How to Design a Wireless Medical Device In Two 'Easy' Steps: Step 1: Establishing The Requirements

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Agenda

- Who am I?
- Why two sessions?!
  1. Establish requirements for the device/system
  2. Choose the technology (Phil Raymond)
- Examine ways to define the device/system
- Explore usage scenarios that take into account existing technologies, the regulatory environment, and data needs
- Map the scenarios to the necessary requirements
- Establish the framework based on the essential requirements for Wireless Technology

Define the device/system

- The big question: what is it?
  - Too many times we come up with the answer before the question (such as 42 – *Hitchhiker's Guide*)
  - It is essential to have the context for technical requirements
- High level device/system attributes
  - What problems should it solve?
  - What is it supposed to do?
  - Who/what is the competition?
  - Who will pay?
    - *<u>Not</u> part of this presentation, but very important*)

Is it 'Medical' or 'General Wellness'?

- Is it a Medical Device?
  - *"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:*
  - *recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,*
  - ***intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man** or other animals, or*
  - *intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."*
- It doesn't matter whether it is implemented in hardware or software
  - If it is a medical device, it needs to be Approved or Cleared by the FDA and international regulatory agencies
- It *may* be an MDDS…
- *And* there is 'enforcement discretion'… See references.

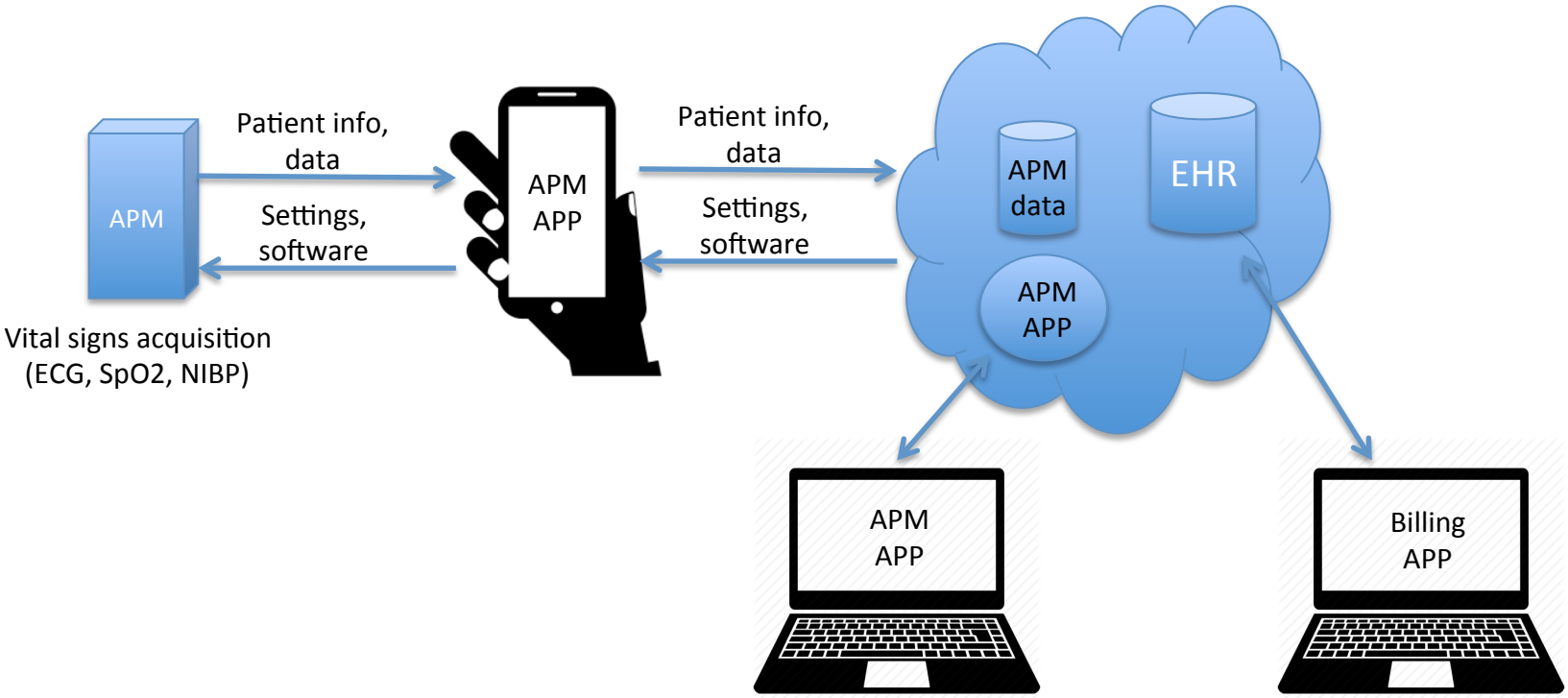
Usage questions generate requirements

- Who is going to use it?
  - Patient
  - Care giver
  - Service/support
- What
  - Data is collected and communicated?
  - Communication technologies exist in the environment?
  - Timing is required for the system data?
- Where is it going to be used?
  - US/international (market affects technology both for regulatory and existing infrastructure)
  - Home
  - Hospital
  - Airplane
- How is it going to be used?
  - Mobile
  - Wearable
  - Bedside

Example: “Home Ambulatory ECG”

- Build a set of scenarios
  - Story Boarding
  - Day-in-the-life
- One example; likely will have several
  - Ms. Smith presented with an MI and is being discharged from hospital after treatment. Home observation is prescribed for ECG rhythm issues as well as adjusting medications for comorbidities (hypertension, diabetes).
    - Post-cardiac follow up after MI
    - MD prescription, administered by home health agencies
  - Questions:
    - What is the patient use timeframe?
    - Will the system be disposable or returnable?
  - Home use and cardiac rehabilitation
    - Increasing patient capability increases usage environments and scenarios
  - Uses patient-provided smartphone app for data communication?
  - How will home health review/monitoring of data?
  - Alert system if issues/concerns?

Home Ambulatory Patient Monitor system architecture for connectivity requirements



To establish 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, …

Ambulatory ECG example requirements

- General: “battery powered”, “disposable”, “body-worn using adhesive”, “interface to smartphones”
- ECG Quality: “shall provide diagnostic quality ECG capable of determining heart rhythm disorders”, “shall provide pacemaker pulse timing”
- Infrastructure: “shall connect using existing in-hospital wireless infrastructure” and all the requirements that come with it
- Information systems: “shall support data flow to EHS including Cerner and McKessen”
- Support: “shall be maintained for 5 years of sales, 10 years of support”
- “shall comply with HIPAA”
- “shall implement appropriate cybersecurity protocols and techniques”
- “shall support US VA sales” - FIPS 140-2

Establishing a wireless framework

- Essential requirements for Wireless Technology
  - FCC & global RF approvals
    - Intentional radiators are not exempt for in-hospital
    - "shall be appropriately approved and/or listed with required govenrnmental standards bodies"
  - Technology standards bodies
    - Eg: Bluetooth SIG, WiFi Alliance
    - "shall meet be tested and listed with appropriate industry standards bodies"
    - Give requirements and guidelines on what is appropriate; what is required and consider what is not
    - Note: Bluetooth is required, but is WiFi Alliance? Is Continua?
- Be careful not to over-constrain (include *only* necessary requirements)

Requirements drive specifications and contribute to technology choices

- 'diagnostic quality ECG'
  - resolution, sampling rate
  - → bit rate
- 'real time data'
  - how real is required; is 100mS latency OK? is 1S OK?
  - → data transmission latency
- 'battery powered'
  - how long? What is the weight/size limitation for batteries?
  - →technology input
- 'home use'
  - is this strictly inside the home?
  - Can it be a store/forward data model or does it need to be 'always connected'?
  - → technology input and short range vs long range technology input

Stay tuned, Part II is coming right up!

- Q&A if time allows

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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

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

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