Secrets of successful medical device connectivity

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Agenda

* The secrets:
  * All medical devices *shall* be connected
  * You *shall* understand the requirements requirements
* Wandering and wondering the wide world of wireless
* Two keys/pleas from me
* Q&A

All medical devices *shall* be connected

* Why?
* Where?
* How?

All medical devices *shall* be connected – Why?

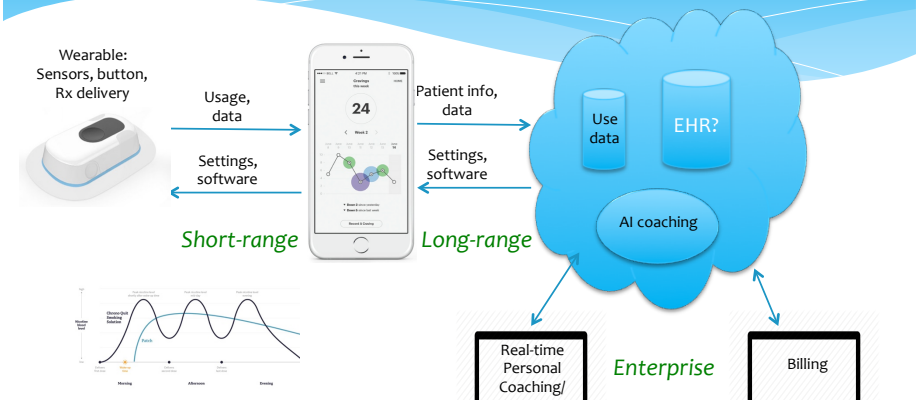
* Replace wired connections
  * Mobility/safety
  * Data collection
* Telemedicine
  * Remote consultation & review (*photo*)
  * Home Health
  * Aging in Place
* Health and Fitness
* Cloud connectivity
  * Electronic Health Record (EHR)
  * Big Data analytics

Emergency!
1972-1977

All medical devices *shall* be connected – Where?

- Classic answers:
  - Hospital
  - EMS
  - Home
- Real answers:
  - Starbucks
  - 37,000 feet
  - Stuck on I-5
  - In the bathroom
  - In the elevator
- Real environments require creative solutions for connectivity

Example: Chrono Therapeutics Technology + Psychology



Photos and information obtained from www.chronothera.com

How: Understand the requirements requirements for connectivity

* Too many times we come up with the answer before the question (42)
  * Connectivity doesn't *make* the product
  * Connectivity *enables* the product
  * Behavior modification: Technology can not directly address Psychology
* Understanding the use model is essential for connectivity decisions
  * Users – note the 's'
  * Environment – home, Starbucks, hospital, EMS, airplane, …
  * International
* Requirements to consider for mobility
  * Power management and charging – batteries, batteries, batteries!
  * Body proximity – antennas, antennas, antennas!
  * BYOD (Bring Your Own Device)

Wandering and wondering in the wide world of wireless

* Two real choices for short range
  1) WiFi
  2) Bluetooth
* Multiple flavors of Cellular for long range (nG, low rate)
* Everything else
  * MICS (Medical Implant Communication System)
  * MBAN (Medical Body Area Network)
  * ZigBee, Thread (802.15.4)
* Heresy: remember that a wire can still be a good thing
  * Remember to consider/compare the wired experience

How to choose?

- Go back to your requirements and environment!
  - If you need long-range, independent connectivity → cellular
  - If you're in hospital and need EHR connectivity → WiFi
  - For anything else → Bluetooth
    - Full disclosure: I'm a Bluetooth geek…
- Right, now which flavor of Bluetooth?
  - Bluetooth classic if
    - Audio
    - High-rate streaming
    - Long range
  - For now… Bluetooth 5 provides for those needs if you can wait

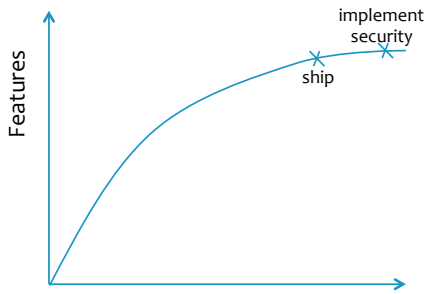
The dual-edge of standards

- The issues:
  - Is there real compatibility?
  - Marketplace – is compatibility an asset or a liability?
  - Regulatory and testing
- Wireless standards bodies
  - Bluetooth SIG – legal requirement
  - WiFi Alliance – marketplace requirement?
- Industry compatibility specifications
  - AAMI – primarily for in-hospital devices
  - Continua Alliance
  - Bluetooth SIG
    - Bluetooth Transcoding Whitepaper
    - Health/medical profiles – use them if you wish
    - With Bluetooth low energy you can make your own
- Medical regulatory *requirements*
  - FDA
  - European regulations (and what about the UK?)
  - Other country specific requirements

Continua
HEALTH ALLIANCE

My pleas – Please!

* Design for regulatory
  * Understanding testing requirements
    * Real-world environment based
    * Interoperability/compatibility
  * Design-in testability features
* Design for security
  * Security as part of hazard analysis & mitigation
  * Don't do this →



Summary

* The true secrets are in Understanding and Planning
* Understand where and how connectivity benefits/ enables your system
* Understand the use models
* Pick the technology and system components based on the requirements, not the cool-factor
* Design-in for regulatory and security up front

Q&A

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Backup slides and reference material

Notes on requirements

- Extract requirements, not solutions
  - Yes: "battery powered", "disposable", "body-worn using adhesive", "interface to smartphones"
  - No: "Bluetooth low energy"
- Identify Interoperability and Compatibility
  - Medical device interoperability – how does it operate/interface to other systems or devices
  - Infrastructure – "shall connect using in-hospital wireless infrastructure"
  - Information systems – "shall support data flow to EHS including Cerner and McKessen"
- Identify Obsolescence and technology life cycle
  - Consider mismatch between Medical Device lifecycle and Wireless technology lifecycle
  - "shall be maintained for 5 years of sales, 10 years of support"
- Consider CyberSecurity
  - "shall comply with HIPAA"
  - "shall support US VA sales" (eg: FIPS 140-2 specification requirement)
- Identify Country-specific regulatory requirements
  - "shall support sales to the following countries"
  - Good to include these in groups – initial countries, 2nd wave, 3rd wave, …

Recommended FDA guidance

- FDA landing page for Digital Health
  - http://www.fda.gov/medicaldevices/digitalhealth/
- General Wellness: Policy for Low Risk Devices
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429674.pdf
- Mobile Medical Applications
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf
- Radio Frequency Wireless Technology in Medical Devices
  - o http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077272.pdf
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices
  - http://www.fda.gov/downloads/MedicalDevices/…/ucm073779.pdf
- SOFTWARE AS A MEDICAL DEVICE (SAMD): CLINICAL EVALUATION (draft)
  - http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm524904.pdf
- Enforcement discretion
  - http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368744.htm

Selected Cybersecurity References

- Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf
- Postmarket Management of Cybersecurity in Medical Devices
  - http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm482022.pdf
- NIST: Cybersecurity Practice Guide, Special Publication 1800-1: "Securing Electronic Health Records on Mobile Devices"
  - https://nccoe.nist.gov/projects/use_cases/health_it/ehr_on_mobile_devices
- NIST: Guide to Bluetooth Security
  - http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-121r1.pdf
- ISO 14971:2007 Medical devices -- Application of risk management to medical devices
  - http://www.iso.org/iso/catalogue_detail?csnumber=38193
- HHS: Your Mobile Device and Health Information Privacy and Security
  - https://www.healthit.gov/providers-professionals/your-mobile-device-and-health-information-privacy-and-security
- Archimedes – Ann Arbor Research Center for Medical Device Security
  - https://secure-medicine.org
- BITAG: Internet of Things (IoT) Security and Privacy Recommendations
  - http://www.bitag.org/documents/BITAG_Report_-_Internet_of_Things_(IoT)_Security_and_Privacy_Recommendations.pdf

AAMI

- TIR57: Principles for medical device security—Risk management
  - https://standards.aami.org/kws/public/projects/project/details?project_id=876
- TIR59: Risk Assessment of radio-frequency wireless coexistence for medical devices and systems
  - https://standards.aami.org/kws/public/projects/project/details?project_id=1114
  - AMSI C63.27

Bluetooth SIG

* Transcoding (and other) Whitepapers: https://www.bluetooth.com/develop-with-bluetooth/white-papers

The 2.4 GHz world…