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Commentary

AI/ML-Based Medical Devices

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PREAMBLE

In order to manage health emergencies, develop universal health care, and encourage healthier communities, access to relevant, reasonably priced, and high-quality health products (including medical devices) is crucial. Without medical devices, it would be impossible to perform common medical procedures like bandaging a sprained ankle, diagnosing HIV/AIDS, implanting an artificial hip, or performing any kind of surgery.

Medical devices range from simple instruments like syringe, catheters, and surgical masks to complex instruments like pacemakers and MR protheses. Today, over 7000 generic devices groups comprise an estimated 2 million different medical devices available on the global market.

Before going deeper into the subject, it would be beneficial to take a brief look at the relevant terms.

INTRODUCTION

Technically, a medical device is any appliance, apparatus, software, material, or other article that can be used by people for medical purposes, such as diagnosis, mitigation, therapy, or prevention of disease, alone or in combination. WHO defines medical devices as equipment whose intended primary mode of action is not pharmacological, metabolic, or immunological.

John McCarthy used the term "artificial intelligence" for the first time in 1956. Artificial Intelligence (AI) is the science and engineering of creating intelligent machines, particularly intelligent computers. The ability of a computer program to carry out a broad range of tasks that normally require human intelligence is known as artificial intelligence (AI). Reasoning and learning are only a few of these tasks.

Machine Learning (ML) is a subset of AI. In machine learning, systems are able to learn from data over time and utilize that knowledge to predict outcomes when fresh, unseen datasets are introduced. ML system can learn from training on a particular task by tracking performance.

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Deep Learning (DL) is another subclass that uses neural networks, advanced algorithms designed to resemble the human brain's neural structures.

AI/ML-Enabled Medical Devices

According to US FDA, "Artificial Intelligence/Machine Learning (AI/ML) -Enabled Medical Device is a medical device that uses machine learning to achieve its intended medical purpose". AI/ML-based technologies aim to improve patient care by collecting new insights from a single patient's data and the collective experience of multiple patients.

Generative Artificial Intelligence (AI), sometimes referred to as gen AI, GenAI, or GAI, is Artificial Intelligence (AI) that has the ability to create original content like text, images, video, audio, or software code in response to a user's command or request.

By extracting new and important insights from the vast quantity of data created during the daily delivery of healthcare, AI and ML technologies have the potential to revolutionize the way that healthcare is delivered.

AI/ML medical device market globally was valued at $4,011.7 million in 2022 and is projected to reach $35,458.2 million by 2032, with a CAGR of 24.35% during the forecast period 2022–2032.

AI/ML-Enabled Medical Devices use software algorithms to learn from real-world use and use this information to improve the product's performance in some cases. However, due to their complexity and the fact that their development is iterative and data-driven, they also present unique considerations. Importantly, this rules out the debatable and controversial reliance on accelerated data and accelerated review!

Important opportunities

More precise diagnosis, a major improvement in healthcare, early disease detection, new understandings of human physiology, applications in all medical specialties, the capacity to learn, adapt, and enhance performance, and personalized diagnostics and treatments are some of the key opportunities for AI/ML-enabled medical devices.

Important challenges

Providing oversight for an adaptive system, ensuring transparency to users, identifying and minimizing bias, finding fit-for-purpose data sets for development and testing, including diversity,

and adhering to specific regulatory guidelines are some of the significant challenges facing AI/ML-enabled medical devices.

Here is an example of how AI/ML-enabled medical devices play a big role in managing drug-drug interactions.

Improved natural language processing helped algorithms to find drug-drug interactions in medical literature. Those who take multiple medications at the same time are at risk of drug-drug interactions, and the risk increases with the number of medications taken. Machine learning algorithms have been developed to extract information on interacting drugs and their potential effects from medical literature. This has eased the challenge of tracking all known or suspected drug-drug interactions. In order to develop a standardized test for these algorithms, researchers at Carlos III University compiled a collection of literature on drug-drug interactions in 2013. Researchers are still using this corpus to standardize their algorithms' effectiveness measurements.

Some algorithms use user-generated content patterns to find drug-drug interactions. These patterns include electronic health records and/or adverse event reports. Doctors can report possible negative reactions to medications through the FDA Adverse Event Reporting System (FAERS) and the World Health Organization's VigiBase. Deep learning algorithms are being used to parse these reports and find patterns suggesting drug-drug interactions.

It is important to note that the US FDA regularly releases a list of AI-enabled medical devices. Updated on May 13, 2024 included 191 AI/ML-enabled medical devices. Following this update, the FDA has approved 882 AI/ML-enabled medical devices. US FDA has approved more AI/ML-based medical devices over the past five years. One example is the estimation of the likelihood of a heart attack using smart electrocardiogram (ECG) devices. Between 2015 and 2023, the number of AI/ML-enabled devices submitted to the FDA nearly doubled.

The 510(k) Pathway

AI/ML-based medical devices are different because they use newer techniques or unique features. As a result, their marketing clearance requires a specific channel. But as of today, there is no specific clearance pathway for AI/ML-based medical devices. This is a serious matter of concern and requires immediate attention. Accordingly, the United States and Europe handle medical device approval and regulation differently. Currently, Centralized FDA clears medical devices in three different ways based on the devices' risks: the 510(k) pathway, the de-novo premarket review (for low and moderate-risk devices), and the premarket approval pathway (for most stringent review for high-risk devices). For simplicity, clearance refers to the authorization of the device to market through all pathways.

Federal Food, Drug, and Cosmetic Act (FDCA) provides only three methods by which a medical device—except class I or other exempt devices—can receive marketing authorization: premarket announcement (Section 510(k)), premarket approval (Section 515), and De Novo classification (Section 513(f)(2). Therefore, the FDA is not authorized by the FDCA to create and implement new authorization processes for any type of medical product.

A 510(K) is a premarket submission that FDA receives in order to show that the device that is to be marketed is as safe and effective as a legally marketed device that is not subject to premarket approval. Incidentally, for obvious reasons, 510(k) pathway remains the most popular amongst manufacturers. Between August 2022 and July 2023, the FDA's 510(k) pathway was used to clear the majority of AI/ML devices. During that time, only two devices were granted de novo clearance. This is in line with past years: between 1995 and 2022, 96% of AI/ML devices that were cleared went through the 510(k) pathway. FDA has generally followed the same regulatory guidelines for hardware and software devices, including quality standards, authorization routes, and device classification.

In India, the Medical Devices Rules of 2017 categorize medical devices in the following classes: (i) low risk—Class A; (ii) low moderate risk - Class B; (iii) moderate high risk - Class C; and (iv) high risk - Class D. The basic principles for classification of medical devices under the Rules state; "software, which drives a device or influences the use of a device, falls automatically in the same class" and "...class-wise list of medical devices shall be published on the website of the Central Drugs Standard Control Organisation".

Good Machine Learning Practice

The US FDA, Health Canada, and the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) have collaboratively designated ten Guiding Principles for Medical Device Development as Good Machine Learning Practice (GMLP). The goal is to encourage safe, effective, and high-quality medical devices based on artificial intelligence and machine learning (AI/ML).

The following are the guiding principles:

- Multi-disciplinary knowledge is utilized throughout the entire product life cycle.
- Good software engineering and security practices are implemented.
- The intended patient population is represented by both clinical study participants and data sets.
- Training data sets are distinct from test data sets.
- Selected reference datasets are based upon best available methods.
- 6) Model design is adapted to the data that is available and shows the device's intended use.

- The performance of the human-AI team is the focus.
- Tests show device function during clinically relevant condition.
- Users are provided clear, essential information.
- Models that have been implemented are monitored for performance and risks associated with re-training are managed.

These guiding principles may be used to:

- Adopt best practices that other sectors have shown to work.
- Adapt other industries' practices so that they are applicable to medical technology and health care.
- Create new practices specific for medical technology and the health care sector.

Applications

The FDA is providing the public the list of AI/ML-enabled medical devices that have been sold in the United States. The devices on this list have fulfilled the FDA's relevant premarket requirements, which include a comprehensive review of the devices' overall safety and efficacy including an evaluation of appropriate study diversity based on the device's intended use and technological features. Thus, publicly available information on AI/ML-enabled devices is listed at: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning.AIML-enabled medical devices. Devices are listed by date of final decision in reverse chronological order. As the technology advances, more medical device companies are incorporating AI into their products.

AI-enabled medical devices can improve image quality, shorten scan times, and help doctors make diagnoses or prepare for surgery. As the industry adopts newer technologies and treatments, digital health and artificial intelligence are gaining traction in the medical device industry. No FDA-approved device uses generative AI or uses large language models, despite the great interest in using it in medical devices.

"We think that AI is poised to transform medicine, delivering new, assistive technologies that will empower doctors to better serve their patients. Machine learning has dozens of possible application areas, but healthcare stands out as a remarkable opportunity to benefit people," says a 'quote' from Google Health,

As a precaution, the use of AI and machine learning (ML) in healthcare raises a number of ethical concerns, such as privacy and data security, the potential for bias to be reinforced, the transparency and explainability of AI algorithms, and issues with patient autonomy and consent. Data drift, limited access, inclusivity, retraining, and regulatory difficulties to keep pace with technological advancements all add to these issues.

Future

It is noted that AI/ML-based medical devices present new opportunities and difficulties. As previously stated, current rules in the United States and Europe are incompatible with adaptive technologies and are not intended for AI/ML-based medical devices. This applies also to India and other countries in the world.

There are several major obstacles to the adoption of AI tools in pharmacy practice. These include a) absence of AI guidelines in pharmacy practice, b) little knowledge or awareness of AI applications in pharmacy, c) regulatory restrictions, d) privacy concerns, and e) fear of job loss. introduction of artificial intelligence in Pharmacy practice has led to a revived focus on collaboration between professionals. Therefore, understanding and familiarizing pharmacists with AI technology is crucial for its successful adoption in the pharmacy field.

Against a lot of unfounded beliefs, it is important to emphasize that the arrival of artificial intelligence doesn't mean less human participation. Instead, it shifts human energy towards more significant goals instead of routine tasks.

Education, too, remains indispensable. University curricula should incorporate AI, preparing the next generation of pharmacists for AI's function and its effects on patient care. In this integration, theoretical knowledge, hands-on applications, and moral considerations of AI in healthcare should all be included.

It is essential to emphasize the benefits and added value that AI/ML systems provide in pharmacy, reducing concerns, and demonstrating the possibility of better patient care and outcomes. At present, a regulatory approach that covers the life-cycle of these technologies may be suggested. Simultaneously, transparency is necessary in order to enable and improve AI/ML-based medical devices' efficacy, safety, and quality.

Anticipating the current and future challenges to the AI/ML-based medical devices, it is necessary that harmonized guidelines be evolved by a global task force. Generating most useful real time data with the help of AI would be the most significant and exclusive feature of AI/ML-based medical devices.

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