The Role of Key Professionals in Improving Patient Outcome through Technology Life Cycle Management – Clinical Engineer

Yadin David, Ed.D., P.E., C.C.E., FACCE, FAIMBE
Biomedical Engineering Consultants, LLC
Asst. Professor, University of Texas School of Public Health
IUPESM Health Technology Task Group (HTTG)
Outline

• Who are the Clinical Engineers?
• Where do they practice?
• What are their competencies?
• How can you measure their contributions?
• What should we do?
• Conclusions

Greeting from the Texas Medical Center, Houston, Texas, USA
The Space Shuttle Enterprise (in Texas 2013) on its way to Museum in Los Angeles
Technology Expanded Role in Healthcare

- **Operations** (Supply chain, Business/Payers, Personnel, Services and Procedures)
- **Pharmaceuticals** (Drugs, Nutrients, Blood, Compounding, Chemical agents, etc.)
- **Physical plant** (Buildings, Utilities, Waste, etc.)
- **Consumers** (Organ substitution, Personal and Home use, behavior modification)
- **Professional** (Clinical skills simulators, ER training, etc)
- **Work place** (Clinical protection, Business, Processes, Safety)
The Future of Medical Technologies (2018)

Top 20 Medtech Companies

Worldwide medtech sales forecast to total $440B

Medtech R&D Spend 2011/18 (millions)

<table>
<thead>
<tr>
<th>Company</th>
<th>Medtech R&amp;D (Sm)</th>
<th>2011</th>
<th>2018</th>
<th>CAGR 11-18</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Johnson &amp; Johnson</td>
<td>1,751</td>
<td>2,072</td>
<td>+2%</td>
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<tr>
<td>2 Siemens</td>
<td>1,674</td>
<td>1,987</td>
<td>+2%</td>
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<tr>
<td>3 Medtronic</td>
<td>1,490</td>
<td>1,814</td>
<td>+3%</td>
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<td>4 General Electric</td>
<td>949</td>
<td>1,166</td>
<td>+3%</td>
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<tr>
<td>5 Philips</td>
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<td>1,101</td>
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<td>6 Roche</td>
<td>1,018</td>
<td>1,047</td>
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<td>7 Boston Scientific</td>
<td>895</td>
<td>997</td>
<td>+2%</td>
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<tr>
<td>8 Abbott Laboratories</td>
<td>851</td>
<td>996</td>
<td>+2%</td>
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<td>9 St. Jude Medical</td>
<td>705</td>
<td>873</td>
<td>+3%</td>
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<td>10 Covidien</td>
<td>554</td>
<td>798</td>
<td>+5%</td>
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<tr>
<td>11 Danaher</td>
<td>419</td>
<td>615</td>
<td>+6%</td>
<td></td>
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<tr>
<td>12 Stryker</td>
<td>462</td>
<td>589</td>
<td>+4%</td>
<td></td>
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<td>13 Becon Dickinson</td>
<td>476</td>
<td>544</td>
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<td></td>
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<tr>
<td>14 Terumo</td>
<td>308</td>
<td>458</td>
<td>+6%</td>
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<tr>
<td>15 Edwards Lifesciences</td>
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<td>+8%</td>
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<td>16 Essilor International</td>
<td>211</td>
<td>343</td>
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<tr>
<td>17 Olympus</td>
<td>320</td>
<td>338</td>
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<tr>
<td>18 B. Braun Melsungen</td>
<td>250</td>
<td>327</td>
<td>+4%</td>
<td></td>
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<tr>
<td>19 Intuitive Surgical</td>
<td>122</td>
<td>317</td>
<td>+15%</td>
<td></td>
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<tr>
<td>20 Zimmer</td>
<td>239</td>
<td>292</td>
<td>+3%</td>
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</tbody>
</table>

Source: EvaluateMedtech World Preview 2018
Where Do Clinical Engineers Practice?

The intersection between healthcare interventions, community of consumers/users and deployment of technology is unique space:

- **Point-of-service**
- **Point-of-use**
- **Point-of-care**
Clinical engineers are the only engineering-trained professionals who are practicing at the Point-of-care and focus on care outcomes impacted by technology.

Integrating Safety & Quality

- is the condition of being free from (or protected against harm or other types of) 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 assets.

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. The provision of rendering care to patient with excellent outcomes.
Clinical Engineer Roles & Competencies

1. College trained engineers with interdisciplinary subspecialty in healthcare technology
2. Assess and guide the impact of technology on safety, quality, and cost of providing healthcare
3. Adopt methodologies and tools that support their enterprise mission over the technology life-cycle
4. Monitor outcomes, recommend and implement system changes and direct medical equipment program with focus on operational improvements such as:
   • Selection and monitoring of collaborative technical capacity (matching user, technology functionality, and availability),
   • Sustainable optimal support for the infrastructure and for systems (mitigating care disruption or delay) through all phases of patient care,
   • Institutionalization of integrated healthcare technology management that is managed across platforms, resilient and efficient technical services that prevent business interruptions.

- Engineering, Life Sciences, Risk Management, Telecommunications, Informatics & Networking, Communication, Regulations & Standards interpretation
- Team worker, critical thinker
- Stewardship
  - An ethic that embodies the responsible planning and management of resources to protect patients
Life Cycle

Innovation

Basic and applied research

Prototype testing

Application

Incorporation

Wide Utilization

Obsolescence

Abandonment

Intended Use

Regulatory Oversight

Clinical Engineer Oversight

Medical Technology Life Cycle

Adopted from David and Judd, Medical Technology Management, 1993
Clinical Engineering Focus is on The Interface Between the Patient/User and the Technology

Biomedical and other Engineering  Clinical Engineers  Safety and Quality Indicators

Adopted from M. Shaffer, IFMBE/Medical & Biological Engineering & Computing, Nov. 1985
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.”
A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care

James, John T. PhD
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, uncapitalized region. With strong potential, Intuitive’s Chinese presence may drive future growth.
What to do (and what not to do) when your $1B system-wide EHR fails

There really wasn’t any support from management on what was going on.

September 10, 2013

The 24-hospital Sutter Health system in Northern California was the talk of the town late August after a software glitch rendered its $1 billion Epic electronic health record system inaccessible to nurses and clinical staff throughout all Sutter locations.

On Aug. 26 at approximately 8 a.m., nurses, physicians and hospital staff were unable to view patient information, including relevant medications and all patient history data, according to Sutter’s 241-bed Mills-Peninsula Medical Center in Burlingame, Calif., one of the Sutter locations that experienced system failure.

"This system really wasn’t ready to come out."

"Everything went down including the backup."

Underestimation of the potential risk to patient safety

1. Inadequate testing

2. Too little time for verification

3. Unrealistic and/or incomplete budgeting and schedule

4. Lack of foresight about the pace of change and the need to plan for it

5. Failure to hire sufficiently trained professionals to support and maintain wireless technology

6. Decision making with false assumptions

7. Failure to properly manage changes made to the wireless network, such as failure to analyze the impact of a firmware change to an access point on the medical devices on that network, or failure to properly analyze and test the impact of adding new applications to the network

8. Failure to embrace vendor site testing of the network

9. Failure to take into account different environments of care, intended uses, and intended use environments

10. Failure to perform routine maintenance

Failure to consider that construction projects, or physical changes to a facility, could impact wireless performance

Wayne Park, FACHE, is senior vice president of Sutter’s executive operations and chief operating officer of the Sutter Health East Valley Hospitals - Sutter Medical Foundation. He is a frequent speaker at Healthcare IT News events, and he co-chairs the HIMSS Health IT Policy Committee. He can be reached at Wayne.park@sutter.org.
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
Managing Risks, Quality and Cost of Integrated Systems & Networks in Healthcare Environments

Face to Face Course

Required eLearning Courses
- Risk Control
  - Adverse Events Investigation
- Network
  - Planning, Design, Expanding, Performance Assessment
- Project Management
  - Change control

Optional eLearning Course
- Task Force Administration
  - Communication, Collaboration, Role & Responsibilities

Each course includes Compliance, Monitoring, Reporting, Documentation, Tools & Resources
Clinical Engineering (C.E.) Objectives

Optimize technology deployment processes (purchase only what needed),

Monitor and manage systems’ risk exposure level (interoperability & integration),

Improve systems’ performance (prevention of adverse event, on-demand & scheduled servicing, uptime, disaster preparedness),

Support technology for care interventions and disease management with optimal use of resources (labor, spare parts, test equipment, vendor services)

Collaborate with other professionals to deliver a continues best possible patient outcomes.
Examples for C.E. Impact on Patient Care Outcomes Through Health Technology Management

1. Volume of HT inventory and HT acquisition cost
2. Ratio of internal service to outsourcing contracted service
3. Cost of Service Ratio to total acquisition value
4. Expenses (waste) for the procurement of inappropriate equipment (Low utilization) or parts
5. Rate of replacement of devices (inventory average age) or parts turn over ratio
6. Parameter that measure changes in equipment down times (defects, missing supplies, repair, lack of operator)
7. Degree of equipment use to capacity
8. Equipment life cycle in comparison to benchmarks
9. Life cycle cost or safety analysis
Examples for C.E. impact on Patient Care Outcomes Through Health Technology Management

1. Wait time of specific clinical procedures due to equipment issues
2. Percentage of scheduled surgical procedures cancelled/delayed due to problems with equipment and devices
3. Rate of equipment incidents/events during surgery, or during other uses
4. Rate of fatal events during surgery due to equipment problems
5. Rate of fatal events during surgery due to operator errors, e.g. HTM user training
6. How many equipment problems during surgery/procedure not resolved due to lack of HTM personnel (e.g. CEs, BMETs) on duty
7. Infection rate due to reprocessing (or lack of it) of multiple-use devices
8. Infection rate due to reuse of single use devices
9. How many adverse events due to malfunctioning equipment reported
10. Number/% of referrals to higher level facility due to equipment problems
11. Accident Trauma survival rates – equipment in place for rapid response
+ … 20 indicators
Recommend WHO and Transnational Organizations Promote Equal Recognition for Clinical Engineers, Medical Physicists and Biomedical Engineers Roles Within the Healthcare Team.
Thank you!