Minimizing the Risk Associated with Processing Reusable Medical Devices while Safeguarding Quality and Implementing Cost Savings

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SKMC, Abu Dhabi, UAE
“In today's ever-changing healthcare environment, patients demand more advanced procedures and equipment that take the pain and recovery time out of surgery. While they seek these advancements, they have forgotten how complicated it is to clean, inspect and test this advanced equipment.”

Mary Ellen Fortenberry
Who Owns the Patient Outcome? We All Do!
Our Challenges

- Challenges in cleaning and decontamination and following the MWI (IFUs)
- Increase use of Loaner sets and reusable implantable
- Increase MIS instrumentation
- Low Instrument Inventory and Quick Turnover of Patients
- Poor OR and CSSD system workflow
- Right Sizing/ Optimization Project Initiatives
- Budget Cuts

WFHSS Osaka, Japan 2012
Tissue/bone trapped in the shaft

- Narrow lumens/cannula entraps tissue
- Inadequate cleaning instructions
- Difficult to visually check

Time for proper cleaning and inspection not often factored into the turnaround time

Clips are very fine and delicate making it hard to assess which ones are soiled

Biopsy Forceps With stopcocks - Problems with disassembly
Figure 1

Crevices where dried debris was found with the aid of a light source.

Dried debris removed from the crevices of an instrument.

Photograph courtesy of Totalcare Sterilizing Services.
Trapped inside the hex driver was "a mixture of bone and blood and saline from the arthroscopy," notes Captain Stephen Parada, M.D., a Madigan orthopedic surgeon. Doctors swiped cannula contaminants into a petri dish and bacteria bloomed, just as it had in the knees of the five soldiers. "Interestingly, other studies have found that this 'dried sludge' in other cannulated instruments was sterile," Dr. Parada says.

"The Pennsylvania Patient Safety Authority collects reports when tools unwrapped during surgery are noticeably contaminated. According to one hospital's report, "When placing the tissue protector on the drill, old dried blood and tissue came out." Another noted that a triple trocar, used to place a pin into bone, "was full of dried blood and smelled foul."
The use of Failure Mode Effect Analysis: a Proactive approach in minimizing the risk associated with processing reusable medical devices

A team-based systematic, proactive technique used to prevent process or product problems before they occur:
- To recognize potential failures in our system
- To eliminate and/or minimize risk before it occurs
- To develop a safe and high quality product
- To identify vital areas of improvement
Multidisciplinary Team (CSSD, Quality & Risk, Nursing)

Brainstorming - identifying potential failure modes and determine their effects within the current process

For each line item, the team reviewed the potential effects of a failure. This led to the assignment of a severity rating based on worst case scenario.

The team then reviewed potential causes that could lead to failure.

Redesign the Process – Based on the result of brainstorming & RPN the actual process was enhanced / improved, recommendation had been prepared for action and implementation. (See FMEA worksheet)
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<tr>
<td>Dirty Instruments after device went thru Mechanical Decontamination or manual washing</td>
<td>1. Delay in assembly &amp; packaging and affect turnaround time of instruments requiring fast tracking. 2. Possibility to be overlooked by CSSD Tech during assembly. 3. Cause delay in OR procedures. 4. When overlooked by Technician, bioburden on surgical instrument can put patient at risk of surgical site infection (SSI). 5. Frustration and Stress on OR staff. 6. CSSD will receive an occurrence report especially when he/she comes off the device during surgery.</td>
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<td>6</td>
<td>358</td>
<td>1st</td>
<td>Overlooked by CSSD Tech during decontamination. The medical device might be multi-part and was not disassembled during decontamination and packed without disassembling for inspection. 1. The medical device might have been handwashed and difficult to clean areas were not accessed during manual washing. 2. Design of Medical Device is complex and thorough cleaning is difficult to achieve.</td>
<td>CSSD Technicians - re-education and training. Attach photo of medical device in every checklist. To find a system that has the ability to link the instrument with its manufacturer’s written instructions especially for difficult to clean medical devices. Find a system that has the ability to trigger the technician of difficult to clean areas and requires stringent inspection.</td>
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<tr>
<td>Missing Instruments &amp; Incomplete instruments returned</td>
<td>1. Delay in processing - tray cannot be processed until status of item missing is established. 2. Change of Care Plan. 3. Delay in OR</td>
<td>8</td>
<td>6</td>
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<td>240</td>
<td>2nd</td>
<td>OR is OR Scrub Nurse did not confirm completeness of the instruments on tray prior to use. 1. Instruments could be damaged during the procedure and was condemned by OR but did not inform CSSD when the tray was returned. 2. The instruments were thrown away with the rubbish. 3. If the instrument missing or incomplete was a multi-part instrument, item missing could have fallen without noticing a procedure. 4. Item may not be returned to its correct tray. 5. More than one tray was used in one procedure or tray mix-up.</td>
<td>Recommend that OR will need to review tray list after the final count. CSSD will need to count instrument upon receipt at Decontamination Area and inform OR Supervisor of any discrepancies immediately. (Challenging especially when there is only one person working at the decontamination area) CSSD to review workflow process to find gaps and resolve issues (i.e. incomplete instruments will not be processed until status is confirmed). Find ways to correctly document tray contents and identify instruments not on trays thru use of labels.</td>
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<td>Sharps on Tray</td>
<td>Sharp injury to staff</td>
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<td>Rubbish are not removed from tray prior to return (especially tray sets from wards &amp; clinics). Mixed instruments on tray from other sets and are not returned to the tray properly by decontaminating any sharps on it. OR staff is tired after a long case and has no time to return the tray set to CSSD - leaving unattended (sometimes happening with ORs on the 2nd level e.g. ENT, Opht or cysto); Carelessness of Staff</td>
<td>Re-education of end-user on sharp safety - incorporating with infection control audit study day and Orientation of new staff.</td>
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<td>Inability to complete Case Cart of instrument set required due to insufficient equipment to meet OR requirements</td>
<td>1. Potentially cause delay or cancellation of procedure. 2. Change of Care Plan; Affect Patient Outcome</td>
<td>8</td>
<td>7</td>
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<td>168</td>
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<td>Insufficient inventory of required Medical Devices. 1. OR shall complete all “Incomplete” Tray set. 2. OR shall provide “Basics of Butter” instruments to replace common instruments that get damaged e.g. broken. 3. OR shall increase their instrument inventory especially on cases that often require fast tracing of instrument sets/trays.</td>
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RESULT of FMEA

1. Dirty Instruments
2. Missing Instruments & Incomplete Instruments
3. Non-functional instruments on trays
4. Increasing FAST TRACKING Requests
5. Mishandling of Medical Devices
6. Lack of Knowledge – the “whys things are done”
Departmental Targets

1. Zero tolerance on “dirty” instruments
2. Reduction of non-functioning and unsafe instruments
3. Reduction of “incomplete” instrument sets in circulation
4. Timely delivery of Sterile instruments sets and trays
5. Optimize processes to reduce waste and save money
Action Plan # 1: Education

EDUCATION is vital to meet our targets

“doing the right thing”

Staff empowerment

Years of Experience in CSSD
- 16 years and above: 22%
- 2 to 5 years: 19%
- 6 to 10 years: 21%
- 11 to 15 years: 38%

Age Group
- 30 to 40 years old: 51%
- 40 to 50 years old: 33%
- 50 years and above: 16%
Action Plan # 1: Education

- Analyzed staff level of knowledge and competence
- Formulated a curriculum directed towards developing and maintaining competency in the core knowledge and skill areas of practice
- Linked education with annual competency
- Team Effort – invested our time

It's not just certification but ensuring they remain competent.
A state of art operating rooms performing sophisticated surgical procedures needs the support of CSSD that is provided with the necessary human resources, who are competent, qualified and educated, and have the right equipment, and instruments necessary to function effectively and efficiently.
Requirements

- **Committed** to complete the program in 1 year
  - 400 hours required to complete the program
    - 160 hours classroom – Academic hours – 9 Modules
    - 240 hours validated actual work- “Proficient to Expert Grade” – Demonstrating mastery in performance and flexibility in decision making – Annual competency
- 80% Attendance to lectures and required workshops
- Submission of a Paper, or Project, or Quality Improvement Initiative

WFHSS Osaka, Japan 2012
Results

- 100% of CS Techs completed two certificates:
  - Certificate in Decontamination and Sterilization
  - Certificate in Surgical Instrumentation

- 100% submitted Projects – were implemented
- 100% HAAD licensed to practice
- 100% CRCST licensed (USA)

“Improved Reprocessing competencies by strengthening training, education and certification” #6. Seven Clarion Themes 2011 Summit Publication: Reprocessing
The systematic identification and elimination of waste, while maintaining or improving quality
Action Plan # 2: Quality Improvement initiatives

- Bi monthly meetings
- Reviewed SOPs and Policies
- Buddy system
- Improved work flow design – increase productivity and eliminate waste
Automate the Process
Install Electronic Instrument Tracking System
iTRAYS (TDOC)

Action Plan # 3:

The system is compatible with current systems and it streamlined existing methods.
<table>
<thead>
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<th>Departmental Targets</th>
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<tr>
<td>1. Zero tolerance on “dirty” instruments</td>
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<tr>
<td>2. Reduction of Non-functioning and Elimination of Unsafe Instruments</td>
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<td>3. Reduction of “incomplete” Instrument Sets in Circulation</td>
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<td>4. Minimize Errors</td>
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<td>5. Timely Delivery of Sterile Instrument Sets and Trays</td>
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<td>6. Optimize Processes to Reduce Waste</td>
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</table>
1. Zero tolerance on dirty instruments

- Document Return of Instruments or Sets
  - Identify Scrub Nurse

- Capability to track instrument sets through the entire cycle

- Alert or "STOP"
  - Special Instructions
  - Disassembly required
  - Hand Wash ONLY

- Refer to Manufacturer’s written Instructions

- Assign Fast Track Code
2. Reduction of “incomplete” or “missing” instrument/s on sets in circulation

- “Pack – On-Screen”
  - Actual Count
  - Photo of instrument assembly
- Alert or STOP
- Special Instructions
  - Multi-part instruments
  - Specialized instruments
- Missing Item Label
- Reduce Instrument Loss
- Accountability
Missing or Incomplete Sets Report

This set requires one (1) of each item but the items on the set are currently zero (0).
3. Minimize non-functioning instrument/s on sets

- “Pack – On-Screen”
- Alert or STOP
  - Special Instructions
    - Insulation Testing
  - Micro Inspection
- Order Repair
  - Emails directly to TL
  - Repair contractor
  - Tracking
  - PPM
- Reduce instrument repair costs

WFHSS Osaka, Japan 2012
5. Minimize Errors

Erroneous Units Report

39 units or 0.56% are “Opened but not used” – these are units wherein an item/s is taken out of the tray due to instrument unavailability from the tray or lack of back up instrument for non-functional or damaged items or extra instrument requirement or instruments were opened in the OR and case was cancelled.

24 units or 0.35% are “Open to add implants/instruments” – these are sterile units on the sterile stock that were removed from stock, opened just to restock implants on the tray or to add new instrument/s on the tray. The units has to be reprocessed again from decontamination to sterilization. WFHSS Osaka, Japan 2012

Reactive and Non-reactive errors or NON Conformance Report

5% of the total production are non conformance
6. Timely delivery of Sterile Instruments and sets

- Web Page – can be accessed by anyone in the OR – most importantly the OR Scheduler to support cases scheduled based on availability of required instruments.

- Clinical waste - delays in or lack of care coordination.

http://corskmapv031/EXEC
Web Module

Provides information on Instrument Availability:
- Minimize or eliminate OR delay due to unavailability of instrumentation.

Order Fast Tracking: Ability to expedite trays required in a timely manner:
- Give sufficient time for reprocessing complex instrumentation (including LOANER Sets) requiring FAST TRACKING.

OR Manager, Specialty Team Leaders, OR Staff Nurses, Surgeons:
- Ability to open the tray (remotely) while in OR (using a Web Module).
- Minimize opening sterile trays, saving reprocessing cost.
- Review/revision purposes:
  - Add or remove instruments.
  - Increase inventory.

OR can assign someone preferably OR Scheduler to have access to Fast Tracking Request using the WEB module.
Once the product is returned to the decontamination area – CSSD Tech is immediately alerted of a Fast Track item – which is highlighted in red in the info-overview and seen throughout CSSD.

### FAST TRACK Plan

**Urgent – 3 hours**

required to be FAST Tracked in 3 hours – due to low inventory and that the schedule is back to back or that more than one surgeon requiring the item at the same time

**Priority – 6 hours**

items listed due to its low inventory or one of its kind and used on urgent cases such as trauma. This is an SOP for CSSD regardless whether or NOT it is requested by OR.

**Standard – 10 hrs**

not on the Priority list nor requested to be Urgent.
This shows the Fast Track Report (3 hours Urgent Plan) by Specialty for the month of June 2011.
### Turn around times, Products (2011-06-01-2011-06-30)

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<td>2 0 19</td>
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**Turn around time report for Laparoscopy Set #1 (June 2011)**

In 30 days—a total of 12 times a Laparoscopy Set #1 was processed with an average of > 6 hours and 11 mins turnaround time from the time it was returned to be decontaminated to sterile stock.

> And an average of 2 days and 19 mins turnaround time from return to be decontaminated to dispatch to the customer.
In case of Product recall – we can easily recall the product using the batch number – which gives us the list of the items that were on the batch. Thus it is easy to recall the items from circulation.
Minimize Recall
"And this one is wired directly to his lawyer..."
5. Optimize processes & reduce waste
Instrument Management

- Reduced unnecessary instrument inventory
- Keep track of repairs and maintenance
- Ability to address any missing instruments – identify OR room #, Scrub or circulating nurse
- FAST TRACK requests are dealt immediately
  - Trending – increase inventory
  - Capture Real Time return of instruments
  - Ability to locate items that never returned back to CSSD
By redesigning and smoothing our process workflow, throughput was maximized to meet demand.

**Workflow Efficiency**

- Reduce/eliminate hours wasted searching for lost instrument/s and or trays
- Reduce/eliminate reprocessing “Opened But Not used”
- Time saved in CSSD related issues increases OR efficiency
- Reduce/eliminate errors inherent in manual process
- Guarantees Tray list/Count Sheet accuracy
Productivity

- Benchmark Productivity of individual staff
- Justify Variance in Employees Cost

### 2012, 2nd Quarter Productivity Hours

- CS Tech CS Tech
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### 2012, 2nd Quarter Overtime Hours

- CSSD Tech 1
- CSSD Tech 1
- CSSD Tech 1
- CSSD Tech 1
- Inv Clerk Inv Clerk
- Inv Clerk Inv Clerk
Maximize Staff Productivity

- Provides a daily overview of the number of units that was produced at each work area, e.g. at the return area, packing area, Batch or sterilizer area, etc.

- Quantities of units per hour are listed and a total is also provided per day and for the entire period.

- Redesigning wasteful processes allows staff to perform to their highest capacity, resulting in higher staff satisfaction and productivity, and safer care.

### Production per Function per Hour (2012-06-01...2012-06-30)

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Production per Function per Hour (2012-06-01...2012-06-30)
### Comparative Chart

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### Total CSSD FTEs

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WFHSS Osaka, Japan 2012
Eliminate Waste (Lean Principles)

1. Transportation
2. Inventory
3. Motion
4. Waiting
5. Over-Production
6. Over-Processing
7. Defects / Rejects Re-work

WFHS Osaka, Japan 2012
We can also generate Total cost of sterile processing so that our customers will be aware that every time they open the tray there is a cost to reprocess.

Likewise, we also want to know our production cost against the budget.

This can be tied up to the total procedure cost if we want to go that far.
Corporate Benefits

- Robust and reliable RECALL system in place

- Corporate Accountability - safeguard CSSD and the organisation - reducing public health risk associated with reprocessing reusable medical devices.

- Assurance - system in place to ensure that CSSD have done reasonable practicable steps to manage the risk associated with processing reusable medical devices
Who will benefit the system

Who Owns the Patient Outcome?

We All Do!
ご清聴ありがとうございます