

Chapter 5: Enhancing diagnostic accuracy using artificial intelligence-powered imaging, lab analysis, and real-time monitoring tools

5.1. Introduction

In vitro diagnostics play a critical role in effective early disease detection and in advancing the diagnosis and treatment response. Smart diagnostics is defined as the in vitro diagnostic application of artificial intelligence (AI) and machine learning technology through algorithm development and integration within the domain of IVD to augment its utility. Despite reducing its predictive performance, a significant proportion of the literature suggested that AI-powered algorithms had generally helped improve diagnostic accuracy in studies using imaging, laboratory analysis, or real-time monitoring tools. This paper presents a systematic review of a range of smart diagnostics and assesses the net effect on diagnostics accuracy in the context of method and reporting quality of the literature.

Smart Diagnostics is a new category of commercialized diagnostics tests dependent on immunodetection with fluorescence following the automation robotic microfluidic capture of target proteins, antibodies, or nucleic acids. Such state-of-the-art diagnostics are supplemented with a capillary-action, biochip-style surface with pre-addressed capture zones for all assay components including cytometry wells, wash reagents, and fluorescent imaging wells. The collisional rate of fluorescently labeled detection regions on the sensors measures the analyte concentration. Trimmed means and fits to a Bayesian logistic regression model are used to overcome problems with method development and systems integration, and to enable better estimates of dynamic range parameters. Data are then interpreted in the context of broader results from repeated capture efficiency measurements and other experiments illustrating how the effect of excessive temperature

on transmissions affects predictions of signal levels. There are trials of diagnostic devices performed with the artificial design that allows all the device subjects administered in the clinical study as the outcome arm allocation study designs. Considering the large investment in the development of diagnostic devices and the substantial cost of clinical trials, there are these practical and small properties because only a subset of possible tests in a single clinical practice occur. The design does diagnose switching policies among some compartmental imaging tools. An equal overall allocation ratio is maintained, but each imaging tool has a different number of device subjects in a trial. As such, a few imaging tools do no sequential analyses of diagnostic performance on a common set of patients.

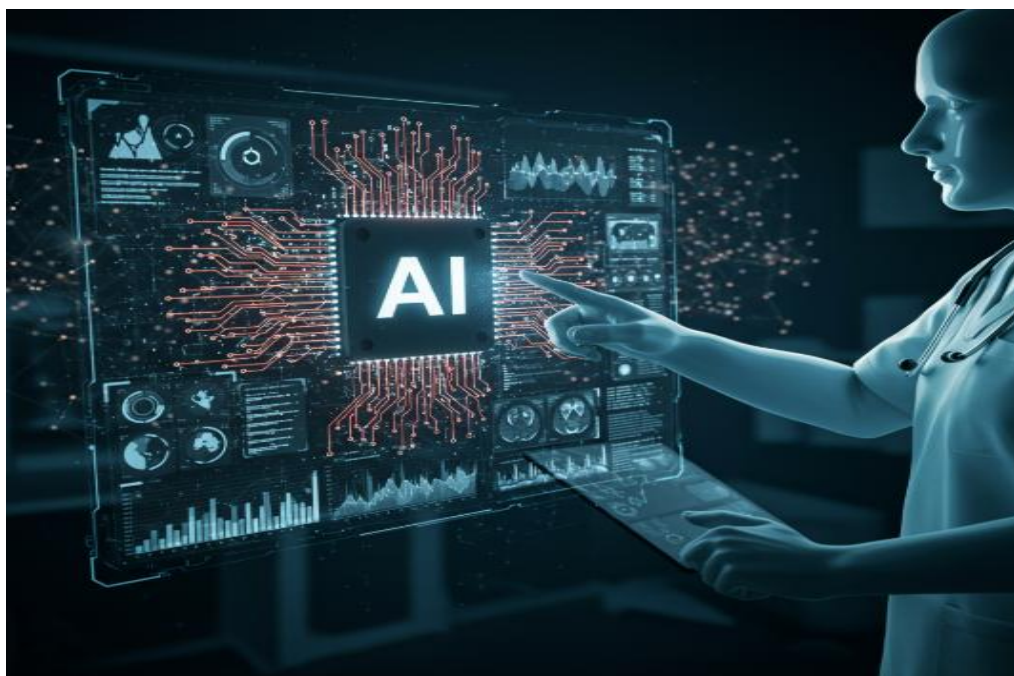


Fig 5.1: Diagnostic artificial intelligence

5.1.1. Research design

This is an adaptive, equal allocation, two-stage procedure for trials on diagnostic devices that use AI-based imaging systems. An application is a comprehensive device which switches among tests using different imaging tools for the ultrasound and MRI. At each stage, the test diagnostic performance is estimated using a stochastic ordering model so that rank-preserving thresholds of diagnostic performance for outcome arm allocation are found. At the first stage, an equal allocation of patients occurs in different imaging tools are assessed. At the second stage, equal allocation is separately occur in the US and

MRI images then an optimal imaging tool is determined using performance assessment of the previous tool. An analytical approach is proposed to calculate the rank-preserving performance threshold of the new test. The limit of an analytical threshold is investigated. When the new test's performance passes the threshold no for the new test and yes for an adjudicator, additional patients are recruited for the new test. The procedure stops when there is a pre-specified number of tests performed to the new test. The adaptive design procedure ultimately provides a novel imaging tool that works equally effectively to the MR in the assessment of the early treatment of breast lesion and, consequently, reduces the necessity for MRI referrals and their consequent morbidity and large dysfunction to the Her2+ and triple negative patients.

5.2. The Role of AI in Healthcare

Healthcare is shaping up with advances in digital healthcare technologies such as artificial intelligence (AI) methodology (Health Data Research UK, 2024; NHS England, 2024; OpenSafely, 2024). AI methods from traditional machine learning to innovative deep learning algorithms are beginning to assume a crucial function in numerous well-being-related domains. For instance, they are presented with the potential of new systems for diagnosing patients in clinical practice, development of patient information and health records, and treating diverse kinds of diseases. The AI techniques are most efficient in identifying the diagnosis of numerous diseases. Given the increasing recognition and, more significantly, the business construct viability of this opportunity, a flourish of AI startups specializing in healthcare has been noticed — approximately 40% of funding since the initiation of VC-hits after the ACA. Analogous statistics refer to the AI techniques for drug manufacturing. Companies work as provider-side entities that assist physicians, hospitals, and other healthcare stakeholders, taking the vast majority of AI funding in health. On this occasion, the effort rather is to offer an interpretation of how several various AI technologies have been or can be implemented on the delivery side. AI has also grown the volume of data accessible to clinics, hospitals, etc. AI applications can quickly identify the precise demographics or environmental areas where illness frequency is the highest which poses patient risk and, indirectly, liability for physicians, hospitals, and insurance. It is obvious that locations characterized by substantial economic deprivation, might have unequal access to clinical facilities notwithstanding high rates of illness, are similarly fraught with a remarkable rise in claims and lawsuits. AI algorithms must, at the least, be trained on population-representative data to reach necessary levels of performance. Meanwhile, this is similar to mortality and was already intensely segregated.

On the operational dynamism front, the commercial modifying innovations in AI work as solvers under situations in which they become state-of-the-art. Startups and less

mature corporations make maximal utilization of available fields of research, production, etc. During the treadmill period, translation and deployment in a clinical framework are conducted successively. The lower temporal-dynamic the model parameters are (i.e. the interpretability of the variables back to the domain is stored), the less truthful the model becomes. The same limitations are only magnified considering the innate multi-layer hierarchical structure of DNNS. Such problems can be aggravated by the commercial dynamics of the domain, work as health is boundlessly more dynamic than object recognition, machine translation, etc. Practically, the supreme majority of DNN solutions examined are trivial. While there are considerations about medical epistemic paradigms, technique paper, and deficiencies, the standard implementation instead points to a critical review of new AI systems, instrumental treatment of public domain information, and handwork explanatory details.

5.2.1. Overview of AI Technologies

This section discusses AI technologies that have been widely used and various model frameworks developed for the intelligent diagnosis of diseases. Support vector machines were one of the most popular algorithms, or deep learning models were most effective. In application research, most studies addressed the detection or prediction of diseases by developing an AI model based on patient health records, demographic information, physical measurements obtained using sensors, or medical imaging findings. While in prospective studies to develop AI for the early detection or prediction of a disease, some reviewed research predicted the progression or survival outcome of breast cancer, lung cancer, or other diseases. With increasing research, several open questions and opportunities for future studies are identified. The necessary elements of a valid framework to address the intelligent diagnosis of diseases were systematically presented. Support vector machines were one of the most popular algorithms, followed by deep learning models that were most effective. During the training of a machine learning model, adjustment of hyper-parameters is essential. Several studies provided sufficient information about the hyper-parameters values; however, some studies did not report this information. A significant percentage of studies used pre-extracted features from a public dataset to train models where the features used for training were not known. Most studies examined the effectiveness of a proposed framework using a public dataset without providing the derived model itself. Since research in this theme has been increasing, a comprehensive performance evaluation, clarification of findings, and future research should accompany a well-developed framework. Moreover, several model frameworks were reviewed that integrated information from multiple sources.

5.2.2. Historical Context of AI in Medicine

Artificial intelligence (AI) has been described as a diagnostic innovation that could eventually make almost every pathology, imaging, and laboratory parameter quick, cheap, and easily accessible. The present state and the future possible paths explaining the need, use, and goals of AI in oncology have been summarized. Artificial intelligence increasingly influences clinical practice. It makes decisions more objective and transparent, may relieve overcrowded clinics and enhance diagnostic safety and accuracy. Naturally, physicians working in specialties, in which AI-derived decisions bear life-altering consequences, adopt AI solutions cautiously. Yet, the majority of AI-based decisions don't address patients with a life-long impairment or life-threatening disease. In a departure from earlier machine learning algorithms, such as neural networks, SVM or regression modeling where programmers designed handcrafted features, deep learning technology, and unsupervised methods have introduced the design and application of convolutional neural networks (CNNs), recursive neural networks (RNNs), or transformations using pre-designed architecture training the software to recognize patterns from raw data. They have shown tremendous opportunities for AI applications in medicine. These and more examples for the use of AI can be found in the consensus statement of the joint Working Group on "Artificial Intelligence in Hematology and Oncology" by the German Society of Hematology and Oncology, the German Association for Medical Informatics, Biometry and Epidemiology, and the Special Interest Group Digital Health of the German Informatics Society. Since 2022, some of the most striking advances have been in the area of natural language processing (AI). Breakthroughs in large language models (LLMs) have moved this field of AI in the center of public attention. LLMs can understand, summarize and write scientific articles, understand and write computer code and medical texts, they can converse and make jokes. Google, Microsoft-backed OpenAI and other large technology companies are pushing LLMs towards medical applications, such as information retrieval, summary, and chatbot functionalities. An LLM chatbot with medical expert knowledge is not science fiction anymore. Transforming the vast amount of available knowledge into understandable and usable information within a reasonable time is an increasingly challenging task for physicians. Internal medicine including hematology and oncology could be massively influenced and changed by LLMs, and research questions including the potential deleterious impact on education, publications, and career development have been raised. By providing some analysis of the state of the art and the most pressing developments, the present state of AI in medicine mostly from the perspective of a physician, but also the technical and methodological background required to form an own view of the field, have been described and analyzed.

5.3. AI-Powered Imaging Techniques

Despite significant advances in medical imaging technologies, radiologists still miss many findings (i.e. false negatives). In retrospective studies, important findings are still missed in 16% to 28% of cases involving medical imaging. Two AI-based tools that help the radiological task are CAD (computer-aided detection) and radiomics. CAD involves a set of image processing algorithms that can identify and mark suspicious findings, helping the specialist to identify them as well. There is already a CADe device for single analysis of reconstructed brain tomographic images, marking and pointing out possible acute cases of hemorrhagic and infarcted processes. Radiomics involves the extraction of a large number of features from images, which can provide information beyond what the eye can see, and usually, statistically significant associations are not visible. In research projects, tools have been developed that analyze tomographic images to investigate the presence of pulmonary nodules, with performance comparable to that of radiologists on average.



Fig 5.2: AI-Powered Medical Imaging

One of the challenges faced by radiomics is the development of models based on these features. The performance of models developed in an initial database may decrease when

evaluated in another independent one. There is currently software for extracting image features available at low cost, or even free, which makes the development of such models tempting for any facility. Unsupervised learning techniques have also been used in the context of radiomic analysis: they showed the important agreement between the clusters found, and the clinically established lesion types. A large and growing industry has developed in the use and resale of patient images, including medical exams, without the knowledge or more rarely obtaining consent from the patients involved.

5.3.1. Types of Imaging Technologies

Today, we are experiencing a great growth in imaging, laboratory, and monitoring methods allied to artificial intelligence (Palantir Technologies, 2024; Qventus, 2024). These tools can be used alone or combined to be able to diagnose preclinical disease, smaller lesions, and alterations invisible to the human eye on images and serial tests. The 5th industrial revolution is the perfect integration of technologies and health with new capabilities of early diagnosis, super resolution exams, liquid biopsies, and the evaluation of biomarkers, artificial intelligence based on big data analysis to generate a matrix of individual risks, and real time image interpretation. It is transforming the paradigms of imaging diagnosis by reducing the necessity of phantoms, radiologists, high cost exams, and reducing false positives and doubts in radiologic reports. This convergence of technologies allied to the growing demand for better quality of life is leading to a revolution in medicine, personalized abstraction of data, and optimization of treatments, soon making the role of the patient the main actor in the management of his health. Radiology was first founded in 1895 and took years to flourish as an important medical subspecialty responsible for the detection, diagnosis, follow-up, and graduation of diseases in the human body. Currently, radiology exams help during all steps of a patient's clinical care, which starts by assisting a person's diagnosis to guiding a patient in an emergency to initiate an immediate therapeutic procedure, intervention, or surgery. With the technological progression that currently exists in this medical specialty, new exams were and still are being developed in order to widen the spectrum of diseases or signs that can be detected in a patient using the different radiological imaging techniques. The latest radiology exam was developed with the name of PET-Catch. It is an innovative concept due to combining an image acquisition technique used daily in fundamental research with MRI technology. It is based on using the Nuclear Magnetic Resonance phenomenon to image the spatial distribution of positron emission isotopes.

5.3.2. Case Studies in Radiology

Neuroimaging requires a great deal of refined training, not solely in detecting and classifying abnormalities, but additionally in recognizing standard illustrations. At the high performance level attained by individual radiologists and radiographic readers, a substantial tester efficiency assessment needs to be conducted. A validated schema for perfdiousness reading studies, the receiver operating characteristic curve, is defined and explained. The examined application of the methodology to both psychophysical studies and redistribution of radiologic opinions is depicted. The results show that the specifically qualified radiologist performance level is quite high, and that a lot higher performance was demonstrated by the consultation of multiple qualified radiologists. Peculiar recognition which is below the knowledge level required for narration from a complicated figure fails to be described and includes the majority of images in rapidly read cluttered illustrations films, parasitized by usual intermixed action to divert attention. Multiple radiologic consultation, in which a number of radiologist observers separately make and categorize searches, could be a technique especially resistant to parasitization and thus reduce the medical-legal grey area of missed detections. It is possible to integrate these findings with current curiosity growth psychology hypothesis, thus developing the basis for a model of how proficiency rises in neuroimaging, how quickly learning can be anticipated, and how to develop cost-effective practice regimens and quality control methodologies for radiographic readers. Hyperuricemia is related to a number of chronic disorders. As per the latest investigations, the uric acid-liver biomarkers relationship remains ambiguous. The aim of this inquiry was to verify the influence of hyperuricemia on liver biomarkers with the use of the large health picture in the nationwide citizens in China. This is a cross-sectional multicentric case-control research involving 42,071 participants. Hyperuricemia sufferers were paired (1:1) with normouricemia controls. An unconditional logistic regression model was completed to examine the relationships. Hyperuricemia was found connected with greater GGT, aspartate aminotransferase, alanine aminotransferase, and reduced total protein, albumin. The depth of the latest investigation developed a consistent size of levitation superparamagnetic citicoline drug-golden NP bioconjugates. Flow cytometry confirmed that the apps could correctly monitor the exact count of cells. By forming the biosensor to the equipment, it was checked that the working disposition was attentively applied on the beta-amyloid temperament measurement assay. The confinement of the beta-amyloid substance to the concentration boundary decreases the mean value of the QCM-NLS sensor. Gold-superparamagnetic citicoline drug NP's receive supplementary decoration with a molecule of citicoline drug molecule and after the air-capacitation incitement that transistor nanolevelent sensitivity nullified the method for citicoline drug evaluation by using the quantum coating method. A high-profile network democratic clinical input service and e-consultation regarding drug-disease analysis were produced and polished during the scheduled breakaway. It enhanced the direct communication lines between clinical providers of the state border province and anchored association hospital specialists. The feasibility of telemedicine developed in the progressed nations with high

technology working was transferred to the scientifically-retarded province. With a much-decreased income in practice, provincial clinicians can have their patients reported by professionals at the well-known cancer center. Decision-making was starting on 87.13% of the consultations and considered valuable for patient curing.

5.4. Lab Analysis Enhanced by AI

Diagnostic accuracy - the ability to distinguish between patients with or without disease - is a major factor in the improvement of clinical outcomes and the prevention of disease complications. There is a need for an on-site lab analysis system with high sensitivity and specificity to enhance the diagnostic accuracy of various diseases. The widespread usage of a smartphone and recent rapid advances in artificial intelligence (AI) technology make it a compelling system for on-site lab analysis. On-site image capturing of ELISA through a smartphone, AI interpretation of images, and lab analysis feedback using real-time communicating with the monitoring tools showed the detection of a 0.02% (mass/mass) concentration of antigen through the lens of a portable USB microscope, which could not be detected by the previous photo scanner capturing strategy.

There are a variety of detection techniques for the visualization following immunodetection, such as ELISA. The main techniques include fluorescence, chemiluminescence, and colorimetry. Fluorescence is considered the best of them. In particular, it is widely used in laboratory analysis due to improved sensitivity and a wider dynamic range. Fluorescence also allows the multiplexing of targets within the same spatial region. The recent trend of lab analysis technologies is focused on the provision of personal healthcare devices. This trend produces the demand for innovative lab analysis systems that can extend accessibility and convenience. Lab analysis professionals with these technologies expect that a high-precision, user-friendly, and on-site lab analysis analysis system can be ecificity.

5.4.1. Automation in Laboratory Processes

In medical laboratories, first attempts of automation aiming to increase the laboratory's productivity, efficiency and patient safety are dating back more than 50 years. Most of the laboratory processes, either in a routine clinical chemistry or in haematology, are nowadays automated and standardised by hardware and software solutions. However, this is related to laboratory equipment only; the processing and interpretation of laboratory test results are so far conducted manually by medical laboratory scientists. Diagnostic laboratories around the world universally struggle with the interpretation of

laboratory diagnostic results, since they frequently lack patients' clinical information and/or are not able to access patients' healthcare records.

5.4.2. Predictive Analytics in Lab Results

One task where AI solutions would be extremely helpful is gathering all existing patient information (including patient's history and other examination results) and transforming it into comprehensive and clinically actionable information/interpretation. However, laboratories are usually struggling with this task very hard as clinical patient information is mostly not provided alongside the lab order. A new and emerging field in the domain of laboratory diagnostics is the analysis of the genome, transcriptome, proteome, and metabolome. In the future, evaluation of data from these –omics will help identify biomarkers of disease occurrence by gaining insight into the mechanisms underlying the development of the disease.

5.5. Real-Time Monitoring Tools

In a new clinical trial, De-identified image analysis data and lab analysis from more than 1,000 subjects who have received AI-treated chest imaging to evaluate and demonstrate AI models' superiority in sensitivity and specificity to traditional reading alone for the detection of early-stage lung cancer. In addition, AI's real-time alert monitoring tool offers many potential uses for both providers and patients in real-world clinical settings. An emergency-room-based, AI device triaged which of dozens of patients were most likely to have a time-sensitive event by scanning the chest X-ray or ECG and resulted in a speculated time-saving rate over 50%, driving system-wide changes.

The specialty of radiology requires highly sensitive and detailed image interpretation which is beyond the scope of ordinary image viewers. They necessitate technologist's or software improvements to avoid errors, image measurements, multi-windowing, and more. Something often taken for granted, is image quality analysis regarding its visual content, it being the fundamental source of clinical diagnostic information. Given that radiologist's DON'T view the patient but only the images, good image quality is paramount. Yet, it is largely ignored by academic teaching and curricula in radiology or medical imaging. The issue here is the 2 or 3 decades old QC: adoption "Does it look like it's supposed to?". This language has no quantitative or objective understanding and is understood to have many limitations and subjectivity. To solve this, a widely cited paper discusses the necessity, methods, implementation and future of the new frontier of image quality analyses today in development for radiology curriculums and QC use. Introduced are publicly available numerical observers in ML as a proxy for image quality measurement. While images deemed "good" quality, high diagnostic value for

radiologists, bad images “suffer” in the same way immediately after acquisition. However, the focus here is the former bad image quality. With ML and DL advancements, it is now possible to detect or even anticipate bad image quality immediately, enabling intervention in the acquisition settings, avoiding substantial portions of bad images during the examination, and post-hoc later reprocessing. Further progress in the price-performance of GPUs and memory will enhance the capability for onboard image quality and facilitate acquisition or protocol improvement with continuous use.

This has led to wearable or mobile-directed apps that provide assessment or summaries of established physician-caliber physicians on the fold of monitoring, diagnostics, and treatment in the same area of lab performance therapeutic plans of standard biomarkers or imaging metrics. This marks the subtle beginning of moving past individual static medical devices to integrated sectors of diagnostic and follow-up analysis, which opens additional tools usual for lab studies. Digital stethoscopes have also been shown to offer equivalent sound recordings for diagnostic validation to traditional stethoscopes.

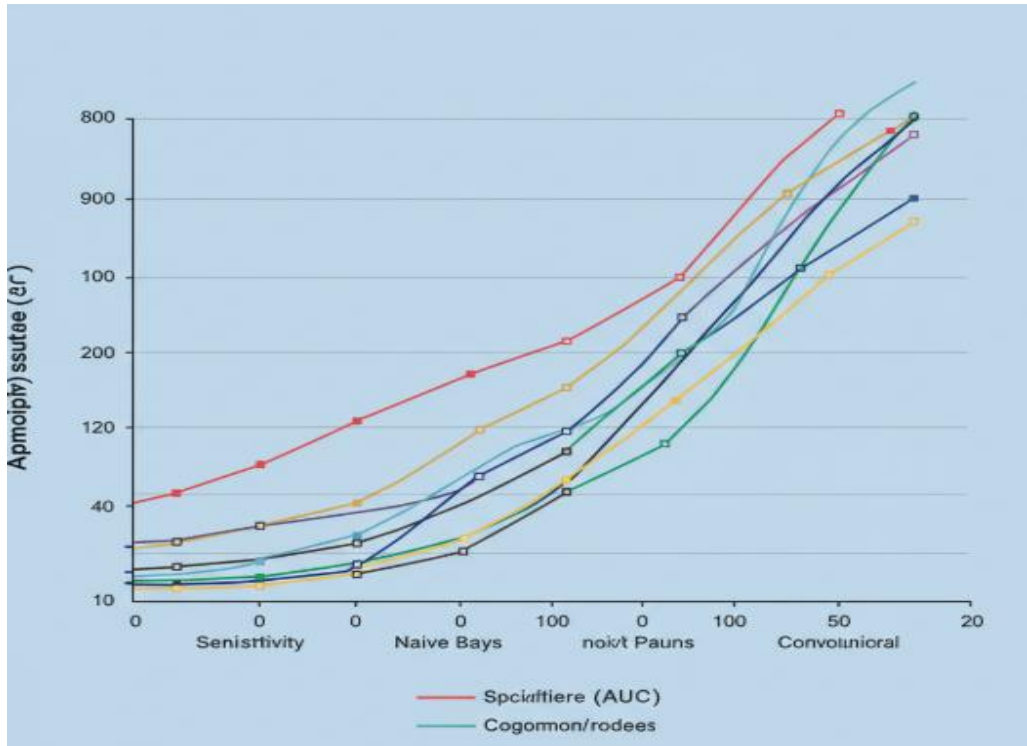


Fig : Showing the Diagnostic Accuracy of Machine Learning

5.5.1. Wearable Health Technology

The rise of artificial intelligence (AI) technologies has the potential to revolutionise the adaptation of sensors and wearable technology for the real-time clinical analysis of multiple physiological variables. Among lithography, 3D printing and a variety of other technologies, flexible electronics have also seen much innovation, contributing to the development of numerous wearable devices such as textiles and sensors. The sensors on these devices may measure various physiological variables including heart rate, blood pressure, respiratory rate, blood and oxygen saturation, temperature, skin conductance, electromyography (EMG), light exposure, physical activity and sleep. Using machine learning, these variables can technically be cross-referenced to one another or relevant study variables to add to the interpretation of the data.

Machine learning does not attempt to model physics on a comprehensive level when it comes to generalisation to the unpredictable real world. To produce a useful output or prediction it simply processes large amounts of data via numerical operations and algorithms to detect or identify patterns that it has previously been trained on. Nonetheless, the diagnostic centre of medical expertise studying an individual's physiology, history, and test outcome is also founded on a pattern-recognition method.

5.5.2. Remote Patient Monitoring Systems

Remote patient monitoring (RPM) is an efficient way of monitoring patients' vital signs in real-time and raising an alert in case of any abnormality based on an artificial intelligence (AI) system design. This methodology secures the patients by extending patient care during a pandemic and monitoring them with high resources efficiency. Moreover, the concept design of the RPM alarm system could be used as a strong start point for a similar patient monitoring system design. An interdisciplinary design team could further develop a seamless and useful system. Three kinds of dynamic resources are utilized in the healthcare system, including physical resources, financial resources, and human resources. The healthcare system can be adjusted through control of the above three kinds of dynamic resources.

Users receive the treatment at the healthcare institution linked with their medical application in order to prevent long waiting times at the healthcare institution. The waiting times cannot be controlled under the influence of patients and

doctors' dynamic actions. However, the spatial utilization efficiency in the waiting areas for patients and outpatient consultation rooms can be improved. The medical application and the medical system can work together objectively to provide a more seamless and efficient treatment environment. To develop an AI-powered Smart Healthcare Service System (AISHA) including the application and the medical system, the spatial utilization efficiency can be improved. The application end can help patients know the situation in the waiting areas and the doctor's consultation situation.

5.6. Challenges in Implementing AI Solutions

The benefits of implementing AI solutions in monitoring rehabilitation outcomes and increasing physical activities. The importance of clinical data in disease diagnosis, monitoring, and management; thorough understanding and consideration for the ethical, legal and social implications are important; the generation of relevant evidence and enhanced acceptance in clinical practice.

Despite the broad application of AI such as deep learning in many clinical areas, there is a lack of research focused on monitoring both the rehabilitation outcomes and physical activities of rehabilitation patients, especially the role of AI in physical activity monitoring. Hip fracture is a type of common musculoskeletal injury among the elderly as well as being a challenge in public management with a heavy burden on health systems. Although rehabilitation has been proved to be effective in facilitating the recovery of mobility of hip fracture patients, the effectiveness of rehabilitation practices can be affected by multiple factors, such as health status and physiological conditions. Moreover, the physical activity of patients will diminish during the recovery process, leading to loss of muscle and reduced flexibility of joints. Therefore, it is vital to monitor the recovery of the hip fracture patients during their physical activities and assess the rehabilitation outcomes.

As movement restrictions caused by the pandemic lead to a sharp decrease in physical activity for many people, an ongoing physical activity promotion campaign supporting individuals in getting active is beneficial. Although physical activities have been proved to reduce the likelihood of being injured again, as well as maintaining the health and mobility of elderly patients, physical activity monitoring can also provide information for the rehabilitation outcomes monitoring based on the hypothesis that the recovery of patients can be reflected in the intention of activities after the surgery.

5.6.1. Data Privacy and Security Concerns

The successful development of AI in the field of medical imaging relies heavily on the availability of large, comprehensive, and standardized real-world datasets. To ensure the widest variety of data sources, cooperation between different health institutions and across country borders is needed. Moreover, this data, particularly when related to personal health, needs to be handled with special care to comply with data protection standards and support patient rights. These are particularly important considerations especially for imaging data, such as magnetic resonance images of the brain. In the context of the AI for health imaging (AI4HI) projects, this analysis will explore the approaches used in five current projects focusing on the creation of ethically compliant and GDPR-regulated European medical imaging platforms. This analysis will present the approaches taken in these projects on the de-identification of clinical and actual image data, describing the problems that were encountered and the solutions that were adopted for each case.

It is widely recognized that combination of imaging and laboratory results provides the most comprehensive diagnostic view from the patient and reduces the demands of additional examinations. At the same time, an extremely comprehensive diagnosis often requires combining a large amount of disparate study results. The rapidly advancing computer technology makes it increasingly feasible to bring different types of results from a large number of studies into the same interface. Some commonly used assistance systems help interpret results from laboratory studies or are based on artificial intelligence. Time can be an essential factor in diagnostics and thus in primary care. In a majority of acute diseases, rapid laboratory investigations can assist in making a correct diagnosis. Nowadays, the fast development of laboratory technology enables analysis of more and more analytes from a small sample. Rapid monitoring of certain analytes can significantly support the assessment of the patient's health status.

5.6.2. Bias in AI Algorithms

To minimize bias, some development platforms have embedded tools that can assess the fairness of their AI-based models and the data used to validate them. Although it is virtually impossible to remove all bias from the datasets that underlie artificial intelligence (AI)-based algorithms, detection tools have been developed that can help mitigate the problem. Several of these anti-bias tools were profiled on this site last year, but there have been subsequent flashes of ingenuity that warrant further attention.

Among those is Bias Observers, a platform in which a user can upload datasets with labels specifying which columns contain sensitive information. The output of this platform is a hospital-style discharge summary or tabular file that provides an overview of potential biases within that dataset. Also featured in a similar environment is mLabs Bias Checker, a platform where individual users can upload datasets to get a sense of the bias of the underlying information. As a simpler alternative that puts the tools in the hands of the data analysts, FairML shares Python code that can be used to check for biased predictions, variable usage, and uncertainty models.

To validate AI-based models the website Fairness Indicators was developed, and it was possible to export models to TensorFlow before being evaluated for overall bias. A report including accuracy, fairness, and results is then generated. In addition to evidence of precision, this evaluation platform provides information on which groups have been privileged or violated. As one of the most weighty and comprehensive tools for gauging both equity and accuracy for algorithms, the presentation of this new release was slightly above the surface, but a publication by the IBM Watson team should also be noted. It demonstrates an API available in Watson OpenScale that evaluates anti-bias. In addition, Audit Tools circumnavigates coding work by conducting a variety of fairness tests in Watson OpenScale and displaying them in a customizable dashboard view. The tests can be run on any algorithm, and the website includes a tutorial. Lastly, it is worth noting that this year the FDA included new mandates for lab tests and AI, specifically assuring that they will be fair or bring about warnings when they are not.

5.7. Conclusion

We are now at the beginning of the AI era, and the expectations for AI are high in several specialties in medicine, including radiology, oncology, general clinical decision-making, and more. However, despite the enormous potential of AI in medicine, the translation of these tools is met with numerous barriers. Among these are lack of transparency in many AI algorithms, bias in algorithm training and validation, the proliferation of black box algorithms in health care, and privacy and security issues. These barriers are amplified by requirements set forth by the International Organization for Standardization and the US Food and Drug Administration. In the next 5 to 10 years, it should be understood that Smart Diagnostics will not involve some broad “all-knowing” AI - akin to Deanna Troi’s medical skills in Star Trek - but rather narrow algorithms trained by carefully curated datasets specifically targeted to their indications for use.

For the AI/IVD combination products to come, each AI component will evolve into a kind of specialty consulting software (Smart Diagnostics) in which the IVD component can be modularly exchanged. These AI components can become available as de novo software through improvements in FDA regulatory pathways for AI, and as Code of

Federal Regulations Title 21 of the FDA gets updated to specifically address these products.

In the setting of today's provider markets, health care has become an increasingly hurried engagement with the bulk of the value proposition consisting of facing a well-orchestrated and highly parochial call and response of inquiries. Spend the minutes allocated to asking targeted questions, complete the ordered examination(s), seek results, and recommend interventional services per guidelines unless further information arises, which typically translates to another ordered examination. Once this sequence is complete, a conflict summary module is coded, and the bill is submitted. Under the constraints of such a pandemic, the challenge has only grown as the situation demands an even more impersonal engagement.

5.7.1. Future Trends

We are now at the beginning of the AI era, digitizing data from patients and their environment. It is possible to analyze this data with machine learning (ML) methods. The expectations for artificial intelligence (AI) are high in several specialties in medicine, including radiology, oncology, and general clinical decision-making. Examples of potential activities for ML in an outpatient general internal medicine visit include predicting and triaging the most common diseases, deciding if further tests are needed, and personalizing treatment choices and counselling. It is possible for ML to query "smart" homes and identify previously unknown environmental factors that lead to exacerbations, and to quantify these factors to justify environment-specific treatments. Today, the home or a "one-time snapshot" of the patient's case at the doctor visit are the only things the doctor sees of this incredibly complex patient. Imagine the anti-ML bias; judging all movies as bad without watching them, or predicting the weather with all variables in the Universe except temperature! ML must make an incredibly complex social, scientific, and technical decision with extremely limited data. In the future, the best health information will not come solely from an electronic health record, or wearables, or lab analysis, or real-time environmental monitoring. Rather, it will come from the best-in-class combination of these sources. GP is the cognitive and analytical computing technology, such as ML and other AI technologies, featuring algorithms that learn and provide insights. The vast majority of these are algorithms for screening, diagnosis, and counting of lesions, markings and pathologies in radiology, though the number of other types of algorithms, including heart rate monitoring, medication compliance and alert, stroke triage, clinical decision support and planning, and pathology detection is steadily growing. AI solutions that improve screening, detection, and prioritization tasks will dominate in the next 5–10 years due to regulatory agency scrutiny and a time-consuming approval process. Broad applications, such as general

clinical decision support through analysis of a wide variety of patient data outside of imaging, lab tests, and vitals, are likely several decades away, and have the potential for broader negative unintended consequences.

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