Responsibilities of Industry and Setting Standards

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Responsibility of Industry
Key Responsibilities

• Job #1 – Focus on patient outcomes
  o Do no harm
  o What is actionable to improve patient outcomes?

• Listen to the customer and understand the needs
  o Direct contact and collaboration
  o Keep up on the professional publications and support best practices
  o Professional meetings, forums, and summits
  o Take individual inputs looking for outcome changing innovators and collate into product change

• Look to the future and innovate
  o Integration example
    • Physiological monitoring alarms now → integration with other medical devices, nurse call, RTLS, etc.
Literature Review

• False alarms may be the most serious shortcoming as the effectiveness of alarms depends upon the alarm system’s credibility (Breznitz, 1984)

• High false-positive rates can lead to disabling of alarms by medical personnel (McIntyre, 1985)

• Humans can’t learn more than six alarm sounds and priority difficult to discern (Stanton, 1994)

• The perceived urgency of audible alarms can be inconsistent with the clinical situation (Mondor, 2003)

• In a 2006 paper in the Am. J. Emerg. Med, 99.4% of the alarms were determined to be false with less than 1% of all alarms resulting in a change of patient management (Atzema)
Literature Review

# of Alarms & Events

<table>
<thead>
<tr>
<th>Source</th>
<th>Setting</th>
<th>Time-frame</th>
<th># Alarms</th>
<th># Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atzema et al, 2006</td>
<td>ED</td>
<td>371 hrs</td>
<td>1,762</td>
<td>11</td>
</tr>
<tr>
<td>Görges et al, 2009</td>
<td>MICU</td>
<td>200 hrs</td>
<td>1,214</td>
<td>64</td>
</tr>
<tr>
<td>Talley et al, 2011</td>
<td>PICU</td>
<td>45 days</td>
<td>2,245</td>
<td>68</td>
</tr>
<tr>
<td>Fidler et al, 2011</td>
<td>6 adult units</td>
<td>2 mos</td>
<td>318,009</td>
<td>19 Code Blues</td>
</tr>
</tbody>
</table>

From Maria Cvach, Johns Hopkins 2011

False Alarms

<table>
<thead>
<tr>
<th>Source</th>
<th>Setting</th>
<th>% False Alarms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lawless, 1994</td>
<td>PICU</td>
<td>95%*</td>
</tr>
<tr>
<td>Tsien &amp; Facklet, 1997</td>
<td>PICU</td>
<td>86%</td>
</tr>
<tr>
<td>Chambrin et al, 1999</td>
<td>5 Adult ICUs</td>
<td>72%</td>
</tr>
<tr>
<td>Atzema et al, 2006</td>
<td>ED</td>
<td>99%</td>
</tr>
<tr>
<td>Görges et al, 2009</td>
<td>MICU</td>
<td>77%</td>
</tr>
<tr>
<td>Siebig et al, 2010</td>
<td>MICU</td>
<td>85%</td>
</tr>
</tbody>
</table>

*Includes false alarms & insignificant alarms induced by staff manipulation.
Key Responsibilities

• Robust design with attention to usability
  o Front end – first get a quality signal
  o Intelligence and integration, e.g. “smart” alarms, multi-parameter analysis
  o Reliability, especially software, a must
  o Human factors – built for the users and the environment
  o Provide users with flexibility and data to manage and improve

• Customer training
  o Strong basic skills and adaptation for use environment
  o Methodology to reach the most users knowing work schedules
  o Support and complement healthcare organization’s educational efforts

• Self-regulate
  o If not, it will be done externally, e.g. regulations
  o Minimum standards is not be adequate
Case Study: Adult Critical Care Units

Alarm Statistics
- Total number of alarms: 2,395,550
- Average rate (alarms/bed/day): 289
- Different alarm types: 171
- Bed avg. time between alarms: 300 sec
- Care area peak alarm rate: 9/sec

Care Area Profile
- Academic Medical Center
- 98 total critical care beds
- Multiple Critical Care Units
- Average occupancy: 93%
- Period of study: 91 days
- Aggregate bed days: 8,292

Top 4 Types

<table>
<thead>
<tr>
<th>Type</th>
<th>Quantity</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVC</td>
<td>825,403</td>
<td>34.35%</td>
</tr>
<tr>
<td>RSP HI</td>
<td>396,839</td>
<td>16.57%</td>
</tr>
<tr>
<td>SPO2 LO</td>
<td>274,388</td>
<td>11.45%</td>
</tr>
<tr>
<td>COUPLETT</td>
<td>105,043</td>
<td>4.38%</td>
</tr>
</tbody>
</table>

From Excel Medical with permission
Best Practice: Default Setting Changes at Christina Care

- Default monitor alarm settings modifications made more than 10 years ago with no change in adverse outcomes.
  - Default V-TACH value $\geq 5$ PVCs. Christiana Care changed to $\geq 10$ PVCs.
  - RUN PVCS, PAIR PVCS, R-on-T PVC, Ventricular Bigeminy, Ventricular Trigeminy &
  - Multiform PVCS – In all cases, Default ON. Christiana Care turned OFF.
  - IRREGULAR HR – ON, but nurse may turn off if patient currently in atrial fibrillation.

Recommendations for Alarm Signal Standardization and More Innovation, AAMI Foundation HTSI Safety Innovations 2012
http://www.aami.org/htsi/SL_Series/Christiana_Care_Alarm_Signal.pdf
Default settings: Other Examples

Threshold: reduce # of alarms by up to 75%

Gross et al, 2011
High HR: 120 to 130 → 50% reduction
Low SpO2: 90% to 85% → 36% reduction
Low SpO2: 90% to 80% → 65% reduction

Welch, 2011
Low SpO2: 90% to 88% → 45% reduction
Low SpO2: 90% to 85% → 75% reduction

Delay: reduce # of alarms by up to 70%

Welch, 2011: SpO2 alarms
5 sec delay → 32% decrease
10 sec delay → 57% decrease
15 sec delay → 70% decrease

Görges et al, 2009: Ignored & ineffective alarms
14 sec delay → 51% decrease
19 sec delay → 67% decrease

45-50% reduction in alarms

Maria Cvach, Johns Hopkins
Setting Standards
Joint Commission

Alarm Hazard Improvement Efforts

• Sentinel Event Alert - February 26, 2002
  o 23 reports of deaths or injuries related to long term ventilation--19 events resulted in death and four in coma.
  o Of the 23 cases, 65 percent were related to the malfunction or misuse of an alarm or an inadequate alarm

• National Patient Safety Goal 6 implemented in hospitals July 2002 thru July 2004 (removal date)
  o Improve the effectiveness of clinical alarm systems
    • 6A: Implement regular preventive maintenance and testing of alarm systems.
    • 6B: Assure that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit.

What were the positive changes?

Did the reported deaths per year decrease?
Joint Commission
Current and Projected Future Actions

• Clinical Alarm Management Environmental Assessment Survey sent to hospitals in March 2012
  o Results not published

• Alarm hazards will not be a National Patient Safety Goal for 2013
  o Possible 2014 NPSG
Design Standards

• AAMI Medical Device Alarm Standards Committee
  • Task Groups
  o Subcommittee: Alarm Best Practices
    • The workgroup’s primary focus is to review and recommend best practices for alarm management. The Alarm Best Practices workgroup’s vision is to collaborate with other organizations in order to identify areas for potential research and to share best practice strategies to reduce alarm fatigue, increase patient safety and encourage the delivery of high quality healthcare.
Guidelines

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Design Standards

• International Electrotechnical Commission (IEC) 60601-1-8:2006, Medical electrical equipment
  o Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems, and Amendment 1
    • Specifies basic safety and essential performance requirements and tests for alarm systems in medical electrical equipment and medical electrical systems and to provide guidance for their application.
    • Defines alarm categories (priorities) by degree of urgency, consistent visual and audible alarm signals and consistent control states and their marking for all alarm systems.
  o Only focused alarm standard
  o Possible US national adoption of IEC 60601-1-8 and its amendment
Design Standards

• IEC/NP TR 80001-2-x, Application of risk management for IT-networks incorporating medical devices - Part 2-x: Guidance on distributed alarm systems (N 19)
  o Work item proposal
American Society for Testing and Materials

• Committee F29.15 on Harmonization of Alarms

• Standard Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care
  - ASTM F-1463-93 (Re-approved 1999)
    • Anesthesia and Respiratory equipment only
Integrating the Healthcare Enterprise

Alarms Communication Management

• IHE Patient Care Device (PCD) Technical Framework Supplement
  o Patient Care Device Profile
  o The communication of alarms
    • Alarm dissemination between alarm source devices and systems
Alarm Communication Management Actors and Flow
Resources

• Healthcare Technology Foundation alarm page
  o http://thehtf.org/clinical.asp

• Association for the Advancement of Medical Instrumentation (AAMI)
  o Healthcare Technology Safety Institute – Clinical Alarms
    • http://www.aami.org/htsi/alarms/index.html
    • http://www.aami.org/htsi/safety_innovation.html

• ECRI Institute Alarm Safety Resource Guide
  o https://www.ecri.org/Forms/Pages/Alarm_Safety_Resource.aspx
Questions?

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