2023-2024 Educational Webinar Series

Incidents Investigation Best Practices

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ACCE – 2023-2024 Educational Webinar Series
About the Moderator

Juuso Leinonen is currently the Director of Medical Device Cybersecurity and Integration at Crothall Healthcare where he leads a team of Cybersecurity and Integration Specialists. Previously, Juuso served at the Device Evaluation group at ECRI where he led various medical technology projects from comparative medical device evaluations to complex medical device accident investigations. Juuso’s research efforts led to over 100 ECRI publications, including some global medical device recalls.

In 2022, Juuso received the ACCE-HIMSS Excellence in Clinical Engineering and IT Synergies Award for his work in tackling challenges of managing medical device cybersecurity. Juuso has presented about the challenges of managing medical device cybersecurity at several international, national and local conferences, including at HIMSS and AAMI.

Juuso currently serves as the co-chair of ACCE Education Committee

Juuso Leinonen, BEng
Director of Medical Device Cybersecurity and Integration
Crothall Healthcare
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.
About the Speaker

Matt Baretich is President of Baretich Engineering, Inc. (Fort Collins CO) and Clinical Engineering Consultant for Lower Mainland Biomedical Engineering (Vancouver BC).

He has been active in medical device-related incident investigation for more than 25 years. He is a Certified Clinical Engineer (CCE), Certified Professional in Patient Safety (CPPS), and a Certified Professional in Healthcare Risk Management (CPHRM).

Matthew F. Baretich, P.Eng., Ph.D.

Baretich Engineering

Lower Mainland Biomedical Engineering
Session Description

• Medical device-related incidents are inevitable.
• HTM professionals need to understand how to investigate adverse incidents and how participate effectively in the organization’s response.
• The objective of incident management is organizational learning for improved patient safety.
Medical Device-Related Incident

A patient care provider has a clinical objective that requires a medical device but is unable to achieve the objective and harm occurs.
1. Take care of the patient
2. Report internally
3. Sequester the device
4. Preserve patient data
5. Investigate the incident
6. Report externally
7. Avoid recurrences
1. Take care of the patient
ICE FUSES AS MARKED
2. Report internally
Report an event Click on the icon that describes the event. Don’t see what you need? Click on “Other”.

- Fall
- Medication
- Adverse Drug Reaction
- Medical Device
- Unsafe Behaviour
- Laboratory
- Blood
- Wound/Skin Injury
- Medical Imaging
- Perinatal
- Surgical Count
- Narcotic Count
- Safety Hazard
- Action ADE
- Visitor Safety
- Security/Property
- Reportable Death
- Other
**Provincial Medical Device Incident (MDI) Report Form**

Use this form to report a medical device incident (MDI).

The definition of medical device is very broad and includes invasive, non-invasive, active and other devices, covering electronic and non-electronic equipment, implants, products, supplies and general items used in all aspects of patient care.

All reported medical device incidents should be reported, regardless of severity. Serious MDIs that lead to death or serious deterioration in health of a patient, user, or other person can be written in a form or in electronic form. All reports must be submitted in accordance with the National Medical Device Reporting System (NMDRS).

If you require assistance, please contact the PHSLS Coordinator at your health authority.

A MDI is an incident related to the failure of a device, deterioration in its effectiveness or inadequacy in its labeling or directions that results in, or could result in, harm to a patient.

**Details of the MDI**

- **Type of MDI**: [Dropdown]
- **Patient Safety Event**: [Dropdown]

**Location**

- **Health Authority**: Vancouver Coastal Health Authority
- **Service area**: [Dropdown]
- **Facility**: [Dropdown]
- **Type of location**: [Dropdown]
- **Specific location**: [Dropdown]
- **Was there a second location, organization or program involved?**: Yes
- **No**

**Discovery Date & Time**

- **Date (MM/DD/YYYY)**: 16/11/2021
- **Time period**: [Dropdown]

**MDI Date & Time**

- **Date (MM/DD/YYYY)**: 16/11/2021
- **Do you know the exact time the MDI happened?**: Yes
- **No**

**Description**

- **Describe the medical device incident**: [Dropdown]
- **DO NOT INCLUDE NAMES OR OTHER PERSONAL IDENTIFIERS**

**Medical Device Details**

Complete all relevant fields.

- **Type of device**: [Dropdown]
- **Category of device**: [Dropdown]
- **Name or description of device**: [Dropdown]
3. Sequester the device
• Out of service and locked up
• Preserve disposables and packaging
• Preserve the settings
• Plug in the device
4. Preserve patient data
• Paper records: hand-written notes, printouts, etc.
• Electronic Medical Record (EMR) systems
• Medical device event and alarm logs
5. Investigate the incident
6. Report externally
Health Canada

- Protecting Canadians from Unsafe Drugs Act
- Vanessa’s Law
U.S. Food and Drug Administration (FDA)

• Safe Medical Devices Act (SMDA)
• Medical Device Reporting (MDR) System
MAUDE - Manufacturer and User Facility Device Experience

The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

Search Database

Product Problem
Product Class
Event Type
Manufacturer
Model Number
Report Number
Brand Name
Product Code
Date Report Received by FDA (mm/dd/yyyy)

02/01/2019 to 02/28/2019

Go to Simple Search 10 Records per Report Page Clear Form Search
7. Avoid recurrences
PLATEN DOOR

UPPER OCCLUDER

LOWER OCCLUDER
Exemplar Tubing: wall thickness is uniform (Good)

Incident Tubing: wall thickness is non-uniform (Bad)
Uniform Wall Thickness

Non-Uniform Wall Thickness, Orientation 1

Non-Uniform Wall Thickness, Orientation 2
1. Take care of the patient
2. Report internally
3. Sequester the device
4. Preserve patient data
5. Investigate the incident
6. Report externally
7. Avoid recurrences
Questions & Discussions

Enter your questions to the Q&A window

Thank You

Please complete the online evaluation form at
https://www.surveymonkey.com/r/2023-2024_session4
or scan the QR code