CHIME

Convergence of Clinical Engineering and Information Technology

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CE & IT Convergence

- History of Clinical Engineering
- Trends in technologies
- Why convergence is necessary
- How to make transition

History

- Hospitals began engaging (employing or contracting) clinical or biomedical engineering in the 1970s as a consequence of
  - ✓ proliferation of and reliance on increasing complex medical equipment
  - ✓ popular reporting of medical equipment related safety issues (“electrical safety”)
  - ✓ advent of JCAH (now JCAHO) standards regarding need for routine medical equipment testing … prospect of federal regulations

Historically

- On the advent of clinical engineering (30-35 years ago), it was primarily thought of as a “maintenance” function … i.e., something like 90% of CE activities were:
  - ✓ inspection & pm (i.e., checking function & safety)
  - ✓ repairs
- Consequently, clinical engineering was typically associated with:
  - ✓ Maintenance Dept
  - ✓ Facilities or Plant engineering

CE Model has changed

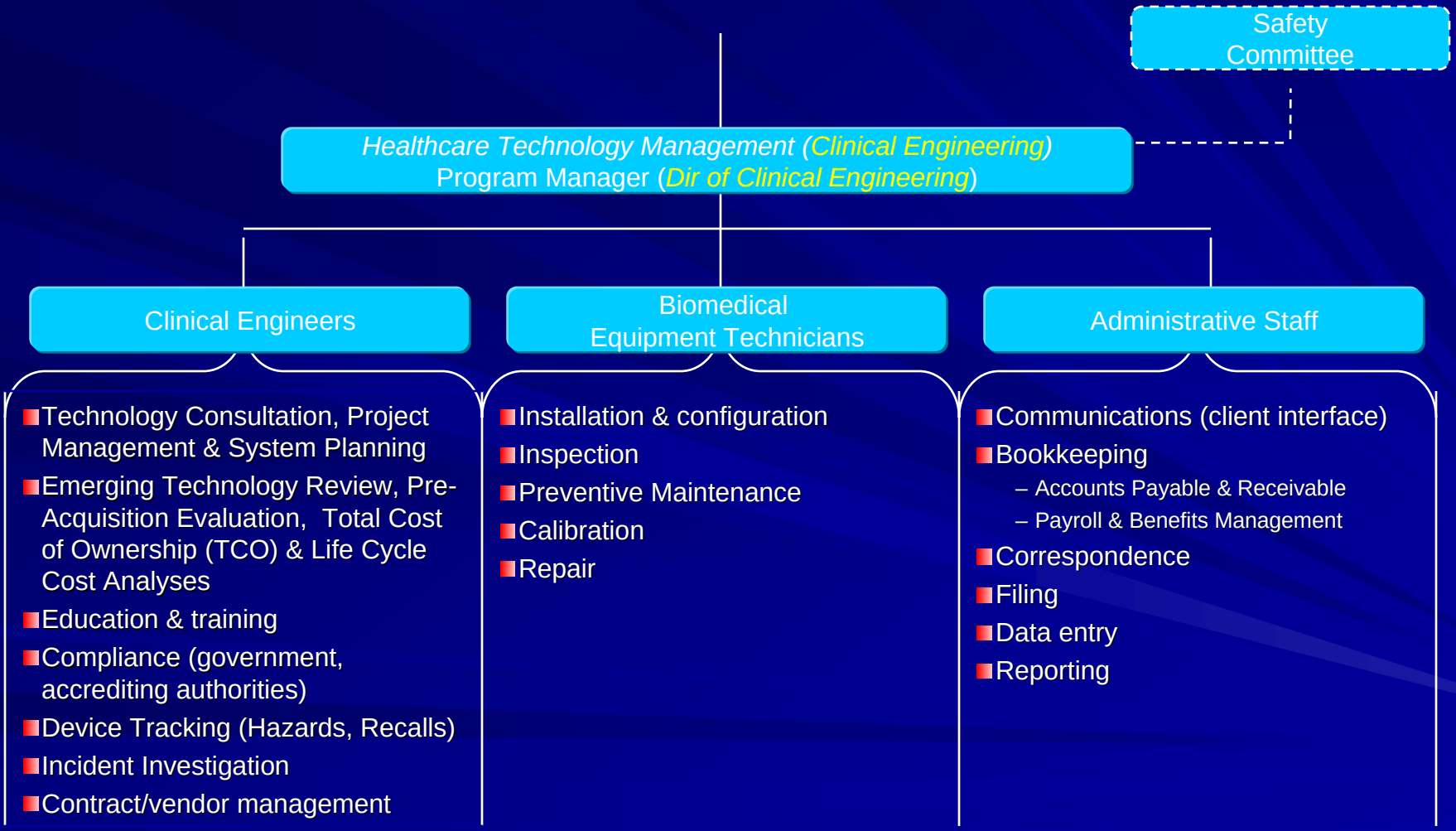
Discrete Equipment Management

- **Management & Consulting Services**
  - ✓ Inventory Management
  - ✓ Safety
  - ✓ Regulatory & standards compliance
- **Support Services**
  - ✓ Testing, Inspection, Preventive Maintenance
  - ✓ Repair

Technology Management

- **Management & Consulting Services**
  - ✓ Inventory & Asset Management
  - ✓ Strategic Planning
  - ✓ Quality & Safety
  - ✓ Regulatory & standards compliance
  - ✓ Vendor management
- **Support Services**
  - ✓ Education (technology users & CE staff)
  - ✓ Help Desk
  - ✓ Installation & Integration
  - ✓ Upgrades
  - ✓ Testing, Inspection, Preventive Maintenance
  - ✓ Repair

Today Typical
Clinical Engineering Program
Organization by Function / Roles



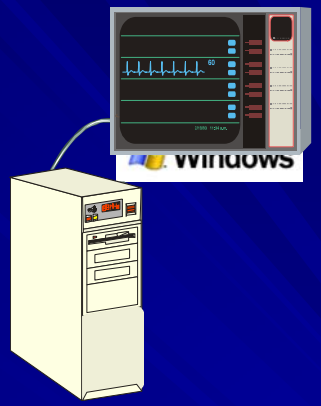
Typical CE Staff Qualifications

- Biomedical Equipment Technicians (BMET)
  - **Associate Degree in Technology (AA) or higher, Military or Manufacturer Training**
  - **Certified Biomedical Equipment Technician (CBET) …**
  - **Specialties: General Biomedical, Laboratory, Medical Imaging**
  - **Rankings: Level I, II, III … higher level reflects more experience, education and/or specialization**
- Clinical Engineers (CE)
  - **Batchelor or Masters of Science Degree in Clinical or Biomedical Engineering**
  - **Certified Clinical Engineer (CCE)**
- Director of Clinical Engineering
  - **Clinical Engineer**
  - **Master's in Business Administration … or business education**

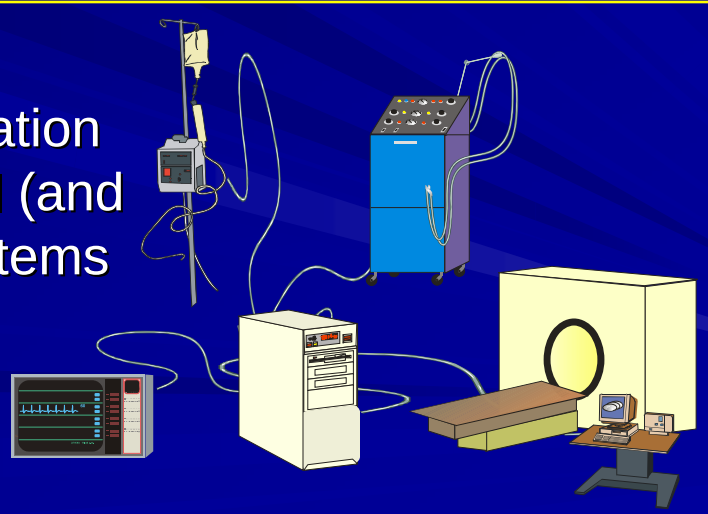
Trends - Changes in Medical Technology

Moving from Discrete Devices to integrated "Systems"

- Medical devices and systems are being designed and operated as special purpose computers … more features are being automated, increasing amounts of medical data are being collected, analyzed and stored in these devices



- There has been a rapidly growing integration and interconnection of disparate medical (and information) technology devices and systems where medical data is being increasingly exchanged



Trends – Integration of Medical Technologies

- Integrating medical devices facilitates
  - ✓ access to, comparison and analysis of rich set of clinical data from variety of sources that can be used to provide preemptive care
  - ✓ automatic charting of data to the electronic medical record (EMR)
  - ✓ closed loop systems … i.e., outputs from diagnostic devices (e.g., heart rate monitors & pulse oximeters) affect inputs on therapeutic devices (e.g., infusion pumps)
  - ✓ patient alarm management
  - ✓ asset tracking (i.e., RFID)
  - ✓ remote device management
    - monitoring data flow integrity & continuity
    - error code monitoring & remote diagnostics
    - software upgrades

Trends in Medical Technology Integration

- Recently a large integrated health delivery system began a plan to integrate its 300,000 to 500,000 medical devices
  - ✓ physiological monitors
  - ✓ vital signs monitors
  - ✓ electrocardiographs
  - ✓ infusion pumps
  - ✓ ventilators
  - ✓ blood gas analyzers
  - ✓ smart beds

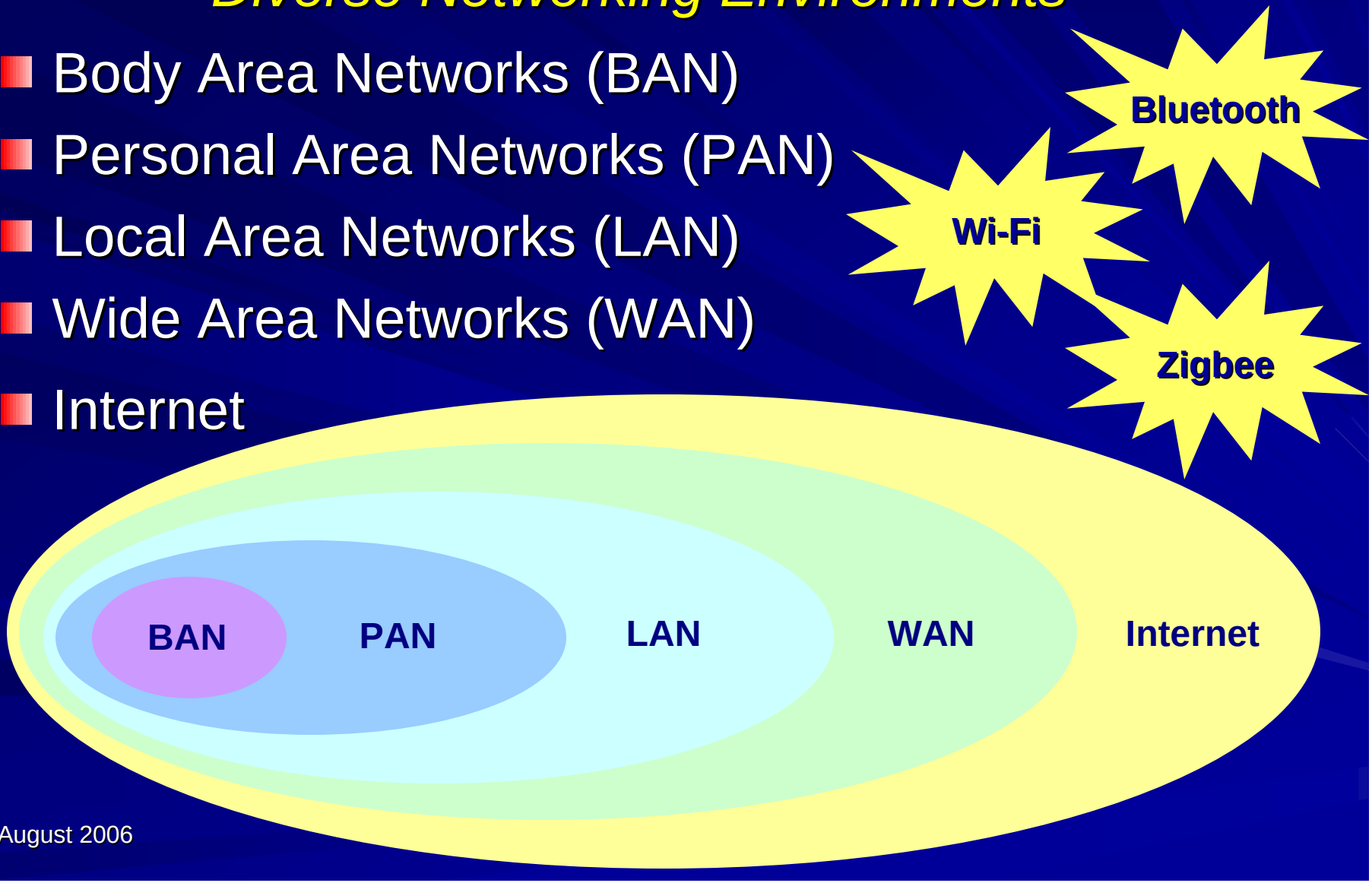
Increasing Common Integrated Medical Technology Systems

- Integrated medical systems whose function includes
  - ✓ store & permit retrieval of physiological data & images
  - ✓ permit remote viewing of stored data/images by physicians & clinicians
  - ✓ chart information automatically to the EMR
- Examples of these integrated medical systems
  - ✓ Database servers (physiologic monitoring)
  - ✓ Cardiac Cath Lab & Diagnostic Cardiac Ultrasound
  - ✓ Endoscopy
  - ✓ Surgery Video
  - ✓ Cardiology Archiving
  - ✓ Labor & Delivery Archiving
  - ✓ Picture Archiving (PACS) for Imaging
  - ✓ Laboratory Information
  - ✓ Pharmacy
  - ✓ Alarm

Significant Medical Device Industry Trends

Medical Devices Increasing Deployed Over Diverse Networking Environments

- Body Area Networks (BAN)
- Personal Area Networks (PAN)
- Local Area Networks (LAN)
- Wide Area Networks (WAN)
- Internet

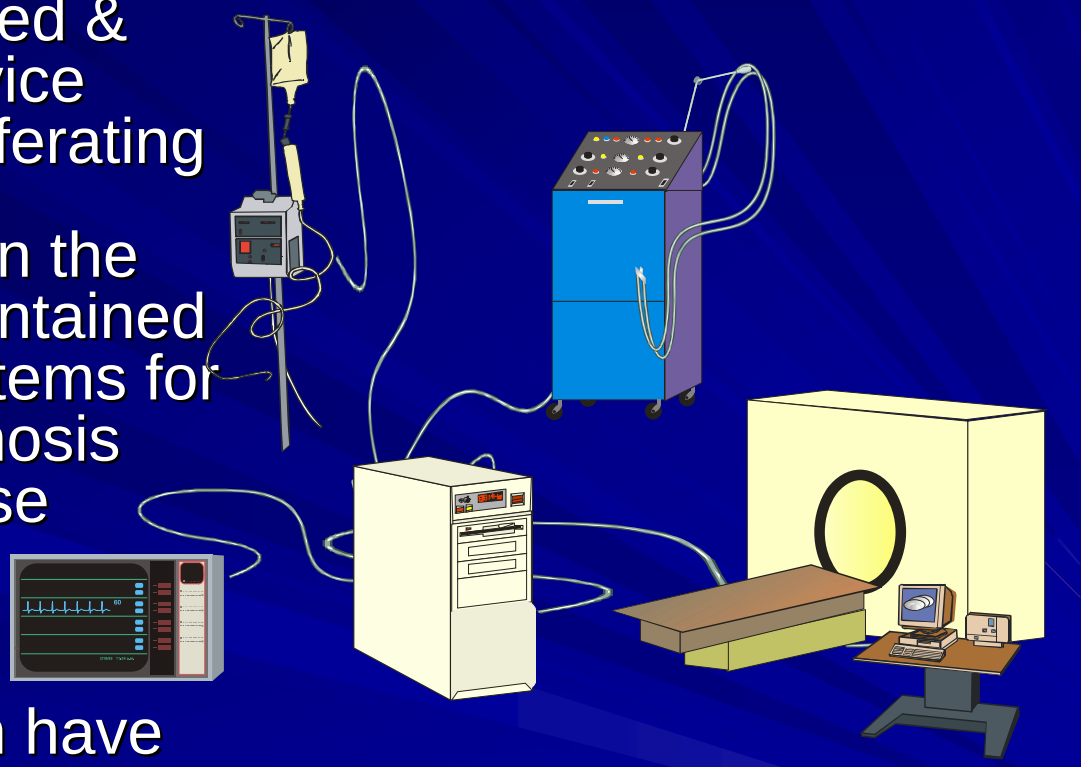


Additional Drivers Leading to CE-IT Convergence

- Information Security – data integrity, availability & confidentiality (e.g., HIPAA, CyberSecurity)
- Integrating the Healthcare Enterprise (IHE) … prelude to the digital hospital
- Patient Safety
- Telemedicine
- Increasing application of
  - ✓ RFID (radiofrequency identification)
  - ✓ DICOM
  - ✓ IEEE 802.11x / WiFi
  - ✓ Bluetooth, Zigbee
  - ✓ IEEE 11073 (medical instrumentation bus)
  - ✓ WMTS

Significant Medical Device Industry Trends and Implications

- The number of integrated & networked medical device systems is rapidly proliferating
- And our dependence on the clinical information maintained and transmitted by systems for effective & timely diagnosis and treatment is likewise increasing
- This dependence on integrated systems can have major implications on our ability to deliver patient care and on our business operations if those systems should fail

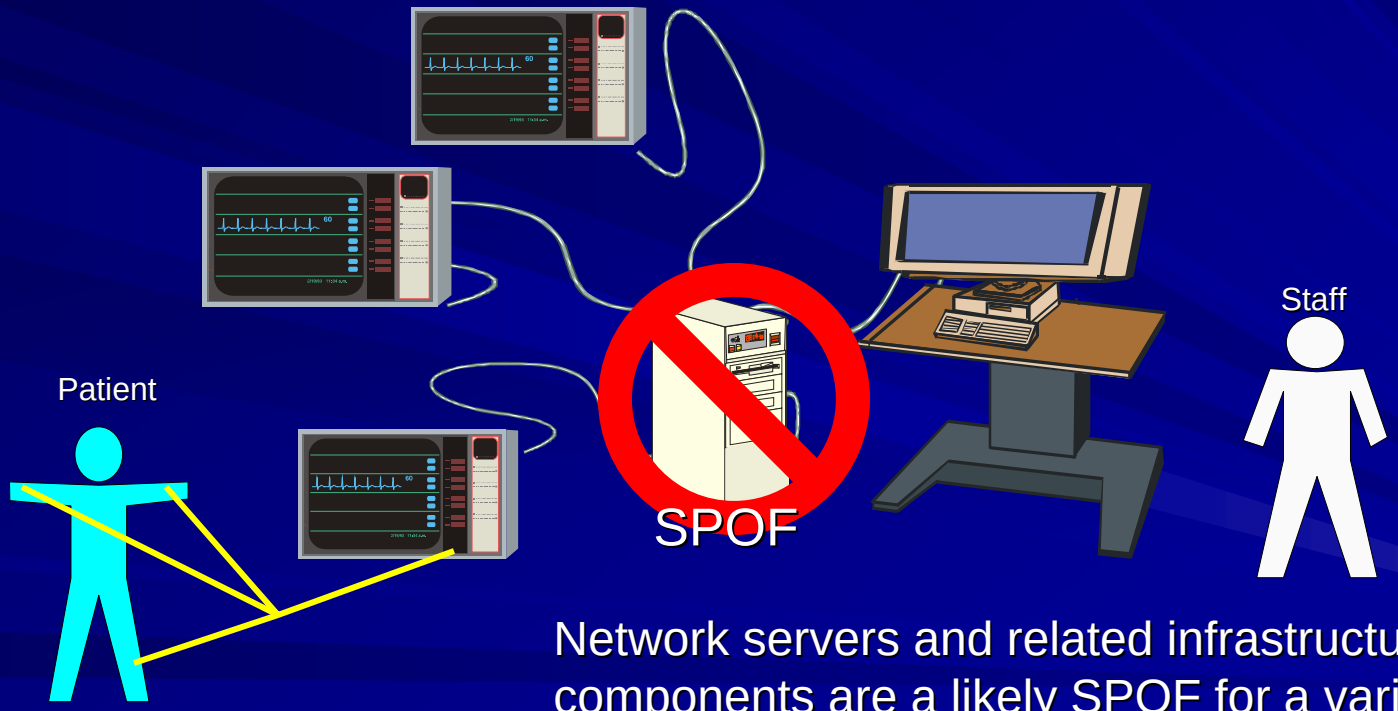


Need for CE-IT Convergence
Evolution of Critical Gaps

- Integrated medical device systems often come in "under the radar" as they
  - ✓ grow up from within clinical departments by connecting existing individual medical devices and networking them to servers
  - ✓ are acquired as new medical device systems without full consideration given to their inherent vulnerabilities and the implication of their failure on continuity of patient care
- "A system *here* … a system *there* …"
  A recent, preliminary inventory revealed that our organization now has ***at least 65 medical system servers*** and given trends in technologies and our organization's needs that number ***will likely double*** in the next 12 to 24 months

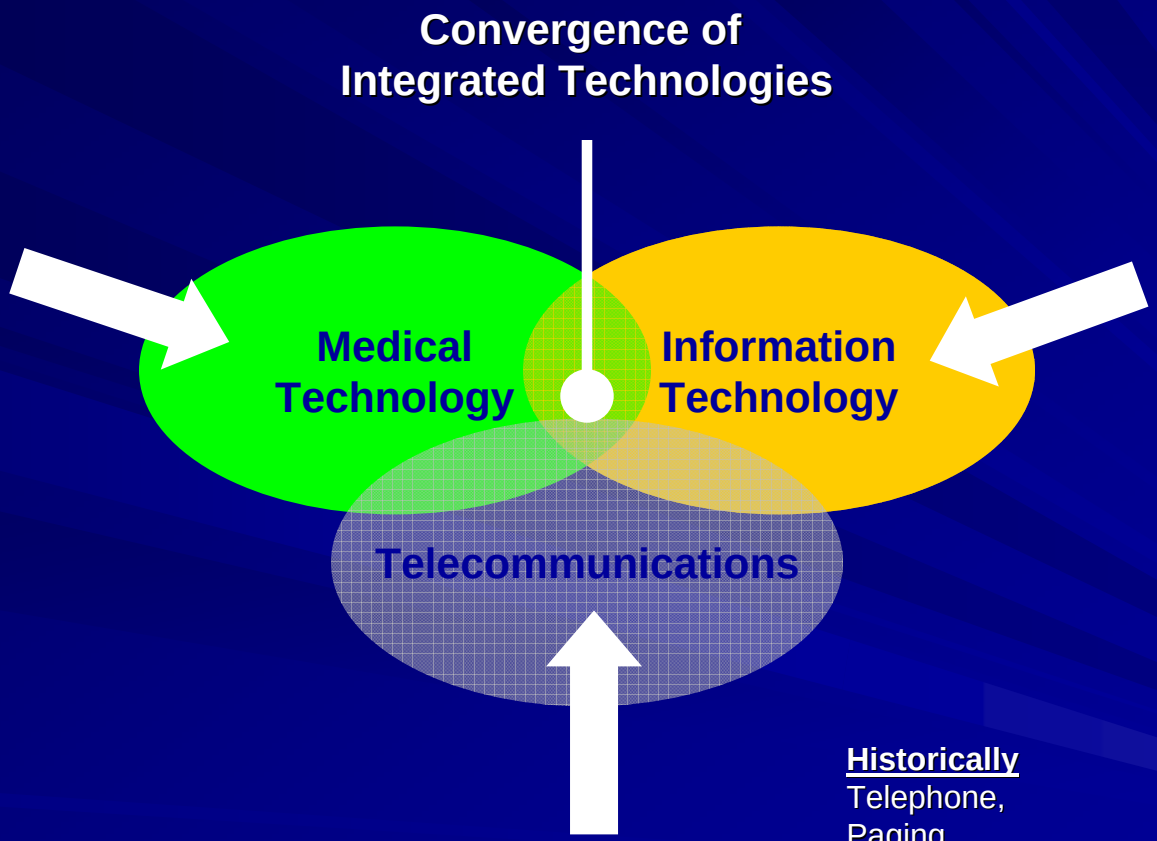
Integrated Systems are particularly vulnerable to **Single Points of Failure (SPOF)**

An SPOF is any part of a system (e.g., person, component or device) whose individual failure will cause the entire (or a substantial portion of the) clinical system to fail



Network servers and related infrastructure components are a likely SPOF for a variety of clinical systems

Inevitability of Convergence



Clinical Engineering Mission
=
Information Technology Mission

- To apply engineering, technical, and managerial expertise to the identification, acquisition and support of safe, effective, and economical technology as needed by this institution for patient care, teaching, research, and community service

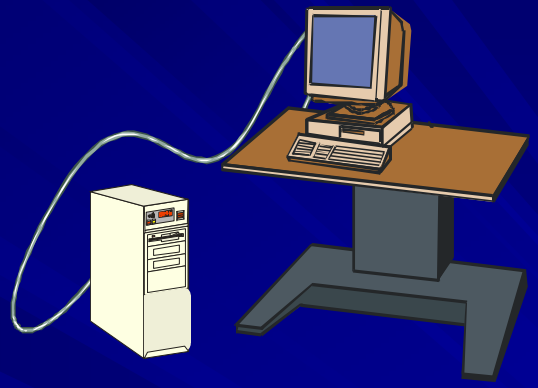
Obstacles to CE-IT Convergence

- Clash of cultures
  - ✓ CE is patient centric
    - structure is geared toward response time in minutes/hours
    - emphasis on patient safety
    - innovation
  - ✓ IT is systems centric
    - structure is geared toward response time in hours/days
    - emphasis on integrity of data & processes
    - rules
- Different and (*sometimes*) Conflicting standards
  - ✓ CE
    - JCAHO (Environment of Care's Medical Equipment Management standards)
    - FDA
  - ✓ IT
    - JCAHO (Information Services)
    - NIST

Traditional Differences Between Medical & Information Technologies

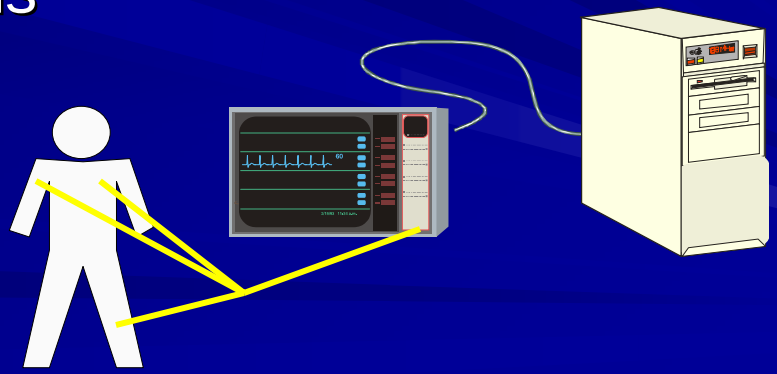
- IT Systems

MISSION CRITICAL



- Medical Devices & Systems

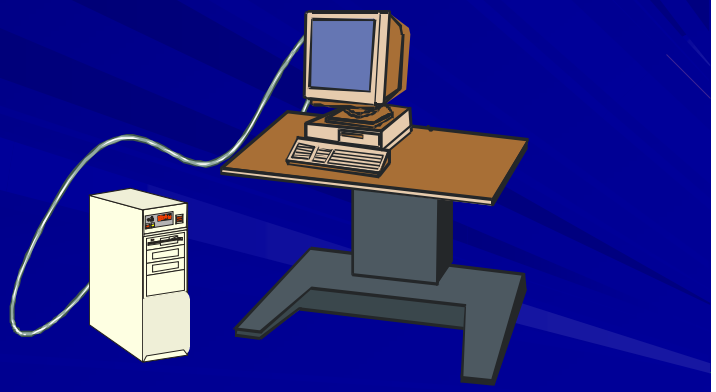
LIFE CRITICAL



Information Technology Systems

- **Mission Critical**
  Activities, processing, etc., that are deemed vital to the organization's business success or existence. If a ***Mission Critical*** application fails, crashes, or is otherwise unavailable to the organization, it will have a significant negative impact upon the business.

  Examples of ***Mission Critical*** applications include accounts/billing, customer balances, ADT processes, JIT ordering, and delivery scheduling.

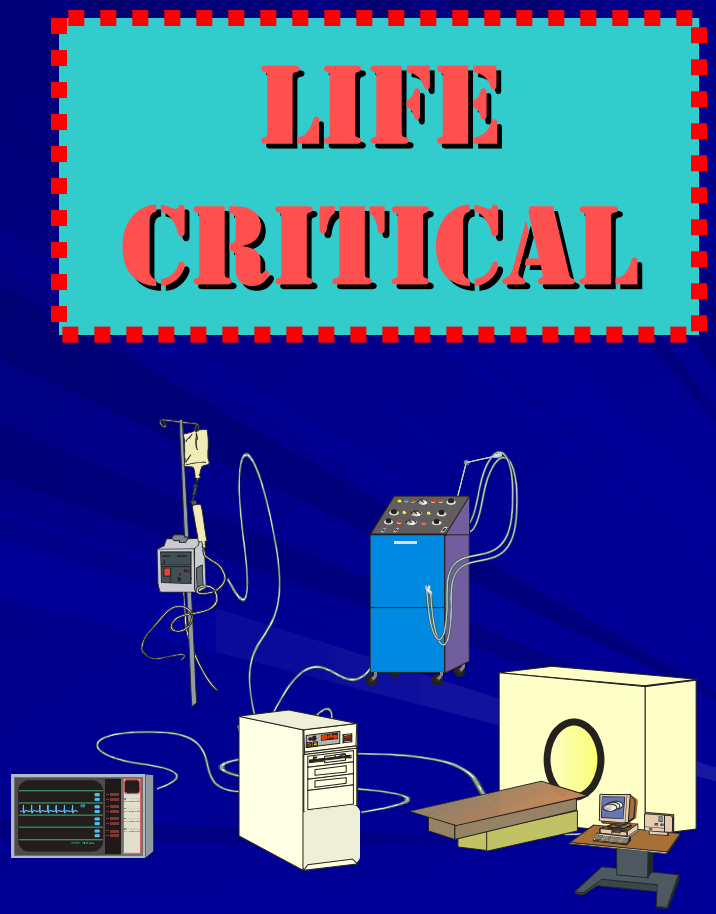


Biomedical Technology Systems

- **Life Critical**

  Devices, systems and processes that are deemed vital to the patient's health and quality of care. If a ***Life Critical*** system fails or is otherwise compromised, it will have a significant negative impact on the patients health, quality of care or safety.

  Examples of ***Life Critical*** systems include physiologic monitoring, imaging, radiation therapy, and clinical laboratory systems.



Issues to Overcome

Cultural "Disconnect" between Clinical Engineering & Information Technology

- **Clinical engineering characteristics**
  - ✓ Early clinical engineering programs were formed with a disproportionate focus on maintenance … as consequence were lumped in organizationally with other hospital maintenance functions
  - ✓ Subsequent developments are leading to more "enlightened" clinical engineering programs taking on responsibility for managing processes associated with technology selection, integration, training & service
  - ✓ "Patient centric" approach

Issues to Overcome

Cultural "Disconnect" between
Clinical Engineering & Information Technology

- **Information technology characteristics**
  - ✓ Historically business, finance (billing) and ADT
  - ✓ Focusing on maintaining integrity of data flow and processing throughout their information systems
  - ✓ Data, process & "systems centric"

Key Challenges leading to Convergence

- *In today's highly "connected" environment, medical technology can only be addressed by bringing the expertise of both professions together in a team effort.*
- *Both professions need to coordinate their efforts and develop solutions at the industry as well as the local (e.g., hospital) level.*
- *Increasingly, effective coordination is leading to the formal integration of departments and a crossing over of skill sets*

Challenges to Overcome

- Complacency
- Turf
- Culture
- Ignorance

Clinical Engineering & Information Technology Synergies

- As an ever-increasing percentage of biomedical technology integrates or networks with computer components, a synergistic relationship is possible and desirable between healthcare IT and the Biomedical / CE programs.
- Synergies come from
  - ✓ Biomedical / CE ‘s intuitive understanding of the medical device – patient dynamic and the
  - ✓ IT personnel’s understanding of computer hardware and information processing concepts.

Moving toward Convergence

- As long as CE/Biomedical and IT departments remain separate entities
  - ✓ Establish regular lines of communication and cooperation at their management and technical levels. Biomedical and information technologies are inextricably entwined and only grow more so.
  - ✓ Cooperate to ensure that technical issues do not “fall through the cracks,” that new technologies are effectively adopted and supported, and that there is appropriate cross-training between staff
- As CE and IT departments merge into a Technology Management Service …
  - ✓ Identify overlaps & gaps in skills, resources, technologies
  - ✓ Fill gaps as necessary, realign skill sets, resources & technologies
  - ✓ Cross-pollinate (i.e., learn from each other)

One Approach toward Convergence

Coordinator for Clinical Systems Integration & Infrastructure Support

Key element of a solution .. Description of new function …

- Maintains current inventory of networked and integrated medical systems (including catalog of services, features, interconnections)
- Coordinates security management process including risk (e.g., criticality & probability) and vulnerability analysis and related documentation associated with interconnected/integrated medical systems
- Coordinates with stakeholders a process to prioritize, develop and implement plan to manage/mitigate identified risks associated with interconnected/integrated medical systems by applying appropriate administrative, physical & technical safeguards

One Approach toward Convergence

Coordinator for Clinical Systems Integration & Infrastructure Support

Description of new function (continued) …

- Maintains the integrity of FDA approval for interconnected/integrated medical systems
- Works with stakeholders to insure effective deployment, integration, and support of new medical systems into legacy systems and non-medical elements of the organization's information infrastructure.
  - ✓ Works to assure systems are deployed into an optimum (i.e., secure & supportive) environment.
  - ✓ Continually reviews system components to determine which are obsolete or otherwise no longer adequately supportable and then
  - ✓ Plans for and implements component upgrades/replacement in a timely manner.

One Approach toward Convergence

Coordinator for Clinical Systems Integration & Infrastructure Support

Description of new function (continued) …

- Identifies and manages appropriate software upgrades, security patches and anti-virus installs for interconnected/integrated medical systems according to industry best practices
- Conducts Root Cause Analysis (RCA) and Failure Mode Effects Analysis (FMEA) on incidents involving integrated medical systems and reports findings to appropriate stakeholders for follow-up action
- Monitors and adopts industry “Best Practices” to insure integrity, availability & confidentiality of data maintained and transmitted across interconnected and integrated medical systems
- Educates stakeholders on security and other implications associated with the proliferation of interconnected and integrated medical technologies.

One Approach toward Convergence

Coordinator for Clinical Systems Integration & Infrastructure Support

Stakeholders the new function / role works with …

- Informatics (including network support, disaster recovery)
- Clinicians (system users including physicians, nurses, technologists, etc)
- Medical system manufacturers/vendors
- Risk management
- Information Security
- Medical procurement
- Clinical engineering

Gartner Research

- A well-known & respected research group that advises clients on predicted implications of IT-related trends in a variety of different industries (e.g., financial, manufacturing, healthcare, etc)
- A recent (Nov ’05) prediction (*controversial*) *“By 2009, 50 percent of healthcare providers will move biomedical device management under the CIO”*

"By 2009, 50 percent of healthcare providers will move biomedical device management under the CIO" … Gartner Research (Nov '05)

Key Findings:

- Biomedical devices increasingly require network support and interoperability with electronic medical record systems.
- Potential network vulnerabilities and infrastructure demands of biomedical devices must be anticipated and managed.
- Progressive convergence of biomedical device planning and support within the office of the CIO is inevitable; executive management needs to orchestrate a smooth transition.

"By 2009, 50 percent of healthcare providers will move biomedical device management under the CIO" … Gartner Research (Nov '05)

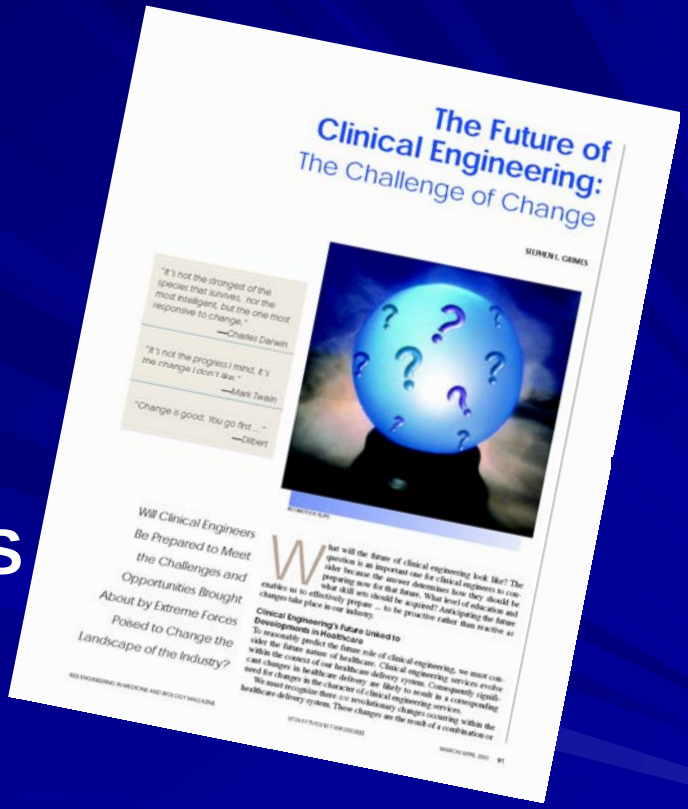
Market Implications:

- Biomedical device management needs to be included within the CIO's strategic, purchasing and operational oversight. Biomedical devices use embedded computer technology and often require network access.
- Too often, IT becomes involved after the fact, when a problem surfaces.
  - ✓ The inability to scan or patch a device is a vulnerability, and biomedical devices can add to the demand for widespread network accessibility and bandwidth.
  - ✓ The extensive interoperability of biomedical devices with electronic medical record systems is a second trigger for convergence.
- Electronic medical record systems can reduce documentation time by capturing data directly from medical devices. The electronic medical record system is also an early warning device that can fire critical trend alerts based on if-then logic and complex multivariable algorithms with biomedical devices as key data sources.
- When *biomedical device – electronic medical record* problems arise, clinical users shouldn't have to know whether it's the device, the interface, the network or the electronic medical records system to call technical support.

Technology's Limitations

Questions?

Thank You!


The Future of Clinical Engineering:
The Challenge of Change

STEPHEN L. GRIMES

"It's not the strongest of the species that survives, nor the most intelligent, but the one most responsive to change."
—Charles Darwin

"It's not the progress I mind, it's the change I don't like."
—Mark Twain

"Change is good. You go first ..."
—Dilbert

Will Clinical Engineers Be Prepared to Meet the Challenges and Opportunities Brought About by Extreme Forces Poised to Change the Landscape of the Industry?

What will the future of clinical engineering look like? The question is an important one for clinical engineers to consider because the answer determines how they should be preparing now for that future. What level of education and what skill sets should be acquired? Anticipating the future enables us to effectively prepare — to be proactive rather than reactive as changes take place in our industry.

Clinical Engineering's Future Linked to Developments in Healthcare

To reasonably predict the future role of clinical engineering, we must consider the future nature of healthcare. Clinical engineering services evolve within the context of our healthcare delivery system. Consequently significant changes in healthcare delivery are likely to result in a corresponding need for changes in the character of clinical engineering services.

We must recognize there are revolutionary changes occurring within the healthcare delivery system. These changes are the result of a combination of

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