Perspectives on Artificial Intelligence in Clinical Healthcare Applications

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ABSTRACT

The concept of artificial intelligence (AI) has a lengthy history. It has become evident that achieving human-level intelligence is more complex than initially expected. Presently, there is a resurgence of interest in AI, driven by a substantial augmentation in computer capacity and an even greater proliferation of data, with advancements in AI technologies such as deep learning. Healthcare is seen as the subsequent sector poised for transformation using artificial intelligence. Although AI methodologies are highly effective for developing some algorithms, biological applications present distinct problems. We suggest six recommendations—the 6Rs—to enhance AI initiatives in the biomedical domain, particularly in clinical healthcare, and to promote dialogue between AI researchers and medical practitioners: (1) Formulate a pertinent and clearly articulated clinical inquiry; (2) Acquire appropriate data that is representative and of high quality; (3) Ensure the ratio of patients to their variables aligns with the AI methodology; (4) Establish a direct and causal relationship between the data and the ground truth; (5) Ensure regulatory compliance to facilitate validation; and (6) Employ the appropriate AI methodology.

Introduction

The concept of artificial intelligence (AI) has a lengthy historical background. Since the 1950s, several innovative assertions have been made on AI supplanting human labour within a few decades. It was revealed, numerous start-ups are targeting various facets of the health continuum in the field of genomics [1-7].

Artificial Intelligence

Nevertheless, attaining intelligence at human levels was more complex, resulting in many "AI winters," during which enthusiasm for AI waned [1]. Presently, there is a resurgence of interest in AI, driven by a substantial augmentation in processing capacity and an even greater proliferation of data collection. With the advancement of enhanced algorithms facilitating the training of deep neural networks, numerous high-tech companies have achieved successes in executing tasks that approximate or surpass human performance, including playing games such as chess and Go, image recognition and computer vision, natural language processing, machine translation, and autonomous vehicles, among others.

Health care is seen as the subsequent sector poised for transformation by AI [2-15]. Alongside several academic initiatives, corporations the phrase artificial intelligence refers to the creation of algorithms designed to do jobs usually carried out by humans, therefore linked to intelligent behaviour. Artificial Intelligence employs several approaches, including deep learning and probabilistic methods such as Bayesian modelling [8,9]; for definitions, [2]. The word is informally used to describe a computer that emulates cognitive processes, including learning and problem-solving.

Application of Artificial Intelligence Techniques in Healthcare

Health care evidently has several demands that might be addressed by solutions built using, or by integrating, artificial intelligence [2,4,18]. This article examines the contributions of AI to clinical healthcare, a field that presents novel and occasionally distinct obstacles for AI implementation. The subsequent sections address significant difficulties and offer our proposals for addressing them.

Although radiological imaging was the pioneer in providing digital data, digital pathology is a more recent transformative advancement. Moreover, hospitals have been digitising their medical patient records for several years. Consequently, a substantial and continually expanding repository of well annotated clinical data has been amassed: partially structured data in machine-readable forms, including medical imaging, and partially unstructured data in plain language. Similar to other industrial sectors, this big data trend is anticipated to be utilised to revolutionise health care and provide remarkable enhancements in the quality of patient diagnoses, treatment, care, and clinical outcomes. Anticipated outcomes include the identification of individuals at elevated risk for a disease, enhanced diagnostic capabilities, tailored treatment alignment for particular patients, and extramural monitoring of therapeutic responses [15-31]. While the potential of these prospects is well recognised, it is crucial to comprehend what can be practically achieved with present state-of-the-art AI technology and which applications require additional advancements in AI to become viable.

Artificial Intelligence Techniques: Supervised or Unsupervised Learning; Knowledge-Based vs Data-Driven?

A variety of AI technologies are accessible for selection [29-41]. Algorithmic learning-based AI can operate in a supervised mode, wherein a ground truth label is accessible for each data sample, therefore directing the AI process and relying on domain expertise. The accuracy of ground truth labels is essential for the effective functioning of an AI solution. The alternative, unsupervised mode occurs when no ground truth is accessible, allowing for the identification of similarities that lack a specified significance [2,16].

Traditionally, machine learning necessitates human intervention to identify data characteristics, employing subject expertise. Conversely, deep learning autonomously identifies such traits from the data. The traits are later employed in diverse models. Some of them may be knowledge-based models that include newly specified characteristics from deep learning in accordance with established knowledge [17,18]. The present industrial interest in AI stems from recent advancements in data-driven methodologies, particularly deep learning, and their relevance to industrial applications including speech recognition, machine translation, and computer vision. Nonetheless, it is anticipated that integrating data-driven and knowledge-based methodologies will elevate AI to a level far closer to human intelligence [17,18].

Artificial Intelligence for Specific Narrow Applications: Radiological Imaging and Digital Pathology Imaging is one of the most researched and effectively implemented potential in artificial intelligence. AI technologies may be utilised to differentiate cell nuclei or specific cell types inside a tumour sample on a histopathology slide, employing pictures captured by a digital pathology scanner [19-21]. These pictures are produced using standardised equipment and obtained in a systematic manner, resulting in homogenous data and offering excellent representations of the phenomena to be simulated. The scope of the problem domain is constrained. During the training phase, the AI system receives raw pictures accompanied with labels for various cell types, supplied by a pathologist. The pathologist is delivering a definitive reference, grounded in established expert knowledge regarding the various cell types or architectural features present in the tissue slide. Deep learning has been utilised for this issue, and AI technologies now surpass manually developed tissue analysis methods [16,20,22,23]. They are anticipated to soon match or surpass human pathologists in specific, well specified tasks related to histological feature detection and quantification, however they have not yet achieved this for clinical interpretation.

Artificial Intelligence for Broader Applications: Integrating Patient Clinical Data with Clinical Outcomes

Conversely, research initiatives are now using multimodal data (i.e., a synthesis of datasets of varying types) to facilitate the prediction of patient prognosis or clinical outcomes following certain treatments. One may utilise medical imaging data in conjunction with histology, clinical laboratory data, and lifestyle information to predict survival, the risk of rehospitalisation within a specified timeframe, and other related outcomes. Such programs continue to pose challenges and have generally demonstrated little effectiveness [5,24]. IBM's Watson for Oncology asserts its capability to amalgamate all accessible cancer patient data and disease information to enhance diagnostic and therapeutic decision-making. In 2013, the MD Anderson Cancer Centre implemented IBM Watson technology to enhance cancer treatment efficacy; nevertheless, the initiative was terminated in 2017 due to its failure to achieve its objectives. The concordance regarding the clinical interpretation of single-modality genome sequencing data, when comparing Watson for Genomics to a clinical genomics expert group, was revealed to be notably high, ranging from 77% to 97%, contingent upon the specific type of discovered genomic alterations [7].

The primary issue for AI in the forthcoming years will be transitioning from effective limited domains to broader, multimodal data systems. A viable strategy is to decompose the overarching AI objective into smaller, more specific goals rather than seeking a singular methodology to tackle every issue. In this utilising this methodology, distinct subsets of the data may be analysed independently using appropriate AI techniques to yield significant, clinically pertinent results. For cardiac ultrasound pictures, one may magnify the image to create a deep learning algorithm for measuring left ventricular volume; similarly, for pathology slide images, one might magnify to design an algorithm for the identification and quantification of a certain cell type, such as lymphocytes. To enhance the likelihood of success, it is essential to formulate a clearly defined, targeted, and clinically pertinent topic for an AI project that can be sufficiently addressed with the available data. The primary takeaway from this section is that a pertinent and clearly articulated clinical question must be prioritized [42].

The Correlation Between Patient or Sample Quantities and Data Variables

Numerous AI methodologies, particularly deep learning, depend on the accessibility of extensive datasets or big data [15]. Domain knowledge can occasionally facilitate the generation of supplementary data drawn from existing datasets. It is essential, however, to differentiate the type of data required. In games like chess and Go, it is straightforward to artificially generate supplementary data of the appropriate type to augment the dataset's size. In the realm of medical and histopathological imaging, substantial volumes of data are accessible since samples are delineated on a pixel-by-pixel basis. Utilising this sort of data, one may generate millions of annotated samples with drawing tools from a limited number of photos. It is quite simple to enhance each sample with intentionally created variants (e.g., mirrored copies, rotated versions, altered intensities, and changing colours) without affecting the annotation [43-57].

Conversely, in clinical healthcare, the data commonly comprises pathology or radiology reports from patients, accompanied with clinical annotations such as diagnoses or therapeutic responses. The quantity of samples often corresponds to the number of patients. The annotation frequently presents more challenges, necessitating an expert physician to establish the underlying truth. Despite the availability of digital records and health devices, there is insufficient multimodal data to identify indicators that predict clinical outcomes. The quantity of patients for whom the requisite multimodal data are accessible is, in precisely the same fashion across different hospitals, including several extra factors. This is a widely acknowledged problem in clinical studies conducted by pharmaceutical corporations [24]. The objective is to reduce undesirable factors in the patient or sample cohort for analysis. A significant portion of this uncontrolled variance is unrecorded or, at best, documented in a highly imprecise manner. The quantity of unidentified parameters that might have affected the result, particularly when its assessment occurs several years post-diagnosis and therapy, is generally undervalued. Instances of AI approach failures attributable to these difficulties encompass several genome-wide association studies focused on identifying clinically relevant genetic risk factors for complicated illnesses, as well as genomic investigations targeted at discovering biomarkers for cancer diagnoses and treatment strategies [27].

Comparable difficulties exist in other fields, although solutions applicable there are unattainable in the healthcare sector. Google Translate is a prominent example in the field of natural language processing. Initially, translations were of substandard quality and faced significant criticism; nonetheless, Google opted to maintain the service. Online feedback was utilised to amass extensive translation data, facilitating the ongoing enhancement of the translation algorithm's performance [28].

In conclusion, the availability of a comprehensive collection of multimodal data from a sufficient number of patients is often inadequate to mitigate the curse of dimensionality when applying AI to multimodal patient data. Dimensionality reduction continues to be a prominent study domain within the scientific community [29-31]. The primary problem in the therapeutic use of AI persists. The initial method is minimising data modalities and aligning the number of variables (P) appropriately with the number of patients or samples (N) for whom a ground truth exists. The proposed approach would condense high-dimensional data into physiologically relevant, knowledge-based characteristics [58]. The implementation of knowledge-based computational methods is anticipated to facilitate the reduction of model flexibility and the management of high-dimensional data [32]. The conclusion of this section is that the ratio of patients to their variables must align with the AI methodology.

Inadequate Data Quality and Numerous Subjective Variables

Generally, the constraint for employing AI methodologies in such contexts integrated data sources to develop a reliable algorithm for risk assessment, diagnostic, or therapeutic decision-making. When the patient population for a certain illness subtype is limited, a common option is to broaden the research to encompass additional patients globally, necessitating the resolution of numerous legal and technological obstacles. Nonetheless, this is still likely to fail in achieving the requisite patient count; while efforts to augment the patient population for data analysis are underway, the variability per patient, encompassing numerous unknown characteristics and variables, tends to increase, resulting in uncontrolled data variation. This results from the significant variability among individuals, including their DNA (consider the 3 billion base pairs and the virtually limitless combinations of genetic variants), lifestyle, familial medical history, and drug usage, among other factors. Furthermore, patients are never administered treatment in the available patient data is typically neither entirely full nor entirely accurate. For instance, diagnoses may be incomplete or inaccurate, or they may have been improperly recorded in the computerised system. The primary diagnosis is often well-documented; however, secondary diagnoses and problems that occur during hospital admission or in the home environment, together with treatment specifics, are less properly or inadequately recorded [5]. For several clinical variables, including diagnoses, the definitive truth is derived from a physician's assessment and cannot be objectively tested or quantified. Histopathology diagnosis exhibit variability among pathologists interpreting the same slide [33-35]. In the capacity of consequently, datasets may be incomplete and noisy, and assumed ground truths may not consistently be accurate. The conclusion of this section is that it is essential to get appropriate data, namely that which is representative and of high quality.

Causal Relationships Compared to Correlations: The Function of Bayesian Reasoning

A data-driven methodology applied to datasets with an insufficient ratio of patients (i.e., samples) to variables may result in numerous false correlations [36]. This indicates that the statistics imply a connection between two elements, but this is only attributable to chance, lacking any underlying explanation or causal relationship. In machine learning, this may readily result in overfitting and the identification of extraneous associations [16,37]. Furthermore, for clinical application, every noteworthy connection (e.g., a feature or combination of traits linked to elevated illness risk) must undergo costly clinical validation, as the absence of causation typically leads to significantly poor success rates. Consequently, transforming a correlation-based algorithm into a viable proposition will generally be more feasible if causal relationships underpin the identified correlations. Knowledge-based reasoning approaches, such Bayesian network models, can mitigate false relationships and overfitting issues by leveraging existing knowledge of causal data relationships to filter out noisy data [11,14]. Moreover, Bayesian models effectively manage uncertainty and absent variables, which are typically prevalent in clinical data [11]. It is not coincidental that Bayesian models analyse patient data in a manner analogous to that of a medical doctor [58-62]. The section concludes that the link between data and ground truth must be as direct and causal as feasible.

Verification of Artificial Intelligence-Driven Solutions

In several AI success narratives, a strong and dependable outcome is often not essential. In the context of a complimentary translation service, the potential outcome of an erroneous judgement is limited to a disgruntled client. Enhancements to these services might occur swiftly, as several AI applications are operational and progressively refine their performance through fresh data, therefore learning from previous errors. Unlike the majority of consumer or lifestyle AI solutions, every clinical application, whether hardware or software, necessitates comprehensive clinical validation to gain acceptance from the professional clinical community for patient care, including diagnostics or treatment decisions, and must receive approval from regulatory authorities [24]. The criteria for clinical validation will be more rigorous when errors or mistakes may yield significant repercussions. In a clinical trial, it is essential to show the accuracy of the produced AI solution in comparison to the clinical standard (e.g., sensitivity and specificity of a diagnostic test). Nonetheless, it remains ambiguous if the satisfactory performance of an algorithm is deemed acceptable when the solution is a "black box" and lacks transparency and reasonable justification [63-71]. Furthermore, the appropriate validation of a continuous learning-based system is not well defined.

The major issue is that the opacity of deep learning-based "black box" algorithms hinders their improvement, unlike Bayesian models, which are founded on a clear framework. Preliminary efforts to address this difficulty are underway [39].

Have AI-driven solutions received approval for clinical application? The previously referenced Watson for Oncology system functions as a "black box," and its recommendations lack clinical validation [26]. Conversely, in 2017, it was asserted that the inaugural deep learning-based algorithm, designed to delineate the contours of cardiac ventricles from magnetic resonance imaging (MRI) to compute ventricular volume, received validation and approval from the US Food and Drug Administration (FDA) for executing the calculation more rapidly than a clinician. This system's scope is far narrower than that of Watson's; the unimodal imaging data utilised were directly and causally linked to the ground truth supplied by the doctor throughout each image analysis. Furthermore, it may be regarded as a measuring algorithm and does not involve a clinical interpretation assertion. Clinical validation and securing regulatory clearance are significantly more challenging for algorithms that include such an interpretation claim [4].

Numerous novel solutions are prepared or capable of executing continuous (i.e., incremental) learning [41]. Currently, laws stipulate that an AI system for clinical applications must be "frozen," preventing it from learning online and promptly applying new information. Instead, it requires offline validation of the acquired "frozen" model using an independent dataset of patients or samples. Subsequent to the following continuous-learning cycle, the validation procedure must be reiterated before the model's renewed implementation. New clinically acceptable methods to expedite validation processes for digital applications in a patient-safe manner should ideally be developed; it is anticipated that specific procedures will be established to streamline regulatory approval of revised algorithms. The FDA is now formulating a strategy to address AI-based software solutions. The optimal use of current information in transparent and causal model methods, such as Bayesian modelling, is anticipated to enhance clinical validation and get regulatory approval for both unimodal and multimodal data. This section concludes that methods must be established to ensure algorithms are regulatory compliant and to simplify validation.

Approaches to Employ

Various AI methodologies have been investigated for the advancement of therapeutic applications. Success has varied among them, mostly contingent upon the sort of application. Deep learning has demonstrated its suitability for automated pathology diagnosis using tissue slide pictures. In addressing broader multimodal issues, such as forecasting clinical outcomes, evaluating patients, and predicting risks, other methodologies that frequently incorporate domain expertise are likely to be more suitable options. Probabilistic approaches utilising knowledge representation are being employed with increasing frequency and facilitate minimisation of the number of influencing factors, identifying relevant characteristics or latent variables. Probabilistic Bayesian modelling is adept at handling intricate biological data (e.g., “omics” data, including genomics and transcriptomics) as well as medical and clinical data; it is increasingly being utilised in diagnostic applications and medication discovery [9,44-49]. In the absence of information, knowledge-agnostic AI methodologies are advantageous; Bayesian reasoning networks are considered to possess significant potential when integrated with deep learning, hence merging the strengths of both domains in Bayesian deep learning [17,18,50]. The conclusion of this section is that the appropriate AI methodology must be employed for the issue at hand.

Guidelines for Employing Artificial Intelligence Techniques in the Development of Clinical Applications: The Six Rs

Given the problems associated with the implementation of AI in healthcare and scientific research, we consider it beneficial to establish criteria for study design. They may also enhance communication between AI researchers and medical practitioners. From the preceding discussion, we have derived six fundamental suggestions.

1. Initially, a pertinent and clearly articulated clinical inquiry. Applying data analytics in the healthcare sector without subject expertise poses a significant risk of yielding clinically inappropriate results. Each new AI project must have well stated clinical issues that are vetted by clinical professionals. The results of the analysis must also be evaluated for clinical and/or biological relevance.

2. Accurate data (i.e., representative and of high quality). Precisely delineate the dataset required to address the clinical inquiry. A clinical dataset including ground

truth must be adequately clean and dependable. Recognise the concealed variability among samples that is not apparent in the dataset. The dataset must be suitable for the research issue and representative of the population being examined.

3. The ratio of patients to their variables must align with the AI methodology. To get meaningful outcomes, utilise sufficiently big datasets (i.e., patient or sample quantities) for the employed AI methodology, and minimise patient variables where feasible. Employ domain expertise to restrict erroneous linkages.
4. The relationship between input variables and the anticipated output variable, regarded as the dependent value, should be as direct and causal as feasible. The clinical inquiry must carefully correlate the empirical reality with the data. Therefore, identifying novel pathological characteristics that most effectively differentiate between two distinct pathology diagnoses may provide beneficial outcomes; however, employing lifestyle information to forecast a 10-year survival rate may not be effective.
5. Prepared for regulatory compliance; facilitating validation. Initially, evaluate how a certain solution can be verified and comply with regulatory standards. Utilising domain knowledge may expedite the validation process by decomposing the AI system into smaller, discrete AI systems. This effectively precludes systems that evolve through continual learning.
6. Appropriate AI methodology. Employ the appropriate approach for the task at hand. Data-driven approaches are usable when sufficient data is available, while knowledge-based methods may be utilised in the absence of adequate data. A judicious integration of both methodologies may provide significant advancements in the creation of clinically relevant healthcare solutions [72-87].

Concerns Regarding Privacy

Recent advancements in big data analysis within healthcare have prompted the implementation of new privacy legislation in Europe, namely the General Data Protection Regulation (GDPR) [51]. To safeguard privacy, individuals govern their personal data, and express informed consent is mandated for data access and utilisation in AI [88-90]. This law is anticipated to complicate the sharing of patient data among various medical centres and with firms engaged in the development of AI solutions.

Conclusion

Although AI methodologies are highly effective for creating algorithms to analyse unimodal imaging data (e.g., radiological or digital pathological pictures), significant obstacles arise in clinical applications due to often restricted patient or sample sizes (N). This contrasts with the quantity of multimodal variables (P) resulting from patient variability, insufficient ground truth data, and the necessity for rigorous clinical validation before clinical use. Artificial Intelligence solutions that integrate domain expertise with data-driven methodologies are thus superior to those relying just on domain knowledge or being entirely data-driven. We present the subsequent 6R model to consider for AI initiatives in the biomedical and clinical healthcare sector:

1. Initially, a pertinent and clearly articulated clinical inquiry.
2. Accurate data (i.e., representative and of high quality).
3. The ratio of patients to their variables must align with the AI methodology.
4. The relationship between data and ground truth should be as direct and causal as feasible.
5. Prepared for regulatory compliance; facilitating validation.
6. Appropriate AI methodology.

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