2023-2024 Educational Webinar Series

Recall Management Best Practices

March 21, 2024

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About the Moderator

Martin Poulin, P.Eng., FCMBES
Director, Biomedical Engineering
Island Health, Victoria, BC, Canada

- Director of Biomedical Engineering for Island Health, Victoria, BC, on the west coast of Canada.
- 25+ years health technology management
- 5 years in the medical device development industry in Vancouver.
- Master of Engineering in Clinical Engineering from UBC
- Past President of CMBES
Logistics

- All attendees have their microphones muted during the presentation.
- Questions to the panelists must be submitted via the “Q&A” feature in Zoom at any time. They will be addressed at the Q&A portion, slide#39.
- If there is any urgent issue, please use the “chat” feature to communicate with the host/moderator.
- Please remember to complete the webinar evaluation after attending. A link will be provided at the end, slide#40.
Review of Recall Management Best Practices to improve patient safety and ensure regulatory compliance. This session will discuss through effective recall response strategies and provides insights from healthcare organizations’ recall management journey.
Tom Toczylowski is the Assistant Director of the ECRI Alerts product, which provides ECRI members with recall and safety notifications to help safely manage medical devices, pharmaceuticals, and other medical products. A proud ECRI employee since 2008, Tom manages a group of writers, editors, and data coordinators who all contribute to ECRI’s Alerts, recall management solutions, and inventory management products.

In addition to his many years of experience with medical device safety, recall management software solutions, and equipment data standardization, Tom has maintained a focus on the clinical laboratory and laboratory research. Prior to coming to ECRI, Tom spent several years working in molecular research laboratories at Fox Chase Cancer Center and Thomas Jefferson University.
Best Practices for Recall Management

1. Have a Recall Policy with intention of enforcing it
2. Sponsorship of Recall Management within a hospital, no matter the size.
   1. No support leads to users not monitoring recalls
3. Primary tracker for each area - (SME) but also have a backup for when that person is on
   PTO or extended leave
4. Maintain up to date user list
   1. Notification sent to head of Recall program regarding employees that have left to maintain up to
      date list of users
   2. Review list of users anywhere from quarterly to yearly depending on frequency of turnover
5. Training manual with how to track recalls per system you are using
6. Regular reporting to ensure tracking
7. High Completion Rate
Successful Recall Management Key Concepts

• How alerts information is obtained and shared

• How to address and monitor program compliance

• Internal and external documentation needs

• How to report to program participants
Leadership and Sponsorship

• Challenges
  • Executive Sponsorship
  • Involvement of Patient Safety and/or Risk Management
  • Promoting Alerts Management as a Patient Safety Initiative

• Best Practices
  • Involvement of Patient Safety and/or Risk Management department
  • Promoting accountability through effective leadership
    • Sponsorship, Oversight, Awareness, Written Policy, Program Cohesion
  • Establish Alert Evaluation Team
Collaboration

• Challenges
  • Promoting and maintaining participation
    • Overcoming resistance to involvement
    • Avoiding duplication of effort

• Best Practices
  • Cultivate a network of safety advocated
  • Sufficiently documented process
  • New employee onboarding process
Alerts Acquisition and Review

• Challenges
  • Have the right information
    • Externally
    • Internally
  • Reliability of sources
    • Accuracy, Completeness, Timeliness

• Best Practices
  • Obtaining and sharing alerts information
  • Manage internal non-recall incidents
  • Preparatory measures when not following recommendations
  • Ensuring alerts are not missed
Documentation and Reporting

• Challenges
  • Complete, accessible record of how affected
    • Did this alert affect us?
    • Has it been resolved?
    • Who did what and when?

• Best Practices
  • Maintaining complete and accessible documentation
    • Internal needs – i.e., Safety Committee
    • External needs – i.e., FDA, Joint Commission
  • Update policies as needed
  • Feedback to sponsors and participants
Recall Management
Measures of Success

- Reporting/Feedback
- Complete Coverage
- High Compliance
- Leadership & Policy
Reporting Routines

• Compliance
  • To ensure that users are addressing Alerts
  • ECRI Recommendation: 95% Completion Rate
  • Send to users on a monthly/quarterly basis

• Percent Tracked as Applicable
  • To ensure that users are addressing Alerts correctly
  • ECRI Recommendation: 5-7%

• List of Alerts Tracked as Applicable
  • To report to Safety/Environment of Care Committees
SHELLY LEACOCK is a Clinical Engineer with the Department of Veterans Affairs (VA) for over 18 years
• Provides direction and support regarding equipment management, alerts, recalls, incident response, continuing education, medical device safety, and more.

AWARDS
• AAMI Young Professional Award (2014)
• AAMI & Becton Dickinson’s Patient Safety Award (2019)

HTM COMMUNITY ENGAGEMENT
• ACCE Board
• AAMI Healthcare Technology Leadership Council
• AAMI Equipment Management (EQ) Standards Committee
• NFPA 99 Medical Equipment Standards Committee
• Medical Device Servicing Community
• ECRI Health Devices Advisory Board
Learning Objectives

1. Learn requirements of an alerts/recalls management process and how to apply them at your hospital or organization.

2. Learn the process that VHA HTM uses for the management of equipment alerts and recalls including the risk and resources evaluation process.

3. Understand the importance of documenting and tracking the corrective actions and their completion.
A Closed-Loop Process for Remediation of Equipment Alerts/Recalls

Agenda

1. Introductions and Background
2. Intake
3. Evaluate
4. Mitigate
5. Continuous Improvement
6. Takeaways
7. Discussion
1 | Introductions: VA HTM

- $10 billion of healthcare technology
- 900,000 medical devices and clinical systems
- 1,800 Biomedical Engineering professionals

1 CENTRAL OFFICE
18 VETERAN INTEGRATED SERVICE NETWORKS
171 MEDICAL CENTERS
1 | Background: High Reliability Organizations
The VA Office of HTM provides policy oversight for the management of medical technology across VA consistent with relevant laws, regulations, industry standards, and accreditation requirements, including:

- **Safe Medical Devices Act of 1990**
  Public Law 101-629

- **Food and Drug Administration**
  21CFR 803, Medical Device Reporting

- **Association for the Advancement of Medical Instrumentation**
  EQ56, Recommended Practice for a Medical Equipment Management Program

- **The Joint Commission**
  Standard Environment of Care
  EC.02.04.01, EC.03.01.01, EC.04.01.01

- **National Institute of Standards and Technology**

- **Department of Veterans Affairs**
  VA policies and standards
A medical equipment recall is a method for **correcting or removing** medical devices from use that are in violation of laws administered by FDA or otherwise deemed defective or potentially harmful to patients.

Alerts and recalls are **initiated** by manufacturers, FDA request or order, and healthcare systems. VA initiates and conducts internal alerts/recalls when a safety issue is found at one or more local facilities and there are risk mitigating actions that can be implemented.

**CORRECTION** means repair, modification, adjustment, relabeling, destruction or inspection of a medical device without its physical removal.
1 | Background: VHA Alerts/Recalls Management Components

Executive sponsorship
Written policies
Comprehensive sources of recalls
Programmatic collaboration to limit duplicative efforts
Ability to target facilities that have the affected equipment
Internal recalls
Specific actions and due dates
Closed-loop process
Clear and consistent communication channels
Training events

is a critical patient safety program with key components:
Process Overview: Intake, Evaluate, Mitigate

01 INTAKE
Receiving and documenting awareness of an alert or recall, checking applicability against inventory, and identifying mitigating activities

02 EVALUATE
Setting priorities and deadlines for mitigating actions through evaluation and scoring of associated risks and resource needs

03 MITIGATE
Communicating mitigating actions, performing them, and “closing the loop” by tracking, measuring, and reporting their completion
2 | Intake: Research Alerts & Recalls

PROACTIVELY RESEARCH ALERTS & RECALLS

MANUFACTURERS & VENDORS
VA HTM departments forward all alerts/recalls to a central POC for processing

PROFESSIONAL ORGANIZATIONS
VA maintains an ECRI Membership and searches postings by ECRI and FDA

INTERNAL INCIDENTS
VA facilities report incidents to a central POC and VA-only recalls are created as needed

INTAKE

Research Alerts & Recalls
Document Awareness
Check Inventory
Establish Mitigation Actions

EVALUATE

Assess Severity
Determine Frequency
Rate Detectability
Score Clinical Impact
Measure Resources

MITIGATE

Track Action Completion
Measure Compliance

MANUFACTURERS & VENDORS

PROFESSIONAL ORGANIZATIONS

INTERNAL INCIDENTS
2 | Intake: Document Awareness

DOCUMENT ALL ALERTS/RECALLS

centrally within multi-hospital program

Document Date Received, Priority/Designation, Status

Discard duplicate issues

Confirm applicability to HTM scope of services

Notify other service lines if relevant
2 | Intake: Check Inventory

SEARCH EQUIPMENT INVENTORY FOR THE AFFECTED MODEL

MULTI-HOSPITAL PROGRAMS
search inventory centrally

STANDALONE FACILITIES
search inventory locally

VA HTM performs nationwide inventory searches and assigns and notifies only the facilities that have the affected equipment.

A complete and accurate inventory with standard naming conventions facilitates this process!
2 | Intake: Establish Mitigation Actions

IDENTIFY ACTIONS

<table>
<thead>
<tr>
<th>WHO</th>
<th>WHAT</th>
<th>WHEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stakeholders responsible for completing actions e.g., HTM, manufacturer, vendor, clinical</td>
<td>Mitigating actions e.g., changes to PM procedures, EOC rounds, or other activities</td>
<td>Timelines to complete actions e.g., immediate vs. future</td>
</tr>
</tbody>
</table>

FOR ADDITIONAL INFORMATION
Reach out to the manufacturer to understand scope of affected equipment, risk factors, mitigation strategies, and required actions – maintain list of manufacturer contacts

Communicate with other facilities to understand issues they may be experiencing, effectiveness of mitigating actions or questions they have

EVALUATE

- Research Alerts & Recalls
- Document Awareness
- Check Inventory
- Establish Mitigation Actions
- Assess Severity
- Determine Frequency
- Rate Detectability
- Score Clinical Impact
- Measure Resources

MITIGATE

- Track Action Completion
- Measure Compliance
3 | Evaluate: Assess Severity

**SEVERITY**

the degree to which the failure causes harm (injury, illness, or death)

| 4 | Catastrophic | Failure can cause death, injury, or illness that requires medical or surgical intervention to prevent permanent loss of function in sensory, motor, physiologic or intellectual skills to patient, visitor, or staff. |
| 3 | Major | Failure can cause permanent lessening of bodily function (including but not limited to sensory, motor, physiological or intellectual) and disfigurement to patients, visitors, and staff. |
| 2 | Moderate | Failure can cause injury or illness that requires medical or surgical intervention, requiring increased length of care or loss time from work to patients, visitors, and staff. |
| 1 | Minor | Failure causes no injury or illness and requires no medical or surgical intervention other than first aid treatment. Requires no increased length of care or loss time from work to patients, visitors, and staff. |
3 | Evaluate: Determine Frequency

**FREQUENCY**

the likelihood the failure will occur in your hospital(s) over a defined time

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Likelihood</th>
</tr>
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<tbody>
<tr>
<td>4</td>
<td>Frequent</td>
</tr>
<tr>
<td>3</td>
<td>Occasional</td>
</tr>
<tr>
<td>2</td>
<td>Uncommon</td>
</tr>
<tr>
<td>1</td>
<td>Remote</td>
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</tbody>
</table>
3 | Evaluate: Rate Detectability

**DETECTABILITY**

the likelihood of the failure being recognized by users before the failure occurs

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**3 | Low**

Vulnerability or defect **will not be identified or detected** by the user.

---

**2 | Moderate**

Vulnerability or defect **may be discovered prior to injury or use.**

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**1 | High**

Vulnerability or defect **will be obvious** to the user and will be **discovered before the patient is harmed.**
3 | Evaluate: Score Clinical Impact

**CLINICAL IMPACT**
the degree to which the failure interrupts clinical operations or functions.

<table>
<thead>
<tr>
<th>Vulnerability or defect</th>
<th>Interruption of Clinical Operations or Functions</th>
<th>Use of Affected Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Interrupts all clinical operations or functions associated with the affected medical device. Use of affected devices may not continue and they must be removed from service. Alternative equipment is likely not available.</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Interrupts some clinical operations or functions associated with the affected medical device. Use of affected devices may continue with deactivation of affected features or alternative risk reduction plan.</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>Does not interrupt clinical operations or functions associated with the affected medical device. Use of affected devices may continue.</td>
<td></td>
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</tbody>
</table>
3 | Evaluate: Risk Score

PRIORITIZE HIGH RISK RECALLS AND ASSIGN SHORTER DUE DATES

Classified as High Risk if any of the following apply:

- Overall Risk Score of 32 or greater
- Severity Score of “4” (Catastrophic)
- Clinical Impact of “3” (High)
- FDA Class 1
- Resulted in death(s)

CLINICAL IMPACT VS. DETECTABILITY

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</tbody>
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INTAKE
- Research Alerts & Recalls
- Document Awareness
- Check Inventory
- Establish Mitigation Actions

EVALUATE
- Assess Severity
- Determine Frequency
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MITIGATE
- Track Action Completion
- Measure Compliance
3 | Evaluate: Measure Resources

RESOURCES SCORE

CRITERIA
must meet 2 of 3 to be labeled as HIGH RESOURCES

1. NUMBER OF AFFECTED UNITS
   - 500+ devices affected

2. NUMBER OF AFFECTED FACILITIES
   - 50+ sites affected

3. COMPLEXITY OF REMEDIATION
   - highly complex remediation
     must meet 4+ subcriteria, requiring:
     - Removal of device from service
     - Clinical precautions before remediation
     - Replacement/loaner before remediation
     - Third-party service on site
     - Return of the device to the vendor
     - Parts/replacements
     - Travel to other hospitals/clinics

HIGH RESOURCES recalls are assigned longer due dates

INTAKE
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MITIGATE
- Track Action Completion
- Measure Compliance
4 | Mitigate: Track Action Completion

DOCUMENT ACTION COMPLETION
Establish a process for assigning alerts/recall records as open/closed

BENEFITS

Closes the Loop!
confirms mitigation of risk

Supports measurement of compliance
must record date of action completion

Informs evaluations of future alerts and recalls
High Reliability Organization!
4 | Mitigate: Measure Compliance

**MEASURE COMPLETION OF ACTIONS**

**Final Action Compliance**
percent complete by the Due Date

\[
\frac{\text{# of Actions where the Final Action was completed and verified by the Due Date}}{\text{# of Actions where the Final Action was Due in a given month or quarter}}\]

**Open Overdue Recalls**
number of open and overdue Final Actions

**INTAKE**
- Research Alerts & Recalls
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**EVALUATE**
- Assess Severity
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**MITIGATE**
- Track Action Completion
- Measure Compliance
4 | Mitigate: Measure Compliance

MEDICAL DEVICE RECALL COMPLETION BY QUARTER

FISCAL QUARTER

% COMPLETE

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%


Cumulative Completion On Time Completion

MITIGATE

EVALUATE

INTAKE

Research Alerts & Recalls
Document Awareness
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5 | Continuous Improvement

**IMPROVE REPORTS**
Improve inventory reporting to better target affected sites and develop and provide more real-time reporting for better performance monitoring.

**IMPLEMENT ENTERPRISE SYSTEMS**
Deploy and utilize an enterprise work order system to issue, track, and measure remediating actions.

**SHARE BEST PRACTICES**
Engage with VA HTM Community and larger industry community to share and learn best practices.

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[webinar series link]

[VA Careers](vacareers.va.gov)
[Job News and Advice](find-fit-tcf-programs.gov)
[VA Jobs](www.va.gov)
[US Jobs](www.usajobs.gov)
6 | Takeaways

1. Establish a program
tailor components of an alerts and recalls management program to create standardized policies and functions

2. Implement a process
span phases of Intake, Evaluate, and Mitigate to manage risks, prioritize resources, and monitor performance

3. Close the loop
document and track corrective actions associated with alerts and recalls to ensure their completion
Questions / Comments / Concerns

Please enter your questions/comments/concerns to both speakers in the Zoom Q&A window.
Thank you

Please complete the online evaluation form at
https://www.surveymonkey.com/r/2024-session7

or scan the QR code

Stay tuned for the April 11th ACCE education webinar