

Battery Issues from Standpoint of Healthcare Technology Managers (HTM)

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About AAMI

(Association for the Advancement of Medical Instrumentation)

AAMI is a diverse community of nearly 7,000 healthcare technology professionals united by one important mission—supporting the healthcare community in the development, management, and use of safe and effective medical technology.

AAMI is the primary source of consensus and timely information on medical instrumentation and technology.

Who do I represent??

- I will try to represent the viewpoint of Healthcare Technology Managers (HTM)
 - AKA Clinical Engineers (CE) or Biomedical Engineers (BME) or Biomedical Equipment Technicians (BMET)
 - Director of Clinical Engineering for 37 years
 - Started consulting firm in 2011
 - Very active in AAMI for 39 years
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General Outline of Talk

- Survey on battery issues sent out to HTM to get data from many institutions
- Data from Aramark Healthcare Technologies
- Overall Conclusions
- One polling question for this group

HTM Survey on Battery issues

216 responses

Does your HTM program routinely replace batteries at specified intervals, without waiting for failure?

84% “YES”, of these:

- 6% said “All medical devices with rechargeable batteries”
 - 49% listed all “Life Support
 - 64% listed debrillators
 - 33% listed IV pumps
 - 26% listed UPS systems
 - 20% listed transport physiologic monitors
 - Others listed IABP, battery operated suction, transport incubators, etc.
 - Others said only sealed lead acid batteries
 - A few said they tested all, and replace bad ones.
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HTM Survey on Battery issues

216 responses

Do you routinely purchase replacement medical device batteries from a 3rd party distributor?

➤ 91% “YES”, of these:

- 8% still bought OEM batteries for some equipment types, like defibrillators or life support equipment
- 3% specified same battery manufacturer
- 4% tested batteries upon arrival. Some on random basis, some only for new battery types
- Most said that they only used one or more trusted vendors

Are there other significant medical device battery issues that should be raised at this workshop?

I got 147 comments

- Need better batteries & chargers
 - Cost & reliability
 - User education – plug in battery
 - How much time before device fails?
 - Battery alarm strategy
 - Battery enclosures - battery leakage & swelling, access to change battery
 - Confusion over battery types, how to handle & store.
 - Recommended a guidance document from UK
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Guidance on the Safe and Effective Use of Batteries and Chargers for Medical Devices

This UK report covers a variety of issues including:

- disastrous failures, where the battery overheats, leaks acid or explodes
 - unexpected battery exhaustion during use
 - inadequate battery and charger maintenance
 - incorrect charging of rechargeable batteries
 - use of replacement batteries that do not meet the required specification
 - poor training of staff in battery usage, maintenance, charging or replacement requirements
 - battery chargers and their leads and connectors overheating
 - use of battery chargers that are incompatible with the batteries in the medical device.
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Evidence-Based Maintenance:
Comparison of Equipment Failure Rates
Using OEM versus non-OEM Batteries

Salil Balar, MS, MBA

Data Analyzed

- Each equipment listed represents a certain brand & model
- Aramark routinely changes batteries on a periodic basis, based on experience with brand & model
- Each hospital uses either OEM-supplied or non-OEM supplied batteries

| EQUIPMENT | BATTERY SOURCE | #HOSPITALS | #UNITS |
|------------|----------------|--------------|---------------|
| Defib A | OEM | 5 | 182 |
| | non-OEM | 4 | 132 |
| Defib B | OEM | 4 | 145 |
| | non-OEM | 13 | 290 |
| Defib C | OEM | 4 | 134 |
| | non-OEM | 13 | 471 |
| Doppler | OEM | 9 | 147 |
| | non-OEM | 8 | 113 |
| PCA Pump | OEM | 2 | 120 |
| | non-OEM | 4 | 126 |
| Inf Pump B | OEM | 1 | 531 |
| | non-OEM | 6 | 1,926 |
| Ventilator | OEM | 18 | 323 |
| | non-OEM | 5 | 90 |
| Inf Pump A | OEM | 7 | 2,798 |
| | non-OEM | 12 | 3,070 |
| | | TOTAL | 10,598 |

Failure Cause Codes for Equipment - SM Failures

| MAINTENANCE TYPE | CAUSE CODE | DESCRIPTION |
|--|------------|--|
| <p>Scheduled maintenance (SM) including inspection, calibration, and preventive maintenance</p> | EF | Evident failure, i.e., a problem that can be detected--but was not reported--by the user without running any special tests or using specialized test/measurement equipment. |
| | HF | Hidden failure , i.e., a problem that could not be detected by the user unless running a special test or using specialized test/measurement equipment. |
| | PF | Potential failure , i.e., a failure that is either about to occur or in the process of occurring but has not yet caused the equipment to stop working or problems to patients or users. |
| | NPF | No problem found. |

Failure Cause Codes for Equipment - CM Failures

**MAINTENANCE
TYPE**

**Corrective
maintenance
(CM),**
including
repairs
performed for
failures
detected
during SM

**CAUSE
CODE**

DESCRIPTION

UPF

Unpreventable failure, evident to user, typically caused by normal wear and tear but is unpredictable.

USE

Failures induced by **use**, e.g., abuse, abnormal wear & tear, accident, or environment issues. Does NOT include use error (typically no equipment failure)

PPF

Preventable and predictable failure, evident to user.

SIF

Service-induced failure, i.e., failure **induced** by corrective or scheduled maintenance that was not properly completed or a part that was replaced and had premature failure (“infant mortality”).

CND

Cannot duplicate. Includes **use errors**. Same as NPF.

FFPM

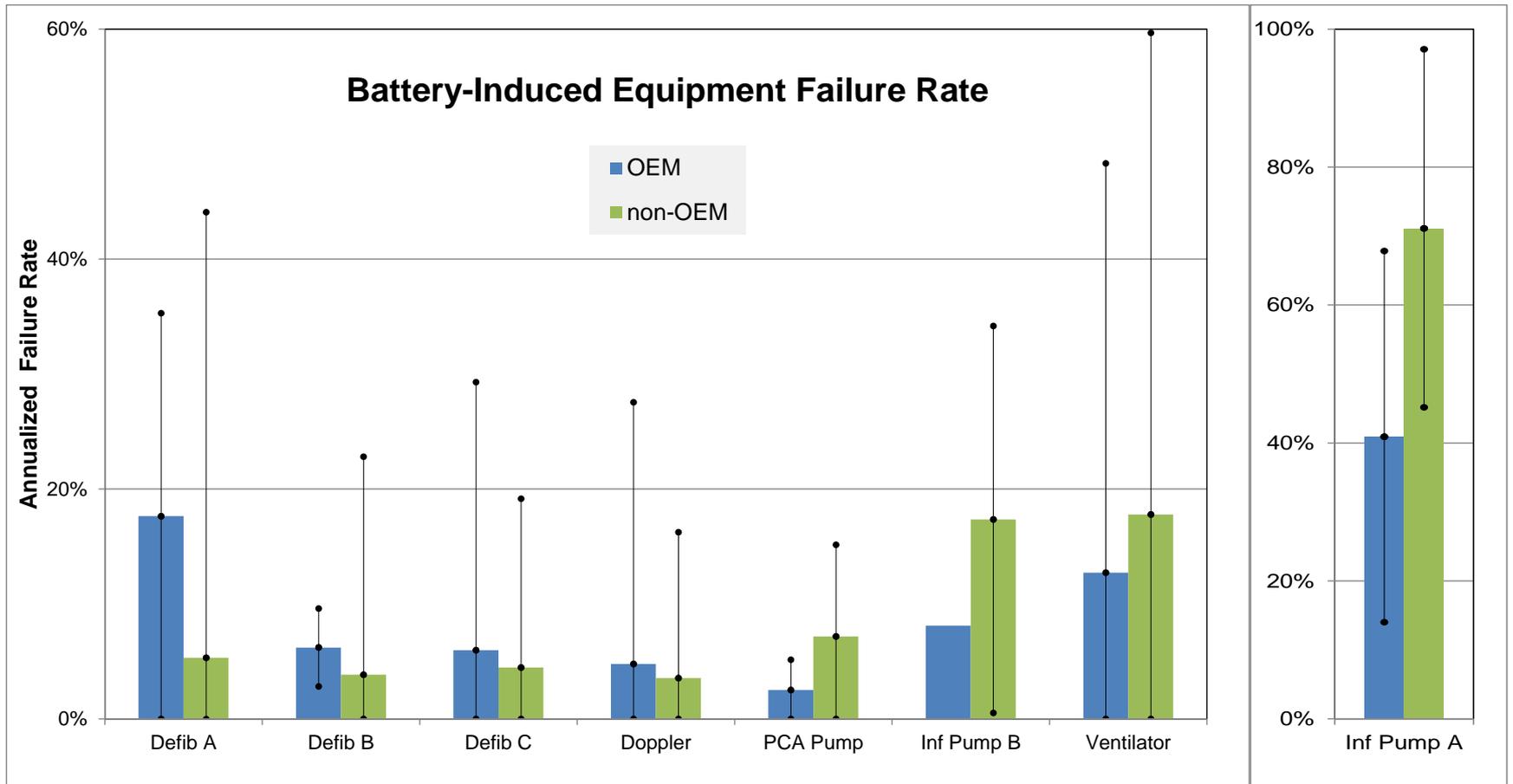
Failure found during PM (to avoid duplication of codes)

Failure Cause Codes for Peripheral Failures

| MAINTENANCE TYPE | CAUSE CODE | DESCRIPTION |
|------------------|-------------|--|
| CM or SM | BATT | Battery failure, i.e., battery(ies) failed before the scheduled replacement time. |
| | ACC | Accessory (excluding batteries) failures |
| | NET | Failure in or caused by network , |

The BATT code is what was used for this study. Each BATT is counted as a “failure” and **failure rate** is computed as: #BATT coded reports/#units, in the period of one year.

ARAMARK RESULTS



ARAMARK CONCLUSIONS

1. The cause of premature battery failures seems to be a **mismatch** between the OEMs expectations and clinical users' understanding and ability to care for the batteries.
2. This is a **human-factors** issue similar to the “use errors” and “alarm fatigue” challenges; numerous medical devices are involved.
3. Strict regulation of medical device batteries is unlikely to solve this issue. Quite the contrary, regulatory approach is only likely to increase costs and waste resources.
4. Recommend that multidisciplinary committee(s) to be created to establish standard practices acceptable to both OEMs and clinical users, as well as HTM professionals.

Overall Conclusions

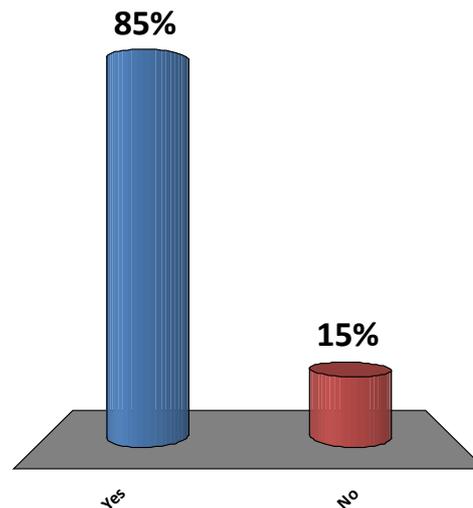
1. Multiple battery technologies present challenges for HTM
 2. Safety risks – device doesn't work; or physical hazards from batteries
 3. Batteries need frequent replacement
 4. Disposal issues are significant
 5. Costs for battery replacement are significant
 6. Need for industry wide group to tackle battery issues collaboratively
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Do you agree that an outcome of this workshop should be a:

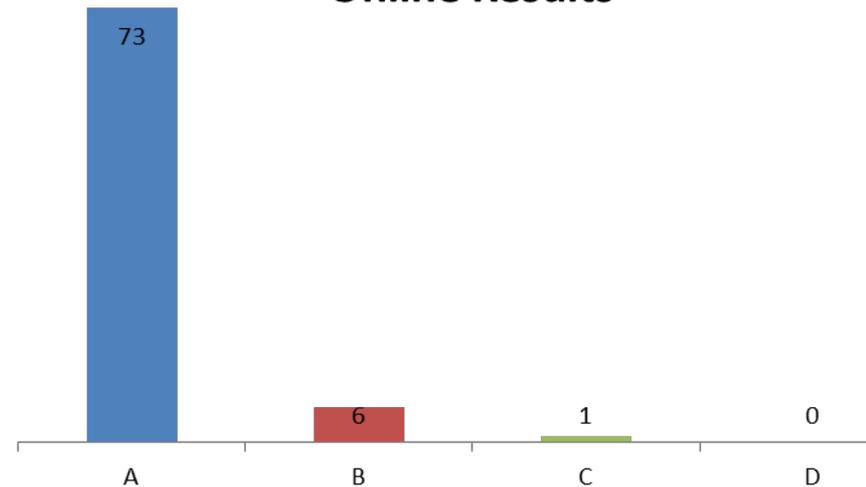
Recommendation that multidisciplinary committee(s) to be created to establish standard practices regarding rechargeable battery care used in medical equipment; acceptable to OEMs, clinical users and HTM professionals?

A. Yes

B. No



Online Results



Please contact one of us for questions or suggestions

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