Future Opportunities for Systematic AI Support in Healthcare

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Abstract. Artificial Intelligence (AI) holds transformative potential to revolutionize healthcare delivery and outcomes. However, the literature suggests that focusing solely on AI algorithms leads to low adoption rates. AI needs to be introduced systematically into healthcare. This paper builds on this approach and synthesizes existing literature and authors' insights to critically examine the current landscape and future opportunities for systematic AI support in healthcare. The multifaceted applications of AI, ranging from disease prediction to personalized medicine, are explored with a focus on AI's potential to optimize employee performance, alleviate healthcare staff burdens, and enhance patient care. However, challenges such as limited access to unbiased data sets, connectivity issues, and ethical concerns pose significant barriers to AI adoption in healthcare.

Keywords: Healthcare · Electronic health record · Digital Decision Support · Artificial Intelligence · Machine learning · Medical data reuse · Primary use · Secondary use · Genome data · personalized medicine · preventive medicine

1 Introduction

Artificial Intelligence (AI) can be a game-changer in the healthcare industry, potentially revolutionizing how healthcare is delivered and received. According

to Sharma [66], AI has been used in the integrated management of cancer, to support the diagnosis and prediction of function changes in urinary bladder control, in stroke prediction as well as in risk prediction for cardiovascular diseases, and to support the decision-making process of diagnosis. In addition, AI can assist in disease diagnosis, drug discovery, and personalized medicine [20]. Secinaro et al. [65] state that AI can help predict and prevent diseases, improve clinical trials, and enhance patient outcomes.

According to [20], AI applications in healthcare can be broadly categorized into three groups: patient-oriented AI, clinician-oriented AI, and administrative and operational-oriented AI. Patient-oriented AI includes tasks such as medical record review, population health trending and analytics, therapeutic drug and device design, reading radiology images, making clinical diagnoses and treatment plans, and even talking with patients. Clinician-oriented AI includes answering the phone, reviewing medical records, and making clinical diagnoses and treatment plans. Administrative and operational-oriented AI includes tasks such as medical record review, population health trending and analytics, and answering the phone.

The benefits of AI in healthcare can be summed up as follows: AI can improve and optimize the performance and productivity of employees, reduce the burden on healthcare staff, and improve patient care and treatment [20,66]. Nevertheless, the integration of AI into healthcare faces several hurdles. These include the scarcity of high-quality, unbiased data sets, challenges with internet connectivity, the absence of robust systems and processes that facilitate adoption, gaps in mindset and knowledge among stakeholders, and significant ethical considerations [5,65,66].

One of the issues of implementing high-quality and unbiased data sets is the semantic heterogeneity of health data. In an ideal world, AI models are trained based on routine clinical and health data. The routine clinical data are considered precious [81], and their secondary use [60] is considered beneficial for policy-makers, public health officers, scientists, clinicians, citizens, and industry [37]. Several initiatives, including the European Health Data Space [22], are searching for solutions to use routine clinical and health data in global content. However, as stated in a survey [71], we currently do not have a unified approach for the semantic heterogeneity of health data and use divide-and-conquer approaches instead. Such semantic heterogeneity-related issues are highlighted also in 2024 [2,28].

AI is often called a game changer for healthcare. However, recent studies show that it is often over-promised and under-delivered [72,8,10,6]. In previous research, we showed obstacles and success factors [11] and introduced the idea of "systematic AI support" to bring AI algorithms for digital decision support into production [6].

Based on our previous work, the current paper analyzes and critically discusses future opportunities for systematic AI support based on a literature review and informed arguments from the authors. Firstly, AI algorithms require large amounts of high-quality data for training, but healthcare data is often

fragmented, incomplete, or inconsistent [49]. We explore this challenge in detail in Sect. 3.1 and provide a potential solution in 4.1. Secondly, there are significant ethical and legal considerations, such as patient privacy and data security, that must be addressed [82]. Therefore, we look into the EU Medical Device Regulation, the EU AI Act, and FDA requirements in Sect. 3.2. Thirdly, the generalizability of AI algorithms is often limited, as models trained on data from one population or healthcare system may not perform well when applied to another [16]. This is where personalized medicine comes into play, tailoring healthcare to individual patients based on their predicted response or risk of disease. Lastly, the complexity of AI algorithms often leads to a lack of transparency, or a "black box" problem, making it difficult for clinicians to understand and trust the output of AI (Sect. 4.3). Further challenges of AI in healthcare, like domain complexity and ethical challenges, have already been comprehensively researched, e.g., in [33,3]. These challenges necessitate careful consideration and ongoing research to ensure AI's safe and effective application in healthcare. We discuss the results of the current paper in Sect. 5, and we conclude in Sect. 6.

2 Related Work

In [76], Pasi Tyrväinen et al. report on an idea-generating design thinking [18] project in service of understanding the potential of AI applications in healthcare. Stakeholders from various groups, including AI users, technology providers, and resource providers, have been involved in a series of design thinking workshops to innovate on the utilization of AI in healthcare in four specific focus areas, namely digital hospital, aging, preventive healthcare, and wellbeing related to sports. A total of 34 best-use case descriptions have been condensed from the overall idea pool of the conducted workshops.

In [64], Deepti Saraswat et al. conducted a systematic literature review (SLR) to investigate the utilization of explainable AI (EXAI) in healthcare applications. For this purpose, they distinguish between Healthcare 4.0 [35,36], and Healthcare 5.0, where Healthcare 4.0 stands for a patient-centric healthcare paradigm that involves sensor-driven analytics, and Healthcare 5.0 [51] transcends Healthcare 4.0 into a healthcare paradigm that involves "smart control, interpretable healthcare analytics, three-dimensional view models, and augmented and virtual reality" [64]. Starting from the general investigation of "evolution and technology trends of EXAI in healthcare 5.0 applications" [64], the SLR in [64] contributes more specifically by analyzing the operational challenges and the data collection process as requirements of EXAI in Healthcare 5.0.

In [74], Vaibhav Thakare et al. discuss the challenges and opportunities in utilizing AI and IoT in healthcare, focusing on applicability, trends, and potential future developments. According to [74], AI and IoT show potential to "improve the accessibility of preventative public health services and transition our current secondary and tertiary healthcare to be a more proactive, continuous, and coordinated system" [74].

In [32], Akshit Garg et al. show a series of medical AI solutions for diagnosis, prognosis, and treatment, particularly in fighting the COVID-19 pandemic. They also give an account of challenges to the wide-scale adoption of AI in the healthcare sector.

In [61], Bhupesh Rawat et al. analyze a series of AI applications in regard to their potential for personalized medicine and disease diagnosis, i.e., in regard to "their ability to provide faster and more accurate predictions, risk stratification, and improved outcomes through augmented intelligence" [61]. According to [61], the challenges of the utilization of AI algorithms and applications in healthcare are data privacy, ethics, and regulation.

In [55], Balakrishnan Mullachery outlines a vision for how emerging technologies from the fields of 5G, Internet of Things (IoT), geographical information systems (GIS), and AI technologies can be orchestrated in service of smart healthcare, eventually enabling "a future smart-connected society emphasizing healthcare and well-being" [55].

3 Current Challenges of AI in Healthcare

3.1 Health data-related challenges and issues

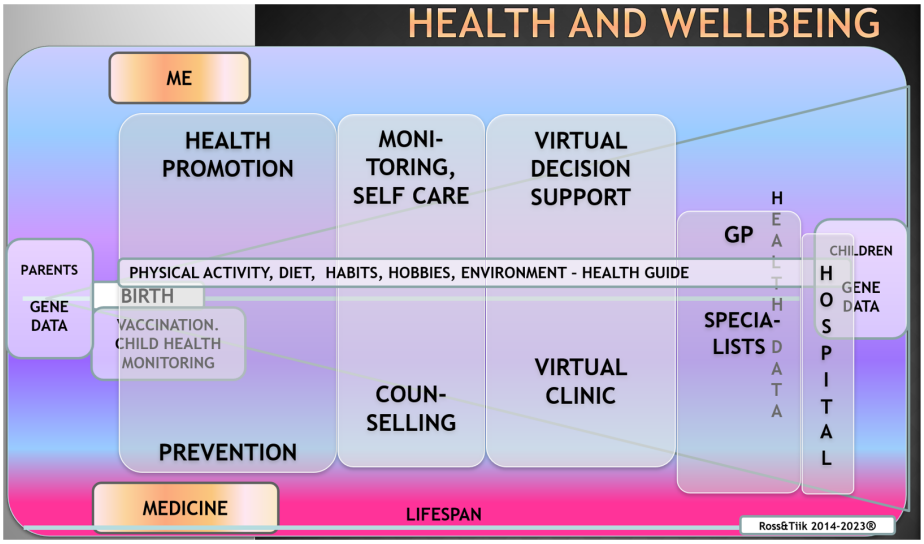

Fig. 1. Variety of a person's health data

Health data plays a pivotal role in the healthcare sector, serving as a cornerstone for informed decision-making, research, and the delivery of quality patient care [83,48]. It encompasses a wide range of information related

to individuals' health and well-being, including medical history, treatment plans, laboratory results, and demographic details [23,50]. Ross and Tiik have illustrated (Figure. 1) the veracity of a person's health data [62]. Some of these data types are electronic health records (EHRs), data generated during clinical encounters, public health data, surveys, and questionnaires, data on lifestyle factors and patient-reported outcomes, data from smartphones, gene sequencing data, environmental health data, social and economic data like income and education, and different biometric data.

A person's health data is usually located in different data repositories and formats, and much of this data might be in the form of unstructured free text [7]. In addition, health data are sensitive personal data [19], and their handling is subject to specific rules of HIPAA or GDPR. All these add complexity and challenges like semantic heterogeneity, data fragmentation, and data preprocessing (anonymization/pseudonymization, cleaning, formalization, etc.) that need to be addressed before using health data for the needs of ML and AI.

The *semantic heterogeneity* in health data refers to challenges arising from differences in the meaning or interpretation of terms and concepts used across various healthcare systems or organizations [28,2]. Semantic heterogeneity occurs when a lack of common understanding or agreement exists on the semantics (meaning) of data elements. The sources for semantic heterogeneity are diverse data standards and terminologies, such as HL7 CDA, openEHR, IHE, FHIR, SNOMED CT, LOINC, and ICD, each with its own set of codes and meanings for clinical concepts. Integrating data from systems that use different standards can lead to semantic mismatches, making it challenging both for humans and machines to accurately interpret and exchange information [75]. In addition, healthcare providers or institutions may use local or customized terminologies that deviate from widely accepted standards. Another source for semantic heterogeneity is ambiguous or inconsistent clinical documentation, such as free-text notes that introduce uncertainty in the interpretation of medical terms and concepts. Automated systems may struggle to extract meaningful information from unstructured data, and human interpreters may derive different meanings from the same text [1]. Further, healthcare standards and terminologies evolve over time to accommodate new knowledge and medical practices, and older systems or data sources may use outdated standards, leading to disparities in the representation and interpretation of clinical concepts [17]. Healthcare involves various disciplines, each with its own vocabulary and understanding of terms.

Interdisciplinary collaboration in healthcare can also result in semantic differences, especially when terms are used across medical, nursing, and administrative domains. Also, inconsistent data entry practices, such as variations in abbreviations or coding conventions, can contribute to semantic heterogeneity challenges. Inaccuracies and discrepancies in data representation hinder the seamless exchange and integration of health information. The meaning of a term can vary based on the context in which it is used. Semantic variations

due to contextual differences can lead to misunderstandings, particularly when data are shared across different healthcare settings. In addition, cultural and regional differences may influence the interpretation of certain health terms and concepts. Health data that are shared globally may need to account for these variations to ensure accurate cross-cultural communication and understanding.

The other challenge with health data is *data fragmentation*. This is an even more complex and challenging issue than semantic heterogeneity [44,34]. Data fragmentation in healthcare poses a significant challenge as crucial health information is dispersed across institutions and data sources, hindering the creation of a comprehensive and cohesive patient health profile. The decentralization of healthcare data among different organizations, such as hospitals, clinics, specialized care facilities, smartphones, and wellbeing apps, leads to a fragmented view of an individual's health history. However, based on big data analysis, Bertl et al. have shown [9,12] that there can be a reliably strong correlation between illnesses that occur in the same person. Therefore, data fragmentation not only obstructs the seamless flow of information critical for providing timely and effective patient care but also jeopardizes the accuracy of diagnoses and treatment plans. In cases of the primary use of health data (diagnosis, treatment, prevention of diseases, longevity, etc.), the person is usually the one who knows and remembers and can, if necessary, restore missing data; in secondary use cases of health data (public health, medical science, policy-making, etc.), the existence of missing data may not be known at all, and the decisions in such a case may be made based on totally incomplete and even totally biased data. When analyzing data on the basis of two or more sets of data, if one and the same person is present in two or more sets of data, there is also no guarantee that said person's data will be correctly linked.

The third serious challenge is the current one-sided nature of health data, which is mainly inclined towards disease and treatment-related data in the second half of a person's life expectancy. While quite a lot of data on human health behavior and physical activity exist, linking these data to medical data is difficult, and so it is also difficult to combine these data in ML and AI applications.

Interoperability issues, incompatible data systems, and privacy concerns exacerbate the problem, impeding healthcare professionals from accessing a holistic understanding of a patient's medical journey. As the demand for integrated, patient-centric care grows, addressing data fragmentation emerges as a pressing imperative in the ongoing evolution of healthcare systems worldwide. Establishing standardized data exchange protocols and promoting interoperability is essential to overcoming these challenges and fostering a more connected, data-driven approach to healthcare delivery. In addition, health data fragmentation also affects primary use, as treating physicians may not know the data entered by a doctor from another hospital and are therefore forced, in many cases, to focus on episodic symptom treatment instead of focusing on continuity of care.

3.2 Regulatory and Legal Basis

The development of AI-supported medical devices is a complex process that meets a variety of regulatory and legal requirements. In the European Union, the Medical Device Regulation (MDR) forms the legal basis for the development of these products. The MDR sets the requirements for the safety and performance of medical devices [57]. The MDR is supplemented by the General Data Protection Regulation (GDPR), which regulates the protection of personal data [24].

In order to obtain approval for a medical device in the EU, a manufacturer must be able to demonstrate that it is capable of producing safe and efficient products. This is preferably achieved by basing its development on harmonized standards that reflect the state of the art, which creates a presumption of conformity that facilitates and accelerates the certification process.

The manufacturer provides proof of this by implementing a quality management system (QMS), for example, in accordance with ISO 13485, and having it certified in conjunction with a notified body. This certification confirms that the manufacturer's QMS meets the requirements of the relevant standards and that the company is able to consistently deliver safe and effective medical devices. It is important to note that compliance with these standards and regulations is not only a legal requirement but also a matter of ethical responsibility. It ensures that patient safety is paramount and that the benefits of AI-enabled medical devices are maximized while potential risks are minimized [40].

As there are currently no harmonized standards that support the development of AI-supported medical devices, conformity cannot be assumed for the development of medical devices. Manufacturers are therefore faced with the challenge of comprehensively documenting the manufacturing process in order to demonstrate and prove the performance of their products [58]. This can be done through extended clinical studies, for example, which is time-consuming and costly. Nevertheless, 219 medical devices for the EU market can be found in the free database "AI for Radiology" [21]. For the US market, over 500 products can be found in the database of the Food and Drug Administration (FDA) [13], the authority responsible for the approval of medical devices.

EU vs FDA. The approval of medical devices under the FDA and the MDR has many similarities. Both require manufacturers to demonstrate the performance and safety of their products using a quality management system (QMS).

The differences lie mainly in the details. These include the requirements for the risk classification of the product, proof through clinical studies, and the requirements for technical documentation. These differences can increase the workload for manufacturers when preparing documents for different markets.

The use of internationally recognized processes and documents, such as those from the International Medical Device Regulators Forum, can help to reduce the effort involved. These international standards and guidelines can help to reduce the complexity of regulatory requirements while ensuring the safety and efficacy of products [41].

FDA activities for the use of continuous learning systems. One thing all markets have in common at present is the use of frozen ML/AI models or the abandonment of continuously learning AI. The background to this is that the approval of a product or, in particular, Software as a Medical Device (SaMD) is granted with a defined version. If the SaMD changes in the field, e.g. through active learning, the SaMD no longer complies with the subject of the approval and is therefore illegal on the market. An evaluation of the change is necessary to decide what the next steps are. In the case of minor changes, such as a bug fix, this would only have to be reported to the authorities with a modified version. If the change is more extensive or has an impact on the performance of the product, it requires prior validation and re-release of the product. And if the change has an impact on the intended use of the product, this must be re-approved [53,79].

The FDA has recognized the challenges in regulating AI-based medical devices and published the discussion paper "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)" in April 2019 [78]. In this paper, a number of activities were presented to promote the development and use of continuously learning AI in medicine. These include the creation of guidelines for the development and validation of AI algorithms.

In April of this year, a proposal for a Predetermined Change Control Plan (PCCP) was presented [80]. This plan is intended to enable manufacturers to identify and evaluate changes to the model. The PCCP defines three areas in which continuous learning should be tolerated differently. These areas include changes to the performance of the model that has a high chance of acceptance, changes to the input that has a medium chance of acceptance and which, in case of doubt, should be evaluated with the FDA in good time, and finally changes to the intended use that requires re-approval of the application and is unlikely to be approved.

EU AI Act and Sync between MDR and AI Act. The recently introduced EU AI Act aims to create a legal framework for AI systems that minimizes risks while promoting innovation [27]. The Act is based to a certain extent on the regulations of the MDR [57], for example by providing for a risk-based approach. The Regulatory Framework defines four levels of risk in AI:

- Unacceptable risk
- High risk
- Limited risk
- Minimal or no risk

However, in the case of an acceptable risk, all AI-supported medical devices fall under the category of high-risk products. The AI Act also requires extensive logging of the algorithm's activities. As part of a medical device manufacturer's post-market surveillance activities, extensive monitoring measures are already required for the products on the market. However, the AI Act goes further and seeks to require the manufacturer to design the AI-powered application to keep

detailed logs of what it evaluates and why it made a decision in order to monitor the performance of the model in the field [25]. This requires additional consent from the patient and the operator to monitor the entire processing of such a program.

Another area that has not yet been further defined is the requirement for sandbox operation, which can best be understood as an independent test laboratory [26]. This should have an insight into the development and verification of the AI model and also have test data available in order to be able to verify the results by themselves. The aim is for the independent authority to check the AI and certify it, similar to the way it is already necessary to carry out an EMC test in accordance with ISO 60601-1-2 in an independent test laboratory for the acceptance of electronic medical devices [39].

The AI Act is currently in trilogue negotiations and is expected to come into force in 2024. The question of how existing regulations, such as the MDR and the AI Act, can be brought together is still open. In order to not inhibit or even suppress innovation, a sensible harmonization of regulations is necessary. The transition to the MDR is already a complex task for all stakeholders. The notified bodies need to be certified for the MDR, which leads to less accredited notified bodies. The Manufacturers need to re-certify their products under MDR or may fall, in some cases, into a higher-risk class, which also needs to be certified [42]. So, the few named bodies are occupied by re-certification and there are manufacturers who need a new body to be notified for their medical devices. The transition of the MDR led to some withdrawal of medical devices in the area of implants, for example, [30]. The synchronization between the EU AI Act and the MDR is crucial to ensure that the regulations for AI-supported medical devices take into account both technological progress and patient protection. The upcoming challenge for legislators and regulators, as well as for organizations and scientists, would be to take appropriate action to ensure a smooth transition while protecting patients and supporting the innovation and development of safe and effective products.

4 Future Opportunities for AI in Healthcare

4.1 Medical Data Storage

One of the promising solutions to tackle all the issues related to health data mentioned in Sect. 3.1 is a total paradigm shift from the current institution-based health data management [54] towards the individuals' privately owned and fully controlled health data. In [45,46,47], Klementi et al., have explained the idea, as well as proposed prospective research topics and a reference architecture towards such a system. They describe an architectural framework as a solution for the pervasive issue of health data fragmentation, which has posed a considerable impediment to the secondary use of health data. This approach facilitates the consolidation of an individual's comprehensive health data within a unified logical repository exclusively controlled by the data owner. Remarkably, this consolidation occurs without incurring an augmented risk to the privacy of

such data. Notably, the proposed solution extends beyond primary health data, encompassing other pertinent data categories commonly referred to as "lifestyle data," including information from wearable devices, home measurement results, and similar sources. This inclusive approach fosters the development of a holistic perspective on an individual's health status, empowering each person to actively monitor their own well-being. Consequently, it has the potential to engender a paradigm shift in the healthcare domain, transitioning the overarching focus from reactive disease management to proactive prevention, with individuals assuming an increasingly prominent role and the associated responsibility. Given the innovative nature of this solution, it necessitates paradigmatic changes in societal conceptions surrounding personal data storage. The authors posit that technological readiness for such a transformation may outpace societal preparedness. Accordingly, prompt initiation of broad-based discussions concerning this approach assumes paramount importance.

4.2 AI Technology and Algorithms

In terms of AI technology and algorithms, we see *humanoid robotics* and *quantum computing* as enablers for *personalized and preventive medicine* as big emerging clusters.

Convergence of Synthetic Intelligence and Cognitive Agents in Humanoid Robotics. The fusion of Synthetic Intelligence (SI) and Cognitive Agents (CAs) represents a significant advancement in the field of robotics. Humanoid robots equipped with SI and CA capabilities are not only capable of mimicking human-like behaviors but also adapting and learning from their environment [43]. This convergence holds the promise of addressing critical issues in healthcare. We delve into the role of SI and CAs in humanoid robotics and their positive impacts on healthcare efforts by analyzing the intricate interplay between SI, CAs, and humanoid robots and elucidating the dynamic ecosystem where these intelligent agents collaborate with systems, remote devices such as IoT, equipment, and humans. This highlights the imperative of fostering responsible AI development and promoting the ethical deployment of Synthetic Intelligence, Cognitive Agents, and humanoid robotics to ensure the harmonious and productive coexistence between humans and intelligent machines as the technological amalgamation is moving forward across many domains.

Synthetic Intelligence (SI) refers to the artificial creation of intelligent entities through the emulation of human cognitive processes [38]. SI systems are designed to learn, adapt, and make decisions, mimicking human intelligence to varying degrees. This technology forms the foundation of intelligent robots. Cognitive Agents are software or hardware entities that possess the ability to perceive, reason, and make decisions in complex environments [63]. They are equipped with advanced reasoning, problem-solving, and learning capabilities, making them crucial components in the development of intelligent robots.

Simulate Human Critical Thinking and Reasoning and Humanoid Cognitive Robotics is the implementation of a Decision by these CAs. Cognitive Agents

reference entities that have the ability to perceive their environment, process information, and make decisions or take actions based on their understanding. These agents often leverage cognitive abilities like human thinking processes. Critical Thinking and Reasoning are cognitive skills associated with the ability to analyze information, evaluate arguments, and make decisions based on evidence and sound logic. In the context of cognitive agents, incorporating critical thinking and reasoning involves endowing these artificial entities with the capability to assess information, weigh evidence, and make decisions in a manner analogous to human cognitive processes. Critical Thinking Framework (CTF-HA) decision-making, problem-solving, and information evaluation by promoting systematic, rational, and evidence-based thinking. It serves as a guide for structuring cognitive processes such as Behavioral Characteristics of Cognitive Agents that Access information specific to the subject matter being evaluated, analyze the logical consistency and validity of arguments, check facts, data sources, and evidence for accuracy and relevance, identify gaps, limitations, or biases in information/data, generate alternate hypotheses and conclusions based on evidence, update assessments as new evidence/data becomes available, and highlight uncertainties and areas needing further analysis.

Quantum Machine Learning. Quantum computing and quantum machine learning represent transformative frontiers in the advancement of AI in medicine [31]. The integration of quantum computing's immense processing power with the sophisticated algorithms of quantum machine learning can potentially revolutionize how we approach complex biological systems and healthcare challenges. Quantum computers, with their ability to perform specific calculations at unprecedented speeds, offer a promising avenue for analyzing and detecting anomalies in vast datasets that are characteristic of the medical field. This capability could lead to the identification of novel therapeutic targets and the development of personalized medicine strategies at a pace far beyond current computational methods. Furthermore, quantum machine learning algorithms are particularly adept at identifying patterns and correlations within these large datasets, which could enhance diagnostic accuracy and predict patient outcomes with greater precision. The synergy of these technologies could also facilitate the design of new drugs by simulating molecular interactions at a quantum level, thus reducing the reliance on costly and time-consuming laboratory experiments [14]. Moreover, the application of quantum machine learning in genomics could accelerate the understanding of genetic factors in disease, leading to breakthroughs in preventive medicine [77]. We see the future of AI in medicine not just as iterative improvements, but quantum leaps in our capabilities to heal and prevent illness.

Personalized and Preventive Medicine. Personalized and preventive medicine represents a transformative paradigm in healthcare, leveraging medical and health data to tailor interventions to individual characteristics, genetic makeup, and lifestyle choices [56,15]. Central to this approach is

the integration of data from various sources, including smartphones and wellbeing applications. These technologies provide a continuous stream of real-time data on an individual's daily activities, exercise routines, sleep patterns, and other health-related metrics. By incorporating this information into medical assessments, healthcare practitioners can gain a more nuanced understanding of a patient's overall well-being, enabling the development of personalized preventive strategies. Analyzing data from smart devices allows for early detection of potential health issues, facilitating proactive interventions to mitigate risks and promote long-term health [73]. As personalized and preventive medicine advances, the seamless integration of diverse health data sources, including those derived from mobile technologies, plays a pivotal role in optimizing healthcare delivery and empowering individuals to actively participate in their health management.

4.3 Explainable AI and Trustworthiness of AI Systems.

For several reasons, a human in the loop is crucial for successfully implementing AI-based decision support systems and automation in healthcare. Firstly, it ensures that the complexity and nuances of medical decision-making, which often require human judgment and experience, are not overlooked. Secondly, it allows for real-time oversight and the ability to intervene if the AI system makes a decision that could potentially harm a patient. This is also of vital importance from a legal perspective. Lastly, it helps build trust among healthcare professionals and patients, as they can be assured that there is human oversight, thus fostering acceptance of AI technology in healthcare.

Currently, we see novel AI technologies gaining momentum, particularly in the field of deep learning, which includes transformers. With such novel AI technologies emerging, we recently witnessed an increasing debate about the explainability and trustworthiness of AI systems. Basically, the utilization of AI systems is considered risky; the trustworthiness of AI systems is the goal, and their explainability is seen as a pre-condition for their trustworthiness; compare with [59]: "The AI community is pursuing explainability as one of many desirable characteristics for trustworthy AI systems." [59] Unfortunately, both explainability and trustworthiness are social constructs rather than naturally given facts and measurable features of an AI system, and, as such, they are hard to grasp and characterize.

With [59], the NIST (National Institute of Standards and Technology) attempts to provide a characterization of explainable AI through the identification of four principles as follows:

- "*Explanation*: A system delivers or contains accompanying evidence or reason(s) for outputs and/or processes." [59]
- "*Meaningful*: A system provides explanations that are understandable to the intended consumer(s)." [59]
- "*Explanation Accuracy*: An explanation correctly reflects the reason for generating the output and/or accurately reflects the system's process." [59]

– "*Knowledge Limits*: A system only operates under the conditions for which it was designed and when it reaches sufficient confidence in its output." [59]

Different sectors and business domains vary greatly in terms of their terminology, perception of phenomena, and social constructs, as is the case with regard to the explainability and trustworthiness of AI systems. Therefore, we argue that it needs domain-specific discussions of explainable AI and its trustworthiness, and consequently also a domain-specific discussion of explainable AI and its trustworthiness in regard to the healthcare sector.

The current discussion of explainable AI puts particular emphasis on the understandability of AI mechanisms, in particular on the explanation of AI systems that are understandable by the customer, i.e., the end-consumer, who is usually a layman in regard to AI technology. We suggest that such focus should be questioned and discussed. For the healthcare domain, consider any other diagnostic tool, such as a laboratory test for a disease. It is unlikely that the layman would understand the biochemistry of the laboratory test, independent of how good the explanation of the test would be. Even the expert, including the medical practitioner, might struggle to completely understand the provided explanation. The problem is that explainability and understandability are not measurable. The level of understanding is measurable, i.e., by an exam, however, at a closer look, such a measure of the level of understanding is also purely a social construct. The very concept of understandability remains un-measurable; all understanding is, eventually, an illusion.[7] As explainability and trustworthiness are social constructs, they can be made subject to the *social science* research technique [4,84,52] with its quantitative and qualitative analyses; however, it is impossible to investigate them *scientifically*, i.e., as subject to the *exact sciences* technique.[8]

Whereas the explainability and trustworthiness of a diagnostic tool are not measurable (in the sense of *exact sciences*), the predictive power of a diagnostic tool is indeed measurable. The confusion matrix of a diagnostic tool is fully specified by its positive predictive value (PPV), its negative predictive value (NPV), and the prevalence of the disease in the investigated population. Assuming that both the group of affected and the group of non-affected individuals in the investigated population are sufficiently statistically significant, the pair of PPV and NPV provides the medical practitioner with a relatively stable measure for their decision-making. The same applies to any diagnostic tool, including those based on AI algorithms.

Furthermore, the current discussion of explainability and trustworthiness in AI seems to be focused rather on AI algorithms than on the quality of the

[7] For example, even if we have perfectly *learned* to apply the field equations of general relativity as the current established theory of gravity, we need to admit that we still do not *understand* what gravity is.

[8] Whereas social sciences, in particular, whenever they follow the stance of *positivist research* as opposed to *interpretivism* [52], might often mimic the *exact science* technique, as an attitude, they would still remain not being *exact sciences*; compare with [29].

underlying data. In extreme cases, the underlying data can be subject to all kinds of statistical paradoxes [68,70,69,67], and even if not, the existence of confounding effects (no matter in terms of latent confounders as well as known confounders) can have severe impact on over-estimating or under-estimating the predictive power of a diagnostic tool. A particular challenge is identifying confounding effects in sparse data such as that utilized by novel AI techniques. Therefore, we see the investigation of confounding effects in sparse data as an important field of research for the applicability of novel AI systems in healthcare.

4.4 Potential Clinical and Healthcare Management Approaches.

Similar to other service areas, the success of information technology implementation in healthcare depends on how it is possible to involve content people and those who know the business side, i.e., clinicians and healthcare managers. The relatively few implementations of AI-based Digital Decision Support Systems (DDSS) in clinical practice over the past decade indicate that collaboration between AI specialists and clinicians has not yet gained momentum.

When implementing AI in healthcare, it is reasonable to look at how the introduction of new technologies has taken place in the past. What has proven successful is not technological discoveries per se but how they have been used to assess or improve human health. For example, X-rays or fiber optics do not have a separate value in medicine but are seamlessly integrated into diagnostic activity or surgery. In the case of AI applications in healthcare, the focus is still on the development of individual algorithms. However, integration of multiple algorithms into a clinical workflow or health promotion is required. Similarly to digital radiography, where X-ray photons act directly on a photoconductor layer collectively, producing positive and negative charges and thus forming images of respective anatomic areas, the application of AI algorithms should be more comprehensive and bring new findings to human health status and support new and more effective approaches in the clinical workflow. It is not only one data source and one deep learning algorithm but an interdisciplinary approach combined with medical, IT, and healthcare process knowledge integrated into current systems.

The material for AI-powered medical applications and tools is data. Since a large part of data in medicine is entered by clinicians and carries potential bias, especially when written in free text, the development of AI algorithms should focus on non-obtrusive data collected by various sensors, genetic data, and well-structured and terminologically consistent data. These sources provide an opportunity primarily for preventive health care, where the biosignals collected by the person from everyday life with portable sensors, enriched with genetic data, make it possible to start preventive and health promotion activities well in advance of the development of disease symptoms. It is also possible to find indicator diagnoses that point to possible hidden new health problems based on electronic health records and personal health records data.

AI solutions can certainly support healthcare financing and health management more broadly. As is known, the determinants of human health are, in addition to medical care and genetic factors, social and economic conditions, education, behavior, and environment. The mutual integration and analysis of these data with AI-supported tools, together with person-reported data and biosignals, has the potential to change healthcare from reactive to proactive. Also, new funds can be brought into healthcare financing if an additional bonus is paid to the funder of prevention activities in the case of the successful completion of a person's personal health plan. This is how, for example, health impact bonds work – a funding model that supports large-scale prevention.

5 Discussion

The integration of AI in healthcare is a topic of significant interest and debate. While the potential benefits are substantial, several critical discussions and considerations arise:

- Ethical Implications: As AI algorithms become more involved in clinical decision-making, ethical questions emerge. How do we ensure transparency, fairness, and accountability in AI-driven diagnoses and treatment plans? Striking the right balance between automation and human judgment is crucial.
- Data Quality and Bias: AI models heavily rely on data. However, biases present in historical medical data can perpetuate inequalities. Ensuring diverse and representative datasets is essential to prevent biased outcomes. Additionally, addressing data privacy concerns is paramount.
- Harnessing new data sources: personalized and preventive medicine based on genome or unobtrusive data for digital phenotype still holds unexplored potential for improving health care.
- Human-AI Collaboration: Rather than replacing clinicians, AI should augment their capabilities. Discussions about how AI can complement human expertise, enhance diagnostic accuracy, and improve patient outcomes are ongoing.
- Regulatory Frameworks: Developing robust regulations for AI in healthcare is challenging. Balancing innovation with safety requires collaboration among policy-makers, researchers, and industry stakeholders.
- Interoperability and Integration: Integrating AI seamlessly into existing healthcare systems remains a hurdle. Ensuring interoperability, data sharing, and compatibility with electronic health records are critical aspects.
- Patient Acceptance and Trust: Patients need to trust AI-driven decisions. It is essential to educate patients about AI's role, its limitations, and the shared decision-making process.
- Resource Allocation: While AI promises efficiency gains, initial implementation costs and ongoing maintenance must be considered. Allocating resources effectively is vital.

- Legal and Liability Issues: Who bears responsibility when an AI algorithm makes an incorrect diagnosis? Legal frameworks need to adapt to this evolving landscape.
- Global Collaboration: AI transcends borders. Collaborative efforts across countries can accelerate research, data sharing, and best practices.
- Long-Term Impact: Finally, discussions should extend beyond immediate benefits. How will AI shape healthcare in the long term? What societal changes will it bring?

With increasing computing power, the potential of quantum computing, and the corresponding impact of areas like personalized and preventive medicine and robotics, the above-mentioned points have become increasingly important. While AI holds immense potential, thoughtful analysis and interdisciplinary collaboration are essential to harness its benefits while mitigating risks.

6 Conclusion

In conclusion, the integration of AI into the healthcare industry holds immense promise. As evidenced by recent studies, AI has already made significant contributions to cancer management, urinary bladder control, stroke prediction, cardiovascular disease diagnosis, and personalized medicine. Its potential extends to predicting and preventing diseases, enhancing clinical trials, and improving patient outcomes. AI applications in healthcare can be broadly categorized into three domains:

- Patient-Oriented AI: This category encompasses a wide range of tasks, including medical record review, population health analytics, therapeutic drug and device design, radiology image interpretation, clinical diagnosis, and even patient communication.
- Clinician-oriented AI: Clinicians benefit from AI in tasks such as medical record management, answering phone calls, and aiding in diagnosis and treatment planning.
- Administrative and Operational-oriented AI: Streamlining processes like medical record review and population health analysis fall under this domain.

The advantages of AI adoption in healthcare are manifold: increased productivity, reduced staff burden, and enhanced patient care. However, challenges persist, such as limited access to high-quality, unbiased data sets, internet connectivity issues, and the need for robust systems and protocols.

As technology advances, addressing these challenges and responsibly leveraging AI's potential will be crucial for realizing its transformative impact on healthcare delivery and patient well-being.

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