The Future of AI-Driven Technologies in Medical Laboratories

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Abstract

In this systematic review, we conclude that many AI models in health care result from volumetric exploration and almost exclusively focus on black box models whose underlying mechanisms or reasons for making specific predictions are not understood by the user. However, most of the current methods are not transparent and difficult to understand due to their inherent black-box nature. Our analysis also shows that medical decision relevant AI models do not yet consider the factors of explainability, interpretability, reproducibility, robustness, and trustworthiness of deployment in clinical routine. All the above-described properties are essential to ensure the quality and safety of clinical decisions based on AI.

Keywords: AI-Driven Technologies, Medical Laboratories, Automation

1. Introduction

All the AI-driven technologies can become an essential part of the future innovative personalized health strategy. Such new technologies allow for the extraction of information through a routine, relatively cheap laboratory test, without adding extra costs for the health care system, or at least minimally adding work to the patient, unlike taking dedicated extra biopsies for next-generation sequencing analytics or their tests that have a higher price and lead to increasing health care expenses.

These requirements are robust and emerging. Emerging technologies, led by AI innovations, must be embraced inside traditional systems. Neonatal wards can use different predictive modeling tools to provide information on both preterm babies and term babies, helping to reduce mortality and to support hospitals' efficient allocation of resources. Advanced algorithms can ease pediatric haematooncology work by automatically extracting leukocyte subtype counts and support differential diagnostic procedures. AI-stationed decision aid pencils could support personalized clinical strategies in the preceding perinatal phases, from the normal pregnancy and reduced fetal movements to the illness-based HIE.

There will be several requests for laboratory work in the future. Demand for post-operative, genetic, and immunological tests is rising, and geriatric patients generate more demand for laboratory tests.

Considering these factors and the global microbiome project in pathology, it is crucial for Medical Laboratories to integrate artificial intelligence- (AI) driven technologies into core laboratory information systems.

1.1. Overview of AI in Medical Laboratories

Starting this trend in the field of laboratory medicine reopens new lines of investigation and understanding of most effective features, DNA and RNA markers, proteins, enzymatic activity, medication metabolizing and, at the end, medical treatments for each single and individual patient. The way to go is to put the development of AI applications at the forefront in focusing most of the attention on protecting patients' health in future. The financial implications in terms of new ADT market demand, healthcare cost reductions, and smart prevention systems justify these efforts and demand for a defection of research, health technology development and health investment [2].

Automation, data digitization, internet access, electronic health records and health applications are transparent, interconnected, and contribute to an accessible database for standard laboratory tests [1]. Artificial intelligence (AI) and translational data extraction and determination of diagnoses. The extract of artificial intelligence has improved the early stages of the diagnosis process, examining a vast amount of data. Laboratory tests and surveys provide important feedback for patients' follow-up and their medical condition. AI also helps in this process by re-organizing data and enhancing classifications of medical data extracted [3]. The valuable and accessible data in the laboratory medicine database has great potential for the modeling and learning capabilities of AI. Therefore, in this era, we have to exploit more systematic facilities to access and analyze data that will not only lead to a better systemization and understanding of obtained data, laboratory and clinical results, but also will facilitate drug recovery and intake, an improvement of technical tools, social collaborations, community interactions, global health promotion, knowledge and idea integrations, and pre-treatment and follow-up curing system concerns in the field of medicine.

2. Current Applications of AI in Medical Laboratories

There is increased partnering between the traditional clinical laboratories and companies that focus on data sciences to apply global algorithm sharing in cloud systems for analysing immunochemistry and pathology histology stains. This can partially automate diagnostic reporting, particularly in resource-poor countries. There is an increasing application of data-mining techniques in predictive laboratory diagnostics considering both patients and quality management needs. It is important to consider data curation, data set size, real-world generalizability (performance across diverse patient populations), abstraction from the original data source, data security and informed consent, the context in which AI was developed and option for independent advice when interpreting diagnostic results [4]. In the future applications of AI in medical laboratories will need to consider this golden opportunity to leverage predictive informatics in health diagnostics for personal risk stratifying newly acquainted diseases and/or the tailoring of cost-effective personalized treatment monitoring [1].

The field of pathology has seen considerable progress with the use of artificial intelligence (AI) [5]. Computational techniques have started to rival traditional histopathologist assessments across different levels of cancer diagnostics. As labs work to improve quality and automation, with ever more complex tests being developed, there will be an increased need for AI in medical laboratories, most prominently in the area of computer vision and AI-based decision-making processes. The successful incorporation of

AI into medical laboratory testing requires a deeper understanding of the limitations of AI-based medical diagnostics, especially with current AI approaches and algorithms.

2.1. Diagnostic Imaging

An example of this potential for big data analysis comes from the increasing number of studies that have reported that the inclusion of deep learning models in clinicopathological risk models can significantly improve risk stratification accuracy. The market growth is also driven by increasing product differentiation, end-user transparency, and growing trust and infrastructure for big patients, high-dimensional, and multimodal healthcare databases. That is the case for example of MammoNu, a mammographic breast density informatics company that generates AI-scored tissue patterns and has generated thirteen outcomes' measures for breast cancer risk, which builds on a concept proposed over twenty years ago [6]. In summary, AI in diagnostic laboratories have the potential to add data-driven value in essentially all areas of diagnostic healthcare, from the laboratory to the clinic.

Details about existing AI-driven systems have the potential to improve consistency, reproducibility, and accuracy of pathology analyses. In radiology, these have the capabilities to enhance and replace human pattern recognition in a variety of ex vivo (mammography, computed tomography, magnetic resonance imaging, and positron emission tomography) and in vivo (abdominal and cardiac ultrasound, and optical coherence tomography) imaging technologies. This results in automation of image feature detection, quantitation of heterogeneity (e.g. through radiomics) and analysis of multi-modal datasets (e.g. mammography and magnetic resonance imaging for breast imaging). The four main ways AI can be employed in histopathology and radiology within diagnostic laboratories are: automation of routine tasks (e.g. slide scanning); decision making and triaging; highlighting areas that contain relevant abnormalities for pathologists and radiologists to prioritise their work; and providing new analyses (e.g. subjective assessment of heterogeneity, quantifying vascular architecture) supported by big data analysis of clinical outcomes.

3. Challenges and Limitations

7 Despite a wealth of external information and knowledge acquired from other disciplines, most of the machine learning (ML) applicability is focused on a single bottleneck learning. Given the large number of available datasets, the focus should now shift somewhat to applications. For the integration of AI- and ML-driven technologies into clinical research and development to succeed, pharma, biotech, and tech companies and the academic schools must converge in a combined and more organized manner, rather than pursue stand-alone, parallel paths [8]. This happens through data aggregation, anonymization, data sharing in a non-competitive manner, and research collaborations in which secrets pave the way for future products and medical devices. Despite the wide dissemination of medical AI literature, many important areas, such as feasibility ranking, screening, disease progression, drug development and trial designs, early warnings and detection of side effects as well as chatbots and software assistants, have been largely ignored. Few studies emphasize AI’s potential in medical management or for clinical care. Inaccuracy, neglect, overstatement, duplication, and absence of multiple expert reviews are often observed. Relying solely on published reports may lead to a grossly incomplete picture of AI’s clinical utility and opportunities for development. Systematic literature reviews, in silico meta-analyses, and a vast body of research covering various medical disciplines, real-world performance assessment, and external validation via improved outcome measure particularly in the context of large sample sizes have

several advantages, potentially leading to previously unknown subgroups and chances for tailored and personalized medicine [9].

3.1. Data Privacy and Security Concerns

Protecting patient privacy and information security is a paramount challenge in the medical AI industry [10]. It is essential for the safety, confidentiality, and trust of all stakeholders. With the increasing use of big data and AI, the scale of AI technology, the risk of data leakage, patient privacy and property security is also increasing. Risks include potential network attacks, privacy breaches, brand image losses, and security problems both in internal and external system operations. As a smart hospital, most medical services rely on network transmission, as well, putting it at risk for network attacks in an emergency. Meanwhile, the more accurate and reliable services provided by data-driven intelligent medicine help increase the data security risks. Problems such as data privacy protection have naturally arisen and protecting privacy and information security while using these valuable data has become an extremely important issue that we need to pay attention to [4,5]. At the same time, the current medical system will still encounter many challenges in ensuring patient data security privacy [3,4]. Cyber-biosecurity, a new and rapidly developing field, has extended the vital practices and conceptions of cybersecurity to the realm of biological science and biotechnology [11]. It aims to counter threats and dangers triggered by malicious users aiming to attack crucial infrastructures and systems (i.e., biooriented processes, production chains, equipment, and data) for harmful economic, political, and social purposes. In the medical field, bringing machine learning (ML) and artificial intelligence (AI) to interventional and diagnostic procedures means that they will not only assist in the identification and correction of cyberbiosecurity-relevant vulnerabilities but also contribute to safeguarding diagnostic and predictive analytics outcomes in real-time. For instance, a highly inter-connected, self-optimizing, self-regulating multi-tier lab-automation level that integrates medical AI technologies could continuously generate recommendations on how to actively increase the likelihood of a diagnosis being accurate and, consequently, enable users to be at the receiving end of early alarming signals due to changes in the true health status, suspicious clinical pathway deviations, and security threats.

4. Emerging Trends and Innovations

In the second paragraph, in medical research, AI may help pathologists and molecular biologists generate better cancer-specific and patient-specific histopathology aided treatment recommendations. AI-based assistance shall be integrated into the histopathologist workflow and especially during molecular pathological tumor board meetings, similar Bayesian Networking that integrates background knowledge to provide probabilistic tumor board recommendations. Progressive AI should not be viewed as substitute of the pathologist, rather as an integral part of the medical team. Finally, AI could be implemented for customer-oriented precision medicine and telepathology [4]. Do not underestimate also GAN-based models, because these may potentially be able to generate seemingly realistic (but artificial) histopathology and molecular pathology data for treatment planning and clinical trials, too. This trend report discusses the above challenges and opportunities of AI and medical science. It provides guidance and perspective of future AI-driven medical laboratory research and practice.

Generative adversarial networks (GANs) have emerged as a sub-domain of AI that focuses on generating artificial data that is strikingly like the authentic ones to fool humans [12]. GAN-based AI technology has the potential to generate surprisingly similar and realistic documents and digital portraits of the real patient's data, without compromising privacy and security. This could simultaneously empower the patient in real time and help the clinician as well (if shared by the patient with full consent). However, there still is a gap between recent advances in GAN based AI and its deployment in routine hospital use, mainly attributed to missing guidelines and safety standards. The standards and regulations must be revised and augmented in view of upcoming growth in this field. This futuristic paper suggests means to set such standards.

4.1. Blockchain Technology in Healthcare

Future studies could broaden and deepen the scope of our study or focus on the development and validation phases of AI-driven technological tools used in the laboratory field. The relative impacts of these fields can be investigated. Topics pertaining to artificial intelligence in the laboratory environment are at an early stage. Therefore, this environment should be balanced by considering various histological data and the industrial structure of our country. It is meaningful to evaluate this study in terms of developing and developed countries and rural areas. AI-technologies play an important role in clinical laboratories, forensic laboratories (crime scene, drug analysis, navigation, and blood spot), research centers, biotechnology and molecular laboratories.

Blockchain technology has a special utilization in the healthcare sector. Authorized stakeholders can securely access patient medical records using the suggested blockchain system. Blockchain technology in health care archives all medical interventions so that they are stored and transferred in a tamper-free way [13]. All applied medical interventions are transparent, immutable and verifiable; therefore, the reliability of the health data is established. By using blockchain, patient data and privacy storage standards will be fulfilled, and patient information cannot be tampered with. As the system saves all the chronological transactions, then physicians can understand all medical interventions that have occurred previously to the patient. Blockchain provides a secure platform and an interface, as well as a synchronous environment, for different stakeholders including patients, healthcare providers, and health insurers. Finally, all blockchain infrastructure including its security protocols, databases, and system scalability will be analyzed. The pros and cons of the proposed blockchain platform were presented since it provides a secure healthcare environment through its user-friendly, interoperability capability, tracing, and immutable blockchain characteristics. Due to the increasing innovations in medical laboratories, the need for professionals who can use artificial intelligence (AI) algorithms in data analysis, develop new algorithms, and perform optimization has also increased [14]. The use of AI-technologies in medical laboratories as the test centers of hospitals has significant effects on workflows, the economic structure of medical laboraties, higher academic education, and the cost of laboratory tests. It can result in the betterment of treatment quality and cost and ease staff shortage by automation and can support clinical decisions. AI technologies can be utilized for the identification of blood and microimage based parasitic infestations, detection of immunohematological abnormalities, and the prediction of hematological malignancies.

Blockchain technology offers potential in health IT such as use in health data exchange. It is a promising technology for instant and decentralized health data exchange using consensus algorithms (like bitcoin), cryptographic algorithms for user identification, and secure data transfer through encoded data [15].

5. Ethical and Regulatory Considerations

Clearer policy guidance on the type of acceptable activities can be established for creating a regulatory framework where AI and human professionals coexist or for governing variations of AI which are ethico-technologically friendly and therefore allowed for serving human interests collaboratively. The importance attributed to AI on a global stage is evident by the growing governmental and nongovernmental cross-disciplinary team discussion regarding AI legislation. Industry professionals, standards development organizations, and regulatory bodies also recognize the requirement for updated and intersectional regulatory guidelines in order to support AI within medical laboratories for instance, public consultation was held by the Medicines and Healthcare Products Regulatory Agency in 2019, where leading professionals and stakeholders in AI and healthcare shared their opinions on the regulatory frameworks for AI used in healthcare, including in medical laboratories. Without more robust ethical guidance, the propensity exists for a parallel myriad of examples where AI systems have been manipulated to disadvantage patients or groups of patients in healthcare like learning healthcare systems should prioritize guiding public value. forEach-ε-fairness approach, of new machine learning algorithms allowing the automation of common laboratory measures. Bioethical issues are likely to later compound the implications of personal decision making. Ethical analytics of AI in laboratory medicine can have fatal implications in patient care and thus necessitate high quality assurance mechanisms for machine learning algorithms, they include pre-processing machine learning data, representing causal relationships, generating explanations of outcomes of AI-based laboratory diagnostics and handling clinical and legal aspects of machine learning algorithms validation process.

The integration of AI into medical laboratories also mandates the development of robust ethical and regulatory frameworks, considering critical ethical considerations such as human agency, transparency, trust, privacy, issues of responsibility, and accountability [16]. These considerations are necessary to engender patient provider AI trust dynamics, especially given the nature of the medical decisions being taken with lab tests results serving as inputs. The quality and safety of medical laboratory investigations, and the information that flows from them, are independent of the modality of technology used to generate such data; thus, standard ethical principles underlying laboratory medicine activities should also guide the use of AI. In a clinical laboratory setting, all healthcare personnel are expected to uphold a code of professional ethics, patient respect, and dignity. Likewise, the decision quality must be high, data handling ethical, privacy regulations upheld, human–computer relationships be explainable, responsibility and trustworthiness be clear, and data be managed in a transparent manner befitting the relevance of information produced. A narrow focus on productivity and efficiency improvement could lead to reverse value protection, privacy invasion, and hence patient welfare jeopardy. It is also acknowledged that despite these concerns, some AI-based diagnostic methods might not only be ethical but even more ethical than medically qualified human experts in conditions that justice of which is yet to be established by studies in the form of empirical validation.

5.1. Transparency and Accountability in AI Algorithms

This necessitates careful monitoring, regulation, and uniform governance. For instance, the federal Drug Administration (FDA) in the US has a unique approach to regulate AI in healthcare. All AI applications will have to undergo the same regulatory rigour as any other medical device to establish their safety and effectiveness. FDA’s role is highly critical for making AI developers and users accountable. The developers will be accountable for the development, construction of the model, ensuring robustness and reliability in its performance while the users will be accountable for the outputs of the model including provision of feedback. It is believed firmly by the FDA that ultimately if something wrong were to happen with a patient, law will come to the rescue and should not pursue AI.

In any clinical practice, a major impediment to approving a clinical decision-support system is its transparency [17]. Many research studies developing explainable AI (AI2) models are trying to fix this problem. It is essential that regulatory agencies start requesting a model's AI2 to be transparent with the rationale informing that clinical decision [18]. This will enable the community to continuously monitor the AI (from labelling the data to generation of class-wise probability scores) while providing feedback for improving its performance and patient safety. Ethics is about right and wrong. A very common characteristic against AI in clinical arena is that big data harbours racial, gender and other disparities beyond human eyes [19].

6. Impact on Healthcare Professionals

Informed by this study, higher education institutions may be in a good position to ensure that this field of technological innovation results in better medical attention as our near future medicine must be served from its early formation. This is necessary to avoid future malpractices in the name of technoscientific innovation and most importantly to ensure that the end-users perceive technology as something worth investing in their professional training and that this leads to social and professional recognition. This exercise contemplates a digital area in our teaching of the medical profession, according to the social context in which these training tasks are carried out, exploring a new critical, reflexive, and vigilant professional profile to ensure accurate practice.

Several medical professionals express concerns about AI use in their daily routine, such as lack of physical verification in testing. This skepticism could be resolved by demonstration of AI’s utility and much-needed trust from professionals. Professionals categorized as lurkers and trustors who trust AI without exhaustive evidence migrators uncomfortable with AI but open to technological evolution—and challengers with critical attitude towards digital medicine [20]. On the other hand, healthcare professionals also consider that the health system’s technological barrier hinders revolutionary innovation [21]. This situation leads to certain different training opportunities being bypassed, namely professional qualifications, so that the near future their medical practice can exploit all the promised advantages of digital medicine, but which also translates itself into an uninvolved and disempowered position within the institutions that they serve [22].

6.1. Role Transformation and Training Needs

The ability of a medical professional to engage with the rapidly evolving information system will be a hallmark requirement of the future [23]. Medical laboratory professionals should learn to appreciate the different classes of information, recognize patterns, draw inferences across diverse sources of data, and model. They should embrace computational thinking and outcome data analytics as critical skills in the decision-making framework. A consolidated approach to transforming the curriculum and incorporating ‘informatics’ education as an ‘embedded and integral’ component of medical laboratory science would be a pre-requisite. Regulatory agencies, accreditation bodies, and educational institutions have started designing and implementing terminal competency indicators and minimal competencies in AI-based technologies, applications, and laboratory information management systems into their curriculum. There has been the development of AI/Correlative Pathology modules by Cancer Imaging Archive in collaboration with Google AI and PathAI.

On the brink of the next decade, the role of medical laboratory professionals has a rejuvenation in the form of Artificial Intelligence (AI) [24]. Over the last few years, it has made its impression by producing valuable data on various aspects of human health. Its performance in recognizing patterns, language and speech (NLP), and taking decisions have already been acknowledged in several other sectors. Deep learning is extensively being employed these days to train prediction models in clinical oncology.

Distinct abstract levels of pictures from Early Breast Cancer Trialists' Collaborative Group (EBCTG), TED-Anatomical Pathology, CAMELYON, and TUPAC had been assumed as concept icons for classification applications where ResNet, GoogLeNet, Densenet, Inception and VGG-16 were used as classification techniques with multiple datasets in addition to transfer learning [25]. The development of computational models had been practicable mostly due to the accessibility of the information handed in various competitions. The recent evolution of CNNs and their usage throughout the longevity of the last decade are put into context and events which discuss important advances in several medical imaging sub-fields, including diagnosing diseases, detecting breast cancer metastasis and interpreting X-rays. There is dialogue on common challenges and pitfalls of using Deep Learning in these diverse problems to facilitate improvements in model training and generalization.

7. Case Studies and Success Stories

Nowadays, the interest in the possibilities of using artificial intelligence (AI) and machine learning for conducting advanced analytics on large-scale genomic, transcriptomic, and proteomic data sets involved in the personalized treatment of patients with malignant tumors has increased [26]. The use of AI in these studies concerns not only the possibility of identifying new prognostic, diagnostic, and therapeutic agents based on large-scale data in a very short time, but also the development of computer models of disease that could be used to support clinical decisions at various stages of diagnosis and treatment. These computer models should have an increasing role in clinical practice. They will be not only the tool of making clinical decisions by a clinician, but perhaps in the future also will support a patient in self-managing their state of health. This chapter presents the main challenges faced by researchers in the context of cancer AI. The integration and learning from different data dealt with in medical decisions will lead to the development of mixed multiomics AI in the nearest future. The development of artificial intelligence is one of the most promising directions for improving the health care system. Moreover, AI technologies play a significant role in making diagnostic decisions [27]. For example, smartphones equipped with dedicated diagnostic applications have already become an official tool in the case of primary care physicians. The development of AI diagnostic systems can save lives, especially in the case of chronic diseases. Innovative forms of telemedicine allow people to be diagnosed at home without leaving the apartment. AI diagnostic systems are particularly important in rural areas, where the availability of health care services is very limited. Moreover, telemedicine can help to receive entirely different measurements than usually performed in the case of patients with chronic diseases and thus provide doctors and researchers with a completely new perspective.

7.1. IBM Watson in Oncology

Most medical consultations in oncology depend on analyzing large volumes of data on individual patients, such as history, clinical status, imaging, histology, genome analysis, and standard clinical guidelines and evidence from published literature. IBM's AI-based Watson for Oncology, implemented by Manipal Hospitals, India, takes these data and provides evidence-based therapeutic options for various cancer types. However, Watson is not aware of the real world, non-standard practice. It tends to suggest unrealizable tandem therapies involving costly molecular targeted agents. Therefore, Watson effectiveness and accuracy depend on physicians' experience, expertise, and judgment.

IBM Watson is a significant AI-driven technology for medical laboratories [14, 35]. It has been trained on more than 3 million medical records and 100,000 academic articles. Watson interprets and analyses healthcare data from disparate sources to provide useful information to doctors for faster and more accurate diagnoses and treatment decisions in various medical fields [28]. Therefore, integration with patient data or diagnostic results can lead to efficient and highly accurate suggestions for therapy or treatment according to patient conditions soon.

8. Future Directions and Predictions

One recent study applied auto-biopsy deep learning models to predict disease progression in patients who had been infected with COVID-19. Models were trained on previously acquired data and surgical specimens to predict immunohistochemistry (IHC) staining using resected diseased tissues from patients with various diagnosis, tissue types, immunostaining, and scanner images from our hospital [25]. The dataset was acquired using three nontumor-like models which were applied to trikernal nanoparticle sRNAs from patients with various cancers and diseases as used in CT with SARS-CoV-2 and phenotypes in 466 tested sRNAs [12]. While sRNAs had potential to recognize NSCLC at least on SN and TM-like CT images, the biomarker patient category reduced from sRNA species range.

Artificial intelligence (AI) has made significant strides towards enhancing healthcare in recent years. With advancements in machine learning (ML) and deep learning (DL), AI has great potential for improving diagnostics, prognostics, and overall management of diseases. Mining large-scale datasets, diagnostic imaging data, and clinical notes using AI and deep learning algorithms has already shown great promise. Predictive models have been developed to indicate the severity of COVID-19 using biomarkers like liver transaminases and complete blood count [2]. These models adequately predicted several clinical endpoints including progression toward severe COVID-19 and mortality. By employing explainable AI models and novel training methods, AI can also be used to predict disease prognosis and treatment response based on electronic medical record (EMR), diagnostic imaging, and genomics data [9].

8.1. Integration of AI with Precision Medicine

The use of AI in precision medicine requires trans-disciplinary research including AI- and molecular biology-related knowledge advancements. Technological solutions and education where the development and monitoring of privacy issues, new jobs and specific education on personal AI techniques to support population health and lovintechnohealth resource planning related to health are important components of civilisation problems. The AI simulation personal capital, which involves primarily preventive or comparatively less risky practical tasks and no direct health harm, can lead to the change of population health indicators at population level, while this is likely to remodel clinical guidelines, causes of personal basic income and guarantees, and ultimately will be personal prescription and of medical interventions against personalized plans by this method. For precision medicine programs and initiatives to gain reliable and trustworthy acceptability around the world, ensuring the best benefit of the analyzed personal cohort and other parties and ensuring that the health system operated leanly and safely with an economic and data-operability, interoperability, and security environment [29].

Even though precision medicine using DNA/RNA profiling, imaging and multiscale data linked to patients, technologies and resources are emerging, these remain expensive and only serve a fraction of the population. Relevant challenges such as the need for additional and next-generation equipment, data handling, and networking, as well as interoperability of clinical and laboratory technologies, should be managed. In addition, the self-minimized efficiency of the omics technologies, technical and knowledge challenges in network pathway and extended gene analysis as a unity system are other barriers. An

Artificial Intelligence (AI) approach with comprehensive and comprehensive machine and deep learning with statistical optimization can speed up genetic analysis and thereby reduce the cost of production and genomic and precision medicine breakthroughs [30].

9. Conclusion and Final Thoughts

At the same time, explainable models would also help build trust with users, ensure ethical deployment, and bolster the release of applications with regulatory approval. While it is acknowledged as essential across applications for the implementation of transparent and interpretable AI, explainability metrics do not exist for every application. At every step, explainability can be requested even in low-stakes decisions, like simply getting a recommendation for a city break, which makes it clear that cognitive science will have to grab the evidence behind it to convince users to trust these programs.

In this systematic review, we conclude that many AI models in health care result from volumetric exploration and almost exclusively focus on black box models whose underlying mechanisms or reasons for making specific predictions are not understood by the user. However, most of the current methods are not transparent and difficult to understand due to their inherent black-box nature. Our analysis also shows that medical decision relevant AI models do not yet consider the factors of explainability, interpretability, reproducibility, robustness, and trustworthiness of deployment in clinical routine. All the above-described properties are essential to ensure the quality and safety of clinical decisions based on AI.

Field testing is usually an essential step in the final transfer to the AI system's end environment. Evaluation against predetermined success criteria, as established in the prior planning step, must be captured and maintained in the final report. Alignment with regulatory standards and ethical considerations and validation of the processes and capabilities of the final AI system are crucial parts of planning. In the context of this Tech Guide, we emphasize this aspect in the planning step but want to explicitly exhort clinical laboratories to comprehensive planning for validation, addressing comparators and gold standards, and planning collaborations with other parties in the healthcare system without underestimating the investment previously included in this process.

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