



Successful Integration of Medical Devices and Information Systems

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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

- **Faculty, Department of Decision and Information Technologies, Villanova University, since 2000**
 - Teaching, research and publishing in health informatics.
- **Vice President, ECRI - 15 years, CIO & CTO**
 - Medical device research, testing, and education
- **Vice President, MEDIQ/PRN - 10 Years, COO & CTO**
 - Medical device & drug distr'n, service, and manufacturing



HIMSS – Healthcare Information Management Systems Society

- Today I am here on behalf of HIMSS as a guest and friend of AAMI.
 - My presentation is intended to continue the process of blending the skills and abilities of Clinical Engineers and Healthcare Information Systems experts.
- I would like to thank HIMSS for asking me to represent them, and AAMI for allowing me to make this presentation.



Presentation Outline:

- **Situational Overview**
and
- **Issues**
and
- **Opportunities**
and
- **Challenges**



Situational Overview

- A “Golden Age” of clinical information systems is unfolding,
 - The goal: solutions at the right time, right place, using the right systems and technologies



ISSUES

- Huge elder patient population is expanding quickly
 - *AND 50-75% shrinkage of worker pool; forecast is only 2 tax-paying workers for each retiree!*
- IT/Medical device convergence is inevitable
 - *Traditional MIS problems well emerge, but new, hybrid CE/IT solutions will needed!*
- Technology solutions will have to be adapted
 - *Must overcome shrinking labor pool and increase reliability, safety of routing, repetitious tasks!*



Right Time...

Right Time 1: rapidly aging population will require more intense - and more effective and efficient - healthcare than ever before!

Right Time 2: our aging population is an "entitled" population, with political, legal, and economic strength to drive demand.

In short, the needs won't be met without employing information-driven strategies that have driven most other business sectors (e.g., CRM, SCM, ERP, DSS, etc.)!



Right Place...

Right Place 1: US market has the technological infrastructure and expert clinical workforce that can - and is - demanding and using more and more information technologies daily!

Right Place 2: our healthcare system is teetering on bankruptcy in many, many places, with a majority of healthcare institutions operating in the red year after year.

Fortunately: Necessity IS the mother of invention! Demand drives innovation, unblocks resistance to change.



Right Systems and Technologies...

Right Systems and Technologies: we are seeing a digital/computerization technology convergence between clinical information systems and healthcare business systems.


Caution: It is becoming harder and harder to find where the healthcare enterprises business information systems and technologies and the clinical ones begin! (Regulations??)



ISSUE Summary

- Need to serve more people, in more diverse locations, with more reliability, and less cost!
- IT solutions are emerging; leadership is needed to identify and mobilize the **correct** resources.
 - *Needed technologies are lagging demand in healthcare but are being applied and proven in many other sectors.*
 - *Healthcare leaders (survivors?) will adapt information technology fully and thoughtfully, but rapidly.*


BUT, the information technologies will have the same vulnerabilities & limitations as in other venues!



A current 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??

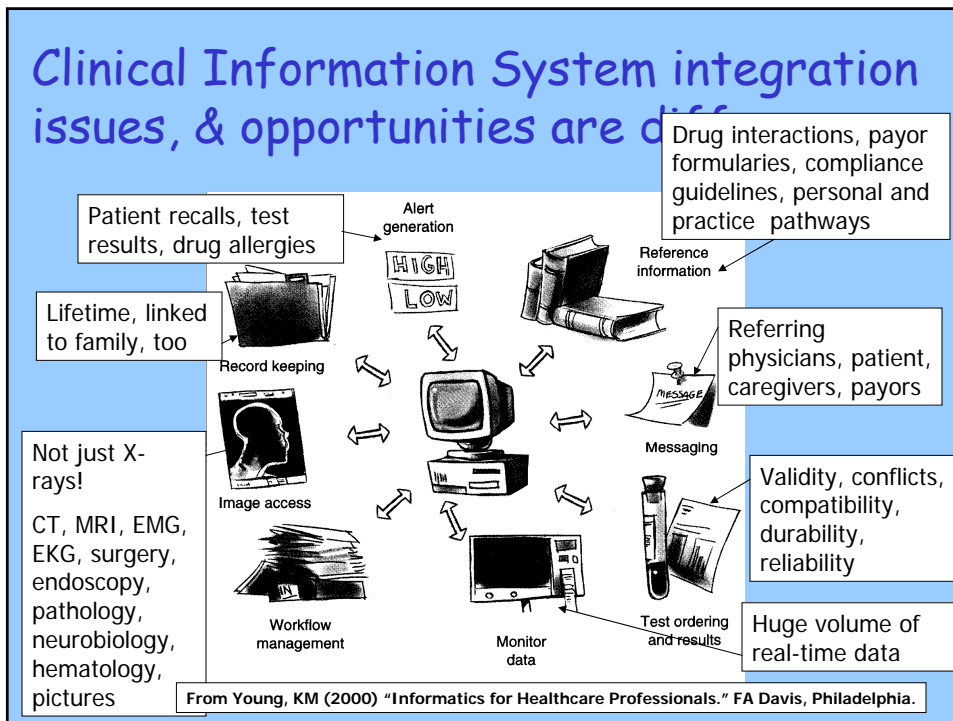


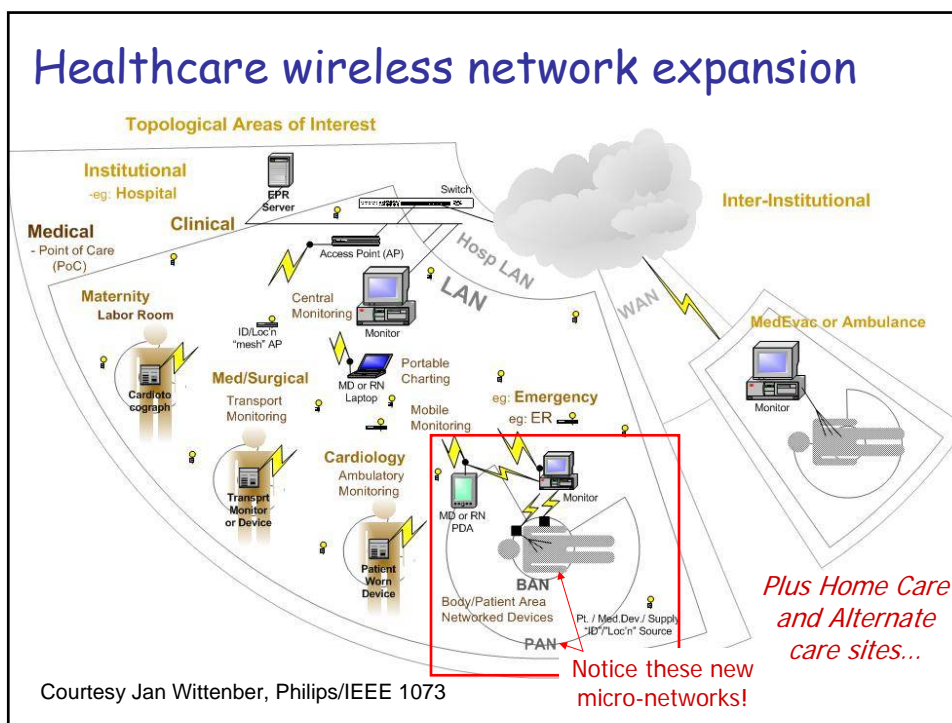
Opportunities

- Pervasive wireless and portable technologies
 - *Allow more aggressive diffusion of medical technologies to many more points of care.*
- Decision support systems
 - *Improve consistency, minimize mistakes, improve consumer-centric care.*
- Electronic Health Records
 - *Prevent redundant services, facilitate immediate intervention, reduce medical errors.*
- Innovate, innovate, innovate! Be prepared to apply IT-powered solutions like robotics, genetically engineered medicines, and eHealth solutions rapidly.
 - *Make efficient use of your resources; prepare to compete!*

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

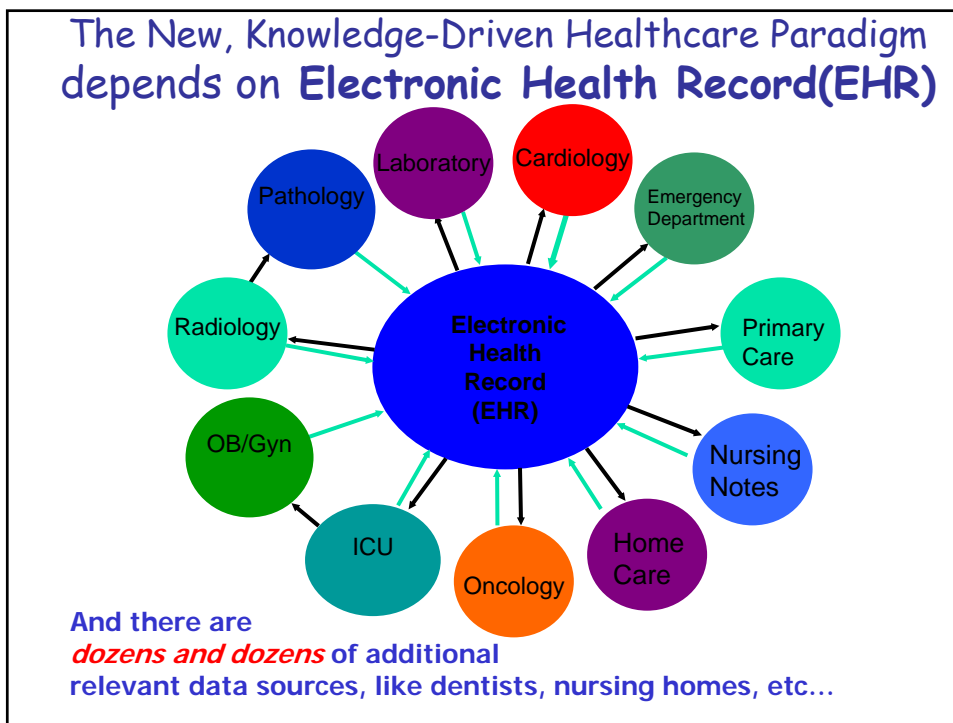
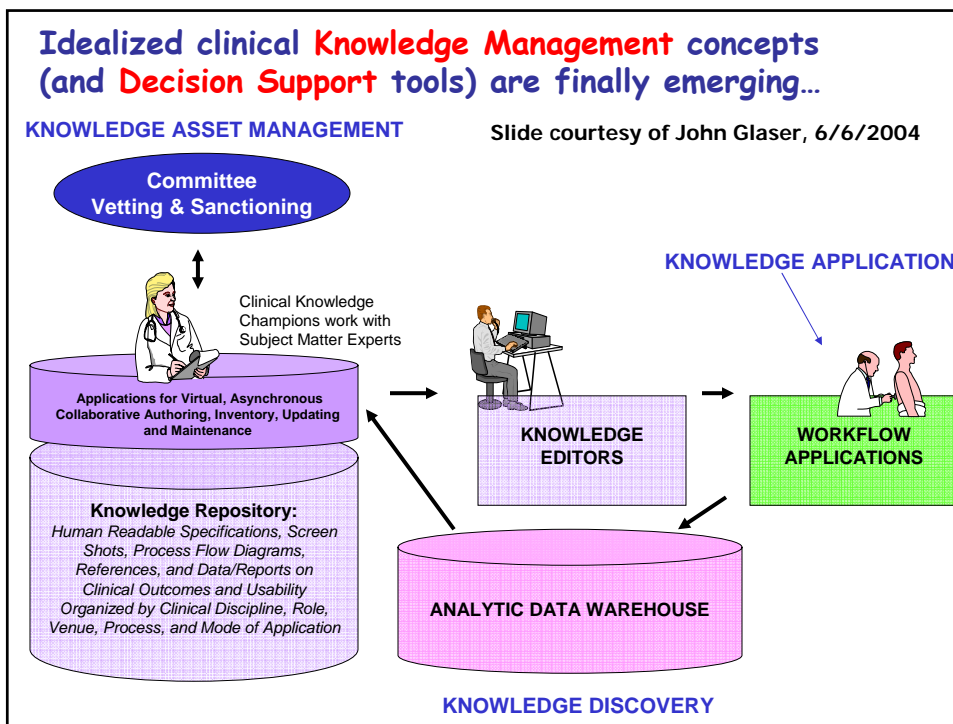
- **Convergence**
... moving toward uniformity ...
- **Integration**
... process of incorporating as equals ...

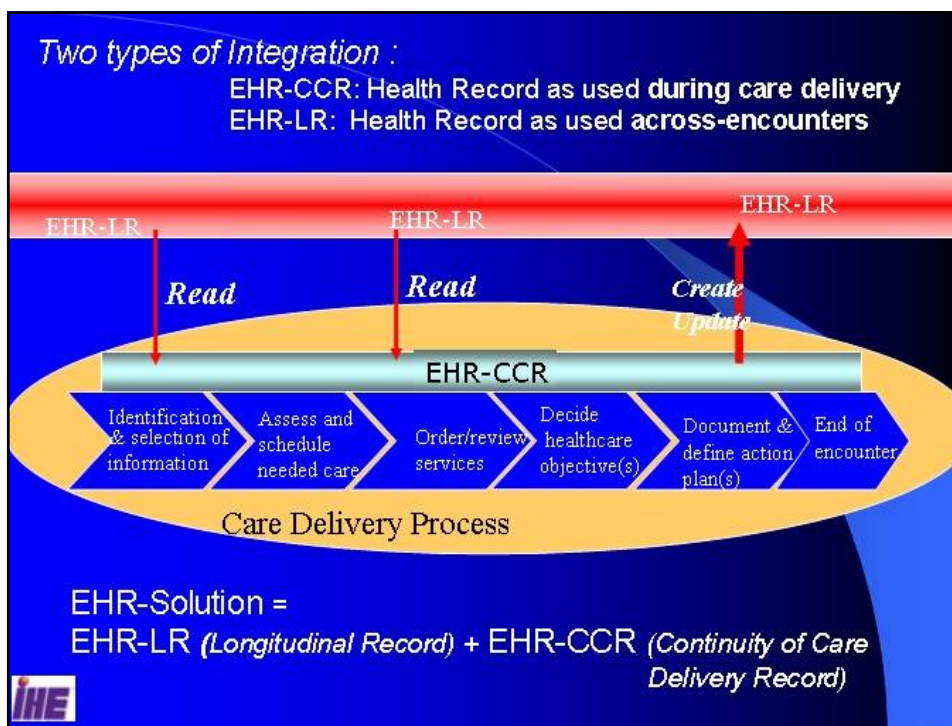




Ubiquitous wired and wireless network access (plus more!)

- **Pervasive, low-cost LAN or IP addressable chips allow connecting devices to information network backbones for only a few dollars**
 - Wired AND wireless
 - Local (Bluetooth and IR) as well as HIS network
- **Recent efforts by FDA, HIMSS, and IEEE on using RFID tags in healthcare will expand **location sensitive networks in hospitals****
 - Currently driven by drug issues (counterfeit drugs and medication errors), but
 - likely to help the technology rapidly diffuse in healthcare over the next 5 years offering major process and material management benefits.





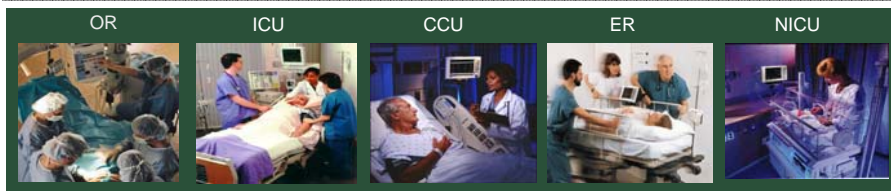
Convergence: IT-oriented generic medical devices can now offer instant customization to most clinical situations

- For example, the new generation of Siemens and GE monitors allow a monitor to “morph” from ER to OR to ICU or NICU applications...
 - Monitor features, sensitivities can automatically change
 - Alarms can automatically reconfigure
 - Monitor can travel with patient through the hospital, carrying relevant data and maintaining EHR

Bedside Monitor Architecture Software configuration

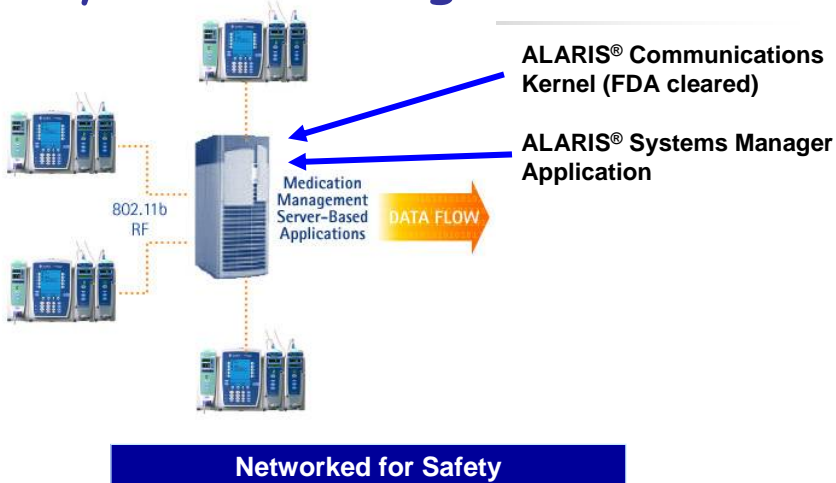
- It is now possible to have the monitor automatically configured to the unique needs of each department
- Monitor can become a *generic asset* that can be shared between departments
- Each clinical environment can have a unique configuration, however

An opportunity for standardization of hardware, BUT time-varying features!



Based on Greg Farah, Stratum Consulting, 2002

ALARIS® Network with Systems Manager



Low-power device capabilities,
plus wireless, allows portability
and diffuse distribution.

- Battery power and ubiquitous wireless support allows transport with patient throughout the whole "extended health enterprise."
 - Ambulance, train, airplane
 - ER/OR/ICU, etc.
 - Homes
 - Nursing homes
 - Community-based living centers
- And, new, innovative technologies like telemedicine, home diagnostic monitoring, and Automatic Electronic Defibrillators (AED's) will become more and more common, even in homes!

Are YOU looking at ALL innovations?

In gadget-loving Japan, robots get hugs in therapy sessions
By Yuri Kageyama, Associated Press

OHBU, Japan — The elderly patients suffer from severe dementia, but their faces light up when they see the dog-shaped robot, swaddled in soft clothing, waddle around the hospital floor. Some clap; others break into feeble smiles. Urged by nurses, a few cautiously reach out and touch it.

"It's cute," one female patient cries out.

This is one in a budding series of robot-therapy sessions at Japanese hospitals and senior citizens' homes. To some scientists, robots are the answer to caring for aging societies in Japan and other nations where the young are destined to be overwhelmed by a surging elderly population.

These advocates see robots serving not just as helpers — carrying out simple chores and reminding patients to take their medication — but also as companions, even if the machines can carry on only a semblance of a real dialogue.

Children on Easter egg hunt find loaded guns Weapons found on grounds of Michigan elementary school, no one injured.

Gadgets get hugs in Japan Japanese hospital, senior citizens' homes use infant-like way to care for elderly, give them companions.

Four Challenges

Don't shoot the messenger!

- **MORE** financial pressure is likely to mount rapidly.
- Medical device / information system standards for convergence **ARE** emerging; needs **YOUR** strong support.
- Information system security is a **BIG** issue!
- **MUST** Develop and deploy effective, robust, innovative, and adaptable **clinical information system** support teams.

Challenges - 1

MORE financial pressure is likely to mount rapidly.

Don't let HIPAA security concerns
let you be blindsided!


The "other shoe" is going to drop!

SERIOUS FINANCIAL PRESSURE
is going to arise from the EDI that
HIPAA enforced...

Motivating reminder:
HCFA has a 5-year plan!
(<http://www.hcfa.gov/publications/5plan/irm5ypln.htm>)

To go from an old "stove pipe" architecture...

...to an integrated data repository
that allows OLAP data mining!
(FY 2001-2005)



CMS, insurers, and JCAHO are scaling up to use the new information-rich data warehouses to enforce compliance and quality standards.

Wake-up Call?

Data may be mined first by payors and regulators, then by lawyers...

...though it might happen the other way around!



Challenges - 1

- **MORE** financial pressure is likely to mount rapidly.
 - Is regulatory and economic intervention into healthcare delivery by CMS, regulators, insurers, and lawyers unavoidable?

Probably.

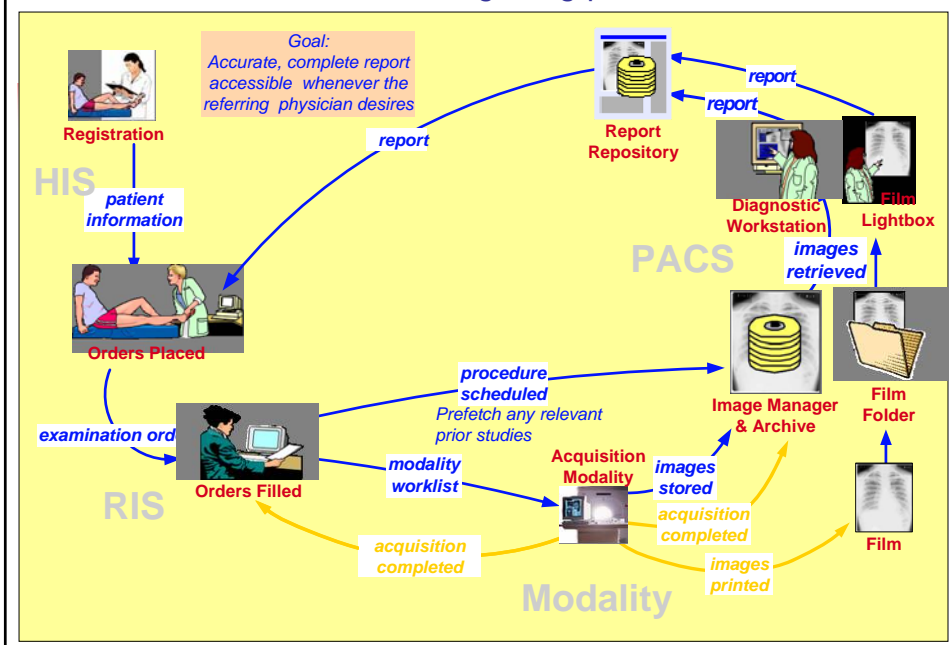
The cows are already out of the barn, though, we cannot waste energy or time.

Develop and implement fresh strategic healthcare enterprise information systems plans NOW.

Challenges - 2

- Medical device / information system standards for convergence **ARE** emerging; needs *very STRONG* hospital (purchasing) support.

Our HIMSS IHE Profiles are integrating process and clinical data:





IEEE-EMBS Support is increasing

- ISO/IEEE 1073 Point of Care Medical Device Communication Standards
 - ISO/IEEE P1073.0.1.1™/D01E Draft Guide for Health informatics Point-of-care medical device communication w/Technical Report on Guidelines for the use of RF wireless technology in healthcare.

Courtesy of Rick Hampton, 2004, "Radio Man" – Partners HealthCare



Challenges - 2

- Medical device / information system standards for convergence **ARE** emerging; needs very *STRONG* hospital (purchasing) support.
 - *Have key staff join, and report on, HIMSS Special Interest Groups in relevant areas: (i.e., IHE, Autocoding and RFID, and Medical Device Security)*
 - *Develop and - drive vendor support and compliance with - your own Institutional Clinical Information System Standards policy.*

Challenges - 3



Information system security is
a **BIG** issue, and going to
get bigger!

Integration of clinical care with IT
exposes us to the growing number of
Computer Security Incidents...



- Rapidly rising statistics reported by Computer Emergency Response Team (CERT- www.CERT.org) Coordination Center at Carnegie Mellon
 - **Not a recent anomaly; the growth pattern is being seen over many years.**

CERT/CC Statistics 1988-2003

The CERT/CC (www.cert.org) publishes statistics for:

Number of incidents reported

1988-1989

Year	1988	1989
Incidents	6	132

1990-1999

Year	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
Incidents	252	406	773	1,334	2,340	2,412	2,573	2,134	3,734	9,859

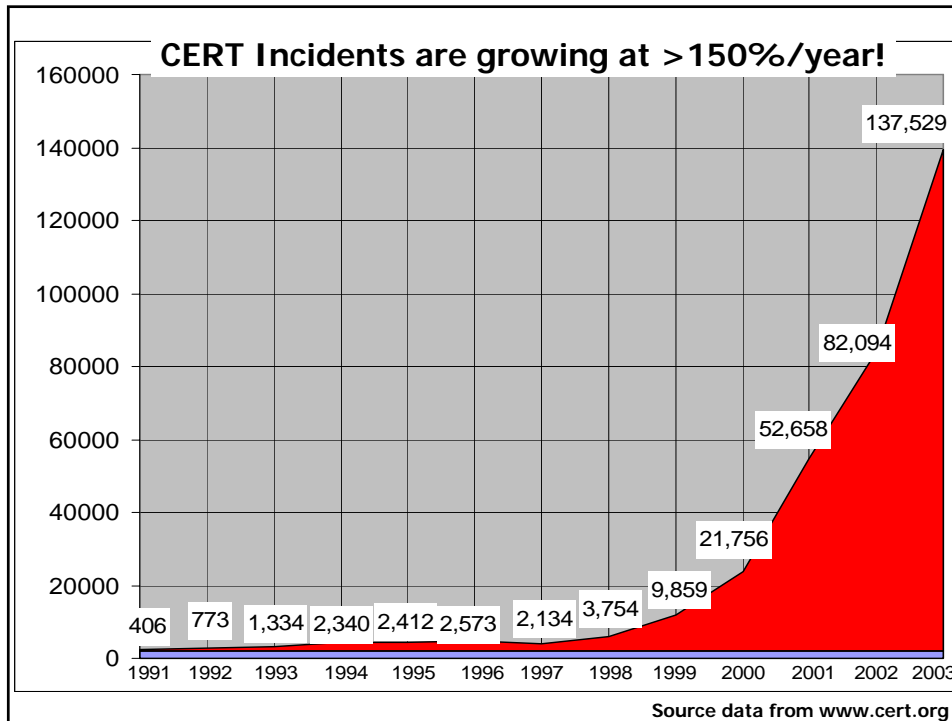
2000-2003

Year	2000	2001	2002	2003
Incidents	21,756	52,658	82,094	137,529

Sasser or Sobig may be reported as ONE incident!

Total incidents reported (1988-2003): **319,992**

Please note that an incident may involve one site or hundreds (or even thousands) of sites. Also, some incidents may involve ongoing activity for long periods of time.



HIPAA's Final Security Rule "General Requirements"

"Ensure the *confidentiality, integrity, and availability* of ***all electronic protected health information*** the covered entity *creates, receives, maintains, or transmits.*"

- **Confidentiality** means the property that data or information is not made available or disclosed to unauthorized persons or processes *
- **Integrity** means the property that data or information have not been altered or destroyed in an unauthorized manner
- **Availability** means the property that data or information is accessible and useable upon demand by an authorized person

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* 68 Federal Register 8376
Feb 20, 2003

Confidentiality: Keeping private or sensitive information from being disclosed to unauthorized individuals, entities, or processes

e.g., If Nurse Jones is allowed to update narcotics dispensing for Patient A, is Jones also allowed to see a **home address**?

How about a **psychological evaluation**? How about an **HIV test result**?

OK, how about in an emergency situation?



Confidentiality Threats...

- Some or all data accessed by unauthorized personnel (locally or remotely)
 - New micro-network wireless technology challenges
- Device/system user misuse/abuse
 - Passwords/PINS defeated or taped to devices
- Procedural violations by device/system users
 - Device with hard drive or FlashMemory sent out for repair without *destroying* patient and hospital ID and data




Confidentiality breach impacts

- Patient treatment information exposed (with possibility that diagnosis can be inferred)
- HIPAA fines, legal action, jail
- Community trust issues; adverse publicity
- Lawsuits
- Extortion
- Password, userid theft



Confidentiality Mitigation

- Secure data access (e.g., lock & key, secure passwords and policies, biometrics)
- Use intrusion alarms/alerts
- Use data encryption, secure private networks (limiting access), firewalls, where appropriate
- Locate operating devices out of view and access of non-authorized personnel
- Educate device users, servicers on measures necessary to prevent, detect and address data confidentiality problems associated with this device
- Unannounced audit for adherence; re-education



Integrity: As applied to data, the ability to protect data from being altered or destroyed in an unauthorized or accidental manner

Example 1. If a new drug adverse reaction is known, was it properly installed in all relevant hospital decision support systems? How about in "smart" IV pumps used throughout the hospital? How about in the home health care IV pumps and computer systems.

Example 2. If a recent blood analysis was done, how can you assure the doctor and nurse sees it, and that the new lab values accurate and directly comparable to the prior ones? How about if it was done in the Doctor's office?



Integrity Threats

- Device/System Errors (e.g., "out of calibration")
- Electromagnetic Interference (EMI) or other environmental factors
- Tampering ... data modified by unauthorized personnel or processes (accessing locally or remotely) ... this includes computer viruses, worms
- Erroneous data input (by processes or personnel) Procedural violations by device/system users
- Device/system user misuse/abuse



Integrity Risks

- Patient or staff injury or death (i.e., therapeutic device and inappropriate therapy can result in patient injury)
- Inappropriate treatment leading to waste, injury, or death
- Delayed treatment leading to injury or death



Integrity Mitigation...

- Include devices in scheduled inspection and maintenance program
- Policy/procedure restricting or controlling use of EMI generating devices in areas where this device is operated
- Incorporate network firewall, VPN as necessary for networked devices
- Locate operating devices in areas only accessible to authorized personnel and patients (when feasible)
- Create physical environment with appropriate safeguards for device operation
- Secure operating controls so as to be accessible to only authorized personnel (e.g., lock/key, passwords, biometrics)
- Ensure current security updates for device operating system are done
- Anti-virus software with program to insure regular updates
- Educate device users on measures necessary to prevent, detect and address data integrity problems associated with this device
- Processes to insure timely updating, upgrading or replacement of biomedical devices/systems, including consideration of security issues



Availability Threats

- Device, component or SYSTEM failure!
 - FDA is eyeing converging IT/clinical systems as medical devices, subject to potential regulation, per Dr. Larry Kessler, acting director, FDA/CDRH
- Interruption of required utilities (e.g., power, cellular, cooling outages), services or supplies
- Physical assault (e.g., fire, flood, theft, vandalism, accident)
- Procedural violations by device/system users
 - Overcrowding of wireless system access points
- Device/system user misuse/abuse
 - Failure to charge or configure portable devices.



Availability Consequences

- Patient injury, death
- Delayed treatment
- Duplicated services
- Wasted resources
- Staff burnout
- Loss of patients as customers
- Grossly reduced revenues



Availability mitigation ideas...

- Perform data backups routinely and store backups in secure and accessible location
- Maintain replacement components (to effect repairs) and devices (to provide backup systems)
- Employ physical safeguards & alarms
- Routine education/re-education device users on measures necessary to prevent, detect and address data availability problems associated with this device
 - Part-time and contract staff poses ongoing risk.




Additional issue/opportunity?

- System planning and validation tools are sadly lacking, even for sole-vendor implementations.
 - Much more R&D is needed for the emerging heterogeneous, pervasive, mobile, location-based systems that are emerging.
- If we don't create the tools, the FDA might create them for us!



Review...

- General security framework?
 - CIA - Confidentiality - Integrity - Availability
AND
- The "Golden Age?"
 - Enabling new clinical paradigms, but it's like the Sword of Damocles: it cuts in both directions!
AND
- The security concerns?
 - Similar to, but different, and more liability, than prior IT challenges, and many more complexities than prior simple devices.
AND
- How can you assess and manage the risks
 - Look for best practices.
 - Weld proven IT and CE strategies together to get results
 - Train your team for the new paradigm ahead.



Recent resource from ACCE & ECRI
Information Security for Biomedical Technology:
A HIPAA Compliance Guide™

- Details compliance process
 - Security Management
 - Risk Analysis & Management
- Provides variety of compliance tools, including
 - Matrix of security standards & implementation specifications
 - Typical risk ratings for biomedical device categories
 - Biomedical Equipment Survey Form & Questionnaire
 - Risk Mitigation Worksheet
 - Security Assessment Survey Questionnaire
 - Sample policies/procedures
 - Security incident report
 - Business associate agreement with security provisions
 - Educational programs (PowerPoint slides & program outlines)

Assessing <i>Criticality</i> of Risk Associated with Biomedical Devices/Systems with ePHI						
RISK LEVEL	Impact on Patient		Impact on Organization			
	Potential degree to which health care would be adversely impacted by compromise of <u>integrity</u> or <u>availability</u> of information	Potential degree to which privacy would be adversely impacted by compromise of <u>confidentiality</u> of information	Potential degree to which interests would be adversely impacted by compromise of <u>confidentiality</u> , <u>integrity</u> or <u>availability</u> of information	Potential financial impact	Potential legal penalties	Likely corrective measures required
High	Serious impact to patient's health (including loss of life) due to: misdiagnosis, delayed diagnosis or improper, inadequate or delayed treatment	Could identify patient and their diagnosis	Extremely grave damage to organization's interests	Major \$1,000K	Imprisonment and/or large fines	Legal
Medium	Minor impact to patient's health due to: misdiagnosis, delayed diagnosis or improper, inadequate or delayed treatment	Could identify patient and their health information (but from which a diagnosis could not be derived)	Serious damage	Moderate \$100K	Moderate Fines	Legal
Low	Minor Impact	Could identify patient	Minor damage	Minor \$10K	None	Administrative

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Assessing Criticality & Probability of Risks associated with Medical Devices/Systems with ePHI (Personal Health Information)

Determining the <i>Criticality/Probability Composite Score</i>		Probability		
		Rare	Occasional	Frequent
Criticality	High	3	6	9
	Medium	2	4	6
	Low	1	2	3

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Criticality/Probability scoring example..

- Programmable, networked morphine infusion pump (*Potential score = 9?*)
 - Potential risk to patient and hospital is high.
 - High quantity of pump rentals and/or deployment to home care, nursing home, or hospice care would increase probability of problems.
 - Integration with "uncontrolled" computerized drug supply chain management or expert drug interaction systems would increase probability of problems.
 - Wireless networking might increase probabilities, too.

Another criticality/probability scoring example...

- Ob/gyn office fetal ultrasound imaging system (*Potential score = 3?*)
 - Potential risk to patient and fetus is low, but to hospital/physician (liability) is high.
 - Device unlikely to leave premises, so patient ID and data are relatively secure
 - Maintenance/repair policies, practices become critical...
 - User authentication, controlled access to printouts and removable media are critical.
 - Networked connection to hospital, EHR, may increase risks, though.

This is one resource, Hopefully more are coming...

Information Security for Biomedical Technology:

Highlights of the HIPAA Compliance Guide

- A CD-ROM that facilitates customization of forms, survey documents, policies, and procedures
- Recommended best practices
- Checklists for inventoring and analyzing risks
- Self-assessment tools to analyze ongoing levels of compliance
- Tools for setting priorities and implementing a mitigation plan
- Sample information security incident report and business associate agreement
- Typical policies and procedures

A HIPAA Compliance Guide™
A CD-ROM from ECRI and ACCE

ECRI
A NONPROFIT AGENCY
www.ecri.org

ACCE
A NONPROFIT AGENCY
www.acce.org

Details should be available shortly at www.ecri.org



Invitation to join:

- HIMSS Medical Device Workgroup
 - Chaired by Steve Grimes, ACCE

- Don't sit back waiting for these issues to be solved for you; get involved and help us solve the emerging challenges so we can continue to reap the benefits!



Challenges - 3

Information system security is a BIG issue, and going to get bigger!

- Assign a champion
- Create a top-level team to address
- Inventory affected technologies in the hospital
- Create a risk profile for devices based on patient, institution impacts
- Create an action plan to mitigate problems

Challenges - 4

MUST Develop and deploy effective, innovative, robust, and adaptable **clinical information system** support teams.

Primary care, acute care, and high-acuity alternate site care strategies for *consistent, high-quality* healthcare is still relatively new and uncontrolled.

Significant challenges and ideas are emerging. US was leading in this area, but Europe and Japan are breaking new ground!

**YOUR team needs to be prepared to
Lead, Follow,
or Get Out of the Way!**

Summary of the Scope of the Outpatient Challenge (1) Gandhi T et al. Adverse drug events in primary care, under review, NEJM. (2) Gandhi T et al. Drug complications in outpatient settings J Gen Int Med 2000. (3) Gandhi TK et al. Adverse drug events in primary care, under review, NEJM. (4) Poon E, et al. Failure to follow mammographers recommendations on marginally abnormal mammograms: determination of associated factors [abstract] J Gen Intern Med 2001. (5) Gandhi T et al. Communication breakdown in the outpatient referral process J Gen Intern Med 2000. (6) Maviglia SM, et.al. Using an electronic medical record to identify opportunities to improve compliance with cholesterol guidelines J Gen Intern Med 2001

For Every:	There Appear to Be:
1000 patients coming in for outpatient care (1)	14 patients with life-threatening or serious ADEs
1000 outpatients who are taking a prescription drug (2)	90 who seek medical attention because of drug complications
1000 prescriptions written (3)	40 with medical errors
1000 women with a marginally abnormal mammogram (4)	360 who will not receive appropriate follow-up care
1000 referrals (5)	250 referring physicians who have not received follow-up information 4 weeks later
1000 patients who qualified for secondary prevention of high cholesterol (6)	380 will not have a LDL-C, within 3 years, on record

Courtesy of John Glaser, 6/6/2004

Partners' Knowledge Management Practices

Attributes of Knowledge	Knowledge Management Practices	Dissemination of Content Across Sites	Estimated Rows of Knowledge
KNOWLEDGE ASSETS REQUIRING DEVELOPMENT AND MAINTENANCE			
Medication Services			
Drug-Drug Interactions			2000
Allergies			4000
Gerios			100
Nephros			250
Pediatric Content			2000
Chemo Content			500
Drug Dictionary			8000
Other Medication-related Decision Support			
Consequent Lab Display			60
Consequent Orders			60
Indication Screened Orders			20
Antibiotic restriction/decision support			40
Drug-Lab prescribing error decision support			360
Drug-Problem prescribing error decision support			700
Pharmacy ADE/potential ADE notification alerts			80
Physician ADE/potential ADE notification alerts			150
Ambulatory Care Knowledge Bases			
Preventive Reminders			100
Results Manager			100
Specialty Views of Data	To Be Developed		200
Clinician Population-Management Dashboards	To Be Developed		200
Clinical Documentation Templates			
			1000+
Physician Order Entry Knowledge Bases			
Inpatient Order Sets/Templates			500+
End of Visit Order Templates	To Be Developed		200+
Problem List Database			
			1000+

Per John Glaser, 6/6/2004:

Approximately 22,000 rules were inventoried in an initial effort. *My interpretation: this is likely only the "thin shell" of the rules, not covering doctor's own ad hoc (RED) rule sets, too!*

Like the 3+ Million web sites on the "thin shell" surface the Internet. The "deep" Internet (including archives within sites) is orders of magnitude larger than the "thin shell."

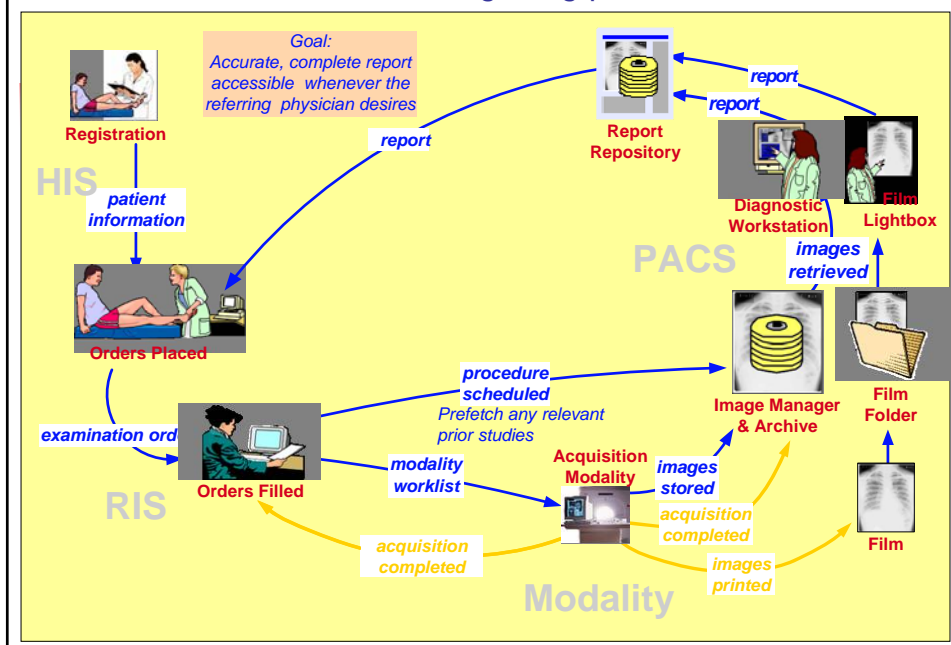
Knowledge Management Practices for Existing Databases:	
Purely Ad-hoc Updating	
Primarily Ad-hoc Updating with Some Active Updating	
Actively Scheduled Updating	

Dissemination of Knowledge Across MGH/B&W/LMR	
1 site	
2 sites	
> 2 sites	

Pervasive wireless network technologies are coming quickly!

- Explosive growth, and challenges, for healthcare network security
 - Confidentiality
 - Weak, non-standard, non-enforced encryption
 - Integrity
 - Intrusion prevention, detection gaps
 - Availability
 - Bandwidth capacity planning
 - Access point capacity planning
 - Overload, failure contingency planning

Our HIMSS IHE Profiles are integrating process and clinical data:



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This is one in a budding series of robot-therapy sessions at Japanese hospitals and senior citizens' homes. To some scientists, robots are the answer to caring for aging societies in Japan and other nations where the young are destined to be overwhelmed by a surging elderly population.

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Gadgets get hugs in Japan Japanese hospital, senior citizens' homes use the latest way to care for elderly, give them companions.

Navigation links: Home, News, Sports, Entertainment, Business, Technology, Health, Education, Local, Classifieds, Marketplace, Weather report sponsored by DELL, 40 great places to see artists' passion for Christ, INSIDE WEEKEND Travel, SAAY.com 10:25 AM ET

From Stephen Covey's Seven Habits...


SHARPEN THE SAW!

Ongoing education and participation in select industry conferences and work groups is critical to meet tomorrow's challenges! (This goes for YOU, too. Lead by example!)



“HOT TIP” – There are experts just dying for good problems!

- Many of your local Business schools have overbuilt eBusiness, Management, and Operations Research researchers and students.
 - Help focus that pent up energy and expertise on well-directed healthcare projects that YOU lead.
- Same is true for Biomedical Engineering and Computer Science schools!



Build STRONG Clinical Engineering and Information System Teams

I don't care WHAT your leadership style is.
Find a way to break down the walls and barriers.

1. **Hire, recruit, inspire, retool, and retain the Best of the Best of both worlds!**
2. **Cross-train to give depth and breadth.**
3. **Think outside the box (e.g., TRAIN NURSES!)**

Last, add this to every IT and CE staff meeting:

- Get every member of your team to **take ownership!** Allow 15 minutes in each meeting to discuss current aspects of this mission statement:

"We will not allow any patient or staff member to be harmed by misuse or failure of any aspect of our medical device or information systems."

Adapted from Dr. Jeff Cooper, Partners HealthCare, 6/5/2004





Meet the Challenges!

- **MORE** financial pressure is likely to mount rapidly.
 - Make and implement your strategic plans NOW.
- Medical device / information system standards for convergence **ARE** emerging; needs **YOUR** strong support.
 - Know and support the standards NOW; work with HIMSS.
- Information system security is a **BIG** issue!
 - Unavoidable cost of doing business; early intervention is better.
- **MUST** Develop and deploy effective, robust, and adaptable **clinical information system** support teams.
 - Commit solid resources to get, and stay, abreast of changes.
 - Lead by example and foster teamwork and systemic change.



We are in a "Golden Age" of Clinical Information Systems:

- Microprocessor-based medical devices, with
 - Rapid software and decision rule update capability, and
 - Instant customization to clinical situations.

New, emergent intelligent hybrid medical device/IT system possibilities (the "Sentient Hospital™").
Government oversight is virtually **guaranteed**.
- Portability and connectability (pervasiveness)
 - Low-power needs for novel portable applications, and
 - Ubiquitous wired/wireless network access.

Flexible care sites defy traditional clinical controls.
- Creating the conditions for Electronic Health Records (EHR) to finally be created.
Government and Payor oversight and intrusion is **assured**.



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and many, many more...



Information Resources

- www.himss.org
- www.ihe.net
- www.IEEE1073.org
- Soon: www.ACCEnet.org/IHE



Consider adopting an institution policy for purchasing medical device and clinical information system. Use emerging standards as the basis.

Email me for a draft sample
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Thank you for your attention!

I would again like to thank HIMSS for asking me to represent them, and AAMI for inviting me to make this presentation. Your feedback and questions are most welcome!

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