



ConnectedHealth

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

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Connected Health Initiative

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



ConnectedHealth

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:*
 - CHI Health AI Policy Principles: <https://bit.ly/3m9ZBLv>
 - CHI Proposal to International Telecommunications Union & World Health Organization, 'Essential considerations for policymakers addressing the role of Artificial Intelligence in healthcare': <https://bit.ly/3CZCCtg>
 - CHI Position Paper, 'Why AI? Considerations for Use of Artificial Intelligence in States' Medicaid and CHIP Programs': <https://bit.ly/2Y2FJle>
 - CHI Good Machine Learning Practices for FDA-Regulated AI: <https://bit.ly/2YaYljk>
- April 2021 public roundtable on improve AI transparency and explainability for caregivers and patients

Explainability and Transparency in Health AI

- *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, auditable 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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