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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References