White Paper: *New Opportunities for BME/CE Health IT Education*

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Abstract: Current US health policy through the Office of the National Coordinator (ONC) of Health Information Technology (IT) of the Department of Health and Human Services (http://www.healthit.gov/) indicates that the standard practice for Biomedical Engineering roles in healthcare will include managing and dealing with comprehensive Medical Device interoperability with Electronic Health Records. A recent workforce forecast from the US Department of Labor predicts that the US will have a workforce of 25,000 biomedical engineers by 2022, and another 60,000 technicians, and 100,000 related IT staff. This White Paper addresses the limited amount of appropriate curriculum and hands-on laboratory resources among the 88 US university-based Biomedical Engineering (BME) programs to prepare the field to manage medical device interoperability and fully engage our current workforce for the transitions occurring today. We conclude that the field is not ready for this challenge, but some leading universities have begun this transition. We are ready to assist in this development.

Situation

Biomedical Engineering and Health Technologies exist in – and contribute to – the 21st Century's healthcare technology environment of *volatility, uncertainty, complexity,* and *ambiguity* (VUCA).[1] In this complicated *system of systems* world, US healthcare badly needs solutions. With a goal of harnessing clinical technology to safely produce desired health outcomes, *where will skills in medical devices and Health IT come from to meet these challenges*?"[2-12]

In February 2014 in Washington, DC, 1700 stakeholders met … to change the US healthcare system … *(*see *Report*[13]*).*

> ***Healthcare Innovation Day 2014: Igniting an Interoperable Healthcare System***, co-hosted by the West Health Institute and the Office of the National Coordinator for Health IT. *An excerpt from their Executive Summary: "…* 1,700 stakeholders critical to driving (medical device) ***interoperability*** and dedicated to transforming the nation's healthcare system. This report presents what we learned at the conference. It highlights, most importantly, that achieving interoperability is a shared responsibility for all stakeholders. It also synthesizes the findings from the conference into our Call to Action, which lays out a vision for the path ahead and the key milestones to achieving an interoperable healthcare system.
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> Why ***interoperability?*** **Because patients are waiting**. You will read here about patients who experienced problems due to the lack of interoperability: devices that won't work together; healthcare providers forced to pay more attention to technology than to patients; and treatment decisions made in the absence of critical information trapped in systems that cannot communicate. We learned during the conference that we can do better. We have a shared goal of a healthcare system that is simple, streamlined, and smart. We want healthcare that's good enough for our patients, our parents, our children, ourselves."

Why This White Paper?

- Healthcare technology requires a systems approach as more and more medical devices become connected to the IT network for interchanging data with the EHR and other medical devices.
- To meet US healthcare medical device-Electronic Health Record (EHR) interoperability needs:
  - To get required knowledge embedded into the existing workforce – both engineers, managers, IT staff
  - To meet a new workforce gap to address interoperability and emerging mHealth requirements (see emerging trends http://www.mhealthnews.com/news/7-mhealth-trends-himss14)
- The profession and educators together need to face the integration of Health IT and medical devices, and create technology solutions to ensure safe and effective delivery of both individual patient and population healthcare.

Background

Devices: For the past decade, few medical devices were designed to operate in a vacuum. Most have one or more embedded computer and communication chips/modules that allow the devices to connect to other devices, hospital information systems (HIS), and/or specialized systems like Laboratory Information Systems (LIS) and Radiology Information System (RIS). Medical devices, HIS, LIS, and RIS products are now being designed to allow or even promote device-system integration and interoperation. Why? This design improves patient safety and quality while reducing errors, and improves care delivery efficiency through automation when feasible.

The "new normal" in healthcare is for medical devices to become part of an integrated "system of systems". Devices must still safely and reliably perform their primary design function(s), but they also now send and receive data and patient information to other devices and the HIS. This diverse environment requires someone who knows and understands how clinical care workflows, medical devices, and IT systems fit together.

Education: Traditional relevant education - biomedical and clinical engineering (BME/CE) - covers broad swaths of general principles, including basic systems theory, electrical, chemical, mechanical, and related engineering topics, plus biology, anatomy, and physiology.[14-15] Most have limited exposure to programming, but more typically as a "user" running applications, not creating or configuring production software. Traditional BME/CE jobs in hospitals afford them with a "trusted" role and wide access, including patient care areas, facilities, and information and communication technology (ICT) resources. For many hospital BME/CE departments, the daily work of health technology management (HTM) focuses on preventive maintenance, repairs, and engineering analysis for technology planning and acquisition. The new requirement is to build on these traditional programs adding the best new information on Health IT.

Assessment

Workforce: Where will the needed 21st Century health technology workforce come from? We examined four sources for workforce projection information:

The US Department of Labor's Occupational Outlook of human capital infrastructure for BME is bifurcated into the biomedical engineers and medical equipment repairers, see http://www.bls.gov/ooh/architecture-and-engineering/biomedical-engineers.htm.

1. *Biomedical Engineers* (BME) have an entry level education of a Bachelor's Degree and an average wage of $86,960 per year or $41.81 per hour. There are an estimated 19,400 jobs in the field and from 2012 to 2022 there is an estimated 27% growth in jobs or 5,200 more positions by 2022 (not accounting for attrition).
2. *CNN Money* identified BME as the fastest growing job in the US in 2012, http://money.cnn.com/pf/best-jobs/2012/snapshots/; the same survey noted BMEs that manage technology in healthcare or *Clinical Engineers (CEs)* as the 54th fastest growing job, see http://money.cnn.com/pf/best-jobs/2012/snapshots/54.html and the American College of Clinical Engineering-ACCE site http://www.accenet.org. There are over 600 current ACCE members, and an estimated 2,000 CEs in the US.
3. Separately, medical equipment repairers, http://www.bls.gov/ooh/installation-maintenance-and-repair/medical-equipment-repairers.htm have an entry level education of an Associate's Degree and average wage of $44,570 per year of $21.43 per hour. There are an estimated 42,300 jobs in the field and from 2012 to 2022 there is an estimated 30% growth on jobs or 12,800 new positions by 2022 (without attrition). This group is called biomedical equipment technicians or *BMETs*.
4. In addition, the fourth category of related *Health IT job titles in healthcare* easily number in the 100,000s, see http://www.bls.gov/ooh/computer-and-information-technology/.

The recently released FDA, FCC, and ONC proposed rule making in response to the Food and Drug Administration Safety and Innovation Act (FDASIA) report identifies ways that Health IT and biomedical technologies are interacting in the marketplace and regulatory arena.[16] Health IT professionals at all levels are finding themselves drawn ever-closer to the patient-safety risk management strategies that apply to other health technologies. The Health IT workforce now finds their systems, skills, and responsibilities more intertwined and interdependent with biomedical engineering and BMETs.

This job data informs educators, practitioners and administrators that the total incumbent workforce delivering services to the healthcare system nationally is estimated at 60,000 (or much higher) with more coming in the next few years. However, as noted above, little, if any, training in Health IT is included in the knowledge and skill sets of this significant professional community. *Will this workforce have the skills necessary to meet the needs of the health delivery system and population health in this second decade of the 21st Century, or will it remain stuck in a 20th century model of service?*

Academia: Recent surveys by professional societies have revealed that there are eighty-eight US-based university based departments/programs in BME, and another twenty five in Canada. Similarly, there are at least fifty programs training BMETs throughout the US. Historically, information technology has not been a core knowledge and skill set delivered in these programs. These programs have the capability to create programs to retrain the incumbent workforce (60,000 plus in the US) in new skills to engage the emerging EHR/EMR technology and its intrusive interaction with the traditional biomedical engineering domain.

Recommendations

A. Skill updates needed: Technical, Health IT Standards, Management, Leadership, and Regulatory Framework

1. **Technical**

In addition to the traditional engineering and science skills, BME/CEs can do a much better job if they understand how the following systems and technologies function in the clinical world, not just the research environment, and how they integrate and interoperate with devices and other Health IT systems, including:

- HIS (Hospital Information Systems), including Electronic Health/Medical Record Systems (EHR/EMR)
- LIS (Clinical Laboratory Information System)
- RIS (Medical Imaging/Radiology Information System)
- Wired and Wireless Networks
- Operating systems such as Linux and Windows
- Databases like MySQL, SQLServer, Oracle, Mongo, and/or GT.M
- Storage Area Networks
- Personal health devices such as those used for home care and telehealth
- Security monitoring/surveillance, firewalls, and antivirus
- BYOD technologies and strategies deployed by healthcare institutions

2. **Health IT Standards:** A portion of the needed skills include understanding of the foundational Health IT standards being used nationally and globally, including: ICD9, ICD10, ICD11 – see http://www.who.int/classifications/icd/en/ - SNOMED (http://www.ihtsdo.org/snomed-ct/) , LOINC (https://loinc.org/), RxNORM (https://www.nlm.nih.gov/research/umls/rxnorm/), IHE (http://www.iheusa.org/) , and HL7 https://www.hl7.org/).

3. **Management:**
   - General Project Management, including Agile Methodologies
   - Software and Systems Development Life Cycle (SDLC) Methodologies
   - Software and System Engineering, including:
     - System of Systems Engineering, aka Complex Systems Engineering, including concepts of interdependencies, modeling and simulation, Software Quality Assurance, including Verification and Validation, including the "V-Model" process and system engineering approach, and Concurrent Engineering
   - Human factors engineering, including human-system engineering
   - Life cycle cost analysis (or Total Cost of Ownership for information and communication technologies-ICT)
   - Lean/six-sigma quality methods
   - Risk management and risk mitigation (ISO 80001 et al)
   - HTM Maturity Models, HIMSS ERM Maturity Model
   - Business process engineering/re-engineering and management of change
   - Contract negotiation

4. **Leadership:**
   - Recruitment, training, and retention of ICT professionals
   - Cross-training and team building for customer service
   - Job descriptions and careers that include analysts, trainers, implementers, etc
   - Human capital management
   - Problem/conflict resolution, mediation

5. **Regulatory and legal frameworks**
   - In the US: The Joint Commission (accreditation of hospitals); ONC (Office of the National Coordinator of Health IT) and current Meaningful Use legislation (reimbursement of healthcare practitioners and hospitals); FDA (US Food and Drug Administration) and FCC (US Federal Communications Commission) for FDASIA Committee and Report.[16]

B. Emerging Teaching and Learning Resources

- Virtual courseware on these topics
- Virtual laboratories (sandboxes) to learn fundamental product, integration and interoperability tools and methods
- Case studies that allow experiential learning based on real-world examples
- Internships to allow development of hands-on skills otherwise unobtainable

C. Academic and Professional Recognition and Enrollment Alternatives

"Accredited" Certification/Recognition; "Accredited" Certificate Programs (stand-alone and post-graduate); "Accreditation" of Higher Education Schools/Departments/Programs; New professional specializations within existing BME/CE undergraduate and graduate programs

D. Case studies and capstone projects

Both successes and failures are instructive!

- University of Connecticut: CE Masters program with hospital internships[14]
- Marquette University / University of Wisconsin Medical School: BME/CE Health Technology Management (HTM) program[15]
- University of Rochester: University BME and IT joining forces with leading hospitals and industry to create a city-wide coalition; see http://www.rochesterbusinessalliance.com/web/2011/01/community_leaders_request_state.aspx

Other External Drivers:

Global considerations

The World Health Organization (WHO) is also tackling the issues of medical device/system interoperability and emerging mHealth in the context of eHealth, see http://www.who.int/ehealth/en/, with two key defining summaries of that work.[17-18] Here is an excerpt from the Executive Summary of the February 2014 meeting.[18]

> As the United Nations agency for health, the WHO recognizes the importance of health data standardization in eHealth systems and services, and the need for interoperability of data and devices between and within those systems and services. Over 190 individuals from 59 countries contributed to the dialogue … The Forum addressed 19 key questions related to six thematic areas.
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> 1. Policy approaches in eHealth standardization and interoperability
> 2. Successful policy interventions to overcome barriers in standards adoption
> 3. Governance, stewardship, equity and health systems integration of data standards and interoperability
> 4. Policy and statutory authority components
> 5. Regional perspectives on governance and stewardship of eHealth standardization
> 6. Essentials of a good policy framework for adoption of standards for interoperability of eHealth systems.

Patient Safety and Risk Management

From the *Institute for Healthcare Improvement (IHI)* perspective on patient safety and risk management (PS/RM): "It is now well known that medical errors in the United States result in an estimated 44,000 to 98,000 unnecessary deaths and more than 1,000,000 instances of harm each year. More specifically, a 13.5 percent level of harm was identified within the US Medicare population by the Office of Inspector General using the IHI's Global Trigger Tool, and a study conducted in North Carolina and published in the *New England Journal of Medicine* found similar results."

Within this IHI context, the linkage between clinical medicine PS/RM and medical devices is best articulated by ECRI Institute's annual *Top 10 Health Technology Hazards Report*. Besides identifying issues such as device-related alarm hazards and medication errors, the 2014 report notes Health IT challenges such as device *data integrity failures in EHRs and other Health IT Systems*, and *neglecting change management for networked devices/systems*. ECRI compiles this report by examining health technology-related problem reports from hospitals and health systems worldwide.

Device cybersecurity

The ability of modern medical devices to connect to multiple platforms and devices create more targets for infiltration and exploitation.

Consequences of cyber attacks:

(1) Disruption of patient care - devices connected to the internet malfunction due to malware and viruses, origins of the infection do not have to be medical device-specific;

(2) Loss of protected health information (PHI) - PHI contains sensitive personal information, healthcare organizations are attractive targets for phishing attacks.

Cybersecurity Importance:

(1) Healthcare organizations are required to protect their medical devices and IT systems; and
(2) consequences of cybersecurity breaches are dire. Here are some FDA MAUDE reporting examples discussed in the HIMSS 2014 presentation *Practical Cybersecurity for Medical Devices*, by Hampton and Sparnon.
   (a) Telemetry
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=3273711
   (b) Patient monitor
   www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=3239402
   (c) Parenteral nutrition mixer
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.cfm?MDRFOI__ID=1621627
   (d) Defibrillator
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.cfm?MDRFOI__ID=2390178
   (e) Bronchoscopy system
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=2224751

Patient and population health outcomes

Chronic conditions are the single largest expense you face when it comes to healthcare, accounting for 85% of every healthcare dollar.[19] What new Health IT and mHealth tools will be needed to assist improving individual patient and population health outcomes? One healthcare delivery system's approach to chronic disease management, also known as population care management, is shown at this link: http://businesshealth.kaiserpermanente.org/invest-in-health/award-winning-chronic-care/. Other examples are from HIMSS 2014 follow:

- One aspect of achieving desired outcomes is finding the *right mix of standardized quality measures*. The quality measurement and improvement cycle typically includes having the evidence-based clinical protocols, pharmaceuticals, and medical devices available. See the National Quality Forum presentation, *Envisioning the Future of Quality Measurement and Reporting: An Urgent Task,* by Christine Cassel, MD.
- Another emerging perspective on improving health outcomes was seen in *Patients: Converting Measurement Reporting to Improved Patient Outcomes,* by Carolyn Clancy MD, Pawan Gowal MD, and Eva Powell MSW, enabled by tools such as the VA's *Blue Button* that *increasingly engages veteran patients in reporting and partnering with their care team* to improve their health, including use of mHealth devices.
- Improved outcomes are also dependent of development of Health Information Exchanges (HIE); HIEs allow for fast, accurate transmission of electronic health data between doctors, hospitals, ERs, labs, and patients. Some day HIE's will be nationwide, with all care providers using EHRs for Exchange Interoperability and national eHealth standards.
  - Exchange Interoperability definitions:
    - Technical: The ability of 2 or more systems to reliably exchange human readable information
    - Semantic: The ability of information shared by systems to be understood
    - Process: Focuses on methods for the optimal integration of computer systems into actual work settings. One key aspect of HIEs will be identification of "providence" of EHR data, e.g., device data sources and accuracy.
  - HIEs in combination with mHealth device tools will particularly be important in *management of chronic diseases and improving population health.*

Conclusions

Just as electrical safety and patient safety helped define and launch the early clinical engineering and biomedical equipment technician fields, the new era of eHealth and the convergence of information and health technologies is transforming care and creating demands and opportunities for new workforce skills. A new generation of health technology and health IT workers is needed who understand clinical and information technologies that feed and interconnect EHR and device systems, the HIE, and ultimately the ever-more-mobile point and moment of personalized healthcare. BME/CEs can become a lynchpin for assuring safe, secure, and reliable data and information flow into the HIE for population health issues ... no matter where care occurs … outside the "four walls" of health locations!!!

The opportunity is clear: *With appropriate education, training, and credentials there is a pivotal leadership role open for BME/CEs in design, implementation, support and management of a growing portfolio of health-related technologies.*

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