Medical Device Interoperability

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Agenda

- The FDA and the definition of medical device
- The scope of the medical device interoperability issue, including the regulatory aspects,
- The current standards environment,
- Why and how this affects nurses and patients,
- What needs to be done,
- What is being done and by whom, and
- Suggestions for nursing involvement.

Photo courtesy of Julian M. Goldman, MD, MGH/CIMIT

FDA and Medical Devices

- In the US, medical devices regulated by FDA/CDRH
  - Title 21 CFR
  - Regulated based on risk and intended use
- FDA definition : "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar article that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease."
- Over 101,000 devices on the FDA listing in 5267 generic product categories
- Does not require manufacturers to follow standards, but has a list of recognized standards
- Does not require devices to be interoperable

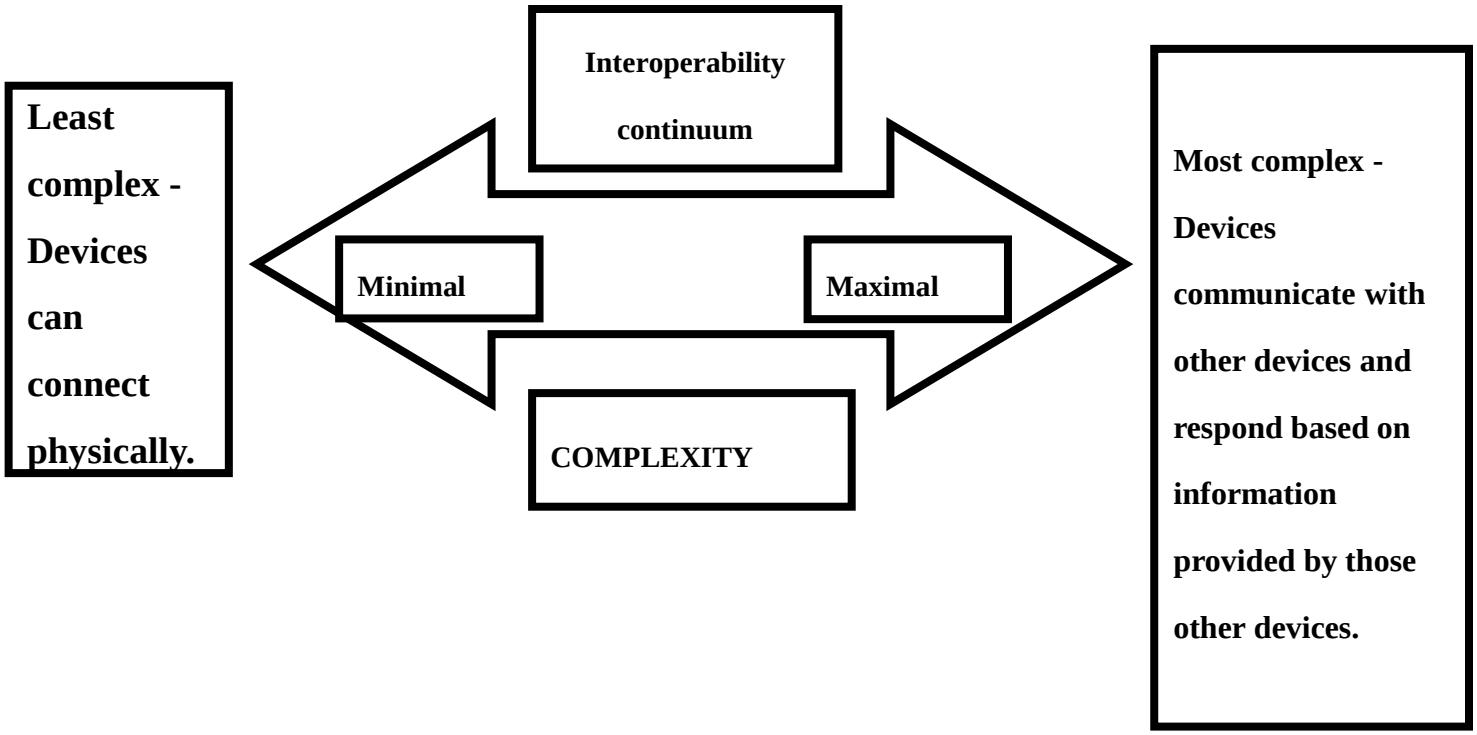
Medical Device Standards Development Organizations

- Lots of standards for general safety and individual devices from multiple SDOs, for example:
  - AAMI - Association for Advancement of Medical Instrumentation
  - ANSI - American National Standards Institute
  - CEN - European Committee for Standardization
  - IEC - International Electrotechnical Commission
  - IEEE - Institute of Electrical and Electronics Engineers
  - ISO - International Organization for Standardization
  - NEMA - National Electrical Manufacturers Association
  - UL – Underwriters Laboratories, Inc.
- Although not an SDO
  - 21 CFR – Code of Federal Regulations

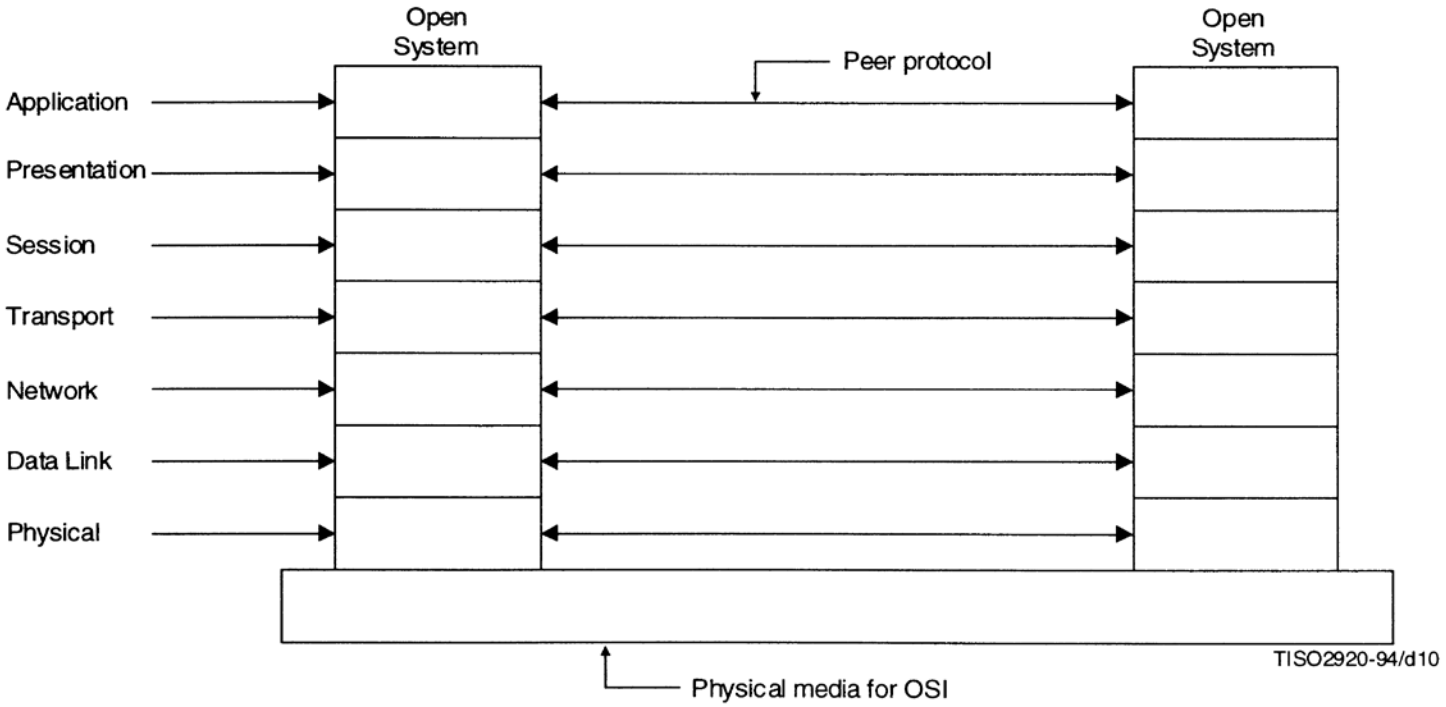
Medical Device Interoperability Standards

- ISO/IEEE 11073 - Health informatics - Point-of-care medical device communication
  - Five parts published by ISO
  - Two parts in development
- CANopen – Controller Area Network open standard
  - A.K.A. EN 50325-4
  - Not specific to medical devices
- IEC 60601-1-10 General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers
- In development by ISO/IEC TC 121 – Medical Devices and Medical Systems – Basic safety and essential performance of the patient-centric integrated clinical environment – Part 1: General requirements for network control

What is interoperability?



ISO/IEC 7498 – Open Systems Interconnection Reference Model



Why are medical devices NOT interoperable?

- There is no incentive for device manufacturers to interoperate with other manufacturers' devices.
- There is a scarcity of acceptable medical device interoperability standards and the existing protocols are complex.
- The healthcare sector, in general, has been lagging behind other industries with respect to computerization and networking.
- Interoperability solutions face complex technical and social problems, including liability and regulatory issues.

What happens if medical devices are not interoperable?

- Patient safety is compromised
- Documentation is incomplete and/or inaccurate

- If device interoperability is desired and no standards are available
  - Vendor lock-in
  - Increased costs for interface development

Impact for nursing (and patients)

- Improved patient safety
- Improved documentation
- Improved workflow
- Improved quality of care
- Reduce clinical errors
- Reduce litigation
- Lower insurance costs
- Improve reliability of data within EHRs and other electronic documentation records
- Improve data quality to research standards
- Assist clinical decision support
- Ability for remote monitoring

Goal

- Interoperability standards that are:
  - Open
  - Easily accessible
  - Unencumbered by excessive fees and/or licenses
  - Intelligible
  - Implementable
  - Simple as possible
  - Extensible

Not ignored, just neglected

A few groups are working on the medical device interoperability issue:

- **Medical Device Plug and Play**
- **Continua Alliance**
- **Integrating the Healthcare Enterprise – Patient care devices domain**
- **ISO/IEEE/HL7/IHE**
- **Brief mention in Emergency Responder-EHR use case**
  - "may include information feeds from automated medical devices such as blood pressure monitors"
  - Development of Interoperability Specification for this use case May-June, public comment period July 20-August 16
- **No mention in any of the three 2007 use cases from AHIC**

What can you do?

- Push for interoperable devices
- Push for medical device interoperability standards
- Participate in standards development
- Provide medical device interoperability use cases to AHIC/ONC
- Provide use cases to vendors
- Provide use cases up your organizational hierarchy
- Make the case for improving patient safety
- Make the case for decreasing costs
- SPEAK UP

Thank you for your attention

References available upon request

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