OPHTHALMIC DIGITAL HEALTH WORKSHOP

Accelerating Innovation To Encourage New Frontiers in Ophthalmic Digital Health

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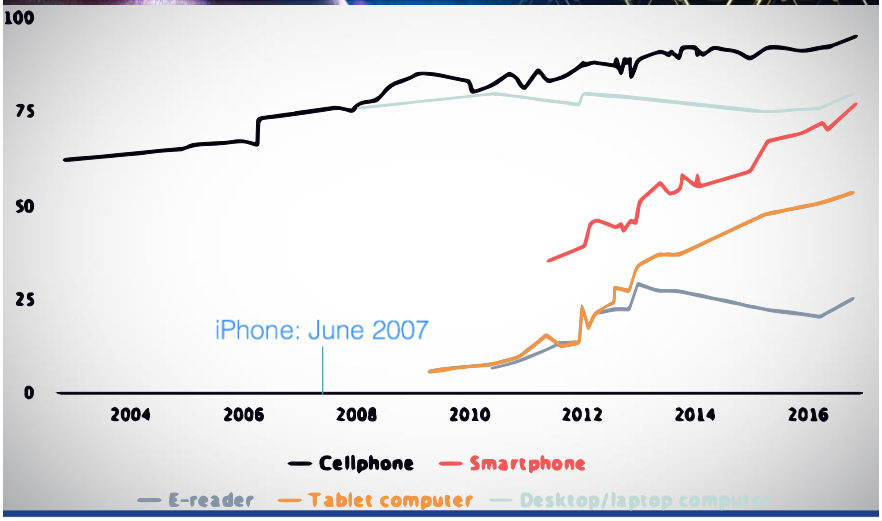
Smartphones and similar mobile devices are nearly ubiquitous



Mobile devices are great medical device platforms

- Powerful computing platforms
- Hardware for advanced image processing
- High-resolution photo, video, and audio capture
- Biometric sensors
- Accelerometer/gyroscope
- Wireless communication
- Flexible, dynamic user interfaces
- Accessibility
- Rapid development and deployment

Medical devices are becoming part of the "internet of things"

- Previously non-digital medical devices are becoming embedded with "smart" technology
  - Wireless connectivity:
    - Bluetooth
    - Wifi
  - Microprocessors
  - Paired applications

What is digital health technology?

- The Federal Food, Drug and Cosmetic act defines a medical device as:
  - not a drug
  - intended for diagnosis, treatment or prevention of disease
- Software, by itself, can meet this definition
  - Software as a Medical Device (SaMD) is defined by International medical device regulators forum (IMDRF) *as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."* http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.docx
- A consumer computing devices becomes a medical device if it meets this definition using:
  - Apps
  - hardware extensions
- Embedded software (e.g. automated perimetry with normative database)

Digital health has great potential

- Telemedicine
- Personalized health data collection
- Home health care
- Disease monitoring
- Innovations for:
  - Screening
  - Diagnosis
  - Management

Challenges for digital health technology

- Understanding what makes a digital health technology a regulated device
- Safety considerations of unmodified hardware (e.g. light hazards)
- Interoperability and wireless coexistence
- Setting (hospital, clinic, OR, ED, school, pharmacy, home)
- Intended users: patients vs. practitioners
- Intended use: diagnosis, treatment, prevention vs automation, clinical decision support
- Small changes can have profound consequences in safety, efficacy and user interactions

Challenges of privacy and cybersecurity

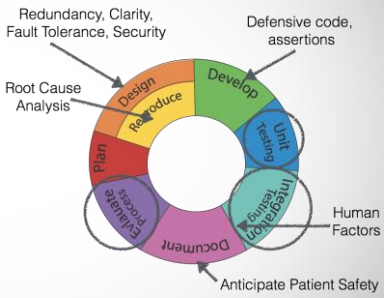
- HIPAA Compliance
  - Institutions may limit access to data from mobile devices
- Data Encryption
- OS Updates and Responses to Security Flaws
  - End-user is responsible for installing updates
  - Developer is responsible for ensuring data security and safety

Digital health and the practice of medicine

- Telemedicine
  - Non-physician users: technicians, photographers, reading centers
  - Where is there a need for oversight?
  - Is synchronous real-time communication necessary?
- Patient self use
  - Performance of the device in the hands of unskilled users
  - Patterns of misuse, errors and associated risk

Strategies for risk mitigation

- Restrict installation to validated configurations (impossible to test all permutations)
- Establish robust quality assurance frameworks
  - Include testing for safety and effectiveness
  - Logging
- Acknowledge the importance of human factors
  - UI/UX design and changes
  - Documentation
  - Clear error reporting



Advantages of digital health technology

- Brings technology to the point of care and improves access
  - e.g. mobile fundus photography, refraction
- Improves efficiency and provides automation
- Streamlines communication between patients and providers
- Gain insights into health states between clinic visits
  - e.g. home IOP monitoring
- Network connectivity provides insight into device performance in the real world
  - Enables real-time monitoring of safety signals and rapid turnaround of fixes

Where to get help

- FDA Guidance:
- https://www.fda.gov/MedicalDevices/DigitalHealth/default.htm
- FDA presubmission program: http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf
- Digital health mailbox: digitalhealth@fda.hhs.gov

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