Improving the Quality of Surgical Trays

By: Stephen M. Kovach

"Performance measurement in healthcare represents what is done and how well it is done. The goal is to accurately understand the basis for current performance so that better results can be achieved through focused improvement actions [1]."

When JCAHO reviews hospitals, Central Service Departments are asked for quality improvement documentation. Traditionally Central Service Departments (CSD) satisfy this by providing information on their sterilization process.

As the Director of Education for a leading infection control products company, I am frequently asked if I have some other types of quality improvement programs that focus in the area of reprocessing other than sterilization monitoring. One example of this is a Quality Improvement Program (QIP) for the cleaning process[2]. Recently, I have been asked for a cross-functional program that involves both the Operating Room and the Central Service Departments.

As a former Central Service Manager, I still shudder at memories of being called into a room and being shown a dirty instrument or a tray that was "missing " a key instrument needed right then for a case. All I could say was *"What can I do for you now to help you complete your surgery. I will follow up on your concern and get back with you once I investigate what happened."* My follow-up procedure was in the form of an official "incident report" as well as a face-to-face meeting with the affected surgeon.

Surgical tray errors are considered an incident because they may put the organization at legal risk. The term "incident" is broadly defined at many institutions as ***"an event that is not consistent with the routine operation of the department."*** This is why a tray quality process should be designed to help ensure a safer environment for patients and staff. This process should provide a method to investigate, report and review surgical tray errors on an ongoing basis. Establishing a surgical tray quality improvement program allows an institution to look at the surgical tray assembly process that is susceptible to error and takes action to install safeguards.

Why Monitor

"Most people ought to be getting the message that there is going to be a requirement that performance be measured and outcomes be measured and we might as well face up to it.[3]"

We all know that JCAHO wants hospitals to adopt Total Quality Management (TQM) programs. JCAHO is not alone in asking for these such programs.

According to AAMI:

"***A problem analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The problem analysis should define and resolve the problem and the system should be monitored to ensure that the problem has been corrected.*** [4]***"***

In addition, Central Service groups ASHCSP[5] and IAHCSMM[6] both support having TQM within Central Service Departments.

Implementing a surgical tray quality improvement process fits perfectly into any hospital's Infection Control[7], or Risk Management TQM program.

The Benefits

A surgical tray quality improvement process will allow a Central Service Department to:

- Work with their customers one on one and increase customer satisfaction
- Make the staff part of improving the quality of the department
- Set up realistic goals and standards concerning tray quality
- Understand departments process better
- Improve patient outcomes
- Reduce costs
- Improve the quality of trays by reducing errors

Working with Customers, Creating Satisfaction

Implementing a tray quality improvement process allows you to interact with your customer in a proactive way. By meeting with them they can let you know what trays they perceive are the "trouble trays" for their service. It might be the orthopedic basic tray that seems to be missing a "key instrument" or a lumen item that never seems to "get clean." You then can identify the tray and monitor that tray with the quality improvement tool.

Customer satisfaction should increase because you are working ***with*** them on what they perceive as the issue and working towards addressing that concern. Based on my experience, involving the various services and departments, helps tremendously. We had staff physicians talk to the CSD staff on how some of the instruments / trays were used and how important it was for the CSD staff do their job correctly.

Make the Staff Part of Improving the Quality of the Department

Central Service Department (CSD) staff sees this as a process to help them do a better job along with meeting the various requirements of the accrediting agencies.

Monitoring the surgical tray with a quality improvement tool allows you to make improvements to the process, which then helps the employee. In most circumstances it is not the employees fault but rather a process that needs adjusting and thus a better understanding of the process is what is needed to solve the concern. Answers to concerns could be as simple:

- Ensuring each assembly table has proper lighting according to AAMI standards[8].
- Providing a magnifying glass to help with delicate instrument inspection [9].
- Adding a flushing system for lumen items like a spray gun in the decontamination area[10].

A quality improvement process helps with instrument tray changes and the necessary updates to the check sheets and timely in-services. For example, if lumen items were added and they were not being flushed properly, the staff has to be in-serviced again. Using a quality improvement tool can reveal this. Let the data help you make the changes that are needed.

The improvement tool could also show that an employee is having a difficulty with a certain type of tray. Once that is known you can work with that employee and help them assemble that tray correctly.

Set up Goals

Everybody wants 100% accuracy when it comes to surgical trays." You don't want the surgeons and end users to be the primary source of identification for unserviceable surgical instruments."[11] Using a quality improvement process helps you reach and maintain that goal. Inevitably, people will make mistakes, but if you are monitoring the process you can catch errors and reduce the incidence of errors associated with surgical trays. You can be a step ahead of potential problems if you are monitoring them on a continuous basis. Goals then become measurable and reachable.

Patient Outcomes

Having a quality improvement process can only enhance patient care. You will be able to track the source of errors and work towards reducing them. An example would be delays to a case from poor quality of trays. If you can decrease your

error rate (improve) you will have a direct correlation to a patient's care. For example, an Operating Room is waiting for a "missing item" to be found or sent to them. The delay keeps the patient under anesthesia longer. So solving the concern improves the outcome of the procedure. Many times CSD staff only hears that the delay of a case correlates to "lost revenue." What really is important is that a patient could be under anesthesia longer and that could be more harmful than just "lost revenue". ***The key to decreasing errors is making sure everybody understands the bottom line is the patient's outcome***. Errors take on a completely different meaning once everybody understands the life-changing result of errors.

Reduce cost

Almost any article on the subject states that a quality improvement process can save money. An example would be tears in wrapped trays. If the concern is tearing, finding and fixing the source will reduce repackaging and thus reduce costs. It could be as simple as lining wire shelves or teaching the Operating Room staff not to pull the trays out of case carts. It also might prevent going to a heavier weight wrap that costs more. It could also support the movement toward buying containers for certain types of trays. Finding where and when the tear happens is so important to reduce the finger pointing. How many times have we all heard "*I sent it up with no tears*" or "*they did it*" and "*they*" can mean anybody. The quality improvement process helps you find the reason and work on changing the reason for the tear. This program will help reduce both the cost and the finger pointing.

Understanding Your Process Better

By implementing a quality improvement program one is able to fully understand the process. All parties involved will have to learn and use new skills to look at a concern in a quality way and really try and show it is the process that needs improvement. If done correctly gains will be made across all departments. When used properly these tools will help make sure the improvements are made and maintained.

Overview of the Tray Quality Audit Form

The form is simple in design asking the major questions on the possible reasons a tray might have a quality problem. You can add or delete questions based on your hospital but these are the most frequent areas of concern based on my experiences.

A simple tracking form can be used which allows you to look at the responses to various questions. Questions that have a **NO** checked then can be investigated

and solutions can be implemented. (See Table 1) The form allows you to look for patterns in an objective manner. You can track the responses and work first on "the low hanging fruit" (the easy solutions) and then start to tackle the more difficult issues. You will be able to objectively look at data that will help point you in the right direction.

In auditing of the trays when a **NO** is indicated this allows the CSD staff to investigate and head off a concern. Understanding each question and what a **NO** means will allow you to solve the concern easily.

A good example is if you have been using the quality improvement program for any length of time and the audit suddenly shows that instruments "feel different," or have an "oily feeling" or "a stain appears," an investigation can begin immediately to find the cause. Question #9 "*Are items visual clean*?" would now have a lot of **NO's** marked on the audit form.

You then look at the various causes. What kind of stain is it? Blood ? Water stain? Something else? How did the stain get there? Was this stain missed during the inspection assembly process? Did the stain happen during the sterilization process? Was it caused by some solution in the cleaning process? Why do the instruments feel oily?

Getting answers to these questions is important. The first step would be to determine if the stain was blood or something else. There is a new technology that can detect if a stain on an instrument is blood. It is called the **HemoCheck**™ and it is an all-in-one test, which provides a result in 30 seconds, is simple to interpret and indicates blood residue down to 0.1µg.[12]

This is important because if the stain is not blood it makes you look in a different direction. It could be a water stain that appears during the sterilization process. The source of the stain could be caused by something as simple as residual detergent (poor rinsing in the cleaning process) or poor quality of steam. If it is blood then where the stain is located leads you in another direction. For example, if the blood remained in the box lock location: were the instruments in the open position during the automatic cleaning process? The process improvement can also reveal that the staff that assembled the tray did not attend an in-service on this tray (by reviewing your in-service records for this tray). It could be this person was sick the day of the in-service and the proper information was not communicated to them. The improvement process helps you solve the problem and make the proper changes rather than just finger point. It forces you to look at the process and - become a real detective - a ***"Central Sterile Service Investigator (C.S.S.I.)*©** - finding the answers - then implementing the solution – thereby improving the process.

Each question in the audit has its own unique set of action items to a **NO** answer that may be hospital specific. Note that with question #11, "*Was the inside of the*

tray / container wet (moisture) inside," a **YES** answer highlights a major concern with water in a tray so the **YES** is a warning of potential problems. The solution might be as simple as replacing the surgical towel used to line the bottom of the tray with a heavy duty soaker sheet during wrapping to provide for better wicking, as an alternative to increasing the drying time.

Doing the audit on a regular schedule allows you to prevent undesirable preoperative situations. The tool can also be tray or service specific, like orthopedic. For example you might have a concern with a certain type of tray. Auditing trays in this fashion will help you highlight the problem and work on an answer in a positive, proactive manner.

One can see the importance of having a tray quality program to ensure that surgical instrument trays meet specific standards on a consistent basis. The role of having an audit tool is to support the services provided in the Operating Room. Because technology is constantly changing, and both the Operating Room and Central Service are in an ever-changing environment, it is paramount that the tray quality improvement process be implemented to keep up with these changes.

We must remember that a program like this empowers the user to meet their customers' needs by focusing on processes and using the continuous improvement approach. Improvement is then accomplished as a group activity, resulting in team members knowing they can make a real difference in the outcomes and provide better patient care by having complete and accurate Operating Room trays. Monitoring the surgical tray process only makes sense in the drive to continually deliver quality patient care.

About the Author

Stephen M. Kovach is currently the Director of Education for Healthmark Industries located in St.Clair Shores, Michigan. He has been in the Hospital field for over 30 years.

Stephen has been active with his state and national Central Service organizations, having held many leadership positions. He also belongs to the Michigan Lakeshore chapter # 2307 of AORN.

He has received recognition in both his personal and business profession. Stephen is very proud to say he has ***"WORKED IN CENTRAL SERVICE".***

Sample QA Tray Policy

PURPOSE: The purpose of this policy is provide a means of monitoring the quality of trays that are assembled by the Central Service staff as well as being a quality improvement process.

POLICY: The Central Service manager shall be responsible in selecting the type of trays and the frequency of the monitoring those trays (Each hospital puts in the sample size, example might be 20 trays a month). The desired threshold / benchmark is 100%.

RATIONALE: Is that all instrument trays shall be assembled, packaged, sterilized and stored according to standards. The random checking of the trays provides a means of ensuring that each patient has a complete and sterile tray. Checking the quality of trays is part of the hospital infection control /risk management TQM program.

PROCEDURE: Upon direction of the Central Service manager the type and number of trays to be monitored will be established.
Only completed trays will be audited. Audited trays will be taken from a pool of trays that are ready to be used. The trays have been inspected, wrapped and sterilized and place on the shelf ready for use. An audit tool will be used to check all trays (each tray checked has its own sheet). Results are recorded using the Audit Table (table 1) and reviewed and prioritized according to impact to the overall operations.

RESPONSIBILITY: The Central Service manager is responsible for assuring initiation, completion and analysis of the tray monitoring assessment activity.

Audit Table
Table 1
(Results of Audit)

Date of Audit: _____

Audit performed by: _____

Tray name / number: _____

Total number of trays audited: _____

Question #	**Response / YES**	**Response / NO**	**Comments**	
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
Total				

Comments:
_____
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AUDIT TOOL

Quality Assurance check form for instrument set

Audited By: _____Date: _____

Name of Tray Audited: _____

or Initials of Person who assembled the tray: _____

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 the 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
11. Was the inside of the tray / container wet (moisture) inside? Yes No

Note: All items, which are circled NO, must have supporting data written below. If questions # 11 answer is YES, then supporting data must also be given. A question #11 is the only questions that a YES answer highlights a concern.

Notes:

_____
_____
_____
_____
_____
_____
_____

***If more than one item is not visual clean. Select one of the items and test with a HemoCheck™ test according to policy.**

Each tray audited will have an audit sheet.

HemoCheck™ Sample Policy

SUBJECT: Detection of Blood residue on various surfaces

PURPOSE: To test for detection of blood residue on surfaces and to help ensure proper cleaning *and reduce risk to personnel or patients* [13]

POLICY: The **HemoCheck**™ test detects blood residues on various surfaces. The random testing of various surfaces is to be used according to the manufacturer's guidelines to ensure that the cleaning process is being done properly. Test for residues of blood based test soils on: Chamber walls of automatic washers, Ultrasonic cleaner, Operating room tables, work bench, surfaces of surgical instruments are all areas that can be tested for blood residues.

RATIONALE:

"***A problem analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The problem analysis should define and resolve the problem and the system should be monitored to ensure that the problem has been corrected"***.

One such problem is blood residual on various surfaces found in the Central Service and Operating room settings.

Detection of blood residues on surfaces is very important and distinguishing between blood and other type of stains can be very confusing. Finding any stain left on a surface that has been cleaned is never good but if that stain is blood the implications are even more serious.

There has been a growing concern about the effectiveness of decontamination technique for reusable medical instrumentation in healthcare facilities. Studies have shown the ability of sterilization technologies, which under normal conditions achieve acceptable sterility assurance levels, to be greatly impaired by the presence of residual soil containing serum and salt [14]. Residual organic debris on processed surgical instruments is a concern and visual inspection is not a 100% accurate [15]

Testing any surface that is suspect of blood residual is important. The danger of not having a surface properly cleaned or the handling of instruments contaminated with blood is obvious in this age of hepatitis, CJD and HIV. The procedures for sterilizing instruments are based on years of scientific testing of clean instruments. If surgical instruments are not clean, the procedures are ineffective. Dried blood on instruments is hazardous to the employees of the hospital and to the next surgical patient upon which the instruments are used. Have a quality system to help monitor stains that you might suspect as blood is an important function of any Infection Control program. Testing stains with the **HemoCheck**™ and recording results in a log is one such program.

PROCEDURE:

1. Open the protective pouch of the HemoCheck test kit. Included are: A: Indicator-vial (transparent cap), B: activator-vial (green cap) and C: cotton swab.

2. Wet surfaces are swabbed with the dry cotton swab. Dry surfaces are swabbed by moistening the swab with a drop of clean water **(Do not use chlorinated water!).** Swab the sample vigorously.

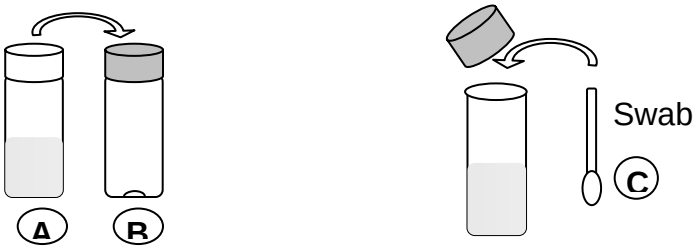
3. Open the indicator vial (A transparent cap) and transfer the liquid into the activator-vial (B green cap).

4. Place the sample-swab (C) into the vial (head down into the liquid) and shake at least 5 times.

5. Monitor the swab for a period of 30 seconds for a color change to blue-green, which will indicate blood residues on the tested surface. In the presence of large amount of blood the whole indicator solution will change to dark blue. Record your result since small amount of blood residue will not form a stable colour. The used test-liquid may change to a light blue-green after several hours, which does not indicate residues.

6. Record results of all tests on Quality form and report results to the appropriate person.

Note: In case of jointed surgical instruments blood residues are most common inside joints, which can be sampled with a swab. Longer narrower swabs can be used for checking inside cannulated instruments.



A: Indicator-vial (transparent cap), B: activator-vial (green cap) and C: cotton swab. Please Note the following

PRINCIPLE

Due to the high content of Peroxidases in blood an enzymatic reaction is used for detection of blood residues.

MEASURING RANGE

The test kit can detect 0,1 µg of blood by showing a slight blue-green spot. 1 µg of blood in the test will already give a dark blue colour.

INTERFERENCES

Oxidising agent like chlorine or hypochlorite (present in some disinfecting agents and detergents) will give a colour change too. In this case the test cannot be used to detect blood residues

STORAGE

Store **HemoCheck**™ in closed pouches in a cool place 2°C- 25°C. Keep away from light and heat

RESPONSIBILITY:

The Central Service manager is responsible for training, assuring initiation, completion and analysis of the monitoring assessment activity for testing of blood residuals on various surfaces.

HemoCheck™ Test Log

Record the Color Change for HemoCheck™ Result

A color changes to blue-green, which will indicate blood residues on the tested surface.

Test Date	Tester Initials	Item Tested	HemoCheck™ Result	Action Taken	Comments	

[1] http://www.jcaho.org/pms/index.htm
[2] Basile,Browne,Kovach; "Measuring Clean in Central Service", Managing Infection Control,8/2004
[3] Gail Warden - CEO - Henry Ford Health System; Quote From Health Management 1/94
[4] page 23, Section 9.2 ANSI/AAMIST35 – 2003
[5] ASHCSP ; Training Manual for Central Service Technicians - Fourth Edition 2001
[6] Central Service Technical Manual; Sixth Edition, 2003: Chapter 15 Quality Assurance and Six Sigma : Published By ; International Association of Central Service and Material Management
[7] Standard IC.1.10: Hospital wide infection control program: JCAHO 2005
[8] page 8 ; section 3.4.6, 2003 Association for the Advancement of Medical Instrumentation ; ANSI/AAMI ST35:2003
[9] Page 5: Section 3.3/gg: 2003 Association for the Advancement of Medical Instrumentation; ANSI/AAMI ST35: 2003
[10] Page 6: Section 3.4.1: 2003 Association for the Advancement of Medical Instrumentation; ANSI/AAMI ST35: 2003
[11] Johnson,S, "Are those instruments sets ready ?"; http://www.outpatientsurgery.net/2005/os11/infection_prevention.php
[12] http://www.hmark.com/HemoCheck.html
[13] ANSI/AAMI ST 35 – 2003: 9.1-General Rationale;9.2 – Quality Process; 9.2e Documentation of Decontamination processing parameters.
[14] Alfa,M.,et al, Comparison of Ion Plasma, Vaporized Hydrogen Peroxide, and 100% Ethylene oxide Sterilization to the 12/88 Ethylene oxide gas Sterilizer, Infection Control and Hospital epidemiology, 1996; 17:92-100
[15] AORR Journal; July 1995,Vol62, NO1;DesCoteaux, Poulin, Julien, Guidoin