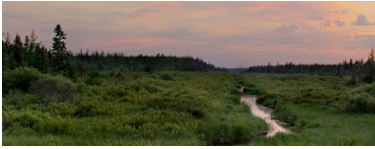



Minnesota Chapter of  
IAHCSMM  
and Healthmark Industries  
Present

Quality Doesn't Cost It Pays -  
Surgical Tray Auditing

October 1, 2021  
The Earle Brown Heritage Center  
Brooklyn Center, Minnesota 55430

Precentor  
Stephen M Kovach BS CFER  
Educator Emeritus

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### Disclosure

- I am an employee of Healthmark Industries Fraser, Michigan USA
- I am involved with the manufacture and distribution of medical products to healthcare facilities and healthcare professionals
- No compensation has been received for this presentation or for travel to and from the seminar
- All opinions are those of the presenter
- This presentation reflects the techniques, approaches and opinions of the individual presenter. This sponsored presentation is not intended to be used as a training guide or promotion. Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for the use of the device(s).

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### Healthmark Policy & Philosophy

**Healthmark's Policy**

Is to provide our customers and the healthcare community with the highest quality, state of the art medical products and support services in a timely and cost effective manner.

This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence. This presentation is part of that commitment, educating our customers.

**Healthmark's Philosophy**

It is more than just buying a product or running a test.

It is about having clinically relevant, evidence-based, products. Along with support for Healthmark products both clinically and educationally with the understanding that an educated customer is our Best Customer.

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## Housekeeping Issue for this presentations

- Who is here today ?
- Questions during my presentation ?
  - Raise your hand at any time
- Pictures help tell a story, you will see a lot of them today
- Cell phones off
- Ready, lets go
- Quote for this program

**The first step in the acquisition of wisdom is silence, the second listening, the third memory, the fourth practice, the fifth teaching others.**

**Solomon Ibn Gabriol**

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## Objectives

This program will help the attendees understand the impact they have on surgical outcomes when surgical trays are not assembled properly. The term quality will be reviewed as it relates to the function of surgical tray assembly.

We have come a long way as they say from the days of just showing a BI as part of our QA program. Today we are being asked to track and monitor many of the functions within an SPD/CPD area.

Various accrediting agencies are come along and asking what you what are monitoring and how are you improving.

A review of the various tools a medical device reprocessing profession needs to provide an error free tray will be reviewed.

Lastly a simple quality improvement program will be shared to help ensure trays are error free when they arrive to be used by their customers ( Operating Room, OB suites, ER ...)

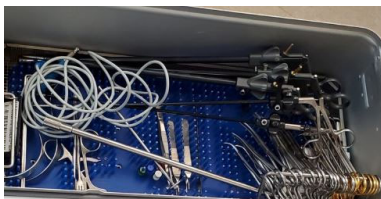
At most facilities surgical instrumentation are one of the largest investments made .

- Define and understand what the word quality means for a SPD.
- Understand the impact of faulty inspection of your surgical trays during assembly.
- Review the tools you need for inspection medical devices
- Learn a simple quality program for surgical trays that you can adapt to your department, now and improve your outcomes?

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## Objective 1

- Define and understand what the word quality means for an SPD.



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Is the quality ?



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Or is this quality ?



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How about this for quality ?



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## Quality, SPD and You is defined by

- The original equipment manufacture (OEM)
  - Instruction for use (IFU)
- Selling in the United States
  - The FDA
- Various Standards and guidelines
  - ANSI/AAMI
  - AST
  - AORN
  - SGNA
  - CDC
  - Peer reviewed articles
  - Other sources
- Your Customer
  - Department forms its Standard Operating Policy(SOP) for tray assembly and inspection of medical devices on the above-mentioned inputs

### H. Visual Inspection

**All routine cleaning instructions should include instructions for visual inspection, which may include use of magnification and adequate lighting. The instructions should advise the user that if the device is determined not to be visually clean at the end of the cleaning step, the user should either repeat the relevant previous cleaning steps or safely dispose of the device. Additionally, the visual inspection instructions should identify acceptance or failure criteria related to device performance (e.g., unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals), as well as instructions to properly dispose of devices that fail.**

\* Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff Document issued on: March 17, 2015 Appendix E of this guidance was updated on June 9, 2017 ; page 17 ; section H

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## Operating Room View of Quality



- Usually, the OR is our #1 customer
- Each room / theater / suite feels that their patient is the most important ( in some hospitals this can be as little 1 up to 75 patients at one time)
- Every item needed for each case must be available and ready to ensure that there are no delays.
- Provide the right item at the right time to the right patient in the right manner.
- Safe, effective, timely for each patient.
- Clean and functional

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## Quality SPD and You

### How Quality fits in:

"In SPD, we must deliver what we promised the customer; a defect-free product, on time...clean and functional and to be able to either be sterilized or HLD...many times needs are coordinated for several rooms and departments at once...how do we accomplish this"

Do we agree on this statement.

Now think of the OR and their view and now our statement

- Both views are right
- Both departments are working for the good of the patient
- Both areas need to understand each others process
  - SPD / OR relationship is another topic

Our number one product is the surgical tray.

How do we ensure we are assembling our trays accurately ?

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## Quality and YOU in SPD

What can YOU do?

- Make a conscious effort to do your job right every time you do it. You are the only person who can do that. With the tools you have at hand.

What causes errors?

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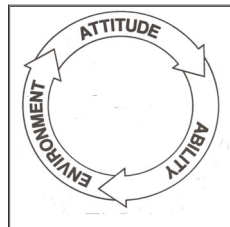
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## Quality SPD and YOU

The cause of errors.

- ✓ Attitude about the work
- ✓ Ability to do the work (education and training)
- ✓ Workplace issues, concerns, problems (the tools you are provide)



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## Quality ,SPD and You

Our Dual Attitude about Defects:

### Work Done For Us:

How many defects are, OK?

- ✓ New car
- ✓ Doctor
- ✓ Dentist
- ✓ Bank account
- ✓ Drug store
- ✓ Paycheck
- ✓ Other examples in our life

### Work Done By SPD:

How many defects are, okay?

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**SPD Says**

- Why is it needed so soon
- You did not tell me of the time change
- That item is in use in another case
- We only have one of them
- It is not in the budget to get another one
- I can't clean, test its function and sterilize it that fast

**O.R. Says**

- What's taking so long
- Why can't we have it back in 10 minutes
- What do you mean we only have 1 of them
- We just added the case
- I can turn it around quicker than you can

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**Quality and inspection**

- "Quality comes not from inspection but from improvement of the process.
- Inspection is part of the process, but one must use the inspection to improve the process to bring about any quality change
- Quality comes not from inspection only but from applying the inspection results to make improvement to the process
- On to objective 2

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**Objective 2**

- Understand the impact of faulty inspection of your surgical trays during assembly.

**Surgical Site Infections Cost at least \$5 Billion a year. Potential causes:**

**Break in sterile technique**  
**Poor patient health**  
**Unclean instruments**  
**Unsterile instruments**  
**We can reduce or control 3 of the 4 causes**

CDC 1999/CAH focus group February 2003  
 Managing I.C. Volume 4, Issue 1

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## Indiana hospital patients potentially exposed to infection diseases from sterile processing errors.

Nov 27th, 2019

Goshen Hospital in Elkhart, IN has alerted 1,182 surgery patients that they may have been exposed to infectious diseases, according to a statement from Goshen Health. The problem was caused by a technician in sterile processing missing an important multistep cleaning process which could result in contaminated surgical equipment.

The hospital issued statement containing the following details:

Recently, the leadership at Goshen Health became aware of a situation that may have impacted a small portion of our surgical patients only at Goshen Hospital from April through September 2019. During this time, one step in a multistep cleaning process was missed for some specific surgical instruments by one of our seven sterilization technicians.



### LATEST IN REPROCESSING EQUIPMENT

Reprocessing Equipment

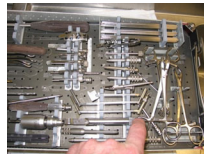
ASP addresses contaminated medical devices reprocessing



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## Dirty facts

- 16% of the loaner instruments tested positive for blood
- When placing the tissue protector on the drill, old dry blood and tissue came out
- Particles of tissue were found in cannulated instruments.



The investigative report said a surgical tool used for inserting a screw in a broken bone was not properly prepared before being sent to be sterilized, containing "biomatter" from a previous patient that should have been removed, the report said.\*

\*6/22/20 - <http://health.heraldtribune.com/2020/06/22/ventnor-hospital-re-bates-staff-after-contaminated-sterilized-surgery-equipment/>

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And you wonder why JC is looking closely at your department

- Training
- SOP not followed
- Link to the story <https://is.gd/6viDum>



### UPMC hospital to face class-action suit over improperly cleaned equipment

**Class-action lawsuit** | November 22, 2019 | 1 min

**IN** **News** New Castle, Pa.-based UPMC Jameson Hospital will face a class-action lawsuit over improperly cleaned ultrasound probes that put more than 200 patients at risk of infection, reports CBS Pittsburgh.

**IN** **News** An internal quality assurance review revealed several staff members did not follow or document proper cleaning procedures for some wands used in internal prostate and OB-GYN exams dating back to October 2017, according to a hospital statement cited by CBS Pittsburgh.

UPMC Jameson immediately implemented corrective measures and notified more than 200 patients who may have been exposed to the dirty equipment. The hospital is also offering affected patients free blood and urine testing, although the hospital said health risks related to the identification breach are "extremely low."

Attorney Dallas Hartman told CBS Pittsburgh numerous patients have already contacted him about the suit, which he plans to file Nov. 22.

"UPMC Jameson is committed to providing high-quality care in the safest environment possible," the hospital said in the statement. "We apologize for the concern and inconvenience this matter has caused our patients and their families."

More articles on legal and regulatory issues:

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### Hospital Inspection Statements of Deficiencies (CMS or State Health Departments completing 2567 forms)

- A medical facility out West\*
  - 1 of 5 sterile processing staff had documented reprocessing competency during orientation
  - 0 of 5 sterile processing staff documented reprocessing competencies in the last 12 months
  - Facility's SOP for ERCP endoscope was missing one IFU line item
- A Hospital out East \*
  - No documentation that reprocessing staff were trained and competency tested
  - No separation of clean and dirty areas (decontamination area not isolated from other areas)

\*Report # 16-00546-388;  
September 2017

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### Past surgical patients at a Denver hospital may be at risk of HIV, hepatitis, state warns \*

CNN reported(4/4/18) that a sterilization breach at a Hospital in Denver may have put patients at risk for infection of HIV, hepatitis B or hepatitis C, according to a release from the Colorado state health department. The hospital is notifying people who had orthopedic or spine surgery between July 21, 2016, and February 20, the release said.

The report also stated the following "Recent survey results released by The Joint Commission, which accredits hospitals in the United States, revealed no errors in our process or protocols," the hospital said."

• <https://www.cnn.com/2018/04/04/health/coronavirus-hospital-sterilization/index.html>

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### FDA – Safety Alert How are you going to meet these requirements?

1/17/2017 - Posted  
ED-3490TK Video  
Duodenoscope by Pentax:  
FDA Safety  
Communication - UPDATE -  
Follow Pentax Validated  
Reprocessing Instructions

"...Immediately remove from service for assessment, and repair or replace any duodenoscope that shows visible signs of damage. Examples of damage may include: loose parts, damaged channel walls, kinks or bends in tubing, holes in the distal end, cracks and gaps in the adhesive that seals the device's distal cap or other signs of wear or damage..."

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## The importance of training

The hospital also did not ensure those employees were competent in disinfection practices, the report said. For example, the inspectors found nurses using a cleaning product without being aware that the liquid had to remain on a surface for three minutes to work.\*

\*<http://www.latimes.com/business/la-fi-infections-ucis-cedars-hospital-20160515-snap-story.html>

For example, at Cedars, inspectors found that employees were not following safety standards as they packed trays of surgical instruments for sterilization in a machine. They found instruments ready to be delivered to the operating room tightly packed in a tray, with employees not opening devices like forceps and clamps at their hinges so that sterilizing fluid could get to all surfaces.\*

\*\*<http://www.latimes.com/business/la-fi-infections-ucis-cedars-hospital-20160515-snap-story.html>

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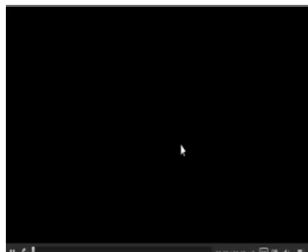
Up to 12,000 children and young adults treated at Seattle Children's Bellevue Clinic and Surgery Center since 2010 could be at risk of infection from surgical instruments that may not have been properly sterilized.

- The lapse was discovered Thursday, 8/20/15, when staff examined some instruments that should have been clean but had tiny amounts of "debris" on them, said Dr. Danielle Zerr, medical director for infection control. "The evidence that there were problems was actually very subtle," she said.
- This is the second time in two years that Seattle Children's has alerted patients about problems with sterilizing surgical equipment.

<http://www.seattletimes.com/seattle-news/health/seattle-childrens-bellevue-clinic-warns-of-exposure-to-potential-risk-of-infection/>

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## Here is what they said 2 years ago



We have seen by the examples presented if we do not do it right each time....patients can be harmed ...on to objective 3

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### Objective 3

- Review the tools you need for inspecting medical devices ?
- Prep and Pack / Assembly
  - Clean and functional
  - Many different tools



- Check instruments for cleanliness, alignment, proper assembly, sharpness, and functionality.
- Follow count sheets.
- Check for holes in all disposable wrappers and filters.
- Check for damage before placing instruments in container systems.
- Utilize enhanced inspection tools when necessary.
  - Lighted magnification
  - Borescopes
  - Microscopes
  - Insulation testers
  - Worktable
  - IFU available
  - Cleaning tests
  - Many other tools

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### Clean and functional

- The Standard is first **"is it visual clean"**
  - Thus first and foremost if it is visual dirty re-clean it
- Enhancing the Visual process
  - Magnification
    - Simple magnifying glass
    - Fiber scopes
    - Computer based microscope magnification
- Is it functional
  - What tests do I use
- Stain identification
  - You want to know what is that stain composed of
    - Organic soil
      - Blood
      - Protein
      - Other
- Understanding the type and source of the stain helps you reduce the chance of it reoccurring
- Who is telling you to visual inspect instruments
  - The manufacture of the instruments with there IFU (Instructions For Use)
  - Standards and guidelines
  - Lastly your customer, wants a quality process
- This becomes part of your quality process
- You check with a QI tray audit

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### Visual Inspection



Support for using a Magnifying Glass  
 ST 79  
 3.2.2.2  
 3.3.7.2  
 Annex D

The most basic verification of the performance of a cleaning process is by carefully inspecting the cleanliness of instruments and materials. All objects should be free of any remaining soils, deposits, pitting etc. Take special care for checking pivots, box joints, instrument serrations. Also cracks can be caused by corrosion, which again is a result of poor cleaning performance. An inspection lamp with a magnifying glass can be very useful for identifying remaining residues.

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Let me sharpen your scissors ?  
I am qualified, really, I am.



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Some of your tools you will need



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## AAMI ST79 New Amendments Inspection of Insulated Instrument<sup>†c</sup>

### 8.2 Inspection of instruments

- “Each time a medical device is processed, it should be visually inspected for cleanliness and integrity”.
- “Enhanced inspection with magnification, borescopes, or other inspection methods to verify cleanliness”
- “And integrity may be used”.



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## AAMI ST79 New Amendments Inspection of Insulated Instruments

8.2.1 Inspection of instruments intended to be used with electric current

- "Damage to insulated instruments including cords can occur during normal use, processing",
- "Instruments should be organized and protected from damage".



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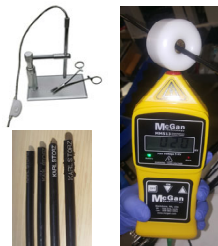
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## Inspection of Insulated Instruments

8.2.1 Inspection of instruments intended to be used with electric current

- "Instrumentation intended for use with electric current should be tested for integrity each time it is processed in accordance with the instrument manufacturer's written IFUs for inspection".
- "The insulation should first be inspected using lighted magnification".
- "Performed following instrument manufacturers' instructions for use".



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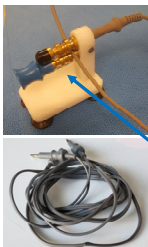
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## Inspection of Insulated Instruments

8.2.1 Inspection of instruments intended to be used with electric current

- "Cables/cords are also a source of concern and need to be inspected and checked for integrity and continuity".



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## Inspection of Insulated Instruments

### 8.2.1 Inspection of instruments intended to be used with electric current

- "The insulation should be checked at appropriate inspection points for the instrument (see Table X and Figure X through Figure X+4)".

Instrument/Device	Inspection Points	Possible Damage	Methods to assist with inspection/testing
Laparoscopic including robotic instrumentation	<ul style="list-style-type: none"> <li>• Shaft</li> <li>• Handles in applicable</li> </ul>	<ul style="list-style-type: none"> <li>• distal tip collar not flush against distal working mechanism</li> <li>• frays at the distal tip of insulation</li> <li>• shaft and handle nicks, cracks, lacerations, gouges, and microscopic pin holes</li> </ul>	<ul style="list-style-type: none"> <li>• insulation tester</li> <li>• lighted magnification</li> <li>• <b>Enhanced magnification (microscope)</b></li> <li>• visual inspection</li> <li>• tactile inspection</li> </ul>

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## Example of a Microscope and Enhanced Magnification



The examples up to now support the next Objective, so onto to 4.

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## Objective 4

- Learn a simple quality program for surgical trays that you can adapt to your department, now and improve your outcomes?



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## Understand the difference QA and QI

- Quality Assurance (QA) measures compliance against certain required standards. Quality Improvement (QI), on the other hand, requires and normally focuses on individuals, while QI is a proactive approach to improve processes and systems.
- Standards and measures developed for QA can inform the QI process. To me, they go hand-in-hand, and you need to be doing both in any medical device reprocessing department.
- Here are real life examples depicting either as QA or QI focus.
- How do we reduce trays errors in our prep and pack/assembly process? This is a QI process.
- A patient had a bad outcome. Is it a nursing, a physician, or some other process at fault? This would be a QA process

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## Use this Approach

- To help you get and maintain Best Practices
- Quality Improvement for Surgical trays
  - Focus-PDCA
- WORK WITH YOUR CUSTOMERS
  - Series of questions
  - Trays checked post sterilization
    - Improving the Quality of your surgical Trays ( Managing Infection Control-3/2006)
      - <http://www.cdguy.net/index.php?c=172&PHPSESSID=795d137fa975f9e8adc93170d87da13b>
- Another step would be to
  - Monitoring your cleaning process
  - Why, if instruments are dirty it starts in the decontamination area
    - That is for another time

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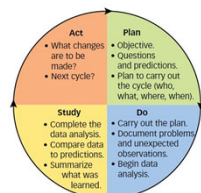
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- Plan
  - What do we want to solve
    - Trays not accurate
    - Damaged instruments
    - Dirty instruments
- Do
  - Design a survey
  - Check standards
    - Yours and your customers
      - ASTAORN, ANSI/AAMI
- Check Study
  - Review data
- Act
  - Now what
- This process does work
- Repeat if needed
  - Adjust

## Focus -PDCA – surgical trays issue



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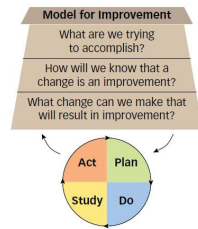
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## Use Your Quality Management Tools to Solve Concerns

- Flow chart
- Collect data
- Fish bone diagram



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## Benefits of a Q.A. Surgical Tray Program

- Data is used to help solve concerns
- SPD professionals interact proactively with customers
- User can identify "trouble trays" in question and they can be monitored using a Quality Improvement tool

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## Benefits, Continued

- Most tray problems are not always employees' fault but rather the result of faulty process
  - Ensuring that each assembly table has proper lighting according to AAMI
  - Providing a magnifying glass to help with delicate instruments inspection
  - Adding a flushing system (spray gun for example) for dirty lumen items
  - Providing a quality insulation tester
  - Worktables that are adjustable
  - Other

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## Benefits, Continued

- Can affect instrument tray changes
  - Updating check sheets
  - Looking at a computer system
  - Data provided from the Q.I. tool can give SPD staff the confidence to support/make changes
  - Indicate that a specific employee is having difficulty with a certain tray and then they can receive help with that tray proactively
  - Buy the correct trays
  - Enhance repair process
  - Protect instruments better
  - Other solutions

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## Benefits, Continued

- Set accurate and realistic goals  
Most employees want to grow, they want to do better, they want to take pride in their work, but they need targets to shoot for  
Unless employees have clearly defined goals, the *path of least resistance* will almost always raise it ugly head.
- Departments that continuously monitor can be one step ahead of potential concerns
- Goals then become measurable and reachable
- Equipment is verified that it is working
- Helps determine the source of errors and work towards reducing them
- Simple Audit tool
  - Questions that help solve the concern
  - Adjust as needed to your facility

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### Circle all responses

1. If sterilization wrap is used is the wrapper free of holes and tears? yes no
2. If a sterilization container is used is it properly locked? yes no
3. Is the tray / set properly labeled on the outside? yes no
4. Does the tray / sets have an instrument count sheet? yes no
5. Does the outside label name match the instrument check sheet name? yes no
6. Is the count sheet filled out completely? yes no
7. Does the tray / set contain proper quantity of instruments? yes no
8. Are all items in the set functional? yes no
9. \*Are all items visual clean? yes no
10. Does the set include an internal chemical indicator? Yes no

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### Example : Orthopedic Basic Tray

- This tray was found to be the #1 orthopedic tray with concerns
- Data is needed to correct the concern
- Find out how many times it is used a week
- Find out how many you have ( each )
- Daily usage ( is a high-volume day)
- What are the concerns with this tray ( rank them in order of reported concerns)

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### Tray Quality Issue Orthopedic Basic Tray

#### • Concerns from your customers point of view

- Incomplete / inaccurate trays (missing items)
- Dirty instruments
- Broken tips

#### • Solutions

- Track problem tray
- Mostly orthopedic type
- Do a post quality check after trays are put in sterile storage

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### Analyze /Solutions

- Check list is it accurate
- When was staff last trained on this tray
- Do you have enough of these trays for your high-volume days
- What type of errors are made
- Is it a specific shift / employee making the errors

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## Solutions

- Have orthopedic rep give in-service
  - No record in last 4 years of this taking place
- Have the head of orthopedic come and give the in-service / resident/ head nurse
- Specific concerns might have specific solutions
  - Dirty instrument / cleaning concerns
    - Dirty lumens
    - spray gun
    - Cleaning equipment not being tested with evidence based clinically relevant product
- Inaccurate counts / training/ check sheets
  - Records showed many changes over the years
- Tip protectors
- Wet packs – soak sheets
- Certified staff

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## Surgical Tray Assembly

Educated

Competent

Certified

Skilled



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## Famous Quotes

“Always do what is right when people are looking” - Mark Twain

“Quality is doing the work right when nobody is looking” - Henry Ford

“What gets measured is improved” - Peter Drucker

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### Quality Quiz

- Do you know who your customers are ?
- Do you know and understand the needs and expectations of your customers ?
- Do you solicit input from customers on their level of satisfaction?
- Is your department easy to do business with ?
- Do you provide legendary, outrageous service to all of your customers?
- Do you treat your employees as well as you treat your customers?

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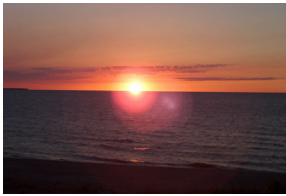
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The sun is setting on this program some closing thoughts...and enjoy the rest of the meeting



- My view is an active QI is very helpful in improving how your department works. It helps you understand your department better and finds new ways to do things, provides a great opportunity for every department to improve, and improvement leads to better patient outcomes. Involve your staff who do the work.
- I also believe that implementation of any quality improvement or risk-based program does not always prevent incidences from happening, but they will help you reduce and understand those incidences better if they do occur.

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### Your Healthmark team here today

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Please share the knowledge you gained today with others where you work.

Thank you too the MN chapter for asking me to speak today.

Scott Pass  
[Scott@medlink-inc.com](mailto:Scott@medlink-inc.com)  
(612) 308-2125



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