What Are the Labeling Requirements for AI Medical Devices?

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Abstract

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Introduction

Artificial intelligence (AI) and machine learning (ML) are rapidly transforming the healthcare landscape, with a surge in the development and deployment of AI-powered medical devices. These innovative technologies offer immense potential to improve diagnostics, personalize treatments, and enhance patient care. However, their increasing complexity and opacity raise critical questions about transparency and safety. Clear and comprehensive labeling of AI medical devices is paramount to ensure that healthcare professionals and patients can make informed decisions about their use. This article explores the evolving labeling requirements for AI medical devices, drawing on recent academic research and regulatory guidance.

The Imperative for Transparent Labeling

The "black box" nature of some AI algorithms, where the reasoning behind a specific output is not readily interpretable, presents a significant challenge. Without adequate transparency, clinicians may struggle to understand a device's capabilities and limitations, potentially leading to misuse or misinterpretation of its outputs. Patients also have a right to know when AI is being used in their care and to understand the basis for AI-driven recommendations. Therefore, effective labeling is not merely a regulatory hurdle but a fundamental requirement for building trust and ensuring the safe and ethical adoption of AI in medicine [1].

The Regulatory Landscape: FDA's Role and Guidance

The U.S. Food and Drug Administration (FDA) has been actively engaged in developing a regulatory framework for AI/ML-based medical devices. The FDA recognizes that the traditional paradigm of medical device regulation may not be suitable for adaptive AI/ML technologies that can learn and change over time. In January 2021, the FDA published the "Artificial Intelligence and Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan," which outlines a multi-pronged approach to regulating these devices [2].

A key aspect of the FDA's approach is the concept of a "Predetermined Change Control Plan" (PCCP). A PCCP allows a manufacturer to pre-specify a plan for anticipated modifications to an AI/ML device, including changes to the algorithm, and to obtain pre-approval for these changes. This enables manufacturers to update and improve their devices without having to go through a full premarket review for every modification, while still ensuring that the changes are safe and effective.

The "AI Facts" Label: A Nutrition-Inspired Approach

Drawing inspiration from the ubiquitous nutrition labels on food products, researchers have proposed the concept of an "AI Facts" label for medical devices [1]. This label would provide a standardized and easy-to-understand summary of an AI device's key characteristics, including:

Performance: *Key performance metrics such as accuracy, sensitivity, and specificity, along with information about the validation data used to assess performance.* **Data:** Details about the data used to train and test the AI model, including demographic information, data sources, and any known limitations or biases in the data. ***Intended Use:*** *A clear description of the device's intended use, the target patient population, and the healthcare professionals who should use it.* **Logic:** An explanation of the AI model's underlying logic and how it arrives at its conclusions, to the extent possible. ***Manufacturer Information:*** *Contact information for the manufacturer and information about the device's version and update history.*

Challenges and Future Directions

While the "AI Facts" label concept holds great promise, several challenges remain in its implementation. Standardizing the format and content of these labels across a wide range of AI medical devices will be a complex task. Furthermore, ensuring that the information provided is both comprehensive and easily understandable to a diverse audience of healthcare professionals and patients will require careful design and user testing.

Looking ahead, the development of a comprehensive labeling framework for AI medical devices will require a collaborative effort between regulators, manufacturers, healthcare professionals, and patients. As AI technologies continue to evolve, so too must our approach to their regulation and labeling. By prioritizing transparency and user-centered design, we can unlock the full potential of AI in healthcare while ensuring patient safety and building public trust.

References

[1] Gerke, S., Babic, B., Evgeniou, T., & Cohen, I. G. (2024). A Comprehensive Labeling Framework for Artificial Intelligence (AI)/Machine Learning (ML)-Based Medical Devices: From AI Facts Labels to a Front-of-Package AI Labeling System — Lessons Learned from Food Labeling. Emory Law Journal, 74*(5), 1297. Available at: https://scholarlycommons.law.emory.edu/elj/vol74/iss5/7*

[2] U.S. Food and Drug Administration. (2025, March 25). Artificial Intelligence in Software as a Medical Device*. FDA. Retrieved December 20, 2025, from https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-software-medical-device

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