Impact Of Clinical Alarms On Patient Safety

American College of Clinical Engineering Healthcare Technology Foundation (AHTF)
In 2004, the ACCE Healthcare Technology Foundation started an initiative to improve clinical alarms

“To improve patient safety by identifying issues and opportunities for enhancements in clinical alarm design, operation, responses, communication, and appropriate actions to resolve alarm-related events.”

**Actions:**

1) Analysis of adverse event literature and databases

2) Evaluation of previous efforts to improve alarms

3) Feedback from meetings and a national survey

4) Recommendations to improve alarm related patient safety

5) Define future directions for improving clinical alarms
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Limitations of clinical alarm systems

- Difficulty in learning more than 6 different alarm signals
  - Surgery and ICU environment >> 6 different alarms
- Difficulty in discerning between high and low priority alarms
- Perceived urgency of alarms may not be consistent with criticality of situation
  - “Better safe than sorry” mentality increases the number of alarms included in devices
  - Some devices do not need alarms
    - more problems than benefits
Limitations of clinical alarm systems

- “99.4% of the alarms were determined to be false with less than 1% of all alarms resulting in a change of patient management.”
  - *American Journal of Emergency Medicine, 2006*

- False alarms/nuisance alarms
  - Procedures
  - Patient conditions
  - Design

- High false-positive rates → loss of credibility → disabling of alarms by medical personnel
The FDA MAUDE database was queried (2002-2004) using search terms:

- “alarm” in the Product Problem field
- “death” as the Event Type selection

237 reports were found

- Of 139 events that could be analyzed:
  - 58 (42%) were related to operator education and training
  - 67 (48%) were related to work conditions or personal problems
DEATHS BY DEVICE • 2002-2004
Term “Alarm” in Product Problem description

Figure 2

<table>
<thead>
<tr>
<th>Device</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
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<tbody>
<tr>
<td>Defibrillator</td>
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<td>Hemodialysis</td>
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<td>Monitor (Physio)</td>
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<td>Bed/Chair Alarm</td>
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<td>Pump</td>
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<td>Ventilator</td>
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<td>Undefined</td>
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ECRI Problem Reporting Systems Database Review

- Of more than 2,200 reports:
  - 12% include the word “alarm” in the Problem Description field
  - 64% of the reports involved:
    - Physiologic monitors
    - Ventilators
    - Infusion pumps

- Physiologic monitors
  - Numerous reports of critical patient events where the monitoring system was reported to produce no alarm
  - Investigation found that alarms were inadvertently disabled

- Ventilator and Infusion pumps
  - Reports discuss device failures that put the patient at risk, but did not result in an alarm to alert caregivers to the failure
Standards

Improvement

Efforts
JCAHO’s Alarm-Safety Goal 6

- Sentinel Event Alert • February 26, 2002
  - Ventilator incidents related to clinical alarms
- National Patient Safety Goals for 2003 and 2004
  - Maintenance and care management
  - Focus on alarm-safety was effective in:
    - Raising awareness of deaths and injuries that occur due to ineffective alarms and inappropriate alarm use
    - Promoting a better understanding of the importance of effective alarm management strategies

Despite the two year focus on alarm improvement, clinical alarm management still requires attention
Design Standards

- **IEC 60601-1-8**
  - General requirements for alarm systems
  - Only focused alarm standard
  - Defines visual and audible alarm signals that can be used to prioritize degree of urgency
  - Not widely implemented in the U.S.
  - Some devices have the option to employ the IEC-defined alarm tones
  - Adopted by the FDA as a reference standard

- **Current AAMI/ANSI standards**
  - Do not address the need for prioritization of alarms emitted from different devices
  - Alarms are generally handled on a device-specific basis
Clinical Alarm Survey

- Demographics
  - Type of facility and location
  - Job type and experience

- Questions – Strongly Agree→Strongly Disagree
  - Design, Standards, Environment, Care management, Integration

- Rating as to primary versus secondary issues
  - Nine categories

- Comment field
Clinical Alarm Survey

The survey was completed by 1,327 individuals

- Nearly all from acute care hospitals
- Over half of respondents were Registered Nurses (RN’s)
- One-third from critical care units
- 2/3rds had more than 11 years of experience
Clinical Alarm Survey: 

*Results Summary*

- **Biggest issue:** False Alarms and Nuisance Alarms
  - Reduce attention and response
  - Disrupt care and reduce trust in alarms

- The majority support:
  - “Smart alarms” and alarm integration systems

- Not reported as significant:
  - Alarm training
Clinical Alarm Survey: Sample Comments

- “Nurses that work around alarm systems e.g. monitors, i.v pumps and etc. tend to tune them out after a while. Too many false alarms occur and the nurses find this to interfere with patient care.” **OR, Clinical Manager**

- “Patient care is about people and not machines. Too much reliance on technology. Nurses get technology overload. NEED MORE NURSES PER PATIENT” **BMET, Clinical Engineering**

- “Different alarms for different parameters (HR, SpO2, etc). Increased accuracy of alarms therefore reducing false alarms and staff being 'anesthetized' to alarm” **RN, OR**
Observations
Observations

- The number and complexity of alarm systems in critical care environments challenge human limits for recognition and action.

- Alarms in critical care environments may not significantly affect care management decisions.

- Alarms are a tool in assessing patient conditions.
  - Should be used in conjunction with direct clinical measurements and observations.

- Disagreement about the role of user operation of alarm systems in alarm system performance.

- False alarms - consistently reported as a major issue.
Observations

- If well designed, remote alarm communication devices can be of value
  - Problems occurred when used as primary alert method

- The IEC/ISO standards are viewed by many as a way to improve alarms by:
  - Standardizing audible and visual alarms
  - Priority and parameter differentiation

- The alarm problem is a *systems* issue and actions toward specific areas must consider their impact on the *system*
Recommendations
Healthcare Recommendations

- Review and revise existing policies related to clinical alarm management:
  - Use of defaults, changing of alarm limits, expected clinical responses to alarm conditions, & consider institutional/departmental standardization

- Perform frequent clinical alarm monitoring rounds, to alert users to any variations from unit specific guidelines

- Develop audit tools to measure compliance with established policies related to clinical alarm management

- Develop and complete a checklist associated with clinical alarm management and document compliance at shift change

- Conduct in-service and simulation training associated with new equipment

- Improve device alarms evaluation prior to purchase
Industry/Standards Recommendations

- The medical device industry must focus on reduction of false alarms
  - Accurate parameter recognition
  - Smart alarms employing advanced signal processing, event recognition and parameter/alarm integration
  - Usability/human factors design

- Consider the scientific basis and value of the IEC 60601-1-8 standards
  - Prioritization
  - Annunciation
    - Audible and Visual
Future
Future Actions

- Widely distribute white paper
- Data analysis update
  - FDA data 2006 & 2006
- Publications
  - Journal of Clinical Engineering – Jan/Mar 07
  - American Journal of Critical Care - TBD
- 2007 Presentations
  - Colloquium - Responding to Medical Device Incidents
  - American College of Healthcare Executives
  - National Patient Safety Foundation
- Website updates
- Re-survey in 2-3 years