ConnectedHealth

Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem

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Executive Summary

Today, the most well-known FDA-approved applications of artificial intelligence and machine learning (AI/ML) technology in healthcare are diagnostic tools that help clinicians read and interpret images to predict, detect, and monitor a number of diseases, including diabetic retinopathy and lung cancer. In the future, the use of AI/ML technology in both operational and clinical settings promises to enable a more proactive approach to healthcare that promotes investments in preventative care that can result in fewer hospitalizations, fewer doctor visits, and fewer treatments. Across use cases, AI/ML technology is helping, and must increasingly help, the healthcare industry move away from a reactive disease treatment approach to a population health management approach that lowers costs and improves care.

The immense potential of AI/ML technology in healthcare may never be fully acheived, however, unless AI/ML technologies first earn the trust of healthcare professionals and patients. The cornerstone of building trust in AI/ML technologies is to enhance transparency – providing sufficient and appropriate information about the AI/ML, including its intended use, development, performance, and, when available, logic. The more understandable the decision-making process is for each individual technology, the more confidence there will be in AI/ML use in the healthcare system.

The recommendations in this Connected Health Initiative (CHI) AI Task Force report, informed by a public roundtable CHI held to address AI/ML transparency and extensive consultations with stakeholders from across the digital health ecosystem, represent a holistic approach to creating and maintaining the trust of both healthcare professionals and patients. The Task Force set out the foundational steps AI/ML tool developers must take to build transparency into their products, but it also outlines the important roles that clinicians, healthcare providers, regulators, academic medical institutions, and accrediting organizations must play.

The medical and technology communities have a shared responsibility to provide caregivers and patients (as well as other stakeholders) with an assurance of quality through truthful representations clearly indicating the AI/ML's intended uses and risks that would be reasonably understood by those intended and expected to use the AI/ML. Uptake will depend on the buy-in of clinicians who first develop trust in AI/ML software as a medical device (SaMD) through use and experience, establishing confidence as it is adopted into practice. Once adopted, clinicians can then work with their patients to explain their use of SaMD AI/ML and inspire the same trust and confidence from the patients in the output of the SaMD AI. Each step in this chain requires buy-in and support from policymakers (both within and outside of government).

The foundation of any successful use of AI/ML technologies in healthcare depends on the trust of healthcare professionals and patients, and we believe these recommendations present a clear path toward earning that trust.

About the Connected Health Initiative

CHI is the leading multistakeholder policy and legal advocacy effort driven by a consensus of stakeholders from across the connected health ecosystem. We aim to realize an environment where Americans can improve their health through policies that allow for connected health technologies to enhance health outcomes and reduce costs. Having members who are developers and users of connected health technologies across a wide range of use cases, CHI serves as an active advocate before Congress, numerous U.S. federal agencies, and state legislatures and agencies. We seek to advance responsible pro-digital health policies and laws in areas including reimbursement and payment, privacy and security, effectiveness, and quality assurance, U.S. Food and Drug Administration (FDA) regulation of digital health, health data interoperability, and the rising role of artificial intelligence and machine learning (AI/ML) in care delivery.

In 2019, CHI formed a Task Force focused on policy challenges and opportunities related to the use of AI/ML in healthcare. CHI's AI/ML Task Force already developed a set of health AI/ML policy principles addressing how policy frameworks should adopt the role of AI/ML in healthcare.[1] A cornerstone of these principles is the idea of requiring those developing, offering, or testing healthcare AI/ML systems to provide truthful representations clearly indicating the intended use and risks that would be reasonably understood by those intended and expected to use the AI/ML solution. Such steps will provide much-needed quality assurances to caregivers and patients (as well as other stakeholders) and assist in resolving data issues that arise when an algorithm is fed bad data that can skew its learning and introduce bias. CHI's AI Task Force later developed detailed Good Machine Learning Practices for FDA-regulated AI,[2] which reflect and elaborate on this priority. The recommendations in this paper build on those deliverables.

Numerous CHI Steering Committee members and other key stakeholders from throughout the healthcare value chain participate in this Task Force and share a commitment to realizing the value of AI/ML in healthcare while protecting patient safety and advancing the quadruple aim. The recommendations in this paper find basis in an evaluation by the Task Force of the healthcare ecosystem's implementation of AI/ML to date, challenges and opportunities reflected by federal policymakers, and the existing and emerging issues created by AI's deployment. This report is also informed by a CHI public roundtable held in April 2021 on how to improve AI/ML transparency for caregivers and patients based on their needs and concerns, during which a wide range of stakeholders contributed to a discussion exploring novel approaches to transparency of AI/ML taken today.

For more information, please visit www.connectedhi.com.

1 https://actonline.org/wp-content/uploads/Policy-Principles-for-AI.pdf.
2 https://bit.ly/3B6nslm.

Artificial Intelligence's Role in a Successful Healthcare Ecosystem Requires Transparency

Responsible implementation of AI/ML in healthcare leads to improved medical outcomes and overall increased cost savings

Today, there are many important operational and clinical AI/ML solutions in use and many more in development.[3] Some of the most well-known applications of AI/ML in healthcare that have received market clearance from the FDA are diagnostic tools that help clinicians read and interpret images. For example, AI/ML image analysis software can assist clinicians in predicting, detecting, and monitoring a number of diseases, including diabetic retinopathy, lung cancer, prostate cancer, and skin cancer. Such AI/ML uses are generally intended to be used to assist human clinicians in providing more efficient and accurate results, rather than autonomously diagnosing disease.

Separately, research projects within and outside of clinical settings continue to further explore AI's potential to revolutionize healthcare. For example, an AI/ML system developed by researchers at Northwestern University's Feinberg School of Medicine correctly identifies small lung cancer tumors nearly 95 percent of the time, while radiologists undertaking the same task unassisted are correct only 65 percent of the time.[4] Researchers at Carnegie Mellon developed a miniature mobile robot called HeartLander that uses machine learning algorithms to make treating ventricular fibrillation (VF)—a deadly type of cardiac arrhythmia that requires cardioversion and then, if the patient survives, surgical removal of faulty heart tissue—far safer and less invasive.[5]

As a recent research paper discussing challenges related to deployment of AI/ML technologies into the clinical setting stated, "the success of a deep learning model does not rest solely on its accuracy."[6]The researchers noted that clinician "experiences with the system, and the socio-environmental factors that impacted system performance" must be evaulated and addressed for these systems to function in the clinical setting with the accuracy rates illustrated in the lab setting.[7] Clearly, if the challenges of integrating AI/ML tools into clinical workflow can be overcome, AI/ML can support clinicians in a wide range of other areas. Its potential to reshape the healthcare landscape is profound, especially in the improvements it can bring to any process within healthcare operation and delivery.

Medical devices and systems that use AI/ML also represent a real opportunity to drive down healthcare costs for consumers, practitioners, and healthcare businesses alike. It is estimated that AI/ML applications can cut annual U.S. healthcare costs by $150 billion by 2026.[8] Most of these cost reductions stem from changing the healthcare model from a reactive to a proactive approach, focusing on health management rather than disease treatment. This focus on using AI/ML as an investment in

3 The FDA now publicly lists AI/ML medical devices cleared for marketing in United States, and includes their intended uses. *See* https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices.
4 https://www.nature.com/articles/d41586-020-03157-9
5 https://onlinelibrary.wiley.com/doi/10.1002/rcs.2297
6 Emma Beede et al, A Human-Centered Evaluation of a Deep Learning System Deployed in Clinics for the Detection of Diabetic Retinopathy, CHI Conference on Human Factors in Computing Systems (April 2020) available at https://dl.acm.org/doi/fullHtml/10.1145/3313831.3376718.
7 *Id.*
8 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7325854/.

preventative care can result in fewer hospitalizations, fewer doctor visits, fewer treatments, and thus fewer side effects. AI-based technology will have an important role in helping people stay healthy via remote monitoring technologies and coaching and will ensure earlier diagnosis, tailored treatments, and more efficient follow-ups.[9]

For example, AI/ML image analysis technologies can reduce medical expenses in several ways. For one, AI/ML systems can be very helpful in augmenting a clinician's analysis and treatment decisions more quickly. AI/ML technologies enable clinicians to provide the same, accurate service in a fraction of the time, increasing the volume of patients without increasing time spent treating them.[10] Second, a patient whose disease is diagnosed early will pay less to treat or cure the disease than one who catches it later. The longer a disease goes undiagnosed, the more damage it causes and more resources it takes to treat, assuming it remains treatable at all. Wearable technologies that use AI, such as remote monitoring technologies, increase access to healthcare and increase engagement in treatment plans by, for example, analyzing user health data in real time and notifying wearers or their healthcare providers (or both) of potential health issues.

By introducing new, accurate, and timely data streams for human clinicians' review, AI/ML medical tools and systems that use wearable technologies can enable practitioners to come up with care and treatment options without having to see a patient in person as much, reducing administrative and in-office visit resource expenditures, and, during outbreaks of communicable diseases, at lower risk of infection to both provider and patient. The use of such technologies will also enhance patient engagement in their own care plans. This same concept also applies to laboratory technologies that use AI/ML systems, where the work hours currently required for repetitive and routine tasks could see drastic reductions, significantly cutting labor costs.[11]

Increased efficiency, precision, and affordability are just some of the benefits that AI/ML can offer the healthcare community and those they serve, but realizing these benefits will depend on the buy-in of the provider and patient communities as well as support for responsible deployments from policymakers. CHI's AI/ML Task Force released detailed policy principles,[12] as well as proposed good machine learning practices for AI/ML meeting the definition of a medical device,[13] to address these challenges. Notably, CHI's AI/ML Task Force has acknowledged that without its processes being understandable by humans and transparency (providing sufficient and appropriate information about the AI/ML, including its intended use, development, performance, and, when available, logic), particularly for patients and caregivers, AI/ML cannot most effectively improve healthcare. Namely, those developing, offering, or testing healthcare AI/ML systems must provide truthful and understandable representations regarding intended use and risks that would be reasonably understood by those intended, as well as expected, to use the AI/ML software as a medical device (SaMD) solution.

9 *Id.*
10 *See* McPhail et al, Stage at diagnosis and early mortality from cancer in England (Br J Cancer 2015), doi: 10.1038/bjc.2015.49.
11 Rong, et al, "Artificial Intelligence in Healthcare: Review and Prediction Case Studies," Engineering, doi: 10.1016/j.eng.2019.08.015 at Sec. 2.2.
12 https://actonline.org/wp-content/uploads/Policy-Principles-for-AI.pdf.
13 https://bit.ly/3B6nslm.

How Can Transparency into Healthcare AI/ML Solutions be Advanced?

While evidence of healthcare AI's potential for widespread benefit continues to build, that potential can never be realized without healthcare professionals and patients understanding and trusting AI/ML solutions. The more transparent the decision-making process is for each individual technology, the more confidence there will be in AI/ML use in the healthcare system.[14] Transparency for healthcare AI's intended uses must happen at several levels, disseminating tailored messaging to specific audiences that require insights into the AI/ML solution to make informed decisions. Building the trust that must be a foundation for the responsible deployment of AI/ML is a shared responsibility amongst developers, providers, and regulators.

Providing transparency into health AI/ML must start with the developers of the AI/ML tools. Then, uptake of AI/ML will need to be built on the buy-in of clinicians who first develop trust in AI/ML SaMD through use and experience, establishing confidence as it is adopted into practice. Once adopted, the provider can then work with his or her patients to explain their use of SaMD AI/ML and inspire the same trust and confidence by the patient in the output of the SaMD AI. Each step in this chain requires buy-in and support from policymakers (both within and outside of government).

The CHI AI/ML Task Force's recommendations for enhancing transparency for health AI/ML include:

Developers of AI/ML SaMD should:

- Prioritize making healthcare AI/ML solutions reasonably safe, efficacious, and equitable from the earliest stages of design, considering the perspectives of both patients and providers, leveraging and where necessary tweaking medical AI/ML guidelines on research and ethics,[15] leading standards,[16] and other resources as appropriate.
- Employ algorithms that produce repeatable results and, when feasible, are auditable, and make decisions that, when applied to medical care (such as screening, diagnosis, or treatment), are clinically validated and where possible understandable using rigorous procedures with documented methods and results, fostering efficacy through continuous monitoring.
- Rigorously identify, disclose, and mitigate biases in datasets used to train algorithms.
- Utilize risk-scaled privacy protection mechanisms for patients' data to account for the fact that the analysis by health AI/ML tools provides greater potential utility of those data items to other individuals, entities, and machines, providing many new uses for, and ways to analyze, the collected data, as well as correspondingly stronger incentives for malefactors to attempt to obtain access unlawfully. Specific uses of data that require additional safeguards (such as genomic

14 https://www.bsigroup.com/globalassets/localfiles/en-gb/about-bsi/nsb/innovation/mhra-ai-paper-2019.pdf

15 *E.g.*, World Health Organization, 'Ethics & Governance of Artificial Intelligence for Health' (2021), *available at* https://www.who.int/publications/i/item/9789240029200.

16 *E.g.*, Consumer Technology Association, 'The Use of Artificial Intelligence in Health Care: Trustworthiness (ANSI/CTA-2090)' (2021), *available at* https://shop.cta.tech/collections/standards/products/the-use-of-artificial-intelligence-in-healthcare-trustworthiness-cta-2090.

information) may necessitate a tailored approach or enhanced protections from discrimination (e.g., pre-existing conditions or genomic information may be needed for patients).

- Comply with all applicable legal and regulatory requirements.
- Develop a tailored communications and engagement plan that gives patients and providers representative of the AI/ML tool's user group a reasonably justifiable level of confidence in healthcare AI's efficacy. Such communications should enable these patients and providers to visualize the AI, and to receive direct and clear information about how their health data are being collected and used (while also avoiding information overload) and how biases in data that exacerbate disparities in healthcare are being mitigated. Reflecting that the division of labor between the developers of AI-enabled tools and the clinician or patient is critical, clearly explain intended uses, including whether a tool might include the restriction that it is not for diagnostic use or for informational purposes only, as well as risks.

Providers should:

- Develop their own risk-based and tailored communications and engagement plan that enables them to explain to patients the development of the AI/ML application, its maintainnace, its performance, and how it aligns with the latest best practices and regulatory requirements to improve patient safety using easily understood and standardized formats. Providers should also acknowledge that "best practices" are dynamic and prone to obsolescence.
- Offer further detail for patients in additional resources that explain the clinical testing of AI/ML applications and the confirmation of the results by clinical experts.

The Food and Drug Administration (FDA) should:

- Leverage its successful approach to authorizing medical device AI[17] that has already safely brought health AI/ML innovations to patients and providers to develop a comprehensive regulatory approach to AI/ML that meets the definition of a medical device. The FDA can accomplish this by, for example, progressing its Software Precertification Pilot[18] to a full program available to all developers of SaMD AI, FDA can also update its rules and processes to realize its envisioned total product lifecycle (TPLC) regulatory approach, facilitating a potentially rapid cycle of product improvement and allowing these devices to continually improve while providing effective safeguards. This new approach should leverage CHI's Good Machine Learning Practices to address both locked and continuously learning AI.
- Evolve its requirements on reporting type and frequency so that such requirements can be adapted and scaled based on relevant factors such as risk, extent, and magnitude of

17 Software as a Medical Device (SaMD): Clinical Evaluation: https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm524904.pdf; Deciding When to Submit a 510(k) for a Software Change to an Existing Device: https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514737.pdf.

18 Pre-Cert Program Version 1.0 Working Model: https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM629276.pdf.

modifications, and the demonstrated reliability of the AI (e.g., quality control plans for updates).[19] Initially, the FDA should finalize guidance on SaMD pre-specifications and algorithm change protocol inputs that FDA should periodically receive.

- Develop methods to efficiently communicate when FDA has authorized a product developed with or that utilizes AI/ML, along with information on how it was developed, is maintained and performs, and aligns with the latest best practices and regulatory requirements that ensure patient safety using easily understood (e.g., infographics) and standardized formats. For example, where approval is required for the deployment of new solutions in the market, the FDA should provide information describing the datasets used to train the AI/ML software and what efforts are being taken to align with ethical standards and to mitigate data biases. This work should build on the recently released database of AI-enabled devices legally marketed in the United States from the FDA's Digital Health Center of Excellence.[20]
- Serve as a coordinator and convenor of other U.S. federal agencies to ensure a harmonized approach to health AI/ML transparency across government.
- Build on its leadership to date within the International Medical Device Regulatory Forum (IMDRF), promote its approach to SaMD AI/ML to improve approaches to transparency internationally.
- Host recurring public events, in partnership with health AI/ML developers, patients, and providers, that feature the FDA Digital Health Center of Excellence's latest approaches and thinking, as well as demonstrations of AI/ML in healthcare today.

The Centers for Medicare and Medicaid Services (CMS) should**:**

- Continue to develop its understanding of medical AI/ML definitions, present-day and future AI/ML solutions, how AI/ML is changing the practice of medicine, and the future of AI/ML medical coding.
- Develop Medicare support mechanisms for the use of AI/ML by providers based on clinical validation, alignment with clinical decision-making processes familiar to providers, and high-quality clinical evidence.
- Build on support provided in the Medicare system for the use of health AI,[21] develop easy to understand resources for Medicare beneficiaries that capture how AI/ML is being used in the Medicare system and what it means to patients. CMS should leverage its Advisory Panel on Outreach and Education[22] to develop this messaging.

19 As the FDA has noted, new reporting mechanisms for a scalable AI/ML medical device reporting structure "may require additional statutory authority to implement fully". Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback (Apr. 10, 2021) at 15. *Available at* https://www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf.

20 https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices. This FDA list currently provides key information such as submission number, device and company name, and date of marketing authorization of the device (510(k) clearance, granting of De Novo, or PMA approval).

21 For example, CMS already provides payment for CPT code 92229 (point-of-care diabetic retinopathy automated analysis and provides a diagnostic report using AI).

22 https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APOE.

The Federal Trade Commission (FTC) should:

- Support ways to mitigate biases or other unfair outcomes from healthcare AI,[23] and, where appropriate, enforce against violations of key laws such as Section 5 of the FTC Act, which prohibits unfair or deceptive practices, where appropriate.

Accrediting and Licensing Bodies, and Medical Specialty Societies and Boards should:

- Develop medical standard of care and ethical guidelines to address emerging issues with the use of SaMD AI/ML in healthcare needed to advance the quadruple aim.
- Develop and disseminate guidance and education on the responsible deployment of SaMD AI, both generally and for specialty-specific uses.

Academic and Medical Education Institutions should:

- Develop and include curriculum that will advance understanding of and ability to use healthcare AI/ML solutions, which should be assisted by inclusion of non-clinicians, such as data scientists and engineers, as instructors. Ongoing training and continuing education should also advance understanding of the safe and effective use of AI/ML in healthcare delivery, addressing both its capabilities and limitations.
- Develop curriculum to advance understanding of data science research to help inform ethical bodies such as Institutional Review Boards (IRBs) that are reviewing protocols of clinical trials of AI-enabled medical devices.

23 https://www.ftc.gov/news-events/blogs/business-blog/2021/04/aiming-truth-fairness-equity-your-companys-use-ai

Conclusion

CHI is pleased to present its recommendations on AI/ML transparency for the consideration of the healthcare ecosystem, policymakers, and others. We are committed to continued engagement with the digital health community writ large to realize the both the responsible deployment of AI/ML across healthcare and its immensely positive societal benefit.