

Error Proofing Your Lab by Turning CAPA (Corrective Action/Preventive Action) Into PACA (Preventive Action/Corrective Action)

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Why CAPA/PACA

- Quality Management Systems require that there be formalized systems for both **CORRECTION** of non-conformances as well as for **PREVENTION** of non-conformances.
- This has led to a great deal of confusion between the two. The increased emphasis on ISO-15189 in the laboratory field has only added to the confusion.

ISO STANDARDS

- 8.5.2 Corrective actions:

“the organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence”

- 8.5.3 Preventive Actions:

“the organization shall determine action to eliminate the causes of POTENTIAL nonconformities in order to prevent their occurrence”

Differences

- Corrective Action eradicates the cause of a **DETECTED** non-conformance and its recurrence. Relies on “catching” the issue or receiving a complaint. **REACTIVE**
- Preventive Action- eradicates the cause of a POTENTIAL non-conformance and its recurrence. Looks for potential issues before they happen and is **PROACTIVE.**

As Applied To Laboratory Medicine

- “Preventive action is also known as Quality Assurance and works on implementing mitigating actions and controls to **prevent** defects or non-conformances from occurring in the resultant outcome (product/service). This is the best approach as it prevents services/products actually reaching customers with defects and can therefore lead to reduced after-service complaints.
- Corrective action is also known as Quality Control which is implementing controls to reduce defects and non-conformances **after they have occurred**. There are obviously times when quality control is essential as the entire process needs to be run through to see the actual outcome as oppose to blind testing.”

Catherine Roberts

- In the laboratory industry, we have traditionally dealt with “non-conformances” or errors through the process of corrective actions.
- The error occurs, we fix it and if we follow common sense, we do a root cause analysis to determine WHY it happened and what we can do to keep it from happening again.
- In practice, a root cause analysis is not always performed and the errors re-occur.

- As QMS processes have become more standard in the industry and Process Improvement Methodologies such as LEAN, 6 Sigma, etc. have become more mainstream, there has been increased pressure to develop clear policies and methods to ensure compliance.

Why The Burning Platform Now

The Answer

- **Customer Satisfaction** – a major new emphasis in hospitals as a result of HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems).
 - Scores are now public and available on the WEB.
 - www.hospitalcompare.hhs.gov

What Is Different About HCAHPS?

- Scores posted on the WEB in a comparative format.
 - Compares your organization to its peers and competitors. A lower score indicates less satisfaction.
- There are financial risks based on your performance and score.
 - Medicare withholds a percentage (1%) of funding and returns or withholds it based on HCAHPS scores.

HCAHPS (continued)

- Part of Pay for Performance (P4P).
- Combines HCAHPS data with Clinical Outcomes (Core Measures).
 - There are 12 Core Measures that will comprise 70% of the P4P score.
 - These are the “clinical outcomes” or QUALITY of Care measures that will be measured.
 - These “Core Measures” will be updated annually.

The 12 2013 Core Measures

- 2 Heart Attack
 - Fibrinolytic agent administered w/in 30 min's
 - PCI w/in 90 min's
- 1 Heart Failure (Dx instruct)
- 2 Pneumonia
 - Culture in ED w/o antibiotic
 - CAP immuno-compromised patient

- 7 Surgical Care: Infection and Improvement
 - Prophylactic antibiotics w/in 1 hr of incision
 - Prophylactic antibiotic selection- pre-op
 - Prophylactic antibiotic w/in 24 hrs of surgery
 - Cardiac pts-6AM post-op serum glucose
 - Beta blocker prior to arrival if received during appropriate period
 - Recommended Venous Thromboembolism prophylaxis ordered
 - Venous Thromboembolism prophylaxis w/in 24 hrs prior and post.

Hospital Acquired Condition Measures (FY 2014)

- 1. Foreign Object Retained After Surgery
- 2. Air Embolism
- 3. Blood Incompatibility
- 4. Pressure Ulcer Stages III and IV
- 5. Falls and Trauma: (Includes: Fracture, Dislocation, Intracranial Injury, Crushing Injury, Burn, Electric Shock)
- 6. Vascular Catheter-Associated Infections
- 7. Catheter-Associated Urinary Tract Infection (UTI)
- 8. Manifestations of Poor Glycemic Control

Patient Safety Indicators (FY 2014)

- PSI 06 – Iatrogenic pneumothorax, adult
- PSI 11 – Post Operative Respiratory Failure
- PSI 12 – Post Operative PE or DVT
- PSI 14 – Post Operative wound dehiscence
- PSI 15 – Accidental puncture or laceration
- IQI 11 – Abdominal aortic aneurysm (AAA) repair mortality rate (with or without volume)
- IQI 19 – Hip fracture mortality rate
- Complication/patient safety for selected indicators (composite)
- Mortality for selected medical conditions (composite)

Mortality Measures (FY 2014)

- 1. Mortality -30-AMI: Acute Myocardial Infarction (AMI) 30-day Mortality Rate
- 2. Mortality -30-HF: Heart Failure (HF) 30-day Mortality Rate
- 3. Mortality -30-PN: Pneumonia (PN) 30-day Mortality Rate

HCAHPS (30% of P4P)

- Doesn't really measure "patient satisfaction"; it measures **frequency** of compliance with key questions.
 - You are only rewarded for "ALWAYS" answers. No credit for "usually" or "sometimes" answers.
 - Relies heavily on Nurse and Physician interaction with the patient.
 - Other Health Care staff are just as important even though they are not necessarily measured.

So How Does This
Relate to CAPA/PACA

- **Voice of the Customer**

A foundation principle of the Toyota Production System (LEAN) and of 6 Sigma.

- If you want to satisfy your customer, you need to know what they consider important.
- Regardless of other things, customers want things done right the first time and every time.
- Non-conformities in performance are customer dis-satisfiers.

CAPA

- In a sense, this is closing the barn door after the cow gets out.
 - We now have to go catch the cow
 - We have to bring it back
 - NOW we have to figure out how to keep the door from opening when we don't want it to.

This does not contribute to customer satisfaction.

Preventive Actions

- Are PROACTIVE
 - Examples: PMs, Error Proofing, etc.
- CA and PA are both part of the Deming PDCA cycle.
- PA is based on “PREDICTION” and relies on “fail safe” systems derived from user input.
 - Staff participation, User Groups, Improvement Teams, VOC
 - Use FMEA proactively

Error Proofing

Refers to the implementation of fail safe mechanisms to prevent a process from producing defects.

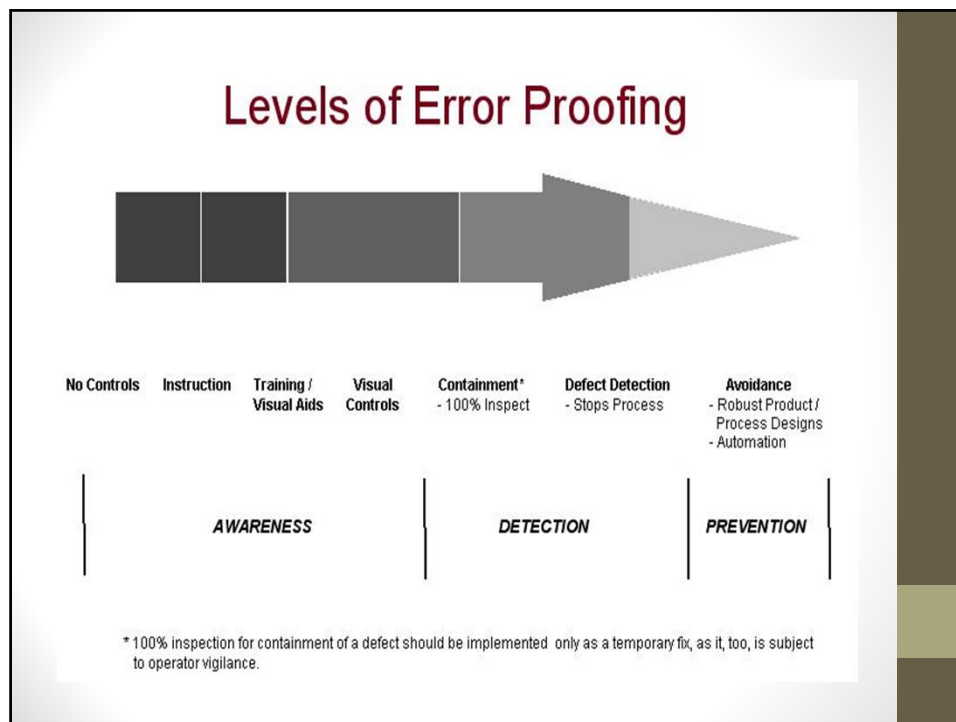
- Poka Yoke (po-ka yo-kay) as championed by Shigeo Shingo at Matsushita
- Jidoka (Gee Do Ka) as developed by Sakichi Toyoda (founder of the Toyota Group)
 - Examples: brake/shift interlock device on your transmission preventing you from starting your car in gear.
 - Automatic pop up on computer program asking if you want to save your work before closing.

Types of Error Proofing

- Warnings
 - Pop ups on computers, software programs
 - Color coding of similar parts, etc.
- Shut Downs
 - Fuse box lockouts to ensure power stays off until proper repairs are done.
 - Electrical breakers shut off if circuit is overloaded
- Auto-Corrections
 - Spell checker software, etc.

Ways to Error Proof

- First FLOW CHART your process
 - Look for areas of potential errors
 - Work backwards to find the source of the errors.
 - Fishbone, FMEA, Root Cause Analysis
 - Look for solutions
 - Elimination – can you eliminate the step?
 - Replacement – can you replace it with an error proofed step?
 - Facilitation – can you make it easier to do it right than it is to do it wrong?



Real Life Examples

- Potential Issue: patient mis-identification leading to specimen collection error.
- Potential Solutions:
 - Barcoded armbands with bar code reading devices that print the specimen label.
 - Armband containing unique information not found on chart & requiring the unique information be noted on the specimen label.
 - Having a second person verify the information on a unit of blood at release from the blood bank and again at the time of infusion.

More Real Life Examples

Computerized Error Proofing Examples

- Automatic pop up in LIS instructing operator with next required steps.
- Automatic Delta Checking in LIS with operator alert via pop-up.
- Liquid Level Sensor alerts on clinical instruments.
- Automatic Medical Necessity Checking at order entry by LIS or MIS systems.
- Biometric sign-on systems to avoid inappropriate use of computer systems.

Tips For Moving From CAPA to PACA

- **Work as a group**
 - Select key stakeholders (include production staff)
 - Group should represent a broad experience
- **Map your processes**
 - Process Map or Value Stream Map
- **Think outside the box**
 - Allow for creativity and candor
- **Close the loop and document!**

Tips For Moving From CAPA to PACA

- Establish a culture of **PREVENTION** (Proactive) versus one of **CORRECTION** (Reactive).
- Encourage and recognize successful preventive actions.
- Continue to search for potential sources of error and prevent them.

Questions?

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