2022-2023 Educational Webinar Series

CE and Risk Management Associated with Medical Device Incident Investigations in the VA Healthcare System

December 08, 2022

Speakers:

Henry Stankiewicz, Jr., CCE
Clinical Engineer
Sigma Healthcare Consulting

Shelly Leacock, MS, CCE
Biomedical Engineer
VA Center for Engineering & Occupational Safety and Health
ACCE gratefully acknowledges the sponsorship of the 2022-2023 Educational Webinar series by
About the Moderator

Nader Hammoud is currently the Biomedical Engineering Manager, at John Muir Health

- Biomedical Engineer with 3 degrees in Biomedical Engineering and an MBA
- International Experience
- Active member of the HTM community
- Member of the Technology Management Council at AAMI
- ACCE Education Committee Co-Chair
- California HTM of the year for 2018
- Recognized by ECRI and FDA for efforts in the domain

Nader Hammoud, BE, MBA, CHTM
Biomedical Engineering Manager
John Muir Health
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.

• 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.
HENRY (HANK) STANKIEWICZ is a Clinical Engineer with Sigma Healthcare Consulting for the past 10 years.

- Worked 35 years as a Biomedical Engineer and senior management roles in the VA
- Led HTM programs as Chief BME at the medical center, regional, and enterprise levels
- Pioneered a regional consolidated HTM Program within VA

AWARDS

- ACCE Lifetime Achievement Award (2021)
- VA Chief BME of the Year (2x)
- ACCE Leadership Award (2011)

HTM COMMUNITY ENGAGEMENT

- Former member ACCE Certification and Awards Committees
- Former VP of the Healthcare Technology Foundation
- Member of ACCE, IEEE, Etta Kappa Nu, and NESCE
About the speaker

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

Shelly Crisler Leacock, MS, CCE, PMP
Session Description

• How the VA investigates the medical device incidents that occur in its 171 hospitals and numerous clinics, the VA Incident Investigation Guidebook

• How the VA communicates the information across the enterprise and manages the risk associated with these incidents; Brief description of the Alert and Recall Management

• Review the data trends from almost 10 years of formal incident investigations
  • Devices involved in incidents
  • Root and secondary causes

• Discuss future directions and activities
Agenda

1. Presentation Learning Objectives
2. VA HTM and Sigma Health Consulting
3. Hospital Roles
4. Incident Investigations
5. Alerts and Recall Management
# Agenda

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Presentation Learning Objectives</strong></td>
</tr>
<tr>
<td>2</td>
<td><strong>VA HTM and Sigma Health Consulting</strong></td>
</tr>
<tr>
<td>3</td>
<td><strong>Hospital Roles</strong></td>
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<tr>
<td>4</td>
<td><strong>Incident Investigations</strong></td>
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<td>5</td>
<td><strong>Alerts and Recall Management</strong></td>
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1 Presentation Learning Objectives

1. Understand the role of VA Office of HTM and Local Hospital Biomed in patient safety - medical equipment incident investigations and Alert/Recall Remediation

2. Understand the roles of Hospital Biomedical Engineers, Risk Management, and Patient Safety Officers in the VA

3. Understand how HTM works on incident investigations and alerts/recalls
## Agenda

1. Presentation Learning Objectives
2. VA HTM and Sigma Health Consulting
3. Hospital Roles
4. Incident Investigations
5. Alerts and Recall Management
2 VA HTM and Hospital Biomedical Engineering

1,800 Biomedical Engineering professionals

$10 billion of healthcare technology

900,000 medical devices and clinical systems

1 CENTRAL OFFICE

18 VETERAN INTEGRATED SERVICE NETWORKS

171 MEDICAL CENTERS
Sigma Health Consulting is a woman, veteran-owned small business (WOSB, VOSB) and leading consulting services firm. Our team of clinical/biomedical engineers, technicians, and management consultants specialize in providing support and services to healthcare technology management (HTM)/biomedical engineering organizations.

Sigma services to VHA Office of HTM:

- Patient Safety | Incident Investigation and Recall Management
- Cybersecurity
- Technology Standards Development
- Equipment Lifecycle Management
- Program Strategy and Communications Management
- Data Analytics and Reporting
- Meeting and Conference Planning and Facilitation
- Program Assessment
Agenda

1. Presentation Learning Objectives
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5. Alerts and Recall Management
3 VA HTM Levels

1. **CENTRAL OFFICE**
   - **HTM PROGRAM OFFICE** | National level
     - Provides national guidance and direction on incidents and compliance
     - Centralizes management of alerts and recalls

2. **VETERAN INTEGRATED SERVICE NETWORKS**
   - **VISN HTM/BIOMEDICAL ENGINEERING OFFICE** | Regional level
     - Coordinates application of national guidance and supports hospital compliance

3. **MEDICAL CENTERS**
   - **LOCAL HOSPITAL BIOMEDICAL ENGINEERING** | Local level
     - Identifies and responds to incidents and alerts/recalls
     - Responsible for mitigation and compliance
3 Hospital Risk Management

Risk management is an integrated function that utilizes several disciplines to reduce the potential for organizational losses. Most hospital risk management activities are proactive or preemptive techniques designed to mitigate or prevent losses.

Because the health care industry is driven by quality measurements and the need for legal compliance, risk management demonstrates it’s worth through reducing risk and incidents thus providing a safer environment and ultimately cost savings.

<table>
<thead>
<tr>
<th>ROLES</th>
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<tbody>
<tr>
<td>HOSPITAL RISK MANAGER</td>
</tr>
<tr>
<td>PATIENT SAFETY MANAGER</td>
</tr>
<tr>
<td>BIOMEDICAL ENGINEERS</td>
</tr>
</tbody>
</table>
3 Hospital Risk Manager

• A hospital risk manager is a professional who continually assesses and minimizes various risks to staff, patients and the public in health care organizations. These hospital administrators play a vital role in reducing potential safety, finance and patient problems.

• Hospital risk managers are trained to handle different ongoing or unexpected PR, personnel, operations or financial problems. They are part of the upper medical administration staff, but their specific duties depend on the position itself and the health care organization.

• Risk Managers may work in clinical research, or they may help hospitals prepare for emergencies. Also, they may work directly with insurance and finance companies to streamline claims management.

• Almost all hospital Risk Managers will assist with incident management involving minor, daily problems and major, unexpected events and in Alert and Recall remediation.
3 Patient Safety Managers and NCPS

- **Patient Safety Managers** at all VA Medical Centers and Patient Safety Officers at 18 VISNs participate in the patient safety programs established by the National Center for Patient Safety (NCPS) at the local medical centers.

- **NCPS** promotes best practices for safe patient care and optimal patient care utilization throughout the organization. Accordingly, NCPS guides the VHA and external stakeholders on policies and strategies to do the following:
  - Measure and mitigate harm to the Veteran and those who support their care;
  - Track utilization and address deficient patient practice;
  - Model characteristics of a High Reliability Organization including promotion of clinical team training and a just and safe culture; and
  - Evaluation of healthcare solutions, technology, and innovations from a patient safety and value-based perspective.
3 Biomedical Engineers

- **Biomedical Engineers** work with Risk Managers, Patient Safety Managers, clinical staff, and others to assess, control, and investigate incidents involving patients and medical equipment.

- When incidents occur, Biomedical Engineers perform an investigation to find the root and contributing causes of incidents, working with local, regional, national teams, including VA Central Office HTM.

- Biomedical Engineers are responsible for acknowledging relevant alerts and recalls within their medical centers, executing mitigation actions, and tracking progress and completion.
# Agenda

1. Presentation Learning Objectives
2. VA HTM and Sigma Health Consulting
3. Hospital Roles
4. Incident Investigations
5. Alerts and Recall Management
4 Medical Equipment Incidents

**WHAT IS A MEDICAL EQUIPMENT INCIDENT?**
An event that could have resulted in harm or did result in unnecessary harm to a patient and involved medical equipment

<table>
<thead>
<tr>
<th>LIFE SUPPORT</th>
<th>THERAPEUTIC</th>
<th>DIAGNOSTIC</th>
<th>MONITORING</th>
<th>ANALYTICAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>sustain and support a patient’s physical life functions</td>
<td>help patients recover after medical treatments</td>
<td>helps clinicians detect and diagnose diseases</td>
<td>allow medical staff to measure a patient's medical state</td>
<td>Medical devices that analyze patients’ biochemistry</td>
</tr>
</tbody>
</table>

**EXAMPLES**

- **VENTILATORS**
- **INFUSION PUMPS**
- **CT SCANNERS**
- **ECG SYSTEMS**
- **HEMATOLOGY ANALYZERS**
4 Incident Investigation Process

HTM Central Office works with:
- Local and VISN Biomedical Engineers
- Local Patient Safety Managers (PSM)
- Local Risk Managers
- Local OEM Field Service Providers
- National OEM Representatives
- VA National Center for Patient Safety

1. VA Medical Center Biomedical Engineering performs initial investigation to find the root and contributing causes.

2. VA Medical Center reports a medical equipment incident or requests “outside” investigation/analysis assistance.

3. VA VISN and Central Office HTM joins the investigation, following the procedures and steps in the VA HTM Incident Investigation Guidebook.

4. Investigation team determines if the issue has national implications so others can be notified, and potential risks can be mitigated.
4 Incident Investigation Guidebook

VA MEDICAL DEVICE INCIDENT INVESTIGATION GUIDEBOOK

A collaboration of the VA Office of HTM, Center for Engineering and Occupational Safety and Health (CEOSH), National Center for Patient Safety (NCPS), and VA Hospital Biomedical Engineers, published Aug. 30, 2018

Guides VHA staff through timely and thorough investigations of medical device incidents

Includes tools and enclosures to effectively support field-based teams in implementing strategies that can improve patient safety within their own facilities

2nd Edition COMING SOON!

ACCE and AAMI Award winning Guidebook!
# 4 Incident Investigation Guidebook

**KEY FEATURES OF THE MEDICAL DEVICE INCIDENT INVESTIGATION GUIDEBOOK**

<table>
<thead>
<tr>
<th>GUIDEBOOK CHAPTERS:</th>
<th>TOOLS AND RESOURCES:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Overview</td>
<td>• Sample Go-Bag Assembly List</td>
</tr>
<tr>
<td>2. Background</td>
<td>• Sample Medical Device Incident Investigation: Response, Sequestering, Analysis, and Reporting Policy</td>
</tr>
<tr>
<td>4. Critical Steps for Conducting a Medical Device Incident Investigation</td>
<td>• Sample Letter for Returning Devices to Manufacturers</td>
</tr>
<tr>
<td>5. Reporting Medical Device Incidents</td>
<td></td>
</tr>
<tr>
<td>6. When to Involve Others</td>
<td></td>
</tr>
<tr>
<td>7. Lessons Learned</td>
<td></td>
</tr>
<tr>
<td>8. Incident Response Preparedness</td>
<td></td>
</tr>
</tbody>
</table>
FOSTER A
JUST CULTURE

A culture of “blame and shame” encourages employees to hide mistakes.

Fostering a Just Culture facilitates the thoughtful detection of vulnerabilities that contribute to harm.

MISSION STATEMENT FOR
JUST CULTURE

“To engage all VHA leadership in the creation and sustainment of a safety culture; one in which employees actively report safety concerns, even their own errors, without fear of a default to reprisals or punitive action, so the organization can learn about its failures and improve its care delivery system; to clearly define the boundaries used to determine individual and organizational accountability.”
4 Incident Investigation Challenges

For the HTM Central Office, remote investigations were always a challenge, COVID-19 magnified those challenges

Not able to see and touch the equipment
Not able to see the workflow associated with the use of the equipment

<table>
<thead>
<tr>
<th>BEFORE COVID-19</th>
<th>DURING COVID-19</th>
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<tbody>
<tr>
<td>Local managers made remote incident investigation possible and successful</td>
<td>Shift to remote schedules for local managers impeded incident investigations</td>
</tr>
<tr>
<td>Local managers were familiar with incident investigation procedures, the proper equipment function, the workflow, and clinical staff</td>
<td>Many managers were not available for “boots on the ground” support and lacked firsthand knowledge of the issue and the ability to work on the incident</td>
</tr>
<tr>
<td>Local managers knew and trusted me, were open and honest, and understood the goal was to solve the issue; not place blame</td>
<td>On-site staff were unfamiliar with incident investigations, the Office of HTM/Sigma’s role, the equipment involved, and the workflow associated with equipment use</td>
</tr>
<tr>
<td>OEMs, who do the detailed forensic work on the equipment, were available to respond to requests for assistance</td>
<td>OEMs, were often slow to respond to requests for assistance and often not available to go into the medical centers</td>
</tr>
<tr>
<td>Equipment was readily available for testing</td>
<td>Equipment was often put in isolation due to covid concerns</td>
</tr>
</tbody>
</table>
4 Solutions to Incident Investigation Challenges

STRENGTHENED RELATIONSHIPS
• Spent more time working with the “Acting Leaders” on the steps and the importance of the local investigation and establishing trust and stressing “no blame”
• Leveraged the VA contacts to engage OEMs
• Involved the Veteran Integrated Service Network (VISN) Biomedical Engineers
• Created Patient Safety Leads positions within each of the 18 VISNs to assist in investigations

OFFERED ADDITIONAL TRAINING
• Shared the skills of doing remote work for several years with the remote local managers to keep them involved and engaged
• Provided monthly training calls for the VISN Patient Safety Leads
• Implemented Patient Safety Courses: Basic 101 and Advanced 201 on Patient Safety Concepts for Biomed and PSMs that include curriculum from “world class” speakers on conducting successful incident investigations
### 4 Recent Incident Trends

Completed 342 incidents since 2013 and assigned each to a primary failure cause category

<table>
<thead>
<tr>
<th>Primary Failure Cause</th>
<th>Fiscal Year 2020</th>
<th>Fiscal Year 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10/1/2019-9/30/2020</td>
<td>10/1/2020-9/30/2021</td>
</tr>
<tr>
<td>Device Use Issues</td>
<td>24</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>47%</td>
<td>56%</td>
</tr>
<tr>
<td>Device Failures</td>
<td>19</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>37%</td>
<td>44%</td>
</tr>
<tr>
<td>Software Issues</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>12%</td>
<td>0%</td>
</tr>
<tr>
<td>IT Issues</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>4%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>51</strong></td>
<td><strong>36</strong></td>
</tr>
<tr>
<td><strong>100%</strong></td>
<td><strong>100%</strong></td>
<td></td>
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</tbody>
</table>

Note the significant drop in incidents from 51 in Fiscal Year 2020 to only 36 incidents in Fiscal Year 2021

Last Fiscal Year, 2022, shows a similar decrease in reported incidents – only 15 incidents through the Fiscal Year mid point.

*It is unknown if there are less incidents or less reporting of incidents*
Agenda

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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.

Correction means repair, modification, adjustment, relabeling, destruction or inspection of a medical device without its physical removal.

Medical Equipment Recalls may be conducted on manufacturer’s own initiative, by FDA request, or by FDA order under statutory authority. Medical Equipment Recalls may also be conducted internally by VHA.

It is VHA policy that each VA medical facility establishes and maintains a safe, reliable and risk-managed medical equipment safety program to ensure the well-being of patients and staff.
5 Medical Equipment Recall Process

**Obtain Notification**

**VHA:** Centrally receive safety reports/notifications involving medical equipment from multiple sources

**Analyze**

**VHA:** Determine and issue remediation actions to ensure successful prevention or mitigation of safety issues

**Disseminate & Take Action**

**VHA:** Communicate actions to all affected VA facilities

**VAMCs:** Verify inventory and implement assigned actions

**Report & Confirm**

**VHA:** Review recall data, distribute completion reports, and share lessons learned

**VAMCs:** Confirm completion of all actions

**Day 1**

**Days 2-14**

**Days 15-28**

**Days 28-118**
# Recall Management Challenges and Solutions

<table>
<thead>
<tr>
<th>CHALLENGES</th>
<th>SOLUTIONS</th>
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<tbody>
<tr>
<td>Cumbersome user-interface</td>
<td>Provides streamlined user interface for both writers and end-user</td>
</tr>
<tr>
<td>Inability to extend individual facility due dates</td>
<td>Has capability to alter due dates for individual sites</td>
</tr>
<tr>
<td>Limited user-roles</td>
<td>Has capability to select different user-role levels and automate new user requests</td>
</tr>
<tr>
<td>No capability for end-users to upload file attachments</td>
<td>Has capability for end-users to upload file attachments</td>
</tr>
<tr>
<td>No help desk/live-support</td>
<td>Has Chatter and Teams help-desk</td>
</tr>
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*ARMS 2.0*
# 5 ARMS 2.0 | Future State

<table>
<thead>
<tr>
<th>New Application</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Model Numbers</td>
<td>Product model numbers, equipment categories and Product Manufacturer information is within the app. Each can be easily accessed, searched for, and selected.</td>
</tr>
<tr>
<td>Files</td>
<td>Files can be attached to any action assignment or Safety Record Assignment. May also be attached after completion.</td>
</tr>
<tr>
<td>Due date extensions</td>
<td>Both blanket and individual due date extensions are available.</td>
</tr>
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</table>
5 ARMS 2.0 | Future State

**New Application**

<table>
<thead>
<tr>
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<tr>
<td>New fields “Total in Stock” and “Total Affected” have been removed for RMD. The new fields “Total in Stock” and “Total Affected” support the RMD business process than Itemized list.</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Chatter</th>
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<tr>
<td>Chatter is a collaboration tool within the application for communicating with other users on specific records.</td>
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</table>

<table>
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<tr>
<th>Both ad hoc and canned report options are available within the application</th>
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<tbody>
<tr>
<td>Existing users set up with appropriate permissions and new users can be given access easily. The new application also supports vetting of reports.</td>
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</table>
5 Recent Alerts and Recalls Trends

Posted 554 alerts and recalls since 2020

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Fiscal Year</th>
<th>Fiscal Year</th>
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</thead>
<tbody>
<tr>
<td>2020</td>
<td>2021</td>
<td>2022</td>
</tr>
<tr>
<td>10/1/2019-9/30/2020</td>
<td>10/1/2020-9/30/2021</td>
<td>10/1/2021-9/30/2022</td>
</tr>
</tbody>
</table>

RMD Alerts/Recalls Posted 156 190 208

FDA medical device recalls and safety notices are growing in numbers every year. As medical technology advances and becomes more complex, it can be more prone to defects that initiate recall actions. Recalls and safety notices can range from low-risk issues that are not likely to cause any harm to those that can cause serious injury or death.
Conclusions

1. More Biomedical Engineering and Patient Safety staff, at more levels of the organization, understand how to conduct a successful incident investigation and how to properly report Alert/Recall remediation. Pre and Post “tests” showed a great improvement in knowledge and understanding.

2. The remote investigation techniques, skills, and knowledge gained by staff will benefit them in future investigations.

3. The new ARMS system will enable easier, sortable, and better alert and recall remediation.
Enter your questions to the Q&A window

Thank You

Please complete the online evaluation form at https://www.surveymonkey.com/r/ACCE_12-08-22 or scan the QR code