What is a clinical alarm?

- One definition – “A method to alert care providers to situations that require urgent attention and might have been missed due to distractions and/or system's limitation and/or use error.” (adopted from Human Factors and Medical devices by H.J.Murff, J.H.Gosbee & D.W.Bates).

Tobey Clark, University of Vermont
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What is an effective alarm?

- For a clinical alarm to be effective it must be triggered by a problem which adversely affects the patient or has the potential to adversely affect the patient, personnel must identify the source and meaning of the alarm, and correct the medical problem prior to an adverse patient event.

AHTF White Paper 2006

Tobey Clark, University of Vermont
Alan Lipschultz, Christiana Care
**History**

- Clinical alarms problematic since the first medical devices were introduced
- ECRI - *Health Devices*
  - First hazard reports on clinical alarms failures in the July 1974 issue related to three hyper/hypothermia incidents
    - *operators not responding to the high temperature warning light*
  - ASTM standard includes alarms design - 1979

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**Alarm Identification: Identify Alarm Sounds from Common Devices**

- 1
- 2
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- 4
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- 8
- 9
- 10
Limitation in the recognition of different device alarm sounds

- Individuals have difficulty in learning more than six different alarm signals (Stanton, 1994)
  - A patient in an ICU environment can have well more than six different alarm sounds associated with their care, as well as the same sound having different meanings when emanating from different devices.
- A study showed that experienced care givers could not identify even one-half of common ICU critical alarm sounds when played back (Cropp, 1994)

Limitation in the recognition the urgency of the alarm

- Care providers have difficulty in discerning between high and low priority alarm sounds in part due to design (Simons, 1997)
- The perceived urgency of audible alarms can be inconsistent with the clinical situation (Mondor, 2003)
False alarms are a significant problem

- 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)
- 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)

Other alarm issues

- 58% of anesthesia staff surveyed stated their patients were placed at risk due to source of alarm not being able to be identified (Griffith, 1992)
- Alarms contribute to stress in anesthesia practice (Griffith, 1992)
- Some devices should not have audible alarms! (Deller, 1992)
- Past manufacturer’s mantra: “Better safe than sorry” led to an increase in number of alarms, volume and degree of irritation (Stanton, 1994)
Clinical Alarm problems

- System Design
- System Performance
- Operator
- Environment

Reported Clinical Alarm problems

Care management
- No response to alarms
  - Attending other patients
  - Ignored
  - Confused as to source
  - Volume off or set too low
- Alarm not set correctly
- Priority of alarm not recognized
- Training inadequate
- Staffing inadequate
- Over reliance on alarm systems
Reported Clinical Alarm problems

Environmental
- Too much background noise
- Competing alarms
- Poor design of facility
- Patient condition

Maintenance
- Alarm failure
- Interconnects defective

Design
- Alarms can be defeated/turned off
- False positive alarms
  - Patient condition
  - Poor design
- Alarm tones and displays not recognized
- Poor human factors design
- Poor integration

JCAHO Clinical Alarms Efforts

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

- Patient Safety Goal 6 - 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.

- Goal implemented in hospitals July 2002 thru July 2004 – dropped, now part of standard
  - [http://www.jcaho.org/accredited+organizations/patient+safety/npsg.htm](http://www.jcaho.org/accredited+organizations/patient+safety/npsg.htm) (see Implementation Expectations)

Contemporary systems still have problems

- Ventilator alarms - none of the evaluated systems provided completely safe and reliable notification of ventilator alarms, falling short in areas such as alarm prioritization and identification from the central station ([ECRI’s January 2005 Health Devices evaluation of physiologic monitoring systems interfaces with ventilator alarms](http://www.jcaho.org/accredited+organizations/patient+safety/npsg.htm))
Contemporary systems still have problems

- Alarm paging systems - the failure of medical alarm systems using paging technology to notify clinical staff. *Veterans Health Administration Patient Safety Alert - July 2, 2004*

The VA recommendations states that

- “Medical alarm systems using paging technology are not designed or intended to be used as the primary method for alerting clinical staff of critical alarms conditions or are they approved for this use by the FDA.”

Alarm Complexity:

**BiomedTalk Listserve Comment**

**Date:** Wed, 7 Sep 2005 08:56:53 -0800 **Reply-To:** Biomedical Engineering Discussion List  
<BIOMEDTALK-L@LISTSERV.AOL.COM>

“Just a question. We determined that our bedside monitors had over 400 different alarm potentials. That is high low pressures, NIBP, Pulse Ox, Heart Rate, arrhythmias, mean pressure alarms, etc.

Do you test all of them? “
Other Issues:
BiomedTalk Listserv Comment

- Isolation Rooms – relatively soundproof
- Philips CMS module software incompatibility causing lack of SaO2 alarm
- Decibel Testing of alarms
- Alarms Testing and Management
- Bed occupancy alarms
- Remote ventilator alarms
- Line isolation alarms

Are Clinical Alarms Still a Problem?
FDA MAUDE Database Review

* Reports of deaths and injuries showed an increase in reports from 189 in 2001 to 449 in 2004

- MAUDE problem description includes the term alarm – not necessarily the cause of the adverse event
What device types are involved?

FDA MAUDE Database Review

 Attempt to look at adverse event cause

FDA MAUDE Database Review

Analysis* of 237 events resulting in death over 2002-2004

- Nearly one-half could not be analyzed due to poor data
- Most classified as use error
  - Training & Work conditions
- Small percentage classified as device, environment or patient caused

Significant limitations in using the FDA MAUDE database to analyze cause

*using the Shepherd System's Risk Model
ACCE Healthcare Technology Foundation

Mission:
- *Improving healthcare delivery by promoting the development and application of safe and effective healthcare technologies through the global advancement of clinical engineering research, education, practice and their related activities*

Major initiatives:
- Public Awareness of safety issues associated with healthcare technologies
- Clinical Engineering Certification
  - Clinical Engineering Excellence Award
- Clinical Alarms Management and Integration
Purpose: Clinical Alarms Initiative

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

AHTF Task Force Agenda

- Research the literature and adverse event databases
- Conduct audio conferences, town meetings and forums
- Develop a survey for clinical and support staff
- Develop educational materials
  - Website [http://www.acce-htf.org/clinical.html](http://www.acce-htf.org/clinical.html)
  - White Paper
Physiological alarms: Techniques for Standardizing Alarms in Your Institution

Saturday, June 24, 2006
3:15-4:30 pm

AHTF Clinical Alarms Project Task Force

- Jennifer Ott, CCE, Director – Clinical Engineering, St. Louis University Hospital
- Thomas Baud, PhD, Technology Manager, Riverside Health Systems, ARAMARK/CTS
- Bryanne M. Parail, BS, MLS, FACCE, Biomedical Engineer, US Department of Veterans Affairs, National Center for Patient Safety
- Izabella A. Gieras, MS, MBA, Clinical Engineering Manager, Beaumont Services Company
- Marvin Shepard, PE, DEVTEQ
- Saul Madowink, MEE, CCE, Director, Clinical Engineering Memorial Sloan-Kettering Cancer Center
- Jeff Heyman, Senior Project Engineer, ECRI
- Ode Keil, MBA CCE, Dir. of Quality Management, Provena Mercy Medical Center
- Alan Lipschultz, PE CCE CSP, Director, Clinical Engineering Christiana Care Health Services
- Bruce Hyndman, Director of Engineering Services, Community Hospital of the Monterey (CA) Peninsula
- William Hyman, PhD, Professor, Biomedical Engineering, Texas A&M University
- James Keller, Vice President, Health Technology Evaluation and Safety, ECRI
- Matt Baretich, PE, PhD, President, Baretich Biomedical
- Wayne Morse, MSBME, President, Morse Biomedical
- Co-chair: Tobey Clark, MS CCE, Director, Instrumentation & Technical Services, University of Vermont
- Co-chair: Yadin David, PhD, Director of the Biomedical Engineering Department at Texas Children's Hospital

Collaborative Organizations

- MedSun – Social & Scientific Systems
- AORN - Assoc. of periOperative Registered Nurses
- AACN – Amer. Assoc. of Critical-care Nurses
- ECRI – Emergency Care Research Institute
- ACCE - American College of Clinical Engineering
- META – Medical Equipment & Technology Assoc.
- AAMI – Association for the Advancement for Medical Instrumentation
- NECES – New England Clinical Engineering Society
- Virginia Biomedical Society
- Supporting publications: 24x7, J. of Clinical Engineering, Biomedical Safety & Standards

Tobey Clark, University of Vermont
Alan Lipschultz, Christiana Care
AHTF Clinical Alarms Survey Tool

- Online and paper format
  - Paper forms allowed internal analysis
- 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

AHTF Clinical Alarms Survey Tool

- 1327 respondents – nearly all from acute care hospitals
- Over half of respondents were Registered Nurses
  - One fourth Respiratory therapists and other clinical
- 15% Clinical Engineers and Biomedical Equipment Technicians
- Almost one-third of respondents work in an intensive care unit
- 2/3rds had more than 11 years of experience
Physiological alarms: Techniques for Standardizing Alarms in Your Institution  
Saturday, June 24, 2006  
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**AHTF Clinical Alarms Survey Tool**

Sample of Results

- Nuisance alarms occur frequently
  - Disrupt care and reduce trust in alarms
- The majority support “smart alarms” and alarm integration systems
- Biggest issue – false alarms
  - Reduced attention and response
- Not significant – alarm training

*Full results will be presented in an AHTF White Paper*

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**AHTF Clinical Alarms Survey Tool**

Sample Comments (of several hundred)

- “Nurses that work around alarm systems e.g. monitors, i.v pumps and etc. tend to tune them out after a while. To 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**

*Full results will be presented in an AHTF White Paper*

Tobey Clark, University of Vermont  
Alan Lipschultz, Christiana Care
### Actions to Improve Alarms

<table>
<thead>
<tr>
<th>Design</th>
<th>Care management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smart alarms</td>
<td>Training</td>
</tr>
<tr>
<td>Integration</td>
<td>Monitoring (rounds)</td>
</tr>
<tr>
<td>Usability/human factors</td>
<td>Use best practice guides</td>
</tr>
<tr>
<td>Standards</td>
<td>Institutional standards</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Environmental</th>
<th>Clinical engineering</th>
</tr>
</thead>
<tbody>
<tr>
<td>Better design of facilities</td>
<td>Evaluate purchased items for usability</td>
</tr>
<tr>
<td>Monitoring (rounds)</td>
<td>Test alarms in their environment</td>
</tr>
<tr>
<td>Communication</td>
<td>Software setup/testing</td>
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<tr>
<td>▪ Alarm integration to pager, cell phone, etc.</td>
<td></td>
</tr>
</tbody>
</table>

### Alarm Standardization

- **Institutional**
- **Manufacturer**
  - Operational and output standardized
- **Integration**
  - Physiological monitoring system or custom
- **Design standards**
  - ANSI/AAMI
  - IEC/ISO

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Tobey Clark, University of Vermont
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Physiological alarms: Techniques for Standardizing Alarms in Your Institution

SCOPE IEC/ISO
Standard 60601-1-8

- Priorities
- Annunciation
  - Audible - Pulse burst, frequency, harmonics, volume
  - Visual – Color, flash frequency
- Presets including defaults
- Limits
- Security
- Interruptions
- Inactivation
- Resets
- Latching and non-latching alarms
- Distributed systems
- Logs

Multi-national vendors allow device configuration to US or IEC standards

Some US healthcare institutions have switched to the IEC/ISO standard

THANK YOU!

QUESTIONS?

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