

# Clinical Alarms Management & Integration: *Issues, Changes and Emerging Technologies, and Clinical Engineering Initiatives*

ACCE Audio Conference  
June 16, 2005

## Audio Conference Hosts

- Yadin David, PhD, Director of the Biomedical Engineering Department at Texas Children's Hospital & President, ACCE Healthcare Technology Foundation
- James Keller, MS, Director, Health Devices Group, ECRI
- Tobey Clark, MS, Director, Instrumentation & Technical Services, University of Vermont

## Thanks to the AHTF Clinical Alarms Project Task Force

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- *Co-chair* Yadin David, PhD, Director of the Biomedical Engineering Department at Texas Children's Hospital

## What is an alarm?

### Alarm 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).*

## Alarm source and recognition

- Humans have difficulty to reliably recognize more than 6 alarms at one time.
- Sound specific alarms were correctly identified by OR personnel (M.D.s, R.N.s, technicians) in various studies between 33 – 59% of the time.
- False alarms need to be better managed. Poor alarm design, application or setting contributed to false positive alarms reported in 2 studies between 72 – 75% of all alarms in routine general anesthesia. These alarms did not required corrective action. False positive alarms is a significant problem.

## Clinical Alarm problems

- System Design
- System Performance
- Operator

## 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
- Human factors interface poor
- Poor integration

## VA National Center for Patient Safety

- Bryanne M. Patail, BS, MLS, FACCE, Biomedical Engineer, US Department of Veterans Affairs, National Center for Patient Safety
- PDF file attachment
  - Bryanne\_VA\_alarms defining the problem.pdf
- Work in progress

## Actions to Improve Alarms

### Design

- Smart alarms
- Integration
- Standards

### Care management

- Process change
- Training
- Monitoring (rounds)
- Patient Safety Goal 6

### Environmental

- Better design of facilities
- Monitoring (rounds)
- Communication
  - Alarm integration to pager, cell phone, etc.

### Maintenance

- Alarm testing focus
- More active role by clinical engineers and BMET's in clinical alarms

## History

- Clinical Alarms problematic since beginning of medical technology revolution
  - 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
  - Formation of the Anesthesia Patient Safety Foundation in 1984
  - National Patient Safety Foundation – 1997
  - IOM report – patient error related to alarms one of the adverse events reported - 1999

*This is just an example of work on clinical alarms*

## Anesthesia Patient Safety Foundation

- **Founded in 1984**
- **1986 Grant study:**
  - A Safer Anesthesia Machine Through Model Based Alarms, 1986
    - Prototype Workstation Has 'Expert Alarm'; Computer Finds Error, Flashes Warnings
    - D.R. Westenskow, Ph.D., R.G. Loeb, M.D., J.X. Brunner, Ph.D, and N.L. Pace M.D.

## APSF Clinical Alarms Initiative

- **The APSF Board of Directors' Workshop**  
Friday, October 22, 2004  
Moderated by Drs. Michael A. Olympio and Robert K. Stoelting  
**"On the Use of Audible Beep Tone from the Pulse Oximeter and Audible Physiological Alarms"**
- *To stimulate anesthesia leadership, practitioners, and industry representatives to consider and debate an APSF initiative regarding the use of audible pulse oximeter tones and physiological alarms in the perioperative arena.*

## National Patient Safety Foundation

- NPSF Awards First Patient Safety Research Grants 1999  
*"Auditory Warning Signals in Critical Care Settings", Yan Xiao, PhD of the University of Maryland*  
<http://www.npsf.org/html/research/1998award2.html>

Also, see IEEE publication:

- Xiao, Y. et al, *Organizational / Historical Analysis of the "Failure to Respond to Alarm" Problems*, IEEE TRANSACTIONS ON SYSTEMS, MAN, AND CYBERNETICS—PART A: SYSTEMS AND HUMANS, VOL. 34, NO. 6, NOVEMBER 2004

## 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*

## American Society for Testing and Materials

- This specification covers defining the characteristics and requirements of electrically generated alarm signals for use with medical equipment intended for use in anesthesia and respiratory care.
  - It does not specify the condition that activates the alarms, nor does it specify the devices used for the production of audible and visual signals.
  - This specification does not address informational sounds produced by devices such as ECG monitors, surgical lasers, and electrocautery units.

## International Organization for Standardization (ISO) International Electrotechnical Commission (IEC)

- **IEC 60601-1-8, Medical electrical equipment – Part 1-8:**
  - General requirements for safety – Collateral Standard: Alarm systems -- requirements, tests and guidelines – General requirements and guidelines for alarm systems in medical electrical equipment and in medical electrical systems

## JCAHO Clinical Alarms Efforts

- **Sentinel Event Alert • February 26, 2002**
  - 23 reports of deaths or injuries related to long term ventilation- 9 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> (see Implementation Expectations)

## Hospital Information & Management Systems Society (HIMSS)

- HIMSS 2005 Annual Meeting  
*Patient Care Devices - Focus on Alarm Integration and Interoperability, Elliot Sloane, PhD, Assistant Professor of Information Systems, Villanova University*

*Example of effort and work done at HIMSS*

## Association for the Advancement of Medical Instrumentation

- Town meeting on Clinical Alarms Management and Integration, Annual Meeting, May 2005
- 2005 Health Technology Horizons articles:  
*Five Steps to Integrated Alarm Management: Improving Clinical Decision Making and Patient Safety”, Michael McLean, CEO Emergin*  
[http://www.emergin.com/library/WP\\_FiveStepsAlarmManagement.pdf](http://www.emergin.com/library/WP_FiveStepsAlarmManagement.pdf)

*Example of effort and work done at AAMI*

## VA National Center for Patient Safety – Bryanne M. Patail

- First, a matrix format is listed. The alarms and systems in facilities are determined. Then, a collaborative process will take place to determine how to rank the priority of alarms and systems.
- The matrix draft is a table that has two governing columns – top horizontal column is criticality of alarm and left vertical column is alarm category. The body of the matrix will show the particular device or system and where it is categorized.

## VA National Center for Patient Safety – Bryanne M. Patail

ACCE MATRIX - Clinical Alarms Management Matrix

	Critical	High	Medium	Low
Life Support				
Therapeutic				
Diagnostic				
Utility				
Support Systems				

## VA National Center for Patient Safety – Bryanne M. Patail

Life Support	<ul style="list-style-type: none"> <li>•Ventilators</li> <li>•Heart-lung machines</li> </ul>
Therapeutic	<ul style="list-style-type: none"> <li>•Infusion pumps</li> <li>•General</li> <li>•PCA</li> </ul>
Diagnostic	<ul style="list-style-type: none"> <li>•Patient monitoring</li> <li>•EKG</li> <li>•Blood pressure</li> <li>•Pulse ox</li> <li>•Bedside lab testing machine</li> <li>•Escape/elopement</li> </ul>
Utility (*direct patient impact)	<ul style="list-style-type: none"> <li>•Electrical system</li> <li>•Medical gas system</li> <li>•Medical air/vacuum system</li> <li>•Communications</li> <li>•Paging system</li> <li>•PA system</li> <li>•Internet</li> <li>•Network systems</li> <li>•Codes</li> <li>•Critical lab values</li> </ul>
Support systems	<ul style="list-style-type: none"> <li>•Facility HVAC</li> <li>•Emergency exit alarms</li> <li>•Elevator alarms</li> </ul>

## 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*
- AHTF website: <http://www.acce-htf.org/>

## ACCE Healthcare Technology Foundation

### 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 resolve alarm-related events.

## Town Meeting on Clinical Alarms

- AAMI Annual Meeting, Tampa
  - Moderators: Robert Stiefel, Univ. of Maryland Health Systems & Tobey Clark
  - Speakers: Jim Keller, ECRI & George Mills, JCAHO
  - 90+ Attendees
  - Results derived from discussion and consensus

## Town Meeting on Clinical Alarms

- Discussion points
  - Alarm priority is an issue
    - Have to respond to alarms not related to potential or actual patient adverse condition (e.g. leads off) as they could lead to more serious problem
    - Alarms must be prioritized by a multi-disciplinary staff team
      - Alarm management system – pre-planning
  - Consider the IEC standard for alarm sound characteristics and color
    - Already designed into new devices sold in the U. S.
      - User mode selection

## Town Meeting on Clinical Alarms

- We can not train our way out of the alarm problem
  - Turnover, different systems, short staffing
- Communicate with the manufacturers regarding needs
- Hospital design and environment matters
  - E.g. Open unit versus older “sleeping car” design
- We have to look back at what is the purpose of the alarm

## Town Meeting on Clinical Alarms

Consensus Vote: *What should be the area of focus to improve clinical alarms management and integration?*

- Design – 35% of attendees
- Integration – 50%
- Care management - >50%
- Standards - >50%

*All agreed that the clinical alarms problem is a system issue*

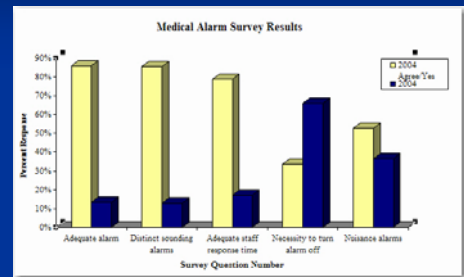
## AHTF Task Force Agenda

- Contribute to awareness and education regarding clinical alarms management and integration
  - ACCE Audio Conference
  - Town meetings directed toward interest groups
- Develop a survey
  - Clinical staff survey administered by clinical engineers, technology managers and BMET's
  - Survey response from biomedical engineering community
- Grass roots awareness via societies and member sites
- Research clinical alarm related incidents
- Develop educational materials

## Clinical Survey Example (from Jennifer Ott, St. Louis University Medical Center)

Total Responses: 217						
Question Number	Survey Question	04 Agree/Y	%	04 Disagree/N	%	
Adequate alarm	1	The alarms used on my unit/floor are adequate to alert staff of potential changes in a patient's condition.	186	86%	29	13%
Distinct sounding alarms	2	The medical equipment used on my unit/floor all have distinct enough sounds and/or signals that clearly differentiate one piece of equipment from another.	185	85%	28	13%
Adequate staff response time	3	Staff is sensitive to the sights and sounds of my unit/floor and quickly respond to patient alarms.	171	79%	37	17%
Necessity to turn alarm off	4	In the past year I have found it necessary to turn an alarm off?	73	34%	143	66%
Nuisance alarms	5	Do you experience frequent nuisance alarms?	114	53%	79	36%

## Clinical Survey Example (from Jennifer Ott, St. Louis University Medical Center)



## AHTF Clinical Alarms Draft Survey Tool

- 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
- Comment field

## AHTF Clinical Alarms Draft Survey Tool

- MS Word document for direct distribution at healthcare facilities by CE and BMET staff
  - Draft provided for this conference
    - Please provide comments to [ybdavid@TexasChildrensHospital.org](mailto:ybdavid@TexasChildrensHospital.org) by June 23<sup>rd</sup>
  - Document will be emailed to ACCE members and other interested parties
- Future availability on AHTF website
  - Automated process

## Future Planning Discussions

- Collaboration with national organizations
  - Nursing, information management, adverse event reporting, patient safety, standards, and industry
- Thorough database review
- Website enhancement
  - On line survey
  - Project update
  - Resources/links
  - Educational materials
    - Simulation video
    - White paper for professional and lay readers

## Join this Clinical Engineering Initiative

- Be part of the task force
- Distribute the survey to your staff
  - Return it to AHTF
  - AHTF  
5200 Butler Pike  
Plymouth Meeting, PA 19461-1298
  - Use web based survey when on-line
- Provide input to the task force
- Build awareness and develop solutions in your organizations

## Clinical Alarms References

- ACCE Healthcare Technology Foundation  
<http://www.acce-htf.org/>
- Anesthesia Patient Safety Foundation  
<http://www.apsf.org/>
- ECRI <http://www.ecri.org/>
- National Patient Safety Foundation  
<http://www.npsf.org/>
- VA National Center for Patient Safety  
<http://www.patientsafety.gov/>

THANK YOU!

QUESTIONS?

