EVIDENCE-BASED MAINTENANCE
FROM EVIDENCE-BASED MEDICINE TO EVIDENCE-BASED MAINTENANCE: A MUCH-NEEDED PARADIGM SHIFT FOR MIDDLE EAST COUNTRIES

Bassam Tabshouri, HTMA, Lebanon
Binseng Wang, Sodexo HTM, USA
Classical Approaches to Medical Equipment Maintenance

1. Risk-Based Criteria (the Fennigkoh & Smith model)

EM = Function + Physical Risk + Maintenance Requirements

If EM > 12 include into PM inventory and the frequency depends on value of EM

If EM < 12 exclude from PM inventory and repair upon failure.
Classical Approaches to Medical Equipment Maintenance

2. Reliability-Centered Maintenance (RCM)

RCM uses a decision process to determine the best maintenance strategy according to an analysis of the failure modes and effects.
Classical Approaches to Medical Equipment Maintenance

2. Reliability-Centered Maintenance (RCM)

Challenges in Medical Industry

1. Manufacturers do not share the software embedded into the medical equipment.

2. RCM recommends redesigning the device - FDA issue

3. Maintenance schedules & work instructions must be provided by the manufacturers
The New Paradigm - EBM

* A continual improvement process that analyzes
  the effectiveness of maintenance resources,
  structure and processes deployed
  in comparison to outcomes achieved

* Analyzes maintenance data from hundreds of hospitals whenever those are available
EVIDENCE-BASED MAINTENANCE

The New Paradigm - EBM

* Aim:

increase productivity and revenue by:

- improving capital planning
- increasing utilization
- reducing unnecessary maintenance

- delaying premature replacement
- enhancing safety
- protecting against cyberattacks
The New Paradigm - EBM

* Maintenance Strategy Selection (Planning)

(1) Scheduled Maintenance (SM)
   a. Preventive Maintenance (PM): replacement of parts with predictable deterioration
   b. Safety & Performance Inspection (SPI): detection of hidden and potential failures

(2) Corrective Maintenance (CM) restoring the equipment to its original safety and performance specifications
The New Paradigm - EBM

* Evaluation of the Maintenance Strategy EB

In EB Medicine, a drug or medical procedure must be evaluated for its safety and effectiveness before it can be marketed.

In EB Maintenance, we evaluate the maintenance strategy for its safety and effectiveness.

To measure effectiveness of the EBM strategy, we use reliability, i.e. availability of the equipment for use whenever needed.
The New Paradigm - EBM

* Safety Evaluation Using EBM

1. **record all patient incidents** (including “near misses”) involving medical equipment failures.
2. **perform a root-cause analysis (RCA) and assign the appropriate FCC (Failure Cause Code).**
3. **determine** whether these **failure causes** are related to individual actions or maintenance strategy, i.e.:
   a) “unsafe acts” (or “active failures”) committed by individual staff
   b) “latent conditions” due to oversight or deliberate violation of regulations, codes or standards.

<table>
<thead>
<tr>
<th>Code</th>
<th>Failure Cause Description</th>
<th>SM/CM</th>
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</thead>
<tbody>
<tr>
<td>NPF</td>
<td>No problem found (or the reported problem was not duplicated).</td>
<td>both</td>
</tr>
<tr>
<td>UPF</td>
<td>Unpreventable failure, typically caused by normal wear and tear but is unpredictable.</td>
<td>CM</td>
</tr>
<tr>
<td>ACC</td>
<td>Accessory failure, excluding batteries, typically caused by normal wear and tear</td>
<td>both</td>
</tr>
<tr>
<td>BATT</td>
<td>Battery failure, i.e., battery(ies) failed before the scheduled replacement time.</td>
<td>both</td>
</tr>
<tr>
<td>NET</td>
<td>Failure in or caused by network, while the equipment itself is working without problems.</td>
<td>both</td>
</tr>
<tr>
<td>USE</td>
<td>Failures induced by use, e.g., abuse, abnormal wear &amp; tear, accident, or environment issues.</td>
<td>CM</td>
</tr>
<tr>
<td>EF</td>
<td>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 tester.</td>
<td>SM</td>
</tr>
<tr>
<td>SIF</td>
<td>Service-induced failure, i.e., caused by CM or SM that was not properly completed or a part that was replaced and failed prematurely (“infant mortality”).</td>
<td>CM</td>
</tr>
<tr>
<td>HF</td>
<td>Hidden failure, i.e., a problem that could not be detected by the user under normal circumstances, unless running a special test or using specialized tester.</td>
<td>SM</td>
</tr>
<tr>
<td>PF</td>
<td>Potential failure, i.e., failure is either about to occur or in the process of occurring but has not yet caused equipment to stop working or problems to patients or users.</td>
<td>SM</td>
</tr>
<tr>
<td>PPF</td>
<td>Preventable and predictable failure, typically caused by wear and tear that can be predicted or detected.</td>
<td>CM</td>
</tr>
</tbody>
</table>
Discussion & Conclusions

* EBM Limitations

While EBM tries to imitate the methods of EB Medicine, there are some fundamental differences:

1. Equipment is less complex and better understood than human beings

2. Equipment does not suffer from psychosomatic effects, so double-blind approach is not needed

1. Cannot blindfold CE professionals when performing service. It is not possible to conduct “double-blind randomized clinical trials” (RCT) like drug testing.
Discussion & Conclusions

* Lessons Learned

Data analysis show that:

- **SIF (Service induced failure) is very rare**

- **Most maintenance errors are caused by active failures** (human) instead of latent conditions (maintenance strategy).

- Thus, there is **no reason to follow OEM maintenance recommendations**

- **True PM is becoming obsolete with technology advance** and will not provide job security
Discussion & Conclusions

* How can EBM improve equipment maintenance?

Allows CE departments to reallocate its limited resources to:

- Help plan and select better equipment before purchase
- Help users to understand and use better the equipment
- Help users to understand and take better care of the equipment
- Help to determine when equipment needs to be replaced
- Help to investigate patient incidents related to medical equipment
- Address recalls promptly to reduce risks to patients and users
- Address cybersecurity issues presented by equipment
THANK YOU !