Convergence of Clinical Engineering and Information Technology: Trends, Opportunities & Challenges

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CE & IT Convergence

- History of Clinical Engineering
- Trends in technologies
- Why convergence is necessary
- How to make transition
- Challenges we face
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 "The Joint Commission") 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
Today the CE Model has changed

Discrete Equipment Management  Technology Management

- The industry is (slowly) recognizing that “electrical safety” is not now (nor ever really was) a major patient safety problem.

- Discrete devices today are have fewer components subject to “wear & tear” (i.e., and therefore often don’t benefit from “preventive maintenance”) … formally a 40-50% of CE’s workload.

- Effective support of medical devices today requires they be considered as “systems” …. “systems” of devices (many “integrated”), people (patients & staff), environment, and processes.
Today the CE Model has changed

Discrete Equipment Management → Technology Management

Management & Consulting Services
- Inventory Management
- Safety
- Regulatory & standards compliance

Support Services
- Testing, Inspection, Preventive Maintenance
- Repair

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

Broadened Scope
Today Typical Clinical Engineering Program Organization by Function / Roles

Healthcare Technology Management (Clinical Engineering)
Program Manager (Dir of Clinical Engineering)

Clinical Engineers
- Technology Consultation, Project Management & System Planning
- Emerging Technology Review, Pre-Acquisition Evaluation, Total Cost of Ownership (TCO) & Life Cycle Cost Analyses
- Education & training
- Compliance (government, accrediting authorities)
- Device Tracking (Hazards, Recalls)
- Incident Investigation
- Contract/vendor management

Biomedical Equipment Technicians
- Installation & configuration
- Inspection
- Preventive Maintenance
- Calibration
- Repair
- Inservice training of staff (often impromptu)

Administrative Staff
- Communications (client interface)
- Bookkeeping
  - Accounts Payable & Receivable
  - Payroll & Benefits Management
- Correspondence
- Filing
- Data entry
- Reporting

Safety Committee
Growing 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.
A Consequence of Trends
Leading to Convergence of
not only Technologies but also Associated Professions

Historically
Patient Safety, Compliance, Testing, Repair

Convergence
... or a perfect storm?

Historically
Business, Finance (Billing), ADT

Historically
Telephone, Paging

Clinical Engineering
Information Technology
Telecommunications
“People” Challenges to Overcome in Convergence

- Complacency
- Turf
- Culture
- Ignorance
Challenges
Reconciling Traditional Differences
Between Clinical Information & Information Technologies

- Clash of cultures
  - Clinical Engineering 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

- IT Systems
  - MISSION CRITICAL

- Medical Devices & Systems
  - LIFE CRITICAL
Successful Convergence Requires Recognizing & Encouraging Key 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.
Convergence of Technologies Inevitable

Ultimately Success Depends Cooperation &
Coordination Between Key Stakeholders

- In today’s highly “connected” environment, medical technology can only be addressed by bringing the expertise of clinical engineering and information technology professions together in a team effort.

- Both professions need to coordinate their efforts and develop strategic solutions at the industry as well as the local (e.g., institution) level.

- Increasingly, effective coordination is leading to the formal integration of departments and a crossing over of skill sets.
Moving toward Convergence

As long as CE 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 Healthcare 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)
Considerations for **Successful** Convergence …

**Distinctive …**

*but under one strategic & collaborative Healthcare Technology Domain*

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**The Healthcare Technology “Tent”**

- Clinical Engineering
- Information Technology
- Telecommunications
Our 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

Clinical Engineering

Information Technology

Our FOCUS

Physicians, Nurses & other Providers

Patient
Additional Technical Challenges

Why we need to “get it right”
and some ideas on “how”
Challenges

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
Challenges

Convergence & Integration Increases Security Vulnerabilities

i.e. increased opportunities for compromising
data integrity, availability & confidentiality

Data Integrity

Data Availability

Physiologic Monitor

Patient

Central Station

Clinician with Authorized Access

Data Confidentiality
Challenges

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.

May 2007
Supporting Changes and Challenges in America’s Healthcare System

Clinicians, Clinical Engineering & Information Technology must navigate a vast Sea of Healthcare Technologies.

Icebergs of Vulnerability
- associated with growing number individual “critical” integrated clinical systems

Sea of Healthcare Technologies

May 2007
Critical Integrated Clinical Systems will fail … and some failures will result in significant economic loss and compromised patient care.

The number, frequency and severity of clinical system failures depends on clinical engineering’s ability to develop and provide a service that can identify vulnerabilities and put appropriate safeguards in place to minimize the number & effects of those failures.
What’s Happening?
How Are Gaps Evolving?

The Integration of Medical Devices & Information Systems
Leading to 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 ...”
Last year a preliminary inventory revealed that my institution had **at least 80 medical system servers** and I predicted given trends in technologies and the institution’s needs that number **will likely double** in the next 12 to 24 months ... a subsequent inventory 12 months later revealed **140 servers**
Challenges
Avoiding Pitfalls that represent
*Probable Difference between Success & Failure*

We treat as a collection of isolated systems & incidents

OR

We treat as a series of related systems & events requiring a *strategic* approach

May 2007
One Approach toward Convergence
Coordinator for Clinical Systems Integration & Infrastructure Support
A “Clinical Systems Engineer”

**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
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
A “Clinical Systems Engineer”

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
A “Clinical Systems Engineer”

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
Future Clinical Engineering Programs: Organization by Function / Roles

Healthcare Technology Management (Clinical Engineering)
Program Manager (Dir of Clinical Engineering)

- Strategic planning, deployment & testing of integrated systems (new & legacy) and associated configurations & process
- Inventory & tracking of clinical systems (including catalog of services, features & interconnections)
- Design & maintain support infrastructures that are secure, scalable, flexible, robust, manageable
- Security management
  - criticality & probability assessment
  - vulnerability analysis
  - develop, prioritize and implement plan to mitigate risks
  - upgrade/patch management

Clinical Engineers
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- Emerging Technology Review, Pre-Acquisition Evaluation, Total Cost of Ownership (TCO) & Life Cycle Cost Analyses
- Education & training
- Compliance (government, accrediting authorities)
- Device Tracking (Hazards, Recalls)
- Incident Investigation
- Contract/vendor management

Biomedical Equipment Technicians
- Installation & configuration
- Inspection
- Preventive Maintenance
- Calibration
- Repair

Clinical Systems Engineers
- Technology Strategic Planning Committee

Administrative Staff
- Communications (client interface)
- Bookkeeping
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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.
Questions?

Thank You!

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