Clinical Alarms
Improvement Initiative

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OK, one more time. When the smiley face is lit up, everything’s fine. Skull with flames shooting out of it, call Dr. Fletcher immediately.
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).
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
Alarm source and recognition

- Humans have difficulty to reliably recognize more than 6 alarms at one time (Stanton, 1994)
- Sound specific alarms were correctly identified by OR personnel (M.D.s, R.N.s, technicians) in various studies between 33-54% of the time. (Westenskow, 1993)
- 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. (Westenskow, 1993)
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
## Actions to Improve Alarms

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<td>Alarm integration to pager, cell phone, etc.</td>
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Efforts to study and improve clinical alarms

- National organizations
- Associations
- Standards groups
- Accreditation organizations
ECRI

- Long history of investigating clinical alarm problems and recommending system solutions
- Problems still exist:
  - breathing circuit disconnects, alarms turned off, inappropriate alarm settings, miscommunication of alarm-paging systems
  - AACN/ECRI Survey: 29% of nurses not trained in alarm management
- Excellent guidance information

Anesthesia Patient Safety Foundation (Founded 1984)

- Focus on Patient Safety
  - Much work on technology issues
  - Clinical Alarms Initiative

- The APSF Board of Directors' Workshop, October 2004

**APSF Recommendation Regarding Audible Alarms**

“When the pulse oximeter is utilized, the variable pitch pulse tone and the low threshold alarm must be audible.”

“When capnography is utilized, a capnograph alarm for hypoventilation must give an audible signal.”
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

- Listserv activity on clinical alarms
Wealth of information

- Systems approach to problems
  - Root cause analysis, usability, human factors…
- Sample systems solutions to alarms management
- Reported problem on alarm integration system wireless alert failure – systems approach to resolution

VA National Center for Patient Safety

http://www.patientsafety.gov/
Association for the Advancement of Medical Instrumentation

- Health Technology Horizons *Summer 05:*
  **Five Steps to Integrated Alarm Management:**
  *Improving Clinical Decision Making and Patient Safety*, Michael McLean, CEO Emergin

- Biomedical Instrumentation & Technology *Sept/Oct 05*
  **Is the Warning Effective? Clinical Alarms Remain an Area for Patient Safety Improvement,**
  Tobey Clark, Univ. of Vermont
Increasing number of medical devices attached to the network

Hospital networks used for clinical purposes
  - Alarm integration systems

HIMSS 2005 Annual Meeting

Patient Care Devices - Focus on Alarm Integration and Interoperability, Elliot Sloane, PhD, Assistant Professor of Information Systems, Villanova University
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*
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
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)
*Maude problem description includes the term alarm

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

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 reduce alarm-related events.
AHTF Task Force Agenda

- Audio Conferences, Town Meetings and Forums
  - ACCE Audio Conference in June 2005 – 91 lines called in
- Develop a survey for clinical and support staff
- Grass roots awareness – local, regional, national
- Research clinical alarm related incidents
- Develop educational materials
  - Website http://www.acce-htf.org/clinical.html
  - White Paper
AHTF Clinical
Alarms Project Task Force

- Jennifer Ott, CCE, Director – Clinical Engineering, St. Louis University Hospital
- Thomas Bauld, PhD, Technology Manager, Riverside Health Systems, ARAMARK/CTS
- Bryanne M. Patail, 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
- Paul Frisch
  Director, Biomedical Engineering Memorial Sloan-Kettering Cancer Center
- Frank Painter, Director, Technology Management Solutions LLC, Assistant Professor, University of Connecticut
- William Hyman, PhD, Professor, Biomedical Engineering, Texas A&M University
- James Keller, Director, Health Devices Group, ECRI
- Matt Baretich, PE, PhD, President, Baretich Engineering
- Wayne Morse, MSBME, President, Morse Biomedical
- Co-chair: Tobey Clark, Director, Instrumentation & Technical Services, University of Vermont
- Co-chair: Yadin David, PhD, Director of the Biomedical Engineering Department at Texas Children’s Hospital
AAMI Town Meeting on Clinical Alarms

May 2005 in Tampa – 90+ attendees

Key points

- An alarm management plan should be developed based on recommendations from a multi-disciplinary team
- Consider the IEC standard for alarm sound characteristics and display/color
- We can not train our way out of the alarm problem
- Hospital design and environment matters
- 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 Clinical Alarms 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

- Survey results to date:
  - 337 Surveys completed by 146 RN’s, 8 MD’s, 19 Clinical Managers, 90 CE/BMETs and other support staff
  - Survey will run until the end of November
  - Results available in 2006
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, AACN Newsletter
Support the Clinical Alarms Initiative

- Be part of the task force or provide input
  - Tobey.clark@uvm.edu
  - ybdavid@TexasChildrensHospital.org

- Make staff aware of the survey
  - Online: http://www.acce-htf.org/
    - Survey link is http://www.survey_monkey.com/s.asp?u=339221233056
  - Fax in paper survey or mail
  - AHTF
    5200 Butler Pike
    Plymouth Meeting, PA 19461-1298

- Build awareness and develop solutions in your organizations
THANK YOU!

QUESTIONS?