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ECRI Institute
The Discipline of Science. The Integrity of Independence.

Using software to improve the effectiveness of patient safety & maintenance programmes



WELCOME TO THE EBME EXPO 2019

- APRIL 3RD - 4TH 2019
- ARENA MK, MILTON KEYNES
- 75+ EXHIBITORS
- 15+ SPEAKERS

WITH THANKS TO ALL THE EXHIBITORS FOR SUPPORTING THE EBME EXPO

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What is the ECRI Institute

- Not-for-Profit and independent information provider to 5000 healthcare organisations.
 - Free resources will be provided to support your patient safety and maintenance activities
 - They are Unbiased and evidence based.

Types of software supporting patient safety and medical device maintenance:

- 1. CMMS Computerised Maintenance Management Systems/inventory management
- 2. Medical Device IPM procedures, benchmarking, guidance
- 3. Medical device alerts & recalls management
- 4. Medical device evaluations

CMMS benefits

- Knowing which assets you have and how they are maintained have obvious benefits – reducing time and cost in locating or managing/maintaining equipment and optimising their replacement strategies benefit safety both directly and indirectly

The role of CMMS in safety and maintenance

- How can CMMS improve safety?
 - Save time and resources that can be redirected to lowering risk
 - Identify recalled devices more rapidly
 - Better evidence based maintenance scheduling
 - Options for IOT or RFID integration – with the resulting additional benefits
 - Better data better reviewing/improvement possibilities
 - Drive better replacement planning
 - Identify optimal rationalisation programmes

CMMS developments

Traditional features:

- Equipment inventory information,
- Work orders,
- Service contracts,
- Spare parts,
- Purchasing and stock-control

CMMS developments

- **Recent developments**

- Cloud based and utilising portable devices (phones, tablets etc.)
- Tracking
- Image rich to assist with locating and maintaining devices – possibly including augmented reality in the future
- Building in complementary software and reports – IPM benchmarking, equipment replacement planning etc.
- Supporting cybersecurity...

Supporting cybersecurity

CMMS - A complete medical device inventory is a priority for effective threat response

Recommendations:

- Prerequisite for other actions (e.g., legacy device assessment)
- Fill in gaps in inventory during PMs
- Must include IT-related elements (e.g., software revisions)
- Will require significant resources required to complete

Recommended Inventory Data Points

- ▶ Software/firmware versions
- ▶ Operating system
- ▶ IP address
- ▶ MAC address
- ▶ Network configuration such as DHCP (Dynamic Host Configuration Protocol)/static wireless configuration
- ▶ Nature of data stored or transmitted (and magnitude of that data)
- ▶ Authentication, authorization, and auditing methods
- ▶ System owner
- ▶ Criticality of care (life supporting, therapy delivery, diagnostic)
- ▶ Age (product life cycle)

Top Ten Health Technology Hazards

- ▶ 2018 - #1. Ransomware and Other Cybersecurity Threats
- ▶ 2017 - #6. Software Management Gaps Put Patients, and Patient Data, at Risk
- ▶ 2016 - #10. Misuse of USB Ports Can Cause Medical Devices to Malfunction
- ▶ 2015 - #9. Cybersecurity: Insufficient Protections for Medical Devices and Systems



Types of software supporting patient safety and medical device maintenance:

(2) Medical Device IPM procedures, benchmarking, guidance

- When did you last review and compare your IPM procedures? Do they include cybersecurity processes?
- Do you benchmark the PM time-taken, frequency and cost?

Types of software supporting patient safety and medical device maintenance:

Medical Device IPM procedures, benchmarking, guidance

- Have you considered guidance on spending more time on impacting higher risks?
- Have you considered risk levels and developed a risk strategy (weighing impact and likelihood)?

Types of software supporting patient safety and medical device maintenance:

(3) Medical device alerts & recalls management

- Is there value in also accessing other alerts & recalls systems outside of the MHRA (FDA, BfArM, etc)?
- Is an alerts management system of value – ensure alerts are distributed appropriately, promptly, are auditable and reducing ‘noise.’

Types of software supporting patient safety and medical device maintenance:

(4) Medical device model evaluations & technology safety guidance

- When planning medical device procurement do you look at outside evaluations on factors around safety or consider the risks around that type of technology/procedure?

Example: OR table evaluation

Safety—Good

Major Advantage

1. Anti-collision feature:

a) The table includes a collision detection feature that will stop the movement of table components if they are in danger of colliding with the floor, running gear, or column. The risk of collision is determined by calculating the geometry of the table; therefore, the feature does not detect objects placed on the base or other accessories that may alter table geometry. If a potential collision is detected, the system will automatically stop any unsafe movement before the collision can occur. The hand control will then indicate the commands the user can execute to continue movement while avoiding the collision path.

b) Anti-collision features protect patients and users from injury that may result from adjusting the table into an unsafe configuration.

Minor Advantage

1. Safety alerts:

a) The hand control has visual messages and audio tones, and the OR table has audio tones, to warn the user of potential failures. The hand control displays numeric error messages in addition to a wrench symbol.

b) Proactively warning users of predictable failures may prevent injuries to patients and staff.

Minor Disadvantage

1. Base design:

a) The base has a flat design and does not restrict the placement of equipment or supplies on it.

b) It is common for equipment and supplies to be placed on the base of OR tables if space is available. This can cause damage to the equipment and the table if the tabletop is lowered onto the equipment.

ECRI free patient safety resources for ebme attendees:

- CMMS Computerised Maintenance Management Systems/inventory management
- Software Management Gaps Put Patients, and Patient Data, at Risk
- Medical Device IPM procedures, benchmarking, guidance
- Measuring Up: A Clinical Engineer's Introduction to Benchmarking
- Optimizing an IPM Program
- Medical device alerts & recalls management
- Medical Device Hazards and Recall Management
- Medical device evaluations – choose a technology and we will supply a report with safety guidance

Other free resources

- 2019 Top 10 Health Technology Hazards Executive Brief
- Biomed-IT Collaboration Critical to Ensuring Proper Functioning of Medical Devices Residing on Hospital IT Infrastructure
- Cybersecurity Risk Assessment for Medical Devices
- Stop Over-inspecting Equipment

Thank you.

- See me to receive resources of interest.
- Stand A30
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