Clinical Engineering, eHealth, and ICT Global Overview

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Disclosure: I have no conflict of interest with the materials provided.
My bio? An IEEE Senior member for nearly 45 years!!
HIMSS, AIMBE, & ACCE Fellow

"The Road Less Traveled"
Over Four Decades at the Convergence of Health Technology and Information Systems!

15 years in non-profit research, development, & independent testing, standards, and forensic investigation of medical technologies
   At ECRI Institute, from “bench” to CIO and COO
      - Worked with FDA on medical device standards
      - Computerized arrhythmia detection disclosure and apnea monitors
      - Forensic investigations of patient injuries and deaths
      - Breakthrough computer systems for medical device nomenclatures, “Hazard Reports,” feature comparisons, product directories, medical device maintenance, and safety assurance

10 years in a publicly-traded corporation, medical device manufacturing, repairs, 24x7 rental/delivery, and medical device and drug manufacturing and distribution
   At MEDIQ Life Support Services, from COO through CTO and CRO
      Registered with FDA as device and drug manufacturer
      Owned and managed a fleet of 500,000 medical devices nationwide

15+ years as a professor, consultant, businessman, and AAMI/ACCE/HIMSS/IEEE leader
   - CHIRP’s President and Founder, a non-profit focused on Medical Informatics, Health Systems Engineering, Medical Device Data Systems Research, Security and Privacy, Wireless Medical Devices, and Patient Safety
   - Serve AAMI, ACCE, HIMSS, IHE, and IEEE privacy, security, standards, and education committees

Ongoing Graduate instructor at Villanova and South University, PA and FL respectively,
A bit of history...

• USA’s FDA received regulatory authority for medical devices in 1975

• I began testing medical devices at ECRI in 1975, and investigated and published my first medical device-related death in 1976!

• I began advising WHO and PAHO on medical device management and safety on behalf of ECRI in 1978, the same year I also began running ECRI’s “computer department.”
  • Over the decades, I assisted WHO and PAHO in adapting US and European medical device, pharmaceutical, AND information technology regulatory programs to meet WHO Member State priorities

• I have been working and living at the intersection of clinical engineering, clinical technologies, and information and computing technologies (ICT) through the mainframe, minicomputer, PC, handheld, and wearable technology evolution!!!
Automated, secure data capture and exchange

Endoscopy since 2010
Pharmacy since 2009
Pathology since 2006

Eye Care since 2006

Quality Research & Public Health since 2006

Dentistry since 2012

Surgery since 2012
Radiology since 1998
Cardiology since 2004
Laboratory since 2004
Radiation Oncology since 2004

Mobile devices Under way for 2016!

(Healthcare) IT Infrastructure since 2003

Patient Care Devices since 2005

Patient Care Coordination since 2004
Now including home care devices, telehealth, and PHRs

User driven & vendor neutral; based on HL7, ICD, and similar global standards.

Look carefully: MOST Domains capture device AND workflow data; data transfer is accurate and near-immediate.
Low-cost, FDA-approved medical devices can now be apps-based, using inexpensive sensors and tablets.

WOW! Here are three examples of $30 USD medical devices that are FDA-approved, and work with any smartphone or tablet, and output data in simple Excel or PDF format! From more and more vendors, and sold in simple online stores like Amazon!
The traditional **C.I.A. Cybersecurity Triad** is NOT enough for healthcare; **Clinical security needs SAFETY assurance**!

- **Medical Device/System Safe Zone of Operation**
  - *Danger Zone*: e.g., Alarms that cannot reliably get through a wireless network fast enough, or if the network is compromised, reconfigured, etc.

- **Confidentiality**
  - *Danger Zone*: e.g., Inconsistent or incomplete drug interaction libraries, or wrong dosing rules (a la Dennis Quaid’s children).

- **Integrity**
  - *Danger Zone*: e.g., EMR system that cannot notify if a ventilator sensitivity setting is too low, turned off for too long, OR multi-vendor device message mapping is defective.
Nobel’s First Law: 
*The Conservation of Trouble*

First presented by my friend and mentor, Joel J. Nobel, MD, during his AAMI 2003 Dwight Harkin Award Speech

“Think of it as the engineers’ variant of the Legislators’ Law of Unintended Results. It simply states that *trouble is incompressible*. You *squeeze it here, and it oozes out there*. … first expressed … at US Senate Health Subcommittee hearings on medical device amendments in 1973. *It proved prescient in the early years of device regulation.*” (emphasis mine, E Sloane)
SO, Clinical Engineers are faced with a new paradigm:

HOW will CEs manage converged/converging clinical and ICT devices for patient diagnostics and therapeutics!

Challenges include:

1. Ensuring the clinical performance is accurate and patient safety is assured, regardless of updates to operating systems, hardware, and communication technologies!

2. Can existing CE or ICT procurement and life-cycle methods be merged?

3. Who ensures devices are used correctly (e.g., BP w/o clothing interference)?

4. Who ensures the right data is recorded/matched to the right patient?!?

5. WHO VALIDATES entire systems of devices and ICT tools after updates, maintenance, and repairs occur.

6. **Will separation of ICT and medical device responsibility REALLY be possible??**
Open discussion forum - GLOBAL perspectives!

- How are you and your colleagues preparing for these challenges?
- What education/training/tools do you need?
- How can “legacy,” stand-alone devices simultaneously be supported?
- What computerized inventory and management tool enhancements are needed?

- How does cybersecurity and privacy fit into the whole picture?
THANK YOU!

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