FDA Virtual Public Workshop - Transparency of Artificial Intelligence/Machine Learning-enabled Medical Devices

October 14, 2021

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About the Connected Health Initiative

- Not-for-profit multi-stakeholder consensus advocacy effort to advance uptake of digital health tools widely

- Intersection of medical/health and technology communities:
  - Reimbursement/payment
  - Privacy/security
  - FDA regulation of digital health
  - Health data interoperability
  - The role of AI/machine learning in care delivery

- Advocate before Capitol Hill, US agencies, European Commission, OECD/UN, etc.

- Active in key public-private initiatives (Health Sector Coordinating Council, etc.)
About the Connected Health Initiative
CHI Health AI Task Force

- Formed in 2019, an open and collaborative effort to proactively advocate for the responsible deployment of AI in the healthcare sector.

- **Deliverables so far:**

- April 2021 public roundtable on improve AI transparency and explainability for caregivers and patients
A shared responsibility amongst:

- Developers of AI SaMD
  - Prioritize making healthcare AI solutions safe, efficacious, and equitable from the earliest stages of design (“____ by design”)
  - Demonstrate repeatable results, auditble and validated using rigorous procedures, monitoring
  - Appropriately scaled privacy protection mechanisms
  - Tailored communications and engagement plan

- Providers and payers
  - Tailored communications and engagement plan
  - Resources for patients that explain the clinical testing of AI applications
Explainability and Transparency in Health AI

- A shared responsibility amongst:
  - FDA
    - Continue development of comprehensive regulatory approach to AI
    - Evolve its requirements on reporting type and frequency
    - Enhanced public communications re legally-marketed AI
    - Coordination of federal government
    - IMDRF leadership
  - CMS
    - Continued development of Medicare support mechanisms for the use of AI
    - Medicare beneficiary communication
  - FTC
    - Educate (& enforce where necessary) re biases or other unfair outcomes from healthcare AI
Explainability and Transparency in Health AI

- A shared responsibility amongst:
  - Accrediting and Licensing Bodies, and Medical Specialty Societies and Boards
    - Development of medical standard of care and ethical guidelines
    - Development and education on the responsible deployment of SaMD AI (incl for specialty-specific uses)
  - Academic and Medical Education Institutions
    - Develop and include curriculum that will advance understanding of and ability to use health AI solutions

- Next step: finalize CHI AI Task Force recommendations (~1-2 months!)
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