## Toward Better Medical Alarm Systems

John Hedley-Whyte

The earliest human alarm systems appear to have been deployed at Pinnacle Point on the south coast of South Africa between 135,000 and 175,000 years ago. 1.2 Ochre dye signs cautioned of dangers on the way to food supplies.

Patient monitoring systems are deployed to optimize the workload of trained medical personnel; many of the tasks they once performed have been reallocated to machines. But patient monitoring systems are, in general, inadequately designed. The alarms produce both caregiver and patient alarm fatigue. Far too many false alarms bedevil us. Alarm systems should instruct and not alarm.

For the last century the problem of medical alarm systems support of high technology has been the subject of numerous publications. <sup>3-8</sup>

The causes of the lack of progress in the sophistication of medical alarm systems are multifactorial:

- Standards for alarm systems should never be set by narrowly based committees. For instance, standards development progress has been indirectly compromised by the lack of clinicians and lack of clinical control of specifications for deployed alarm systems.
- 2. At many medical research university hospitals, the distributed alarm systems for research laboratories are more advanced than the systems for patients.

- Too often, alarm systems are not intelligently agreed upon between different departments among which patients are transferred during their hospital stays.
- 4. With 80% of U.S. surgical operations carried out without admission to hospital, the requirement for distributed alarm systems in home care is essential, but is only being met in housing that is being specially modified.
- 5. The relationship between civil authorities and home care distributed alarm systems is still fragmented and rudimentary. Police, fire protection authorities, and providers of electric power and other utilities for domestic use should be informed of the deployment of high-tech medical equipment within patients' homes and nursing homes.
- The advances in burglar alarm systems including voice transmission of information are often superior to those in hospital alarm systems.
- 7. Privacy and confidentiality concerns for alarm systems vary by country.
- The policy for utilization of batteries in motor vehicles for support of home care equipment should be further refined and standardized.
- The number of deaths caused by alarm system fatigue of the caregiver should be more closely investigated, as should the

## **About the Author**

John Hedley-Whyte, MD, FACP, FRCA, is David S. Sheridan Professor of Anaesthesia and Respiratory Equipment, Harvard University and chairman of ISO/TC121/SC3, Anaesthetic and Respiratory Therapy, Lung Ventilators and Related Devices. He is the ISO co-convener of the ISO/TC121/SC3-IEC/TC/SC62A/Joint Working Group 2, Alarm Systems. Email: john\_hedley-whyte@hms.harvard.edu.

The following is my list of safety and performance requirements for medical alarm systems in the 21st century:

- 1. Alarm systems shall not alarm either patient or caregiver.
- 2. Medium- and low-priority alarm signals should be informative; so, ideally, should high priority.
- 3. Alarm systems shall readily distinguish between serious deterioration of the patient and malfunction or failure of equipment.
- 4. Distributed alarm systems should be able to escalate in an intelligent and predetermined manner.
- 5. The time of response to the alarm system by the designated caregiver should be retrievable.
- 6. The rate of escalation of the alarm system should be retrievable.
- 7. Alarm-setting limits shall be discussed for each individual patient, with review and possible adjustment at least daily.
- 8. Equipment for life support and for patient monitoring shall have an identifiable alarm system, the data of which are retrievable.
- 9. The dissemination of an alarm system shall take into account the exact location of back-up equipment.
- 10. For each piece of life support equipment including infusion pumps, the totality of alarm system activation shall be retrievable between each designated service interval.
- 11. The regular assessment of the distributed and escalating alarm system function complexities and designated personnel shall be reviewed at an agreed preset interval.
- 12. The requirements listed above and their fulfillment and practice shall be agreed by the chiefs of services involved and shall be agreed with the chief executive officer of the medical institution and available for presentation to trustees and regulatory authorities.

## References

- 1. Marean CW, Bar-Matthews M, Bernatchez J, Fisher E et al. Early human use of marine resources and pigment in South Africa during the Middle Pleistocene. *Nature* 2007:449:905-8.
- Winchester S. Atlantic: Great Sea Battles, Heroic Discoveries, Titanic Storms, and a Vast Ocean of a Million Stories. New York: HarperCollins, 2010, pp.56-60.
- 3. **Hedley-Whyte J.** Helping to ameliorate a health-care crisis—General requirements and guidelines for the application of alarms in medicine. *ISO Bulletin* 2003;34(4):23-5.
- Hedley-Whyte J ed. Operating Room and Intensive Care Alarms and Information Transfer. ASTM STP 1152. Philadelphia, PA: ASTM, 1992.



number of patient deaths and serious injuries caused by medical device alarm system dysfunction.

- 10. It is crucial that a system of data from distributed medical alarm systems be automatically distributed to appropriate electronic records and be retrievable for an agreed period. Iris recognition for entry to distributed alarm data may be better than voice recognition.
- 11. Standards for distributed alarms systems for use with medical robots should be developed concurrently with international standards for the safety, cleanliness and efficacy of medical robots. Such devices may be designed to serve as stand-alone repositories of patient monitoring data and other electronic health records where extra confidentiality and security must be assured.
- Deller A, Konrad F, Kilian J, Schühle B. Alarms in an operative intensive care unit—Response of the nursing staff, p. 19-26. In: Hedley-Whyte J ed. Operating Room and Intensive Care Alarms and Information Transfer. ASTM STP 1152. Philadelphia, PA: ASTM, 1992.
- Eriksson B. Medical information management: Toward a life support system. P.27-31. In: Hedley-Whyte J ed. Operating Room and Intensive Care Alarms and Information Transfer. ASTM STP 1152. Philadelphia, PA: ASTM, 1992.
- 7. **Stanton NA**, **Edworthy J eds.** Human Factors in Auditory Warnings. Brookfield, VT: Ashgate, 1999.
- 8. **Block FE Jr.** "For if the trumpet give an uncertain sound, who shall prepare himself to the battle?" (I Corinthians 14:8, KJV). *Anesth Analg* 2008;106(2):357-9.