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A Review on Artificial Intelligence and Machine Learning in a Medical Device

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Abstract

Medical Device manufacturers have been interested in artificial intelligence (AI). However, there is a constant need to evaluate its use and performance due to system complexity, the variety of their architecture, as well as ethical and legal problems. This study offers a narrative commentary on the past, present, and future applications of machine learning (ML) algorithms and artificial neural networks (ANN) in medical devices. Finding challenges and issues with AI integration in medical devices was one of the study's main research goals. From clinical engineering to medical applications, artificial intelligence is transforming healthcare. Prior to realizing the full potential, though, ethical, legal, and social issues must be addressed. Its application must also be scrutinized and regulated in terms of fair access, privacy, suitable uses and users, liability, bias, and inclusivity.

Conclusion

The goal of this study is to comprehend technology's accessibility, recognize artificial intelligence's enormous potential in the healthcare industry, and keep tabs on recent scientific advancements to motivate fellow researchers. Up until now, privacy and security, trust, bias, and accountability and accountability issues have dominated ethical discourses on artificial intelligence and health. As the technology's scope continues to grow, more issues will surely surface.

Artificial Intelligence is relatively new when it comes to medical devices. Manufacturers of medical devices are predicted to abandon their conventional business models until 2030 in Favor of new digital artificial intelligence techniques. It is necessary to create a regulatory framework before introducing AI-based MDs to the market. The process of defining AI regulations and policies pertaining to MDs is still in its early stages, according to prominent regulatory bodies globally. In order to facilitate the adoption of regulatory frameworks and standardize the market, international standards pertaining to AI in MDs are required. Organizations like IEEE, ISO, and IEC are working to standardize data quality management and the use of AI in ways that impact human welfare.

Even with acknowledged barriers, it is possible to draw the conclusion that AI has already fundamentally altered the way traditional medicine is practiced, greatly raised the caliber of medical care, and ensured universal health. It remains to be seen how the human population will be affected by the potential for future development of medical AI in addressing issues like chronic illnesses, infectious pandemics, and the aging population.

Keywords: AI (Artificial Intelligence); ML(Machine Learning); MD (Medical Device); USFDA; SaMD (Software as a Medical Device); Good machine learning practices (GMLP); Artificial Intelligence Medical Devices (AIMDs)

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1. Introduction

The science and engineering of creating intelligent devices, particularly intelligent computer programs, has been generally described as artificial intelligence. Expert systems that largely rely on if-then statements, machine learning, and models based on statistical analysis of data are some of the different strategies that artificial intelligence can employ. (1)

Designing and training software algorithms to learn from and act on data can be done using the artificial intelligence technique known as machine learning. To create an algorithm that is "locked" so that its function does not change or "adaptive," where behaviour can change over time based on new data, software developers can use machine learning. (1,2)

Examples of applications for artificial intelligence and machine learning in the real world include:

- ❖ an imaging system that uses algorithms to provide patients with skin cancer diagnosis data.
- ❖ a sophisticated sensor that calculates the likelihood of a heart attack. (O.W.USFDA)

By gaining new and significant insights from the enormous amount of data generated daily during the provision of healthcare, artificial intelligence (AI) and machine learning (ML) technologies have the potential to revolutionize the healthcare industry. Manufacturers of medical devices are using these technologies to innovate their products in order to better support medical professionals and enhance patient care. One of the biggest advantages of AI/ML in software is its capacity to learn from usage and experience in the real world and to enhance performance. (3-5)

1.1 Transforming of medical device

By gaining new and significant insights from the enormous amount of data generated daily during the provision of healthcare, artificial intelligence (AI) and machine learning (ML) technologies have the potential to revolutionize the healthcare industry. Manufacturers of medical devices are using these technologies to innovate their products in order to better support medical professionals and enhance patient care. One of the biggest advantages of AI/ML in software is its capacity to learn from actual usage and experience and enhance performance. (1)

2. Artificial intelligence in Medical Device

2.1 Artificial intelligence of medical device-past

The advancement of AI techniques is closely related to its use in medicine. Early in the 1970s, the idea of AI was introduced in medicine with the intention of increasing the effectiveness of medical diagnosis and treatment. Due to a number of technological obstacles that have been removed by the development of deep learning, it took about 30 years from its introduction to its widespread use in the healthcare industry. (6-8)

2.2 Artificial intelligence in medical device: present.

Manufacturers of medical devices are utilizing these technologies to innovate their products in order to better assist healthcare professionals and enhance patient care.

The rapid development of wearables like smart watches, which include digital health-monitoring applications, has been made possible by new AI advancements in hardware and software that have made it possible to interpret physiological data from sensors. The market for digital health monitoring is impacted by this trend of a growing number of wearables entering the market. A lot of data is used in the disease detection, diagnosis, and treatment

processes thanks to the ongoing development of assistive diagnostic technology. It can be difficult for clinicians to organize and analyze these data quickly. (9)

As a result, AI is being used more and more in medicine to assist doctors in predicting diseases and treatment outcomes.

These technologies have shown tremendous potential for improving healthcare, from the analysis of medical imaging such as echocardiograms, computed tomography (CT), endoscopy, and skin photographs to tissue histology and physiological data, such as electrocardiograms (ECG). They are intended to, among other things, screen for diseases, categorize malignancies, and provide personalized treatment recommendations, frequently sooner than has been possible with conventional technologies.

One of the most successful algorithms in machine learning is machine learning. Recent years have seen ML play a significant role in medicine, particularly in the diagnosis and prognosis of diseases. A higher rate of ulcer recurrence may be seen in patients who have a history of idiopathic hemorrhagic ulcers. The patient's safety is in danger if serious side effects (like an ulcer that has ruptured) develop. The IPU-ML model, which stands for idiopathic peptic ulcer rebleeding, was developed in 2018 using machine learning. (6,10,11)

2.3 Artificial intelligence in medical device: future

The future of AI application in medicine can be seen in the harmonization of standards and laws that specifically govern AI use in medical devices. The FDA has already made some strides in the field. In a document titled "Proposed Regulatory Frame- work for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)," which was released in April 2019, the FDA, in contrast to European legislators, has shared its position on artificial intelligence.

In this document, the difficulty of continuously learning systems is discussed. However, it notes that earlier medical devices with AI-based processes that were approved operated with "locked algorithms". Leading manufacturers are switching from conventional manufacturing models to data-driven intelligent models as regulators take on the industry. Medtronic, for instance, is dedicated to incorporating artificial intelligence into its current surgical sector, including advanced imaging, robotics, and navigation, as well as increasing recruitment for remote patient monitoring. A preoperative platform by the name of UNiD ASI that uses predictive modeling algorithms to reconstruct the spine for digital modeling and perform measurements is one of the key products that Medtronic plans to use in surgery. Medi- crea GROUP, a French-based medical device company that offers surgical solutions to neurosurgeons and plastic surgeons, created UNiD ASI. The future of AI application can be seen in the rise in treatment accuracy as well as the number of preventable injuries and fatalities brought on by medical errors. These big data structures can be used to forecast the safety and performance of medical devices because the healthcare industry generates a lot of data, just as every medical device does. For instance, the use of intelligent infusion pump systems has emerged as the go-to technique for guaranteeing the security of intravenous medications. The majority of these systems are based on AI expert systems rather than ML, but due to their robustness and dependability, applications based on ML have become more comprehensive, such as implantable insulin pumps and emerging closed-loop artificial intelligence Some key points are shown in Figure 1.(4,12,13)

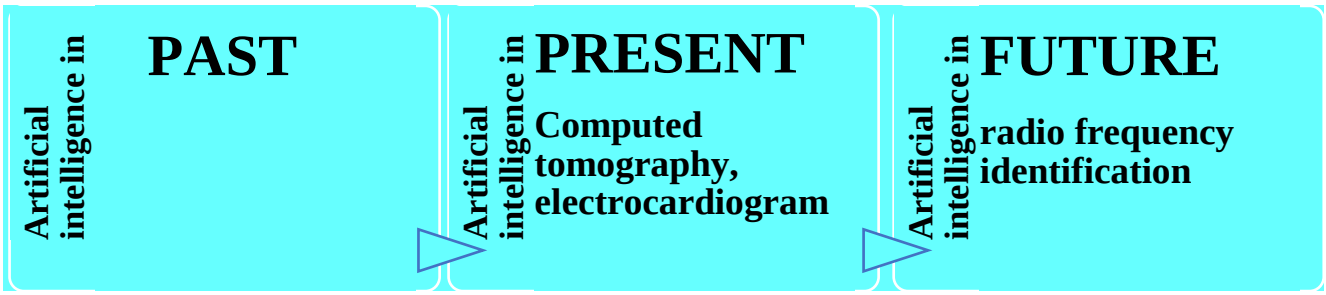


Figure 1. Artificial intelligence in Medical Device

3. Goals of artificial intelligence

By analysing human behaviour and applying the findings to create intelligent systems, artificial intelligence (AI) can be attained. For instance, they act in specific circumstances, learn, and make judgements. observing people as they solve problems with basic tasks and applying the learnings to create intelligent systems.

The creation of technology that enables computers and other machines to function intelligently is the overarching research objective of artificial intelligence. Subproblems within the larger issue of producing or imitating intelligence exist.

The most common symptoms are those listed below. These consist of unique characteristics or skills that scientists anticipate an intelligent system to possess. Eric Sandwell places a strong emphasis on learning and planning that are pertinent to the current circumstance. Goals of Artificial Intelligence Shown In Figure 2. (14-16)

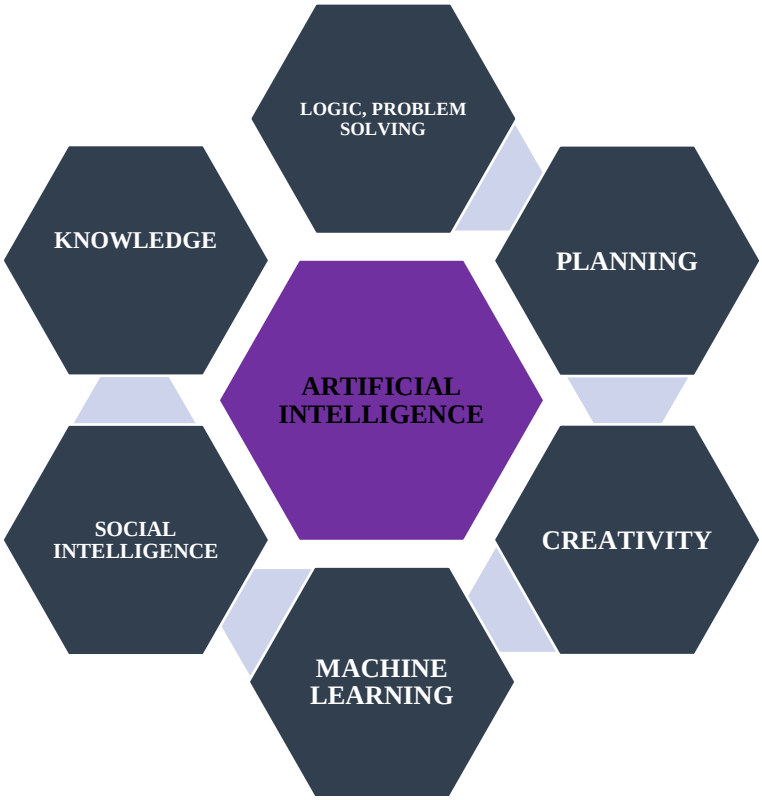


Figure 2. Goal of Artificial intelligence

3.1 Logic, problem solving

Early researchers created algorithms that mimic human step-by-step reasoning when solving puzzles or drawing logical conclusions. Logic and problem-solving. By the late 1980s and early 1990s, methods for handling uncertain or insufficient information had been developed by AI research, utilizing ideas from probability and economics. The amount of memory or computer time needed for problems of a certain size becomes astronomical when dealing with difficult problems, which is why most algorithms experience a "combinatorial explosion".

A top priority is the pursuit of more effective problem-solving algorithms. (14)

3.2 Planning

Intelligent agents must possess the ability to set and accomplish goals. In order to make decisions that maximize the utility (or "value") of the options available, they need a way to visualize the future, which includes a representation of the state of the world and predictions about how their actions will change it.

The agent can be certain of the outcomes of its actions in classical planning problems by making the assumption that it is the only system acting in the world.

In contrast, it necessitates that the agent reason under uncertainty if they are not the only actors. It requires an agent to evaluate its environment, make predictions, assess those predictions, and adjust in response to that evaluation. (14)

3.3 Creativity

Theoretically (from a philosophical and psychological perspective) and practically (through the implementation of systems that produce original and useful outputs), a subfield of AI addresses creativity. Artificial intuition and artificial thinking are two related fields of computational research. (14)

3.4 Machine learning

Since the beginning of AI research, machine learning has been a key concept. It is the study of computer algorithms that automatically get better with use. The capability to identify patterns in a stream of input is known as unsupervised learning. Both classification and numerical regression are included in supervised learning. It is possible to identify which category something belongs to through classification after viewing several examples of items from various categories. Regression makes an effort to develop a function that explains the connection between inputs and outputs and forecasts how the outputs should change as the inputs change. (14)

3.5 Social intelligence

The study and creation of systems that can recognize, understand, process, and simulate human activity is referred to as effective computing. It involves elements of cognitive science, psychology, and computer science. Although the field's roots can be found in early philosophical investigations into emotion, Rosalind Picard's 1995 paper on "effective computing" is credited with giving rise to the more contemporary branch of computer science. (14)

3.6 Knowledge

The foundation of AI research is knowledge engineering and knowledge representation. It will be necessary for machines to have extensive global knowledge to solve many of the problems. Objects, attributes, categories, and relationships between objects, as well as circumstances, events, states, and times, as well as knowledge about knowledge (what other people know about what we know), are all things that AI must be able to represent. There are also many other, less well-researched domains. (14)

An ontology is a representation of "what exists": the set of things the computer is aware of, including things like relationships, concepts, and other things. Upper ontology, which aims to serve as a foundation for all other knowledge, is the most general. (14)

4. Methods of artificial intelligence –

After defining artificial intelligence, tell us about the underlying philosophical principles. Each piece of AI research falls into one of the two categories listed below.

4.1 Symbolic method

The symbolic method, also referred to as the "top-down" strategy, simulates intelligence without taking into account the biological makeup of the human brain. As implied by the name, this approach uses symbol processing to examine how the human brain thinks.

4.2 Connectionist method

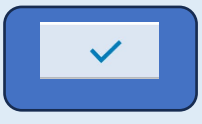
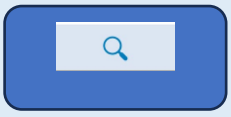
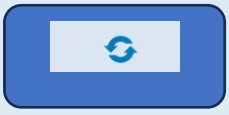
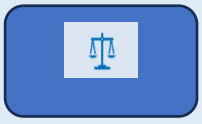
The connectionist approach, on the other hand, focuses on creating neural networks by modeling the biological makeup of the human brain. This strategy, also called the "bottom-up" approach, activates the more basic brain cells. (17)

5. Artificial intelligence and medical learning software as a medical device action plan

This AI/ML-Based Software as a Medical Device Action Plan, which builds on the Agency's long-standing commitment to support innovative work in the regulation of medical device software and other digital health technologies, was created in direct response to the stakeholder feedback described here. The Agency has identified the following actions in order to continue to advance the ideas from the AI/ML discussion paper toward a realistic oversight of AI/ML-based SaMD and of the field as a whole. (4,18)

5.1 Tailored regulatory framework for artificial intelligence / machine learning

Table 1. Regulatory Framework for artificial intelligence. (19)

			
Enhance patient access to high quality digital medical products	Maintain a reasonable assurance of safety & effectiveness	Enable manufacturer to rapidly improve software products with minor changes	Least burdensome

In the discussion paper, a framework for modifying SaMDs based on AI/ML was proposed, and it is based on the idea of a "Predetermined Change Control Plan." As was mentioned above, the Algorithm Change Protocol (ACP) describes "how" the algorithm will learn and change while remaining safe and effective. The SaMD

Pre-Specifications (SPS) describe "what" aspects the manufacturer intends to change through learning. Stakeholders approved of the Agency's facilitation of evolving and bettering algorithms, and many developers welcomed the opportunity to proactively collaborate with the Agency on ideas for potential changes to their products. The elements that could be included in the SPS/ACP to support safety and effectiveness as the SaMD and its associated algorithm(s) change over time were specifically mentioned by stakeholders.

In addition to feedback regarding the SPS and ACP, other areas also received feedback.

There was general agreement that the kinds of changes to AI/ML software devices suggested in the discussion paper were pertinent and appropriate, but there were suggestions for other kinds of changes to be specifically mentioned as kinds of changes that should be covered by this framework.

Additionally, the organization got inquiries and suggestions for the "Focused Review" of a Predetermined Change Control Plan's content, procedure, and timeframe.

FDA is dedicated to making more advancements in the creation of the framework outlined in the discussion paper. The Predetermined Change Control Plan has garnered considerable community interest, so the Agency plans to release a draft guidance for feedback. The proposed content for an SPS and ACP to support the security and efficacy of AI/ML SaMD algorithms is part of this draft guidance. The Agency will make use of recent submission experience as well as docket input obtained on the AI/ML-based SaMD discussion paper. Improvements to the framework's identification of the types of modifications that are appropriate will be made in addition to details on the focused review, such as the submission/review procedure and submission content. (4,19)

6. Good machine learning practices (GMLP)

A set of AI/ML best practices (such as data management, feature extraction, training, interpretability, evaluation, and documentation) that are comparable to good software engineering practices or quality system practices were referred to in the discussion paper as good machine learning practices, or GMLPs.

By encouraging manufacturers to follow well-established best practices and/or standards, the development and adoption of these practices is crucial for both guiding the industry and product development and facilitating oversight of these complex products. To date, many efforts have been made, including those listed below, to describe the standards and best practices that could make up GMLP.

Stakeholders generally expressed a strong support for the GMLP concept and its significance. Additionally, FDA was asked to promote coordination of the numerous efforts.

The Agency has actively participated in a number of GMLP development-related initiatives due to the need for them, including standardization efforts and collaborative communities. For instance, FDA keeps in touch with the International Organization for Standardization's Joint Technical Committee 1/ Sub Committee 42 (IEC JTC 1/SC 42) - Artificial Intelligence and the Institute of Electrical and Electronics Engineers' (IEEE) P2801 Artificial Intelligence Medical Device Working Group. Additionally, FDA takes part in the AAMI/BSI Initiative on AI in medical devices. Along with its participation in the Collaborative Community on Ophthalmic Imaging, FDA this year formally joined the Xavier AI World Consortium Collaborative Community, the Pathology Innovation Collaborative Community, and other collaborative communities. The Agency also takes part in the Artificial Intelligence Medical Devices (AIMDs) Working Group of the International Medical Device Regulators Forum (IMDRF).

The FDA is committing to intensifying its work in these communities as part of this Action Plan in order to promote consensus outcomes that will be most beneficial for the advancement and regulation of AI/ML-based technologies. These GMLP efforts will be pursued in close cooperation with the Agency's Medical Device Cybersecurity Program, in keeping with FDA's long-standing commitment to a robust approach to medical device cybersecurity. Overview of Good machine learning practices shown in fig 3. (4,19)

7. Patient centre approach incorporating transparency to user

The Agency understands that AI/ML-based devices have special considerations that call for a proactive, patient-centred approach to their development and use that considers issues like usability, equity, trust, and accountability.

The FDA is addressing these issues in part by promoting the openness of these devices to users and patients more generally regarding their operation. Promoting transparency is a crucial component of a patient-centred strategy, and we think it's crucial for AI/ML-based medical devices, which may learn and make mistakes. algorithms that may contain elements that evolve over time and exhibit some opacity.

Numerous stakeholders have discussed the particular difficulties in labelling AI/ML-based devices and the requirement for producers to provide precise information about the data used to train the algorithm, the applicability of its inputs, the logic it uses (when possible), the purpose of the output, and the proof of the device's performance. The FDA's position on the transparency of AI/ML technology in medical device software has drawn interest from stakeholders.

The Agency is dedicated to promoting a patient-centred approach, which calls for manufacturers to be transparent with users about how AI/ML-based devices work in order to ensure that users are aware of the advantages, risks, and limitations of these devices. To this end, the Agency held a Patient Engagement Advisory Committee (PEAC) meeting in October 2020 specifically focused on AI/ML-based devices in order to gather feedback from patients on what influences their trust in these technologies. Our suggested next step is to hold a public workshop to share lessons learned and to solicit input from the larger community on how device labelling supports transparency

to users. The Agency is currently compiling the input gathered during this PEAC meeting.

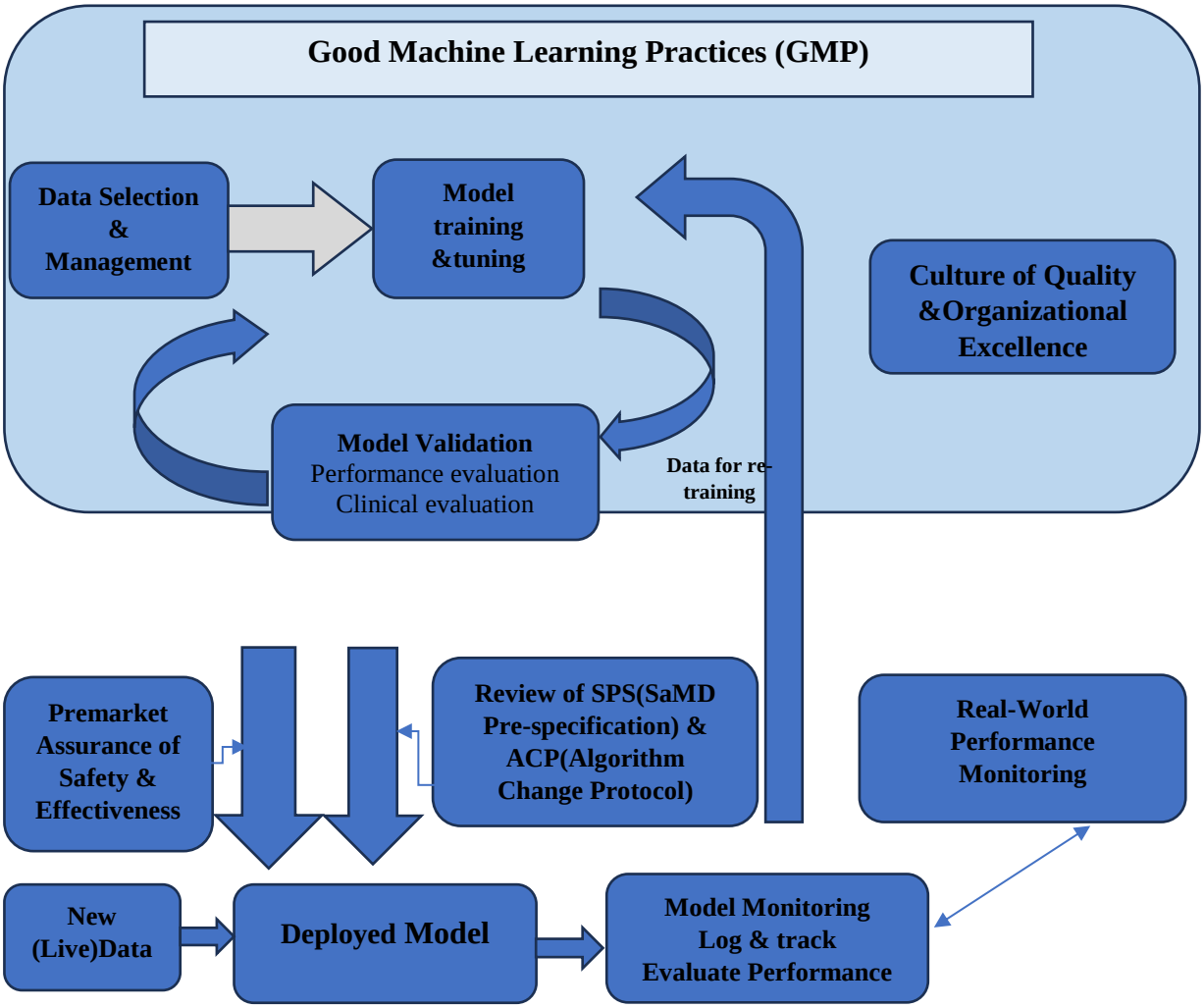


Figure 3. Good machine learning practices overview (19)

We plan to consider this feedback when identifying the categories of data that the FDA would advise a manufacturer to include in the labelling of AI/ML-based medical devices to support user transparency. The FDA's involvement in community initiatives, such as standards development and patient-focused programs, will inform these efforts to support the openness of and trust in AI/ML-based technologies. They will be a part of a larger initiative to support a patient-centred strategy for AI/ML-based technologies built on user transparency. (4,19)

8. Regulatory science methods related to algorithm bias and robustness

The problem of bias and generalizability is not limited to AI/ML-based technology. It is crucial to carefully consider these issues for AI/ML-based products due to the opaque nature of the workings of many AI/ML algorithms and the disproportionate role we anticipate these devices to play in healthcare.

Due to the fact that AI/ML systems are created and trained using historical datasets, they are subject to bias and are likely to replicate it. Because the delivery of healthcare is known to vary depending on factors like race, ethnicity, and socioeconomic status, it's possible that algorithms could unintentionally introduce biases that already exist in our healthcare system.

The Agency is aware of the critical need for improved methodologies for the identification and improvement of machine learning algorithms as well as the critical importance for medical devices to be well suited for a racially and ethnically diverse intended patient population. This covers techniques for detecting and eliminating bias as well as the robustness and resilience of these algorithms to deal with shifting clinical inputs and circumstances.

The FDA is funding a wide range of regulatory science research initiatives to create these techniques for assessing AI/ML-based medical software. Leading researchers at our Centres for Excellence in Regulatory Science and Innovation (CERSIs) at the University of California San Francisco (UCSF), Stanford University, and Johns Hopkins University are working with us on this project in collaboration. As we continue to work together on initiatives to improve the assessment and development of these novel products, we will develop and expand these regulatory science efforts and share our learnings. Regulatory science method related to algorithm bias and robustness collaborative community shown in figure 4. (4,19)

Figure 4. Methods related to algorithm bias and robustness (19)

8.1 Real word Performance (RWP)

The discussion paper outlined the idea that adjustments to AI/ML-based SaMD applications could be aided by gathering and keeping track of real-world data in order to fully embrace a total product lifecycle (TPLC) approach to the supervision of these SaMD. It may be possible for manufacturers to learn more about how their products are being used, spot areas for improvement, and take proactive measures to address safety or usability issues by collecting performance data on the actual use of the SaMD. Manufacturers can reduce the risk associated with AI/ML-based SaMD modifications by utilizing real-world data collection and monitoring. This can help support the benefit-risk profile when evaluating a specific marketing submission.

Among the many queries put forth by stakeholders was the following: What kind of reference data are suitable for gauging the effectiveness of AI/ML software devices in the field? To what extent should each stakeholder undertake oversight? How frequently and in what quantities should data be sent to the Agency? How are the claims, models, and algorithms going to be verified and tested? In what ways can end-user feedback be integrated into AI/ML-based SaMD training and assessment processes? Stakeholder feedback generally indicated that this area needs more direction and clarity.

As part of this Action Plan, the Agency will collaborate voluntarily with stakeholders to support the real-world performance monitoring pilot program. This will be carried out in tandem with other ongoing FDA initiatives that emphasize the application of real-world data. The goal of this work is to assist FDA in creating a framework that will enable the easy collection and verification of pertinent RWP parameters and metrics for AI/ML-based SaMD in practical settings. Furthermore, assessments carried out in conjunction with these. The most important metrics for the RWP of AI/ML-based SaMD, such as those that could be used to proactively address safety and/or usability issues, and those that could be used to gather end user feedback, could have thresholds and performance evaluations established. The public will be involved in these initiatives. (19)

8.2 FDA Considering Regulation of Artificial Intelligence and Machine Learning Medical Devices

The FDA has historically reviewed medical devices via the proper premarket pathway, such as premarket approval, De Novo classification, or premarket clearance (510(k)). Depending on the importance or risk that a modification poses to patients, the FDA may also review and approve changes made to medical devices, including software. Find out what the most recent FDA guidelines are for the risk-based strategy for 510(k) software modifications.

Adaptive artificial intelligence and machine learning technologies were not intended for use with the FDA's conventional paradigm of medical device regulation. Many of these AI- and machine learning-driven software updates to a device may require a premarket review under the FDA's current policy regarding software modifications.

The FDA outlined its foundation for a potential premarket review procedure for artificial intelligence and machine learning-driven software modifications in a discussion paper titled "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," which was published on April 2, 2019.

The principles of risk categorization proposed by IMDRF, the FDA's benefit-risk framework, the software modifications guidance's risk management guidelines, and the organization-based total product lifecycle approach—which is also envisioned in the Digital Health Software Precertification (Pre-Cert) Program—are all incorporated into the ideas presented in the discussion paper. These ideas are supported by practices from our current premarket programs.

The FDA envisions a "predetermined change control plan" in premarket submissions, as outlined in the framework in the discussion paper. This plan would outline the kinds of expected changes (called "Software as a Medical Device Pre-Specifications") as well as the methodology (called "Algorithm Change Protocol") being used to implement those changes in a controlled way that minimizes risks to patients. (20)

The FDA would anticipate, under this proposed approach, that manufacturers would commit to openness and real-world performance monitoring for software based on artificial intelligence and machine learning used in medical devices, as well as regular updates to the FDA regarding the modifications made in accordance with the approved pre-specifications and the algorithm change protocol.

The FDA and manufacturers might be able to assess and keep an eye on software products from premarket development to post market performance under such a regulatory framework. With this strategy, patient safety could be guaranteed while the FDA's regulatory oversight could embrace the machine learning and artificial intelligence-based software's capacity for iterative improvement as a medical device.

The FDA is making clear as part of the AI/ML Action Plan that it intends to revise the suggested regulatory framework that was outlined in the AI/ML-based SaMD discussion paper. One way it plans to do this is by issuing draft guidance on the predetermined change control plan. (4,21,22)

9. AI in Medical Devices

It's possible that you've noticed a rapid advancement in the creation of intelligent products by major tech companies, like wearables. Many of them are creating new AI applications and utilizing AI to provide fresh, creative, and patient-friendly functionalities.

Beyond major tech firms, it is evident that the use of AI in medical devices is accelerating—both in Europe and globally. In fact, artificial intelligence is creating opportunities for the medical device industry by enabling producers of equipment and medical devices to:

- Utilize the information they gather in creative ways with no restrictions on processing volume or speed;
- Discover unobserved correlations in their data, occasionally in real time;
- Create novel approaches to patient care and new, occasionally one-of-a-kind products;
- Reach out to new clientele groups.

9.1 AI solution as a medical devices

Prior to recently, the regulatory definition of a medical device was relatively narrow; however, artificial intelligence (AI)-based solutions serving medical purposes have gained the status of medical devices. In fact, the European Union released Regulation EU 2017/745 on Medical Devices (Medical Devices Regulation), which states that software applications developed with the express purpose of being used for medical purposes fall under the definition of medical devices. This expansion of the definition of a medical device impacts goods that are specifically designed to monitor or prevent illness without serving a therapeutic or diagnostic function. As a result, AI-based health technologies that support disease detection, prediction, monitoring, and prevention are now categorized as medical equipment.

9.2 AI be used by medtech companies

In the exciting field of artificial intelligence for medical technology, new applications are created nearly every week. These are the typical applications of AI that MedTech companies use.

- **Diagnose:** result in an earlier and more accurate diagnosis of a medical condition. Diagnose eye pathologies, for instance.
- **Prevent**: Predict pathologies so that the caregiver can act quickly. Identifying early indicators of blood cancer, for instance.
- **Care**: Assist in automating patient follow-up in even remote environments. For instance, elderly patients can be remotely monitored to reduce their risk of injury.
- **Personalize**: Individualize the care you give each patient. An example would be a personal forecast of the chance of experiencing atrial fibrillation.
- **Beyond these uses, AI can also:**

Contribute to raising the standard of medical data so predictive analytics can use it. An illustration would be the augmentation of medical images to improve their comprehension by an AI system.

Boost care facilities' operational effectiveness. For instance, keeping medical equipment up to date with predictive maintenance.

9.3 Challenges

Naturally, there are still some obstacles to be solved in the MedTech sector when it comes to the application of artificial intelligence.

9.4 Data incompleteness

Medical data, such as that derived from electronic health record systems, may have issues with consistency and/or incompleteness. This difficulty was especially clear in a study conducted in the last ten years on the survival of patients with pancreatitis using information taken from the electronic health record of Columbia University Medical Center. According to the study, 52% of the patients lacked

knowledge about their disease's stage, including the size of the tumor. Correct and comprehensive data is essential for the effective application of AI in medical devices. Fortunately, artificial intelligence (AI) can also aid in data preparation and enhance the caliber of medical data.

- **Legal & Ethical Concerns:** As AI-based software has grown in popularity, some ethical and legal issues have begun to surface. more precisely, the question of when, if at all, the informed patient consent principles ought to be applied. How much of the patient's education should be done by clinicians regarding the type of machine learning the system uses and the types of data it collects? In particular, there has been continuous discussion in the US and the EU about how to handle patient data for AI/ML-based SaMD.
- **Need for safety & transparency:** One of the main issues with AI in healthcare is safety. Given the intricacy of AI algorithms, it is critical to guarantee AI's efficacy and safety. Providing comfort to medical professionals about embracing AI may increase their confidence in judgments made using AI. For instance, being aware of the fundamentals of the AI program, the output, its applicability, and how to use it. Additionally, AI developers should be sufficiently transparent about things like the type of data they use and whether there's a chance that the AI will make biased decisions or have illegal biases.

9.5 Opportunities

Future AI-powered medical device technology will present the following noteworthy opportunities:

- **Towards augmented users and clinicians:** AI is now assisting medical professionals and patients by "augmenting," or providing them with astute insights that make them more knowledgeable and capable. Because of this, there is a twofold demand for AI in healthcare: on the one hand, healthcare professionals and providers see more and more opportunities from AI. Conversely, patients are calling for more remote health management, and this demand is growing.
- **Saving Lives:** A Deloitte and MedTech Europe report claims that AI has the potential to save about 400,000 lives a year.
- **Saving time & financial resources:** AI in medical devices has the potential to save up to €200 billion annually and cut down on the number of hours needed to complete some medical tasks by up to 1,8 billion annually. In this manner, medical personnel could better utilize their time; for instance, physicians could see more patients rather than completing medical records.
- **Improving patient care:** AI can enhance every phase of the patient journey, from early detection and prevention to diagnosis, treatment, and care management.
- **Smarter medical devices:** According to a recent survey, 82% of MedTech executives believe AI is critical to their businesses. We should anticipate seeing an increasing number of machine learning-enhanced medical devices hit the market due to AI's potential to greatly improve device performance. Without a doubt, AI has the potential to increase the automation, accuracy, and dependability of medical devices.
- **Healthcare to everyone:** AI-based SaMD hold great promise for bridging the gaps in healthcare effectiveness, affordability, and accessibility. For instance, AI-powered smartphone medical devices that diagnose illnesses can make healthcare more accessible and affordable for all people, anytime, anywhere. We may anticipate that artificial intelligence (AI) will continue to find applications in medical devices in the future, such as when it comes to combining AI with virtual reality. (23, 24)

10. Conclusion

The goal of this study is to comprehend technology's accessibility, recognize artificial intelligence's enormous potential in the healthcare industry, and keep tabs on recent scientific advancements to motivate fellow researchers. Up until now, privacy and security, trust, bias, and accountability and accountability issues have dominated ethical discourses on artificial intelligence and health. As the technology's scope continues to grow, more issues will surely surface.

Artificial Intelligence is relatively new when it comes to medical devices. Manufacturers of medical devices are predicted to abandon their conventional business models until 2030 in Favor of new digital artificial intelligence techniques. It is necessary to create a regulatory framework before introducing AI-based MDs to the market. The process of defining AI regulations and policies pertaining to MDs is still in its early stages, according to prominent regulatory bodies globally. In order to facilitate the adoption of regulatory frameworks and standardize the market, international standards pertaining to AI in MDs are required. Organizations like IEEE, ISO, and IEC are working to standardize data quality management and the use of AI in ways that impact human welfare.

Even with acknowledged barriers, it is possible to draw the conclusion that AI has already fundamentally altered the way traditional medicine is practiced, greatly raised the caliber of medical care, and ensured universal health. It remains to be seen how the human population will be affected by the potential for future development of medical AI in addressing issues like chronic illnesses, infectious pandemics, and the aging population.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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