Patient Care Devices: Focus on Alarm Integration and Interoperability

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Past President, American College of Clinical Engineering
Board of Directors, IEEE Engineering in Medicine and Biology Society

BioBrief: Elliot Sloane

"Dual citizenship" in Clinical Engineering and Information Systems and Technology!

30+ Years of CE and IT/IS Expertise

- **Vice President, ECRI – 15 years, CIO & CTO**
  - Medical device research, testing, and education
  - Medical device nomenclature; standards directories; product evaluations; forensic/accident investigations
  - Created information systems that spread worldwide, and still persist today.
- **Vice President, MEDIQ/PRN – 10 Years, COO & CTO**
  - Medical device & drug distr'n, service, and manufacturing
  - Inventory of 500,000 mobile medical devices (e.g., IV, Ventilators, Incubators, Surgical Lasers, etc.) rented to hospitals 24x7
- **Faculty, Department of Decision and Information Technologies, Villanova University, since 2000**
  - Teaching, research and publishing in health informatics.

Presentation Outline:

- Medical devices from the IT point of view

  and

- Understanding medical device alarms

  and

- Issues of medical alarm integration

  and

- Emerging issues and challenges

Medical devices from the IT point of view

- Far more pervasive than most other IT devices
  - e.g., Texas Children's hospital averages 10 medical devices per patient bed.
- Far more mobile, and in different ways, than IT devices
  - Most hospitals use Central Supply strategies and significant rentals to match the moment-to-moment device needs to each patient.
  - Many devices move off-campus, to ambulances, nursing homes, free-standing medical centers, AND homes.
  - Many devices are implanted inside patient, too.

A recent example:

- 9/29/04 USAToday Moneyline box (p. B1):
  - Medicare Coverage of Device May Expand...
    - 9/28 Medicare proposed expanding coverage for implantable defibrillators...
    - 30 day comment period...
    - $25,000 surgery ...
    - ***Boosts eligibility to 500,000 patients...*** (500,000 today; how many in 2010 or 2020?)

BTW, do you think these devices use wireless communications??

The Convergence and Integration of Information and Medical Technology in the 21st Century is driving rapid change!

- ***Convergence***

  … moving toward uniformity …

- ***Integration***

  … process of incorporating as equals …

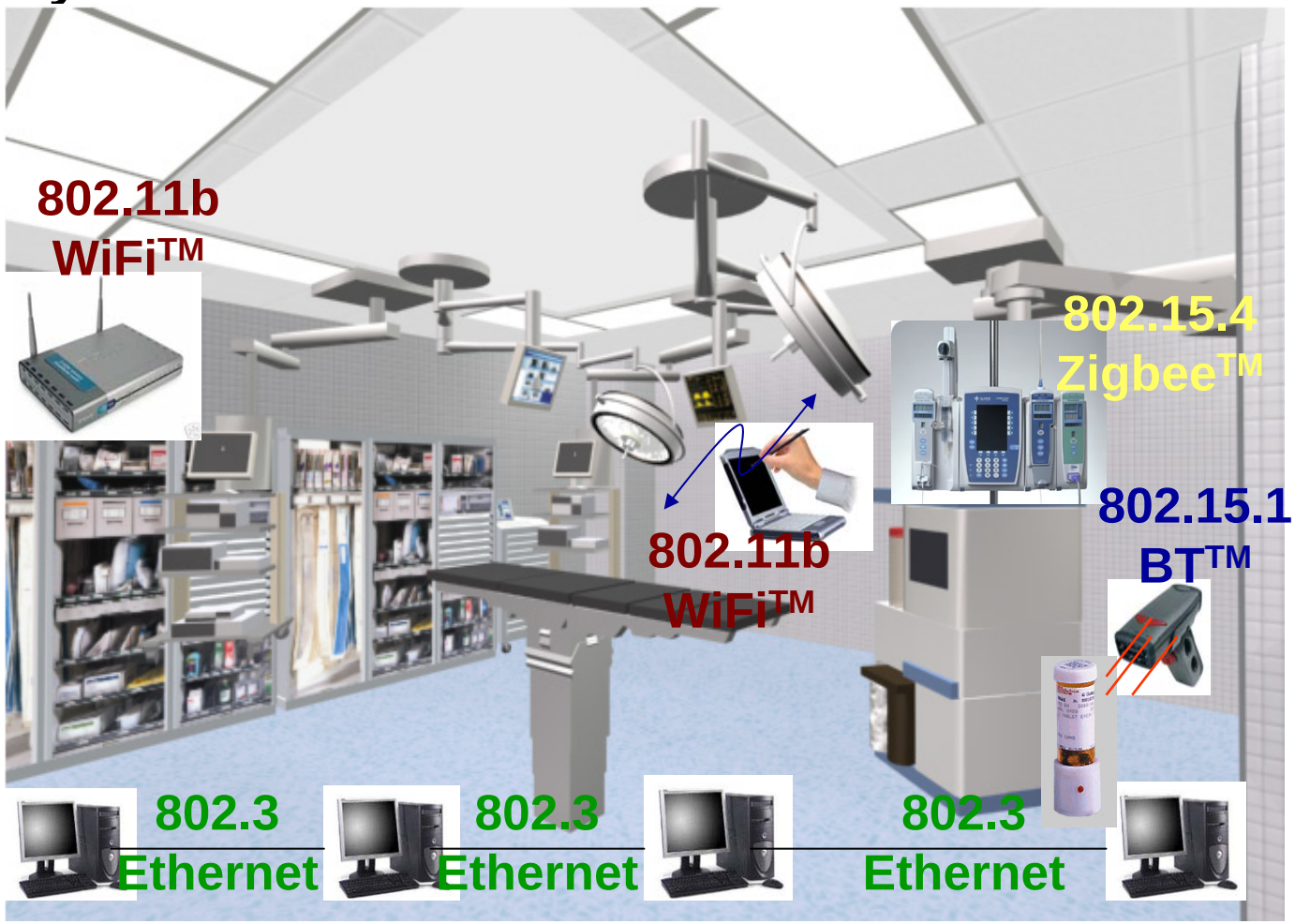
Universal wireless interfaces replace hard wires and proprietary data link communications

Untethered access to information

Mobility

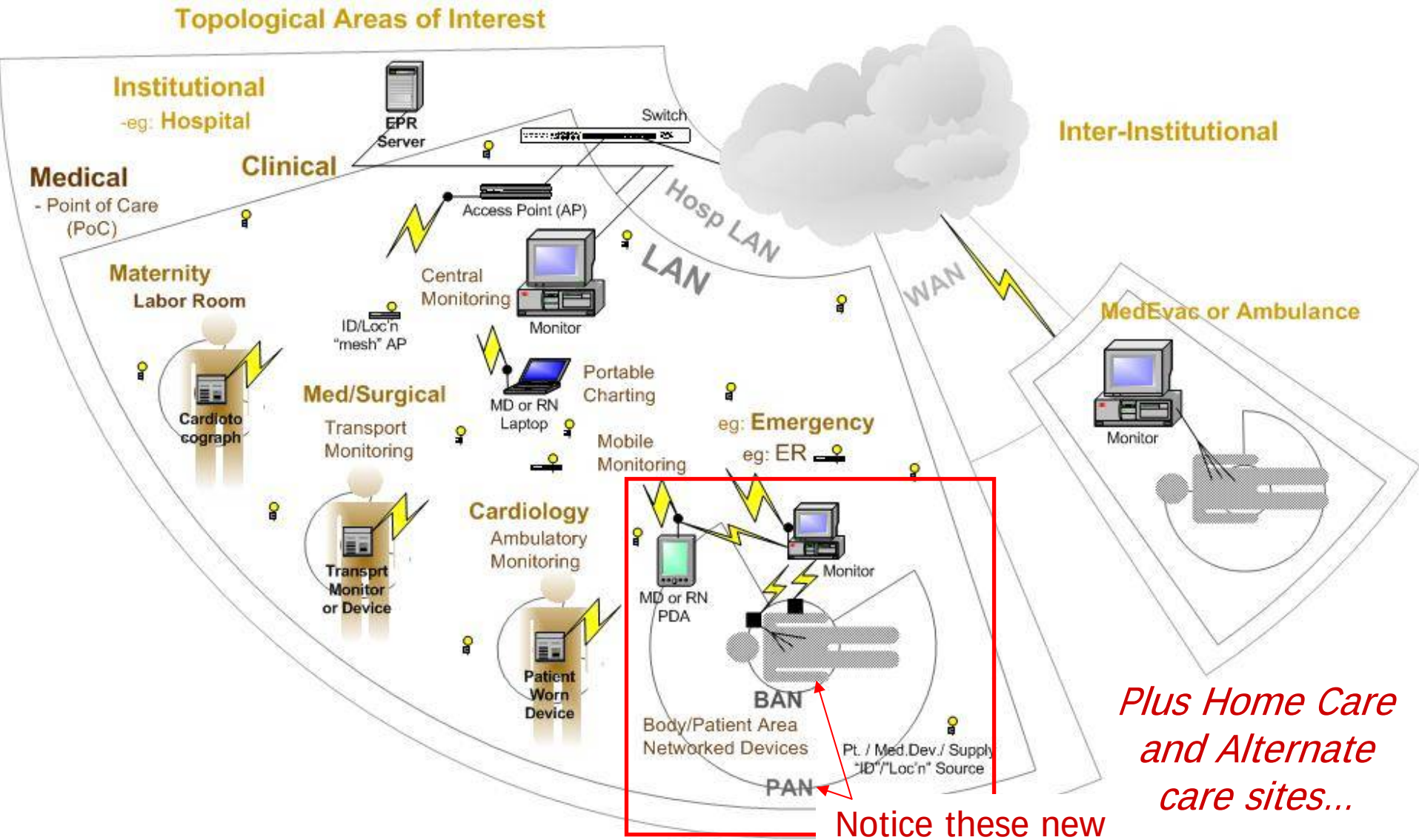
Interoperability

Reduced cost and complexity



Courtesy of NIST

Healthcare wireless network expansion

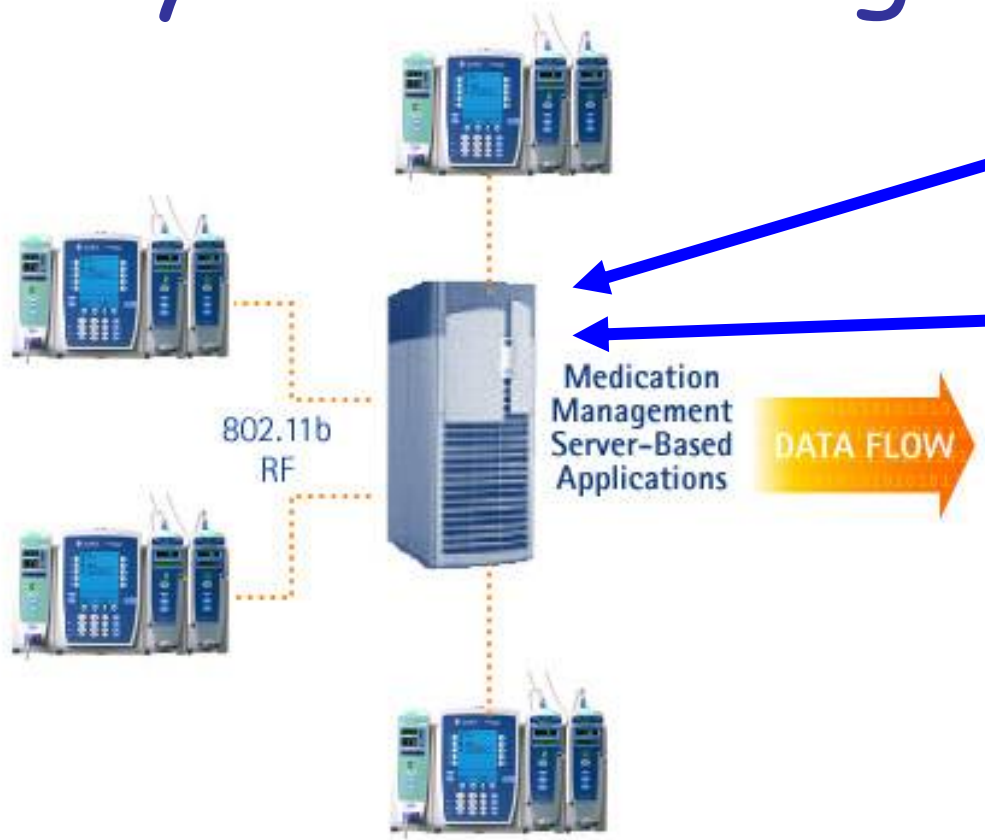


Notice these new micro-networks!

Plus Home Care and Alternate care sites...

Courtesy Jan Wittenber, Philips/IEEE 1073

ALARIS® Network with Systems Manager



ALARIS® Communications Kernel (FDA cleared)

ALARIS® Systems Manager Application

Networked for Safety

Use of Medical Devices is more complex than most IT folks realize.

- Medical devices are pervasive throughout the locations of healthcare delivery,
- They are truly mobile across all locations and may be placed on multiple patients each day,
- And they’re connecting via wireless networks as part of converging Medical Device and IT networks and systems.

Medical Device Alarms are REALLY complex!

- The “good news” is that standards are emerging from efforts driven by the Anesthesia Patient Safety Foundation over the past two decades.

DRAFT INTERNATIONAL STANDARD IEC/DIS 60601-1-8

ISO/TC 121/SC 3 Secretariat: ANSI

Voting begins on
2002-06-07

Voting terminates on
2002-11-07

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION
INTERNATIONAL ELECTROTECHNICAL COMMISSION • МЕЖДУНАРОДНАЯ ЭЛЕКТРОТЕХНИЧЕСКАЯ КОММИССИЯ • COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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

500

Table 201: ALARM CONDITION priorities

Potential result of failure to respond to the cause of ALARM CONDITION	Onset of Potential Harm [a]		
	Immediate [b]	Prompt [c]	Delayed [d]
Death or irreversible injury	HIGH PRIORITY [e]	HIGH PRIORITY	MEDIUM PRIORITY
Reversible injury	HIGH PRIORITY	MEDIUM PRIORITY	LOW PRIORITY
Minor injury or discomfort	MEDIUM PRIORITY	LOW PRIORITY	LOW PRIORITY or no ALARM SIGNAL

An INFORMATION SIGNAL, which conveys information without an injury connotation, may also be used for delayed minor injury or discomfort.

[a] Onset of potential harm refers to when an injury occurs and not to when it is manifested.

[b] Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.

[c] Having the potential for the event to develop within a period of time usually sufficient for manual corrective action.

[d] Having the potential for the event to develop within an unspecified time greater than that given under 'prompt'.

[e] The design of MEDICAL ELECTRICAL EQUIPMENT with a therapeutic function usually prevents immediate death or irreversible injury by automatic safety mechanisms.

Table 202: * Characteristics of the BURST of auditory ALARM SIGNALS

Characteristic	HIGH PRIORITY ALARM SIGNAL	MEDIUM PRIORITY ALARM SIGNAL	LOW PRIORITY ALARM SIGNAL[d]
Number of PULSES in BURST[a & e]	10	3	1 or 2
PULSE spacing (t_s) (see figure 201)			
between 1st and 2nd PULSE	x	y	y
between 2nd and 3rd PULSE	x	y	not applicable
between 3rd and 4th PULSE	$2x + t_d$	not applicable	not applicable
between 4th and 5th PULSE	x	not applicable	not applicable
between 5th and 6th PULSE	2 s ± 0.2 s	not applicable	not applicable
between 6th and 7th PULSE	x	not applicable	not applicable
between 7th and 8th PULSE	x	not applicable	not applicable
between 8th and 9th PULSE	$2x + t_d$	not applicable	not applicable
between 9th and 10th PULSE	x	not applicable	not applicable
INTERBURST INTERVAL[b & c] (t_b)	2,5 s to 15,0 s	2,5 s to 30,0 s	>15 s or no repeat
Difference in amplitude between any two PULSES	Maximum 10 dB	Maximum 10 dB	Maximum 10 dB

Where x shall be a value between 50 ms and 125 ms

Where y shall be a value between 125 ms and 250 ms

The variation of x and y within a BURST shall be ± 5 %.

MEDIUM PRIORITY t_s + y shall be greater than or equal to HIGH PRIORITY t_d + x. It should be greater.

[a] See also Table 203 for characteristics of the PULSE

[b] Unless otherwise specified in a particular standard for a particular MEDICAL ELECTRICAL EQUIPMENT

[c] Manufacturers are encouraged to use the longest INTERBURST INTERVAL consistent with the risk analysis. Long INTERBURST INTERVALS can under certain conditions negatively affect the ability to correctly discern, in a timely manner, the source of the ALARM CONDITION. Writers of Particular Standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application.

[d] The auditory component of a LOW PRIORITY ALARM CONDITION ANNUNCIATION is optional.

[e] Unless inactivated by the OPERATOR, MEDIUM PRIORITY and LOW PRIORITY auditory ALARM SIGNALS shall complete at least one BURST, and HIGH PRIORITY auditory ALARM SIGNALS shall complete at least half of one BURST.

Table 204—Characteristics of alarm indicator lights

Alarm category	Indicator color	Flashing frequency	Duty cycle
HIGH PRIORITY	Red	1,4 Hz to 2,8 Hz	20 % to 60 % on
MEDIUM PRIORITY	Yellow	0,4 Hz to 0,8 Hz	20 % to 60 % on
LOW PRIORITY	Cyan or Yellow	Constant (on)	100% on

There are many more Medical Device Alarm issues that we'll skip at this time...

- Alarm disable information
- Alarm settings information
- Patient-specific data that is needed in order to interpret alarm severity
- Systemic delay/synchronization issues
- Communication artifacts and failures
- Alarm symbol standardization

etc...

Anesthesiologists have wisely used these standards to design safer “cockpits.”

Intelligent alarm management will be needed when medical device interoperability is established...

201.1.3 * *INTELLIGENT ALARM SYSTEM*

An explanation of any algorithm that can change the previously assigned priority or relative prioritization of a particular ALARM CONDITION or its effect on ANNUNCIATION shall be disclosed in the instructions for use.

If an ALARM SYSTEM can ANNUNCIATE more than one ALARM CONDITION of the same priority and it internally ranks the relative priority of the ALARM CONDITIONS within that priority, then an explanation of the effect this ranking has on ANNUNCIATION shall be disclosed in the instructions for use (see 201.2.5.2).

If an INTELLIGENT ALARM SYSTEM is provided, an overview of the logic decisions for ESCALATION and DE-ESCALATION and ALARM CONDITION DELAY(S) made by the ALARM SYSTEM shall be disclosed in the instructions for use. Alternatively, equivalent information concerning the function of the ALARM SYSTEM required for its safe use shall be disclosed in the instructions for use.

Compliance is checked by functional testing of the ALARM SYSTEM and review of the ACCOMPANYING DOCUMENTS.

Some pressing issues of medical device integration:

- Most manufacturers have not yet considered their device in the context of an integrated information system (as we're creating with IHE and EHRs)
- The further bad news is that that alarms introduce life-critical data onto networks and systems that may not be designed to that level of quality.

Alarm integration presumes the system can localize the device and patient, and the “correct” clinical facts

- This will require ability to interpret significant amounts of data in “real time”
  - Critical alarm “real time” is often 30-90 seconds.

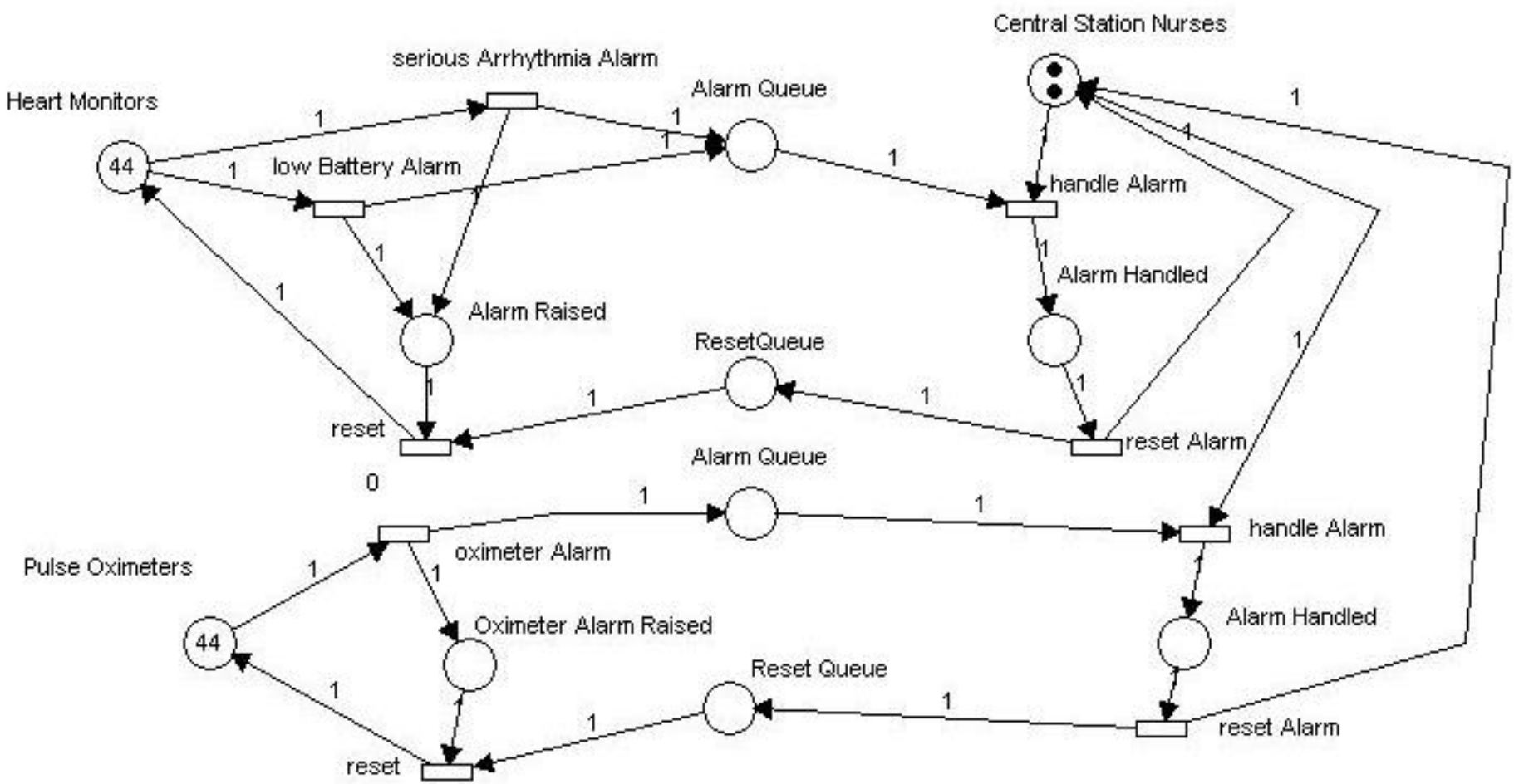
Alarm integration presumes that non-critical alarms will be managed too, not just ignored!

- A patient trending towards a serious condition should not be ignored because higher priority alarms are already sounding

Intelligent integration presumes the alarms “get through.”

- DO THEY?
  - Starting to test the boundaries of emerging wireless medical device proliferation so that we can predict system reliability (and safety).

802.11 wireless patient alarm results can be simulated…



Our alarm simulation results for 802.11-style network...

- For the multi-mode heart/oximetry model in Figure 4, after a few dozen minutes, virtually 100% of the oximetry alarms were queued up, representing missed or grossly delayed alarm situations!. In fact, a very close examination of the simulation data shows that one heart alarm went unanswered for several minutes, and one of the pulse oximetry alarms is not handled for about five minutes, implying thereby a probable endangerment of the associated patient(s).

Realize this is “best case,” not even normal, or worse case...

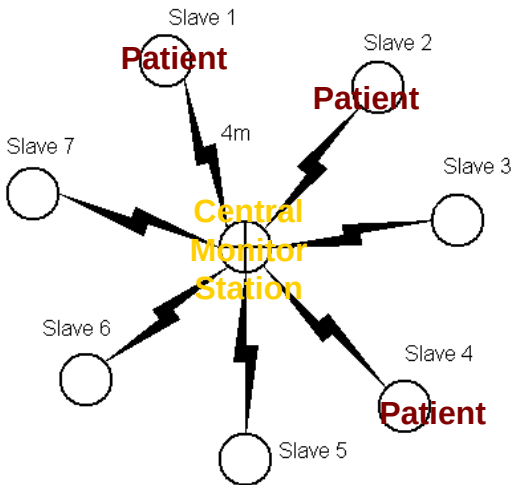
- Voice over Internet and other competing high data rate clinical applications like medical images or parts full EHRs are not tying up the 802.11 access points!
- Patient density in certain areas may be “peak,” especially surrounding disaster response.

Bluetooth or 802.11 hybrids won't solve the problem...

NIST has been doing some early work...

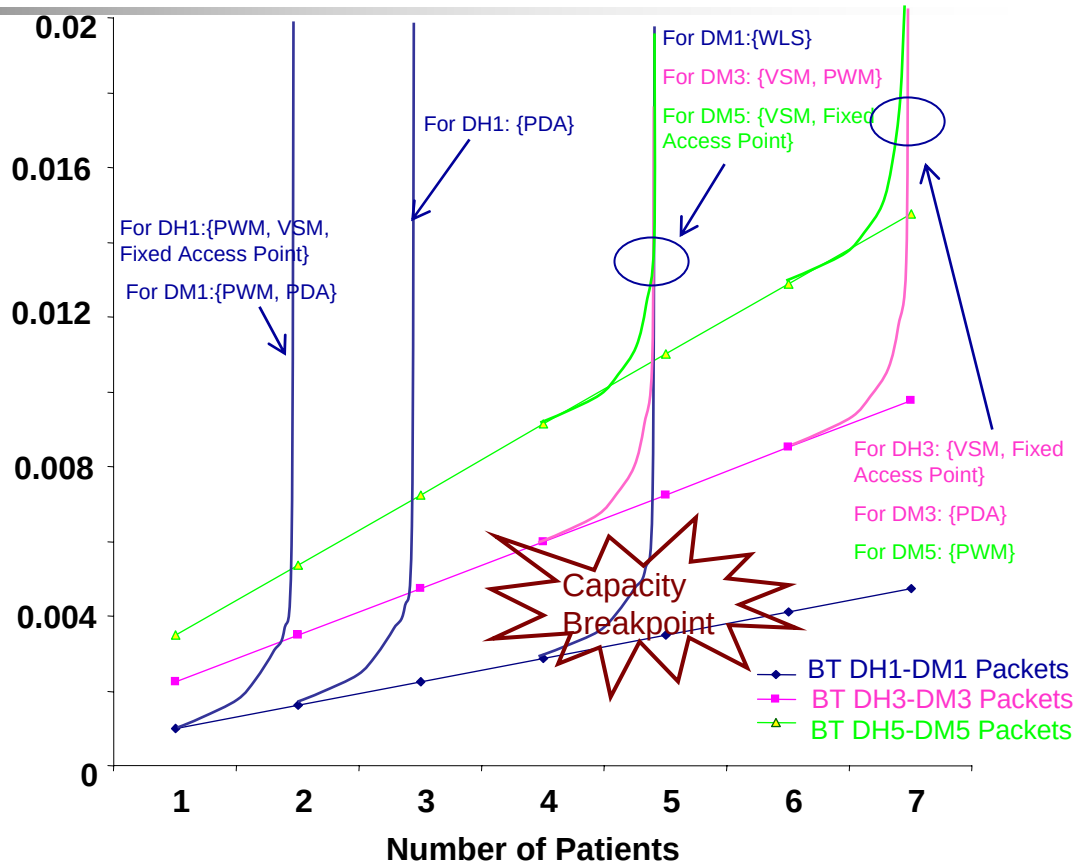
How many patients can be supported in a single Bluetooth piconet?

Comparing results for different **applications** using different **Bluetooth packet encapsulations** occupying 1 time slot (DM1, DH1), 3 time slots (DM3, DH3), and 5 time slots (DM5, DH5)



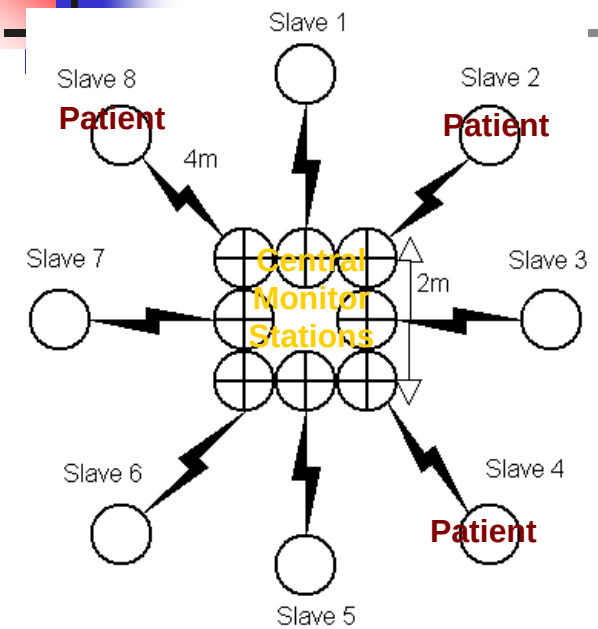
Number of patients supported (up to seven in a single piconet) depends on the bandwidth requirements of the application considered and the packet encapsulation chosen.

MAC Access Delay (seconds)



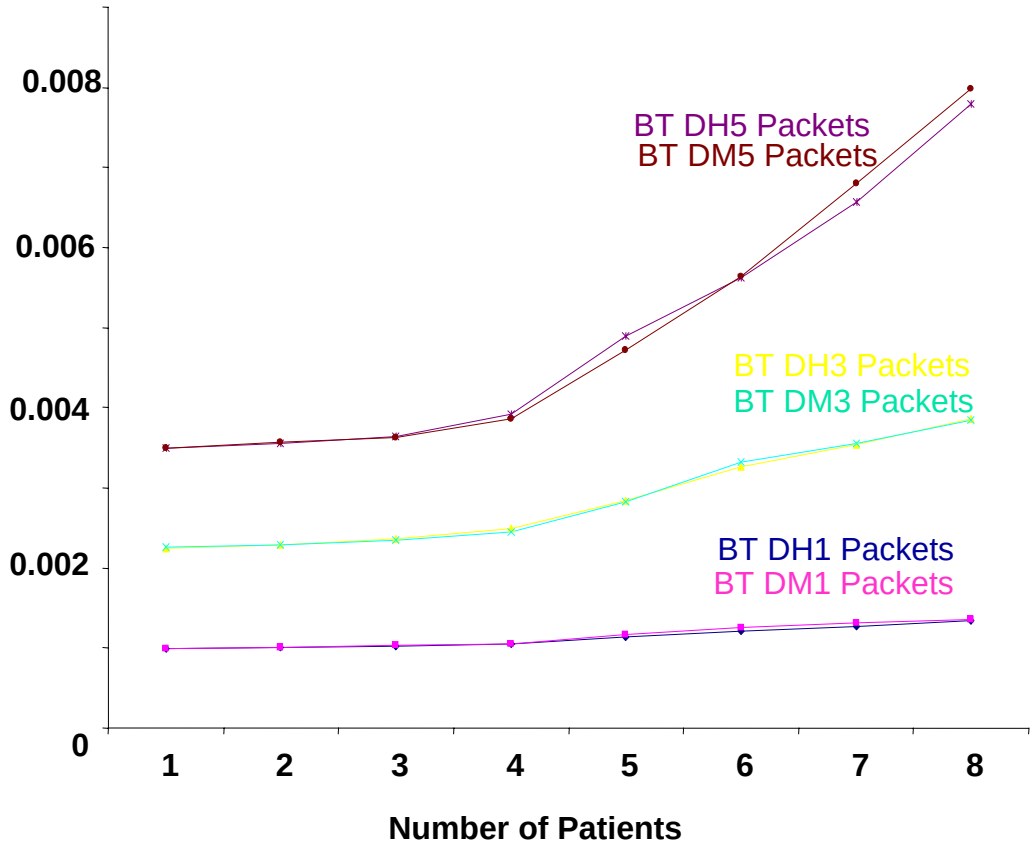
Courtesy of NIST

How many patients can be supported by Point of Care Device using multiple Bluetooth piconets?



As more piconets are added, multi-piconet interference causes higher packet loss and an increase in the access delay (double for 8 piconets)

MAC Access Delay (seconds)



Courtesy of NIST

The emerging issues and challenges?

Even more information overload AND cognitive dissonance AND **errors!**

Many parties are beginning to collaborate on solutions:

- National Institute of Standards and Technology
- IEEE 1073 Standards Committee
- ACCE/IHE Taskforce for Medical Device Interoperability
- Partners Healthcare / Mass General

and a major new national project has just been initiated...

Join the effort to improve patient care…

Clinical Alarms Management & Integration

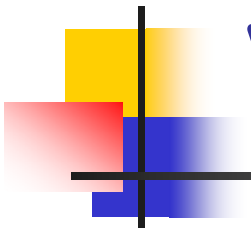
Identifying issues and opportunities to improve clinical alarm design, Integration, operation, response and actions.

Above is a new project sponsored by the

ACCE Healthcare Technology Foundation

Led by Tobey Clark
(tobey.clark@uvm.edu)

www.accefoundation.org



What we covered:

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Thank you for your attention!

Your feedback and questions are welcome!
Please join us in solving these challenges.

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