Optimizing Medical Device Safety: A Closed Loop Process

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Speaker Introduction

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Conflict of Interest

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We have no real or apparent conflicts of interest to report.
Agenda

• Background Information
• Improving Medical Device Safety
  – Recalls: *Closing the Loop*
  – Incident Investigation: *Tools & Training*
• Leveraging Technology to Drive Process Improvement
• Summary & Recommendations
• Q & A
Learning Objectives

1. Define and analyze the complexities of medical device safety issues inclusive of recalls and incident response

2. Apply Lean principles for process re-design

3. Develop tools for a closed loop process for addressing medical device safety issues at healthcare organizations that mitigate patient safety risks

4. Describe a case study of an incident which resulted in a recall of medical devices across 150+ hospitals and the mitigation of vulnerabilities
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Meaning</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>ARMS</td>
<td>Alerts and Recalls Management System</td>
<td>VHA Alerts and Recalls Web Application</td>
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<tr>
<td>BME</td>
<td>Biomedical Engineer(ing)</td>
<td>Profession or Specialty (also known as Clinical Engineering)</td>
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<tr>
<td>CDW</td>
<td>Corporate Data Warehouse</td>
<td>National repository comprising data from several VHA clinical and administrative systems</td>
</tr>
<tr>
<td>CEOSH</td>
<td>Center for Engineering &amp; Occupational Safety and Health</td>
<td>VHA National Program Office</td>
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<tr>
<td>HTM</td>
<td>Healthcare Technology Management</td>
<td>VHA National Program Office</td>
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<tr>
<td>MDNS</td>
<td>Medical Device Nomenclature System</td>
<td>Naming convention for uniformly classifying medical equipment used in VA facilities</td>
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<tr>
<td>NCPS</td>
<td>National Center for Patient Safety</td>
<td>VHA National Program Office</td>
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<tr>
<td>RMD</td>
<td>Repairable Medical Devices</td>
<td>A subset of medical devices that generally receive scheduled maintenance and upgrades</td>
</tr>
<tr>
<td>VA</td>
<td>United States Department of Veterans Affairs</td>
<td>Government Agency</td>
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<tr>
<td>VHA</td>
<td>Veterans Health Administration</td>
<td>VA Administration that operates the nation's largest integrated health care system</td>
</tr>
<tr>
<td>VISN</td>
<td>Veterans Integrated Service Network</td>
<td>VHA is separated into 18 geographical areas</td>
</tr>
</tbody>
</table>
About VHA

- 18 VISNs
- 150+ Medical Centers
- 8.9 Million Patients
- 37,353 Beds
- $7 Billion of Medical Equipment Assets

Veterans Health Administration

To Learn More About VHA Visit:
http://www.va.gov/health/aboutvha.asp
Benefits Realized for the Value of Health IT

The Value Steps Impacted:

ELECTRONIC SECURE DATA

- Enhanced Communication
  - Overall Improved Internal Communication
  - Communication Facilitates Better Care

- Data Reporting
  - Improved Quality Measures Reporting
  - Automated Reporting
  - Improved Joint Commission Reporting
Medical Device Recalls Doubled in a Decade

- Annual recall counts increased 97% in ten years (2003-2012)
- Notable increase in defective devices with a reasonable probability of death (Class I)
- The most common recall causes were resulted from software design failures

US Food and Drug Administration/Center for Devices and Radiological Health (2014) [Medical Device Recall Report FY2003 to FY2012](#)
The Slew of Medical Device Recalls Continues

Since 2012, annual recall totals increased **139%** and Class I recalls increased by **404%**.

Forecasted recall totals to climb over **4,000/year** by 2025.
Optimizing Medical Device Safety

VHA Biomedical Engineers are leading LEAN process redesign efforts for medical device recalls and incident investigations.

This work has eliminated waste, and improved understanding and communication to all stakeholders.

The closed-loop process ensures that facilities complete assigned actions to improve the safety of medical devices in VHA.
Approach to Improvement

A3 Thinking

1. Reason for Action
2. Current State
3. Target State
4. Gap Analysis
5. Solutions Approach
6. Rapid Experiments
7. Completion Plan
8. Confirmed State
9. Insights
Reason for Action:

• Medical device recalls require *REMOVAL* or *CORRECTION*

• Existing national policy only addressed *remove-from-use* recalls

• Legacy process for *corrective action* recalls lacked:
  – Standardization
  – Automation
  – Transparency
Legacy RMD Recall Process

**CO Perspective**

1. **Review Alert Sources**
   - FDA, ECRI, Manufacturer, etc.

2. **Assess Risk Using Scoring Guide**
   - High Potential Risk? (Class I)
     - Yes: Stop
     - No: Go to next step

3. **Is VA likely affected?**
   - Yes: Proceed
   - No: Stop

4. **Discuss Issue w/ MFR (if needed)**
   - No: Proceed
   - Yes: Proceed

5. **MFR's process adequate to address the issue?**
   - Yes: Proceed
   - No: Develop adequate process with MFR, HTM, NCPRD

6. **Can affected VAMCs be easily identified?**
   - Yes: Proceed
   - No: Follow through with plan (may mean Patient Safety Alert, or memo, or modified instructions to targeted communication)

7. **Watch for more information to become available & investigate further if time allows**

8. **Stop**

**Facility Perspective**

1. **Receive Recall from a source**
   - FDA, ECRI, Manufacturer, Internal

2. **BME responsible?**
   - Yes: Evaluate inventory in CMMS
     - Does site have affected inventory?
       - Yes: Discuss issue w/ MFR (if needed)
         - Can risk be mitigated per instructions now?
           - Yes: Complete instructions to mitigate risk
             - Enter work order in CMMS and manually track actions and associated information
           - No: Watch for more information to become available; issue potentially lost in shuffle of shiny objects and squirrels
         - No: End process
       - No: End process
   - No: Proceed to next step

3. **Respond to source that BME not responsible**

4. **Stop**
Hospitals Bombarded by Information

- VA Medical Centers
- VA Contracting
- VHA Program Offices
- External Health Care Systems
- Manufacturers
- Distributors
- Third Party Servicers
- Other Govt Agencies (e.g., FDA, CDC, DOD)
- Research Institutes (e.g., ECRI)
Addressing the Gaps

**Standardization**

**2011: Nomenclature Standardization**
- Mandatory naming standards for all RMD

**2013/2014: Process Development**
- RMD Patient Safety Work Group
- Initial ARMS Trial

**2015: Process Standardization**
- Enterprise-wide Training
- Full ARMS Implementation

**Automation & Transparency**

**2016: Useful Reporting & Compliance Monitoring**
- Meaningful enterprise-wide reports
- Key Performance Indicators
Initial Challenges

• Creating useful reports presented a number of challenges:
  – Database not created with SQL reporting in mind
    • Duplicate entries for items when they were assigned to multiple staff members
    • Table structure was not optimized for joining the desired data
  – What data is most meaningful to each level
  – Overall presentation of the data
• Organizational Culture Barriers
  – Resistance to change
The New & Improved
RMD Recall Process Overview

Obtain and Catalog Notification
Analyze and Disseminate
Validate and Take Action
Report & Confirm
Completing RMD Recalls in ARMS

Facility Perspective

PRO-10990 (Philips Allura Xper R/F Systems with software...)

This Repairable Medical Device Was Completed On 10/11/2016 18:16

AFFECTED IN STOCK: Yes  TOTAL ITEM COUNT: 1

ACTION 1

Verifed: On 10/08/2016 16:24

Due Date: 10/17/2016

ACTION: Determine whether your facility has the Allura Xper R/F System or the UNIQ X-Ray System in the inventory, or if these systems have been acquired but not yet been entered into the inventory.

Assigned To:


ACTION 2

Due Date: 04/03/2017

ACTION: If your facility has the affected systems, Biomedical Engineering shall:

1. Identify whether your software version on the Allura Xper is R8.2 or software version on the UNIQ X-Ray is R1.0.
   a. Complete this recall as all instructions are completed, and upload an attachment in the final instructions that states the devices are in stock but with different software versions.
   b. If your software version is R8.2 on the Allura Xper, or R1.0 on the UNIQ X-Ray,
      a. Complete this recall as all instructions are completed, and upload an attachment in the final instructions that states the devices are in stock but with different software versions.
      b. Forward this notification letter to clinical end users so that they are aware of the potential issue.
      c. Contact your local Philips service representative to schedule replacement of the affected DCPS.

Assigned To:


ACTION 3

Due Date: 04/10/2017

ACTION: Document completed actions in AEMS/IMERS or Maximo work order.

Final Action Attachments (1)

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<tr>
<th>ID</th>
<th>Description</th>
<th>File Name</th>
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<tr>
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<td>500_RE_[EXTERNAL] RE_Philips Allura Software Revision Number and__UNIQ Xray__ PRO-10990.pdf</td>
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</table>
Closed Loop Verification of RMD Recalls

**CO Perspective**

### Real-Time Status Updates

- **Pink: Unassigned**
  - No action taken

- **Purple: Assigned**
  - Assigned out for action but not yet closed

- **Yellow: Pending** (may be waiting for credit)
  - The check = compliant with the due date

- **Green: Complete**
  - Stations that have completed all actions but did not meet the final action due date will show as green but will not have a check mark for compliance.

- **Green: Complete with a Check**
  - Stations that have completed all actions and are compliant with the due date will show as green and also have the check mark.

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**Action Response Grid**
Improved Data Reporting

Before

After
# ARMS Action Compliance Reports

## ARMS Action Compliance Report

**Report Description:** This report shows the facility's currently pending as well as completed first and final actions of RMD hazard alerts/recalls using the NCPS Recall database in real-time. This data is part of the Key Performance Indicators in the HTM Scorecard.

## Currently Open Recalls

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<tr>
<th>Priority</th>
<th>Action Type</th>
<th>Status</th>
<th>Recall ID Number</th>
<th>Date Posted</th>
<th>Product Name</th>
<th>Product Model</th>
<th>Action Due Date</th>
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<tr>
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<td>Fding</td>
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<td>Backman Coulter UniCal Dvi Stainman Stainer Cellular Analysis Systems Part/Reference (REP) No 778223</td>
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<tr>
<td></td>
<td>Final Action</td>
<td>Open And Ovrdue</td>
<td></td>
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## Closed Recalls

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<tr>
<th>Priority</th>
<th>Action Type</th>
<th>Status</th>
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<th>Action Due Date</th>
<th>Product Name</th>
<th>Product Model</th>
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<th>Action Complete Date</th>
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<tr>
<td>Class 1 Recall</td>
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<td></td>
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<tr>
<td>Standard Recall</td>
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Medical Device Incident Investigation

• Standardization of medical device incident response and investigation also needed to improve safety.

• Frontline staff critical to ensuring thorough investigation and determination of root cause(s).

• Quicker identification of issues leads to quicker solutions for risk prevention or mitigation.
Critical Steps for Conducting an Investigation

1. Emergency Response
2. Secure the Area
3. Identify Potential Witnesses
4. Collect Evidence & Record Data
5. Impound All Devices & Disposables
6. Establish Chain of Custody
7. Examine Suspect Device
8. Conduct Interviews
9. Review Data
10. Prepare Incident Report
Key Elements of a Successful Incident Investigation

Facilities are trained to:

• Provide back-up equipment or spare equipment
• Preserve all the evidence for the investigation
• Sequester equipment
• Report and document findings/conclusions
Medical Device Incident Response & Investigation: Sample Go-bag Assembly
Medical Device Incident Response & Investigation: Sample Go-bag Contents

- Investigation Forms
Medical Device Incident Response & Investigation: Sample Go-bag Contents

- Investigation Forms
- Tags/Labels/Markers
Medical Device Incident Response & Investigation: Sample Go-bag Contents

- Investigation Forms
- Tags/Labels/Markers
- Tools / Analyzers
Medical Device Incident Response & Investigation: Sample Go-bag Contents

- Investigation Forms
- Tags/Labels/Markers
- Tools / Analyzers
- Camera
Example: Medical Device Incident Investigation

• After procedure, staff attempted to return imaging table to lowest position.

• Staff reported hearing an unusual noise after exiting the area with the patient.

• Imaging table (~900 lbs) found tipped onto its side prompting an investigation.

• No harm occurred; however, this failure has the potential to cause injury and/or death (close call).
Example: Medical Device Incident Investigation

Correctly Installed Table Pivot Assembly

VHA Identifies & Ensures Manufacturer’s Correction of All Misinstalled Table Pivot Assemblies

Bush Found Incorrectly Rotated 180°

Bush Found Incorrectly Rotated 90°

Bush Found Incorrectly Rotated 90°

Screws Missing
Facilitating Better Care Through Training

- BME RCA participation improved by 71%

- Overall BME time spent on medical device safety & risk management activities increased by almost 4,000% (300 to 11,885 hrs)

- Increased participation leads to better solutions and better care

  **Safer Systems • Safer Care**
Example: Using ARMS to Aid RMD Investigation

FACILITY INVESTIGATION
- VHA Staff Proactively Identified a Medical Device Safety Issue

NATIONAL INVESTIGATION
- ARMS Used to Elicit Frequency and Determine Cause of Failure

MANUFACTURER CORRECTIVE ACTION
- Software Defect Corrected Enterprise-wide

OUTCOME
- Prevented Patient Harm!

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<tr>
<th></th>
<th>26-Jan</th>
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<td>85</td>
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<td>97</td>
<td>95</td>
<td>94</td>
<td>88</td>
<td>75</td>
</tr>
</tbody>
</table>

*The NBP-Dias and the NBP-Mean readings that are outlined in RED are switched on the Vital Signs graph pulled from the CIC.

*The NBP-Dias and the NBP-Mean readings that are outlined in GREEN are in the correct row on the Vital Signs graph pulled from the CIC.

Close Call: BP Data Inversion
In Summary...

• Medical device recalls and reported safety issues have significantly increased in the past several years

• Streamlining and standardization necessary (e.g., process, data, behavior)

• Closed-loop process developed using LEAN for addressing medical device safety issues across healthcare system that mitigate patient safety risks

• Provided tools and training to the field to facilitate successful medical device incident investigations

• Safer systems, safer care!
Benefits Realized for the Value of Health IT

The Value Steps Impacted:

ELECTRONIC SECURE DATA

- Enhanced Communication
  - Overall Improved Internal Communication
    - Communication Facilitates Better Care

- Data Reporting
  - Improved Quality Measures Reporting
    - Automated Reporting
    - Improved Joint Commission Reporting
Recommendations for Other Hospitals

- Establish an enterprise-wide medical device inventory.
- Standardize nomenclature for medical devices.
- Standardize work action codes for work completed on medical devices.
- Develop a standardized process for reporting incidents with medical devices.
- Implement closed-loop processes for important safety issues.
- Create valuable reporting tools that are necessary for monitoring facility compliance with important safety issues and completing the closed loop process.
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Questions

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*Please remember to complete the online session evaluation.*

Thank You!