrument-to-Patient Tracking

The ITIS as of FY2014 was limited in the capability of tracking specific individual instruments and devices that did not have barcoded tags or unique identification beyond the manufacturer’s model number. Instrument sets can be identified by barcoded set trays, but over time the individual instruments inside get replaced or merged with similar instrument tray sets in the reprocessing workflow (e.g. cleaning to inspection). The ITIS database does have the granularity to distinguish between instruments with unique marks. However, the Direct Product Marking (DPM) printing technology required to uniquely identify 300,000+ hard metal surgical instruments/devices in just one CSS facility at over 1$ per DPM had been cost prohibitive.

Newer DPM printing technology using diamond tipped styluses rather than laser etching decreased the total cost of ownership to proceed with the planned project. The project placed new DPM printers in each CSS facility for under $125K, and FTEs were approved to add one CSS technician per facility to DPM the current inventory and maintain the capability over future instrument replacements or acquisitions. The DPM 2D etching is occurring in phases, with full implementation by FY2017. The unique DPM 2D etching references the instrument model-number and digit filler to make the unique DPM across all instruments with the same model-number.

The granularity of the unique DPM allows tracking individual instruments/devices in the surgical procedures where they are issued, providing individual instrument/device traceability to patients and vice-versa. Similarly, the IUSS history as well as process contextual data is traceable across individual instruments/devices. The potential granularity in process data analysis is promising and the ability to confidently identify instrument-to-patient traceability meets TJC and possible CMS requirements [43]. Figure 2 illustrates the DPM 2D mark on a surgical instrument.

6. Discussion

Reprocessing KPI metrics currently monitored through the ITIS data include: CSS sterile loads; CSS instrument sets reprocessing; CSS instrument/device reprocessing; CSS case cart reprocessing; and IUSS per surgical procedure. The following sub-sections discuss how each KPI are applicable to explaining the surgical instrument/device reprocessing within the CSS facility servicing GENOR and CVOR from October 2009 to May 2015. The last sub-section discusses general comments on the observed effects.

6.1 CSS Sterile Loads KPI

The CSS sterile loads KPI represents the total number of successful sterilization cycles executed during the time period, which in Figure 3 is over the past 68-months. The trend line suggests the current number of instrument sterilizations occurring in CSS has increased dramatically since October 2009 (e.g. 31.4% increase). This KPI shows an increase in the number of sterile loads processed in CSS successfully, which may reflect a volume increase in instrument/device reprocessing or an increase in the inventory turns of surgical instruments/devices.
6.2 CSS Instrument/Device Reprocessing KPI

The instrument/device reprocessing KPI represents the total number of individual instruments/devices that flowed through the CSS workflow each month during the time period. The two low deep valleys in Figure 4 are during the month of February, which has fewer days. The trend line is slightly decreasing meaning the reprocessing workflow volume is slightly less now than it was earlier in the time period. Comparing the trends in Figure 3 to Figure 4, it appears CSS is achieving more inventory turns of instruments/devices.

Figure 4 – Instrument/Device Reprocessing

6.3 CSS Case Cart Reprocessing KPI

The case cart reprocessing KPI represents the number of case carts returned to CSS for instrument/device reprocessing. The trend line in Figure 5 is increasing, reflecting more surgical procedures and more patients in the recent schedules and more reprocessing volume. In comparing Figure 3, Figure 4, and Figure 5, there appears to be more instrument/device sterilization, more case cart reprocessing, and about the same amount or less volume of instrument/device reprocessing. These three figures in combination reflect an increase in inventory turns and a decrease in instrument/device inventory levels.

Figure 5 – Case Cart Reprocessing

6.4 IUSS per Surgical Procedures KPI

The IUSS per surgical procedure KPI represents the average number of IUSS occurrences per surgical procedure (e.g. patient) each month over the time period. Figure 6 illustrates a dramatic decline in IUSS occurrences as the trend line is decreasing rapidly (e.g. 46.5% KPI decrease) over the past three years compared to the first two years in the time period. Reprocessing sterilization is occurring less in the OR where the three-step process [21] is not standardized, subject to variation, and risks patient safety.

Figure 6 – ISUS per Surgical Procedure %

6.5 General Comments on Observed Effects

During mid-FY2013, the CSS/OR supply workflow improvement effort was implemented that redesigned instrument and supply flow between CSS and GENOR as well as between CSS and CVOR. The same improvement effort addressed inaccuracies in SPC pick lists as well as implementing a $375K cost-savings in reducing annual hand-held instrument replacements by $7K per OR suite. The impact of the CSS/OR supply improvement and the instrument/device reprocessing workflow within CSS reflects many of the reprocessing guidance, standards, and best practices across the hospital industry as well as perioperative improvement. From October 2009 to May 2015, other perioperative KPIs met or exceeded targets. The average OTS KPIs for GENOR and CVOR during FY2012 were close to the 70% benchmark at 69.3% and 55.2%, respectively. The average OTS KPIs for both OR groups during the next two years exceeded the 70% benchmark in FY2013 and exceeded 80% in FY2014. UTIL and TAT yielded similar process feedback.

6. Conclusion

This study highlighted BPM practices applied to surgical instrument/device reprocessing within a hospital’s perioperative process. The observed effects focused on reprocessing workflow, the best practices employed within the workflow, the ITIS and workflow
integration as well as implementation of an instrument-to-patient tracking capability that promises to add new levels of granularity to perioperative data analysis.

Empowered individuals, integrated IS, and a holistic framework for analysis, evaluation, and synthesis of end-to-end process measures with established benchmarks prescribed an a priori environment to support reusable instrument/device reprocessing as well as IUSS measurement, control, and improvement. Moreover, BPM practices were adaptable to explain the instrument/device reprocessing as well demonstrate overall perioperative process complexity and improvement efforts. The cycle of analysis, evaluation, and synthesis also reinforces communication and stimulates individual as well as collective organizational learning.

Our case study contributes to the healthcare IT literature by examining how continuous process improvement and BPM are applicable to the reusable instrument/device reprocessing workflow as well as the management of the perioperative process within a hospital. This study prescribes an a priori framework to foster their occurrence. This paper also fills a gap in the literature by identifying perioperative process complexity and how perioperative process data is both a performance measure and a management tool.

This study was limited to a single case, where future research should broaden the focus to address this issue along with others that the authors may have inadvertently overlooked. The case examples presented in this study can serve as momentum for BPM in healthcare methodology, comprehension, and extension. The study’s results should be viewed as exploratory and in need of further confirmation. Researchers may choose to further or expand the investigation; while practitioners may apply the findings to create their own version of instrument/device reprocessing workflow management, control, and improvement within the hospital environment.

7. References:


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