Incident Investigations: Following the Clues

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Incident Investigations: Following the Clues

Agenda

1. Learning Objectives
2. Introduction & Background
3. Medical Device Incidents
4. Reporting & Investigations
5. VA MDII Guidebook
6. Incident Investigations Data
7. Conclusions and Questions

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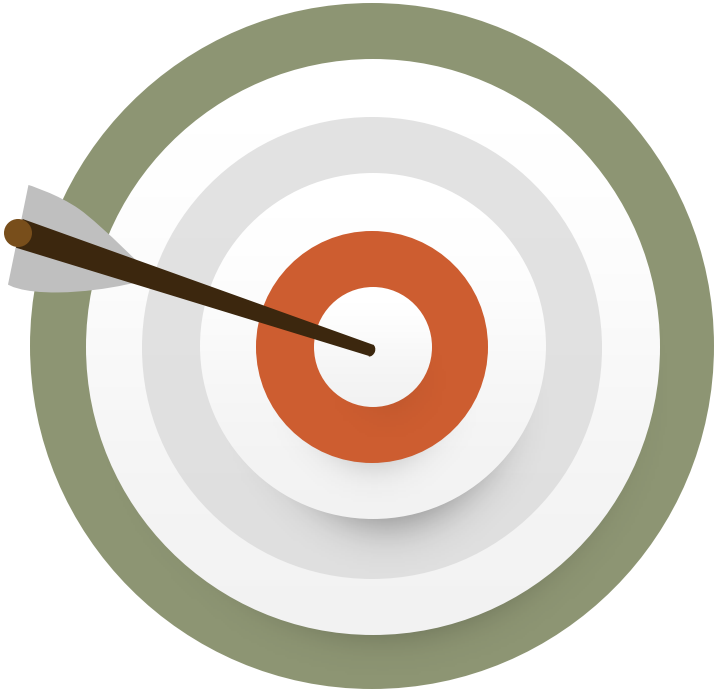
1 | Learning Objectives



1. Understand the **importance** of conducting an extensive medical equipment incident investigation
2. Learn **how to conduct** an incident investigation using the VA investigating process
3. Review the **steps** of a successful incident investigation

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2 | Introduction: **Henry (Hank) Stankiewicz, Jr.**

Hank Stankiewicz

Consultant

Sigma Health Consulting

ROLE & RESPONSIBILITIES:

Part-time employee for Sigma's Healthcare Technology Management consulting practice in its support of VA Healthcare, primarily in the HTM area.

- Conduct Patient Safety Incident Investigations
- Conduct BME (and Central Sterile Supply) Program Evaluations
- Develop standards and best practices for planned maintenance, scope of HTM services, and organizational alignment and structure

EDU/CERTS:

- Certified Clinical Engineer and Fellow of the ACCE
- Master of Science in Biomedical Engineering
- Bachelor of Engineering in Electrical Engineering

2 | Background: **Sigma Health Consulting**

Sigma Health Consulting

provides technical and management services to healthcare technology management and biomedical engineering organizations

VOSB

SBA WOSB Woman Owned Small Business

CYBER SECURITY	PATIENT SAFETY	TECHNOLOGY STANDARDS	LIFECYCLE MANAGEMENT
Networked Inventory Management	Safety Risk Assessment	Inventory Standardization	Market Analysis
Technology Risk Assessment	Incident Response & Investigation	Technical Specifications	Life Expectancy Analysis
Vulnerability Management	Recall Remediation & Tracking	Deployment	Equipment Planning
Security Audit Preparation		Technical Configuration	Technical Evaluation
		Planned Maintenance	

DATA ANALYSIS & REPORTING	MEETING & CONFERENCE FACILITATION	COMMUNICATIONS	PROGRAM ASSESSMENT
Data Preparation & Management	Onsite and Virtual Facilitation	Executive Communications	At-Risk Program Evaluation
Data Visualization	Agenda Planning	Field Communications	Program Health Check
Dashboarding	Audience Engagement	Training & Education	Program Scope Assessment
Performance Measurement	Presenter & Travel Logistics	Web Development	Staffing Modeling and Optimization
	Venue Sourcing	Strategic Planning	Organizational Alignment

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3 | Medical Device Incidents

"When you have eliminated the impossible, whatever remains, *however improbable*, must be the truth!"

- Sir Arthur Conan Doyle

What is a medical device?

Any instrument or system used for the diagnosis, treatment, physiological monitoring of patients or **used in patient care** that is not a drug, biological or food. Examples of medical devices include:

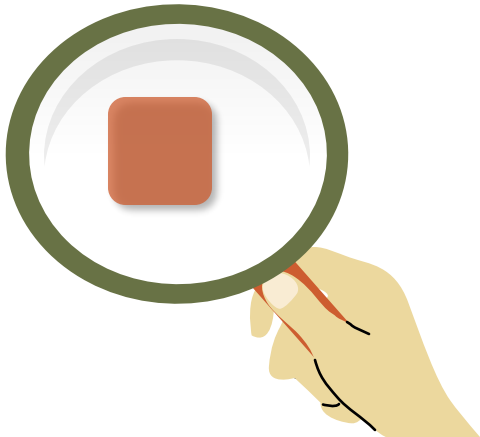
- Ventilators
- Patient monitor
- X-Ray machine
- Hip implant
- Catheters and needles
- Trocars and staplers
- IV tubing
- Tongue depressors

What is a medical device incident?

A patient safety medical device incident is an event that could have resulted in harm or did result in unnecessary harm to a patient and involved a medical device. The following are types of incidents:

- Incidents that **could have resulted in harm** can be classified as a “no-harm” event, “near miss” event or a “close call” event.
- Incidents that **did harm** a patient is classified as a “sentinel event” or a “never event” (TJC).

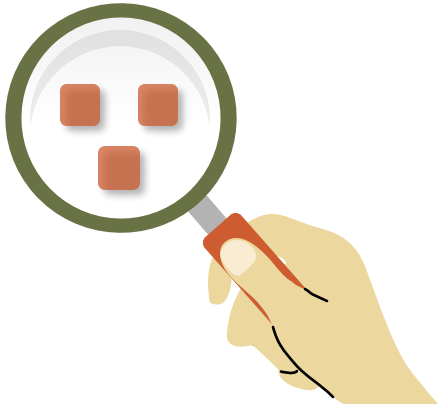
In the VA, **HTM investigates incidents** that involve Medical Devices, Networked Clinical Systems, and even Disposable Medical Devices.



3 | Medical Device Incidents

VA categorizes medical device incidents as the following:

- **Device failure/malfunction**
- **Device use issue**
- Environmental issues
- Software issues
- Interface with the EMR
- Hospital IT network issues (in VA, OI&T)



FDA Classification of Medical Devices

The FDA plays a major role in the regulation of medical devices in the USA. The FDA classifies medical devices based on the risk the device poses to the patient or user. There are **three classifications**:

CLASS I

Device that general controls can assure the device is safe and effective for human use

CLASS II

Device that performance standards can assure the device is safe and effective for human use

CLASS III

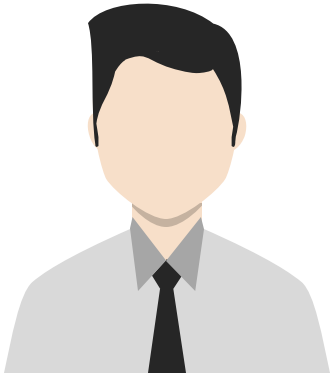
Device that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury

Why investigate patient - medical device incidents?

Hospital errors are the **third leading cause of death** in the United States (John Hopkins study 2018). After an incident occurs, it becomes imperative that a comprehensive investigation is completed to prevent recurrence and limit risk to the organization. However, miss-steps and gaps in the process, or a lack of investigation experience and resources, can leave organizations open to **recurrence** and **costly claims.**

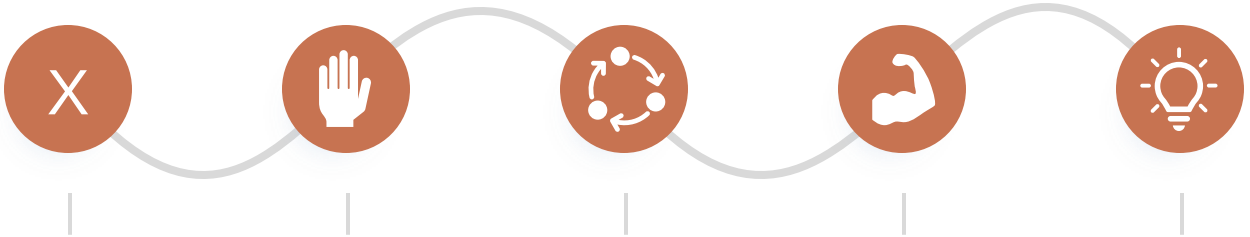
3 | Medical Device Incidents

Why Investigate: a High Reliability Organization (HRO)!



"Experience fewer than anticipated accidents or events of harm, despite operating in highly complex, high-risk environments."

5 Principles of
High Reliability Organizations



- Preoccupation with Failure
- Reluctance to Simplify
- Sensitivity to Operations
- Commitment to Resiliency
- Deference to Expertise

"If we do not strive to understand what went wrong, we cannot possibly expect to prevent it from happening again."

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FDA Reporting: MedWatch

The FDA has a program for medical device incident reporting called MedWatch.

- **Staff** voluntary report actual or potential problems
- **Hospital** must report serious injury and deaths
- **Manufacturers** must report malfunctions, serious injury, and deaths

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

- FDA receives several hundred thousand MDRs of suspected device-associated deaths, serious injuries and malfunctions every year.
- Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data.

Reporting Medical Device Incidents

What to Report	Report Form	To Whom	When
Device-related serious injury	Mandatory *MedWatch Form FDA 3500A*	FDA and manufacturer	Within 10 working days of becoming aware
Device-related death	Mandatory *MedWatch Form FDA 3500A*	FDA and manufacturer	Within 10 working days of becoming aware
Annual summary of death and serious injury reports	Mandatory *Form FDA 3419*	FDA	January 1 of the preceding year
Near misses or injuries to staff and patients, product use errors, product quality problems, and therapeutic failures	Voluntary *Form FDA 3500*	FDA and/or manufacturer	No specified timeline

Local Investigation of Incidents

The **local** VA HTM **investigates** patient – medical device incidents to find the root cause and contributing causes of the incident:

- to **improve** patient safety
- to **promote** a culture of safety
- to **prevent** similar incidents from occurring
- to **reassure** clinical staff medical equipment is safe to use

HTM Program Office Role in Incidents

The VHA **HTM PO** Patient Safety Workgroup **assists** in investigating incidents:

- when the Hospital reports a medical equipment incident
- when “outside” HTM professional assistance with the investigation and/or analysis is requested
- to determine if the issue has national implications so others can be notified, and potential risks can be mitigated

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VA Medical Device Incident Investigation (MDII) Guidebook

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

Purpose is to **ensure** VA staff perform **timely** and **thorough investigations** of medical device incidents

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

CHAPTER 4: Critical Steps for Conducting a Medical Device Incident Investigation

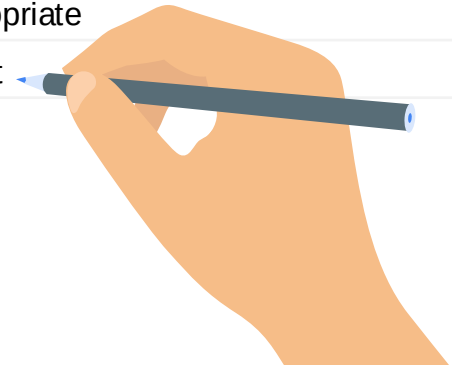
Step 1

Critical Steps for Conducting a MDII	Actions
Incident Response	• Dispatch the Medical Device Incident Response Team • Grab the Investigation Checklist • Grab the Go-Bag and go to the location of the incident • Take emergency measures to minimize threat of harm to patients and staff • Provide back-up or spare device(s) if needed

Medical Device Incident Checklist

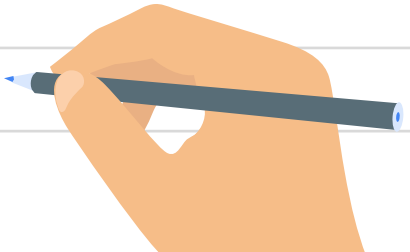
This checklist is intended as a **reminder of the common actions** that should be taken by VA personnel when responding to a medical device/system incident. This checklist may not be all inclusive for every incident. Local policy should be followed.

Respond	❑ Grab the "Go-Bag" and go to the incident/area
	❑ Assemble a **Medical Device Incident Response Team** and do the following:
	❑ Ensure safety of patients, visitors, and staff by minimizing the threat of harm
	❑ Provide back-up or spare equipment for patient care as necessary
	❑ Notify additional medical, fire, police and/or rescue teams as appropriate
	❑ Confirm that the situation is stabilized from staff present at the incident



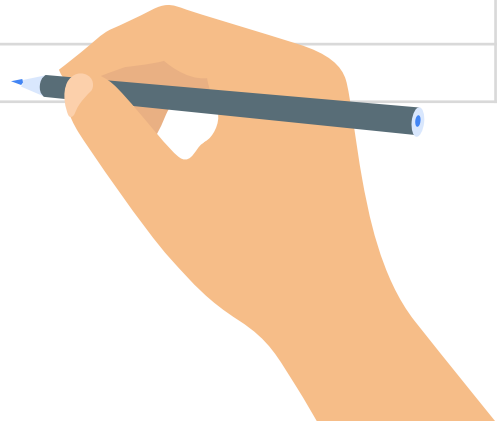
Medical Device Incident Checklist

Secure & Sequester	***NOTE: Do NOT alter anything in any way unless it is absolutely necessary to minimize injury at the time the incident occurs or to avoid additional harm.***
	❑ Secure the area and anything suspected to be involved
	❑ Preserve all evidence for the investigation, including medical device(s) / system(s), accessories, disposables, associated package, and identifying data
	❑ Do not disconnect or change positions of equipment or cables
	❑ Do not shut down, unplug or remove batteries
	❑ Do not clean or process
	❑ Do not allow unwitnessed access to any evidence (incl. the manufacturer)
	❑ Sequester all equipment as well as any accessories and disposables
	❑ Ensure the settings are maintained
	❑ Establish a chain-of-custody for proper collection and handling
	❑ Remove the suspect device/system from service until it has been properly analyzed, tested and approved for being returned to service



Medical Device Incident Checklist

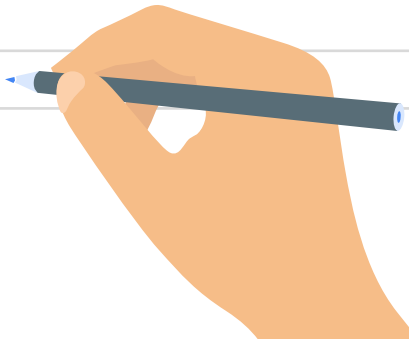
Gather Data	❑ Use the Medical Device Incident Investigation Form
	❑ Determine patient, visitor, and staff involvement who might have useful, factual information
	❑ Collect, tag and document all evidence:
	❑ Take photographs, audio and/or video
	❑ Record identifying data (e.g., manufacturer, model, software version, etc.)
	❑ Document control settings
	❑ Review error/usage logs on the device(s) / system(s)
	❑ Determine if an independent third-party investigator should be utilized



Medical Device Incident Checklist

Analyze	❑ Inspect the suspect device/system documenting all tests and findings
	❑ Attempt to duplicate the issue and determine if it is repeatable
	❑ Review device history records to identify any failure patterns
	❑ Review prior incident reports to detect any trends
	❑ Identify the cause(s) / contributing factor(s) and determine corrective action(s)

Report	❑ Comply with VHA Reporting Requirements
	❑ Comply with FDA Reporting Requirements by submitting MedWatch
	❑ Notify leadership as appropriate
	❑ Document work completed on all involved medical device(s) / system(s)



"Go-Bag"

- Most items are readily available shop contents of can be ordered on a purchase card
- Pen and Notepad
- Investigation Forms
- Emergency Contact List
- Personal Protective Equipment
- Camera (capable of taking photos and video)
- Audio Recorder
- Measuring Tools (e.g., ruler, tape measure, distance meter)
- Basic Test Equipment (e.g., electrical safety analyzer, multimeter)

Purchase and Assembly of “Go-Bag” Components

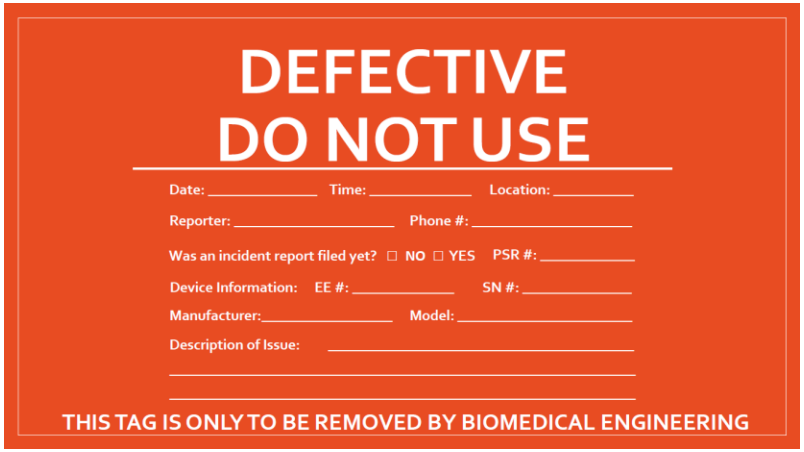
- Most items are readily available shop contents of can be ordered on a purchase card
- Camera, Audio Recorder, and Flashlight – GFE Smart Phone from local OIT
- DO NOT use a personal phone
- If GFE smart phone is not an option, purchase items locally
- Biohazard Bags – Local SPS
- PPE – Local Logistics
- Zip Ties, Defective Equipment Tags, Investigation Forms, Emergency Contacts List – Local HTM
- Multimeter – May be obtained via purchase card or via an equipment committee
- Ruler / Tape Measure, Cation Tape, Notebook, and Bag – Purchase Card

*All the items should be readily available and have a total cost of approximately $1500

Step 2

Critical Steps for Conducting a MDII	Actions
Secure the Area & Device(s)	• Discretely isolate the incident area • Minimize damage to device(s)/item(s) and the area • Use barricades to keep others from accessing and altering the area in any way • Preserve all evidence; including all medical device(s), accessories, consumables/disposables, associated packaging, and identifying information. • Use all appropriate PPE and infection control precautions • Lock out any device(s) that could have been involved

Defective Medical Device Tags



Step 3

Critical Steps for Conducting a MDII	Actions
ID Potential Witnesses	• Make a list of everyone who was involved in or might have witnessed the incident • Look for all types of witnesses; including those who may have seen, heard, and/or smelled anything that may explain the incident

Step 4

Critical Steps for Conducting a MDII	Actions
Collect Evidence & Record Data	• Use the necessary investigative tools from the Go-Bag • Collect, tag, record, and photograph all evidence that can or may be used in the investigation (e.g., materials, parts, tools, equipment)

Step 5

Critical Steps for Conducting a MDII	Actions
Sequester Device(s) & Item(s)	• Do not alter the device(s) in any way • Preserve all device(s) and related item(s), such as any accessories and/or consumables/disposables as well as the associated packaging and identifying data • Do not change the settings positions of device(s) or cables • Do not change control settings on any device(s) • Do not shut down, unplug, or remove any batteries from device(s) as error codes may be stored • Do not clean or reprocess device(s) • Storage and transportation the device carefully • Do not return any device to service until it has been properly tested and verified that it is safe to use again • Use all appropriate PPE and infection control precautions

Step 6

Critical Steps for Conducting a MDII	Actions
Establish a Chain of Custody	• Chain-of-custody protocols should outline proper device collection and handling • Keep sequestered device(s) and related items with appropriate labeling including date, time, and signature of the person responsible for securing the device • Store sequestered device(s) and related items in a locked storage area, separate from where routine maintenance takes place • Require signature of a chain-of-custody form specifying the item and date of return • Ensure that all individuals granted access to sequestered device(s) comply with the chain-of-custody process

Step 7

Critical Steps for Conducting a MDII	Actions
Examine the Suspect Device	• Prior to testing, document all settings and event logs • The manufacturer should not be permitted to take any device(s) and/or related item(s), nor should unwitnessed access to the device(s)/item(s) be allowed • Investigations can be significantly aided by cooperation from the manufacturer • In catastrophic incidents where significant, unpredictable failure resulted in serious injuries or deaths, consider arranging to examine the medical device(s) with representation from the facility, general/regional counsel, manufacturer, and an independent investigator simultaneously and for the duration of the process

Step 8

Critical Steps for Conducting a MDII	Actions
Conduct Interviews	• Develop a list of broad, open-ended questions to ask all interviewees • Talk to each witness separately, starting with the person most directly involved • Begin the interview with assurances that all those present during or involved in the event are being interviewed to gather facts not to place blame • Focus on the who, what, where, when, why, and how of the incident • Document each response and note any discrepancies • Avoid bias

Step 9

Critical Steps for Conducting a MDII	Actions
Review Device Data	• Review all relevant device history records involving equipment inspection and prior incident reports • Identify any patterns or trends • Analyze all data for completeness/accuracy

Step 10

Critical Steps for Conducting a MDII	Actions
Prepare Incident Report	• Document key facts regarding the investigation • Prepare the written report • Share summaries of vital information with managers/supervisors and employees • Keep everyone informed

ECRI's Incident Management and Investigation Plan, Course & Resources

- ECRI has an Incident Management & Investigation Plan that includes a seven-step investigation plan, like the VA's Incident Investigation Guidebook
- ECRI's Healthcare Incident Management and Investigation (HIMI) Course trains risk managers, biomedical engineers, and providers on how to broadly manage and investigate any type of healthcare incident from its inception to potential litigation
- ECRI has a Healthcare Incident Investigation & Technology Consulting Service

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6 | Incident Investigations Data

HTM PO completed **240** investigations from **August 2013** to **December 2020** and assigned each to a **primary failure cause** category:

52% Device Use Issues	**33%** Device Failures	**5%** Software Issues	**3%** Facility Environmental Issues
3% CPRS Issues	**2%** Unknown Issues	**1%** IT/Network Issues	**1%** Consumable Issues

6 | Incident Investigations Data

The below is the HTM PO **simplified incident classification data** from **FY 2020** – **FY 2024**:

Fiscal Year	Incidents	Device Use Issues	Device Failures
2020	51	47%	37%
2021*	36	56%	44%
2022	24	54%	46%
2023	35	54%	43%
2024**	95	47%	37%

*2021 – COVID-19 and/or Vanderbilt Hospital Issue?

**2024 – Data as of 9/23/24

**2024 – Encouraging more reporting of incidents and working more with NCPS

**2024 – 47% & 37% representative of 46/95 incidents that were completed

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Device failures are spontaneous:

- Devices that experienced failure had up to date PM inspection and service records.
- More maintenance, PM, or inspections would **not** have increased device reliability.
- Infusion pumps, ceiling lifts, video scopes, and, recently beds, are involved in a high number of incidents

7 | Conclusions & Questions

Device Use Issues are high:

- Is there an education gap on the safe use of medical device for the clinical staff, especially RNs?
- Should HTM put more emphasis on staff education?

7 | Conclusions & Questions

Questions | Comments | Critiques