Overview of MedSun Survey

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Battery-Powered Medical Devices: Challenges and Opportunities
Public Workshop
July 30-31, 2013
Medical Product Safety Network “MedSun”

• Group of 250 hospitals and other healthcare facilities that send reports about issues, concerns and challenges with medical devices and will answer questions about device use.
Purpose of the Survey

- To talk with healthcare providers and other hospital staff to learn about their experiences and challenges
Small Sample Surveys

• Obtain information quickly from the clinical community

• Responses are
  - Voluntary
  - Qualitative - may not represent all device users’ experiences
Methodology

• 9 telephone interviews with hospital staff conducted

• Respondents:
  – Biomedical/Clinical Engineers
  – Risk Managers
  – Nurses
  – Purchasing Directors

• MedSun hospitals from different regions of the country
Focus of Questions

• Performance
• Preventive Maintenance
• Labeling & Instructions
• Training
• Selection and Purchasing Procedures
• Suggestions for Improvement
Device Performance

• Devices with most frequent issues:
  – Large volume infusion pumps
  – Telemetry boxes
  – Pulse oximeters
  – Thermometers
  – Electric beds
  – Monitors
  – Portable/mobile devices
## Types of Battery-Related Issues

<table>
<thead>
<tr>
<th>Issue/Challenge</th>
<th>Reported/Potential Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to plug in device</td>
<td>Premature depletion; loss of power</td>
</tr>
<tr>
<td>Overcharging</td>
<td>Overheating; fire; explosion;</td>
</tr>
<tr>
<td>Undercharging</td>
<td>Premature depletion; loss of power</td>
</tr>
<tr>
<td>Inaccessible plugs/outlets</td>
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<td>Leakage</td>
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<td>Swelling</td>
<td>Explosion</td>
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<tr>
<td>Confusion with on/off button</td>
<td>Premature depletion; loss of power</td>
</tr>
<tr>
<td>Loose connections</td>
<td>Premature depletion; loss of power</td>
</tr>
<tr>
<td>Incorrect replacement</td>
<td>Leakage; increased heat; fire;</td>
</tr>
</tbody>
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Example

• Infant isolette temperature setting
  – Severe weather caused power loss
  – Emergency generator on after 5-6 seconds
  – Memory battery did not back up setting
  – Temperature reverted to manufacturer default setting
  – Isolette became too hot
Examples

• Temporary external pacemaker
  – No indication battery is low or depleting
  – When depleted, staff have 2 to 5 seconds to replace battery

• MRI conditional monitor
  – Battery cells can go bad even when device is plugged-in
Preventive Maintenance (PM)

• **Proactive battery replacement**
  – Based on level of device risk
  – Manufacturer recommendations
  – Hours of usage
  – Ranges from every 6 months to 5 years

• **Service calls for battery issues**
  – Up to 50% of calls
  – Number depends on person responsible and what is needed
Labeling and Instructions for Battery-Powered Devices

- Most - clear, adequate

- Manuals - often not with the device and may not include when to service or replace battery

- Quick guides are helpful but may not include the time needed for battery-charging and may detach from the device

- Work pressures, constant transport of patients and devices contribute to devices not plugged-in
Training

• Need consistent and on-going education and training

• Provide staff with information about cost implications for replacing batteries
Selection and Purchasing

• Processes and factors similar among hospitals
• Based on high risk versus low risk devices
• Other factors:
  – Cost
  – Facility equipment needs
  – Quality of battery life
  – Technical specifications
Suggestions for Improvement

• Standardization across device types for battery charging, replacement, service intervals, and disposal

• Visual indicators

• Improved and permanent labeling
Suggestions for Improvement

• Improved technology to eliminate the need for manual battery charging

• Access to performance and testing data about device failures

• In FDA recall notices, identify the battery and include if battery problem is associated with root cause
MedSun Survey Report about “Batteries in Medical Devices” on FDA’s MedSun Website

Thank You