Second WHO Global Forum on Medical Devices
‘Priority Medical Devices for Universal Health Coverage’
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Global Perspectives on Clinical Engineering Trends

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IFMBE/ Clinical Engineering Division (CED)
Greetings from your Colleagues at the Texas Medical Center
Outline

• Observations based on 35 years of experience
  • (North America, Central & South America, Asia, Europe, Australia, Africa)

• The ever changing (growing) role of healthcare technology
  • (especially at the point-of-care)

• Are there common characteristics in our profession?

• Competencies to consider
  • (Engineering, Clinical Sciences, Communications, Telecommunication, Informatics, Management, Risk management, Regulation, Systems Operation, Finance)

• Tomorrow’s technical skills
Fundamental Drivers are Changing Healthcare along Several Dimensions

Healthcare Environment

- Advances in Medical Science
- Trends in Demographics
- Cost Containment
- Demand for Quality/Value

- Standardization of Practice
- Customization of Care
- New Care Delivery Models

(IBM Watershed Study in Healthcare)
The Space Shuttle Enterprise (in Texas 2013) on its way to Museum in Los Angeles

Transition

Engineering Marvel
End of an Era
Moving from state-of-the-art device to large systems management
Connected systems
Competencies and cross disciplinary skill

KNOWLEDGE

We are in the midst of changing healthcare

Y. David
In the beginning

Frederick Douglass Hospital's Operating Room, circa 1900, courtesy National Library of Medicine
Mishaps and deaths caused by surgical robots going underreported to FDA

BY: KAISER HEALTH NEWS AND MARISSA EVANS

A Da Vinci Robotic System assists with surgery at Diaconesses hospital in Paris, France in 2012. Photo by Getty Images
The Role of Healthcare Technology

- To better life quality and disease management
- Obtain and transform data into effective knowledge
  - Improve diagnostic, therapeutic & rehabilitation
- Translating efficacy into effectiveness
  - Increase access and Enterprise cost-effectiveness
- Level outcomes variation
  - Expand service and impact area
- Reduce Liability, Use errors, Medical-legal issues
  - Reduce risk & eliminate errors
- Competency & credentialing
  - Attract high quality professionals
Transformation of Healthcare Offers Challenges and Opportunities

• Skills are needed that can measure what is acceptable level of residual risk and how to enable sustainable safe patient care in an integrated networks of medical systems

• 4 main Technology Management areas:
  – Outcomes impacted by Safety indicators
  – Outcomes impacted by Quality indicators
  – Outcomes impacted by Financial indicators
  – Outcomes impacted by Operations indicators (business interruption)
Safety is the condition of being free from (or protected against harm or other types or) consequences of failure, damage, error, accidents, harm or any other event which could be considered non-desirable. Safety is also the state of control of recognized hazards to achieve an acceptable level of risk. This can take the form of being protected from the event or from exposure to something that causes health or economical losses. It can include protection of people (patients) or of possessions (assets).

Quality is an essential or distinctive characteristic, property, or attribute, character or nature, as belonging to or distinguishing a thing character with respect to fineness, or grade of excellence; superiority; degree of excellence a personality or character trait.

http://www.asse.org/

http://www.asq.org/

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CLINICAL ENGINEERING PROGRAM

Clinical Engineering Expertise

Structured Technology Management

Patient Outcomes

Institution Performance

Care Providers Team
Education Elements Should Include C.E. Management

- Planning
- Budgeting
- Coordinating
- Prioritizing
- Monitoring & Evaluating
- Improving

4x Areas
The Professional Clinical Engineer

YADIN DAVID, Ph.D., P.E.
Director, Biomedical Engineering Department, Texas Children’s Hospital, Houston, Texas

There is a growing concern among clinical engineers regarding the degree of professionalism and personal commitment being demonstrated in their field. Clinical engineering is a unique profession. Only in healthcare can a technical profession be involved with such a wide spectrum of issues relating to ethics, human values, professionalism, and the decision processes involved with life, the quality of life, and death.

As healthcare grows ever more technology-intensive and its reliance on that technology increases, the clinical engineer’s role becomes more vital. Indeed, integrating the roles of the various engineering sciences is not the only challenge facing the clinical engineer today. Every member of the healthcare team is a professional, well trained in his or her specialty. And it is the interrelationship of these individuals—with their technical skills, experience, judgment, creativity, ethical values, and communication skills—that in large part determines the patient’s fate.

We as clinical engineers are responsible not only for the equipment we purchase, design, and service, but for our professional standing relative to other members of the healthcare team. The quality of our work must be unquestionable. But just as important, our image must also stand out. Because clinical engineering is in many ways directly influenced—even controlled—by administrative and corporate decisions, we must elevate and then uphold our standing. We must establish and enforce certain standards of education, performance, and conduct. In so doing, we can demonstrate a degree of professionalism and personal commitment which is becoming ever more rare in all industries.

When an engineering student graduates, it is unlikely that he or she has ever been offered a single course in ethics or professionalism. And the temptation to disregard such considerations abounds. One need only check the news for reports of fraud and falsification of documentation in the aerospace industry, or cover-ups of poor quality or misuse. Commitment, responsibility, and accountability should be among the primary values of any clinical engineer, regardless of experience.

The word profession comes from a Latin phrase which means “public declaration.” Webster’s Dictionary defines the term, in part, as “a calling requiring specialized knowledge and often long and intensive academic training.” The following characteristics are recognizable in virtually every field of endeavor commonly recognized as a profession:

- Expertise/knowledge: A special skill or education, for which standards are determined by those already in the field. This is true for professional advancement and education are expected to be ongoing.
- Commitment: This shows the professional’s dedication to both the clients’ (patients’) interest, and those of the profession. Participation in ongoing education, a professional society, or work for a related cause would all be evidence of commitment.
- Autonomy: Analogous to self-control. Members of a profession should establish and uphold standards for education, quality, and behavior, both individually and as a group. Of all the characteristics of a profession, self-government, rather than outside government, is perhaps the most important.
- Responsibility: The willingness to undertake a task, complete with all its implications. Once obstacles have been overcome, the rewards—whether financial or...

**Engineers’ Creed**

As a Professional Engineer, I dedicate my professional knowledge and skill to the advancement and betterment of human welfare.

I pledge:

- To give the utmost of performance;
- To participate in none but honest enterprise;
- To live and work according to the laws of man and the highest standards of professional conduct;
- To place service before profit, the honor and standing of the profession before personal advantage, and the public welfare above all other considerations.

Figure 1

Clinical engineers should exhibit dedication to their profession by establishing guidelines such as those above, adopted in 1954 by the National Society of Professional Engineers.

Journal of Clinical Engineering—September/October 1988 345

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Life Cycle

Innovation

Early Diffusion

Incorporation

Wide Utilization

Abandonment

Basic and applied research

Prototype testing

Application

Obsolescence

Intensity of Use

Adopted from David and Judd, Medical Technology Management, 1993

Regulatory Oversight

Clinical Engineer Oversight

Medical Technology Life Cycle
Clinical Engineering Focus is on The Interface Between the Patient/User and the Technology

Safety and Quality Indicators

Biomedical and other Engineering Clinical Engineers

Adapted from M. Shaffer, IFMBE/Medical & Biological Engineering & Computing, Nov. 1985
Health & Science

Too much noise from hospital alarms poses risk for patients

By Lena H. Sun, Published: July 7 at 8:44 pm

The sheer number — several hundred alarms per patient per day — can cause alarm fatigue. Nurses and other workers, overwhelmed or desensitized by the constant barrage, sometimes respond by turning down the volume on the devices, shutting them off or simply ignoring them — actions that can have serious, potentially fatal, consequences.

A muted monitor

The parents of Mariah Edwards won a $6 million malpractice settlement after their 17-year-old daughter died last year following a tonsillectomy at a Pennsylvania surgery center. After the surgery, the high school junior was given a potent painkiller that slowed her breathing. By the time nurses checked on her 25 minutes later, she had suffered profound and irreversible brain injury. She died 15 days later.

“It’s an enormous issue,” she said. “We’re as at-risk as everybody else.

Has your institution experienced adverse patient events in the last two years related to clinical alarm problems?

#29

The results show a lack of adverse patient events.
The Future of Medical Technologies (2018)

**Top 20 Medtech Companies**

**Medtech R&D Spend 2011/18 (millions)**

<table>
<thead>
<tr>
<th>Company</th>
<th>Medtech R&amp;D ($m)</th>
<th>2011</th>
<th>2018</th>
<th>CAGR 11-18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johnson &amp; Johnson</td>
<td>1,751</td>
<td>2,072</td>
<td>+2%</td>
<td></td>
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<tr>
<td>Siemens</td>
<td>1,674</td>
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<td>Medtronic</td>
<td>1,490</td>
<td>1,814</td>
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<tr>
<td>General Electric</td>
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<td>1,166</td>
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<td>Philips</td>
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<td>Roche</td>
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<td>1,047</td>
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<td>997</td>
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<td>Abbott Laboratories</td>
<td>851</td>
<td>996</td>
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<td>St. Jude Medical</td>
<td>705</td>
<td>873</td>
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<td>Covidien</td>
<td>554</td>
<td>798</td>
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<tr>
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<td>Stryker</td>
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<td>B. Braun Melsungen</td>
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<tr>
<td>Intuitive Surgical</td>
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<td>+15%</td>
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<tr>
<td>Zimmer</td>
<td>239</td>
<td>292</td>
<td>+3%</td>
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</tbody>
</table>

Source: EvaluateMedTech World Preview 2018

Y. David
Intuitive Surgical's robotic surgery systems may be also poised for significant growth in China. The da Vinci robotic surgical system by Intuitive can be used for cardiac valve repair, gynecologic procedures, and minimally-invasive prostatectomies. Approximately one-fourth of hospitals in the United States have these systems. With each system carrying a price tag of $1.45 million, growth for Intuitive has been mostly strong, although the company has seen its stock price decline significantly this year. While the company has experienced some regulatory and legal issues with its system, Intuitive has weathered many of these, allowing for strong growth.

In 2007, the company started to sell its robotic surgical system to luxury Chinese hospitals. However, the company still has significant room to grow. During its last quarter, the company reported that only one-fourth of its revenue came from abroad.

While da Vinci's reputation has been sullied in the United States, the Chinese market represents a clean, uncapsitized region. With strong potential, Intuitive's Chinese presence may drive future growth.
"This system really wasn't ready to come online."

"Everything went down including the backup."

Y. David
Executive Summary

Integrating the Healthcare Enterprise (IHE) is an initiative by care providers (including ACCE, HIMSS and RSNA) and vendors to improve the way information systems communicate to support patient care. IHE defines Integration Profiles that use established data standards to integrate systems for effective interoperability and efficient workflow. IHE makes it possible to achieve the level of integration required in the era of the electronic health record. This handbook targets:

- Administrators who make purchasing decisions
- I.S. analysts
- Clinical Engineers
- Technology evaluators
"The number of recalls that had a global component were up, which really speaks to the challenges of a global supply chain."

Mike Rozembajgier, vice president of recalls for Stericycle ExpertRECALL.
Clinical Engineer Roles & Competencies

1. College trained engineers with interdisciplinary subspecialty in healthcare technology
2. Assess and guide the impact of technology initiatives on safety, quality, and cost of providing healthcare
3. Adopt methodologies and tools that support this strategy
4. Monitor outcomes, recommend and implement system changes and operational improvements including:
   • Institutional and collaborative technical capacity (technology availability),
   • Ongoing optimal support to infrastructure and technology policy and processes (life cycle management),
   • Institutionalization of integrated healthcare technology management that can sustain safe, resilient and efficient technical services over the technology life cycle.

- Engineering, Life Sciences, Risk Management, Telecommunications, Informatics & Networking, Communication, Regulations & Standards interpretation
- Team worker
- Stewardship
  - An ethic that embodies the responsible planning and management of resources to protect patients
Our profession is changing – demanding new skills and competencies in order to make technology connected, integrated, resilient and safe for better patient outcomes.
Managing Risks, Quality and Cost of Integrated Systems & Networks in Healthcare Environments

Overview
- Risk Control: Adverse Events Investigation
- Network: Planning, Design, Expanding, Performance Assessment
- Project Management: Change control

Required eLearning Courses
- Task Force Administration: Communication, Collaboration, Role & Responsibilities

Optional eLearning Course

Each course includes Compliance, Monitoring, Reporting, Documentation, Tools & Resources

C.E.

- Patient Safety
- Medical Technology
- Financial Stewardship

Adopted from AAMI 2013

Y. David
Clinical Engineering (C.E.) Objective

The objective is to optimize the deployment of technology, assess current conditions and develop models to manage and predict the impact of program characters (staffing, training, test equipment, space, inventory, etc.) on technology services and patient outcomes.
In Summary

Challenges of healthcare integration and complex interoperability expose new risks that must be managed.

You can convert this change into Opportunity.

By being prepared, have a plan, take action, commit to education.

Educate your self **beyond** technical skills.

Must understand Risk, Safety, Resiliency (IEC80001).

Learn about regulations, understand standards and measure compliance.

Strategize systems approach to problem solving.

Join teams outside your comfort zone.

Cross function/discipline.

Engage with professional organizations.
Thank you