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The Role of Artificial Intelligence in Custom-Designed Approaches to Treatment with Algorithms

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ABSTRACT

This editorial analyzes the emerging role of algorithmic treatment guidelines in bridging the gap between clinical trials and clinical practice. It then shows how the use of Artificial Intelligence (AI) can synergistically provide a significant strategic advantage in developing, using and maintaining such algorithmic approaches.

Introduction

Large-scale clinical trials have become the gold standard for evaluating the efficacy and safety of new treatments in healthcare[1]. When done correctly, this is a solid scientific tool that is necessary but not sufficient[2-5]. The healthcare community has fallen short in applying study protocols to "real-life" clinical cases in an un-customizable and unmodifiable fashion[6]. This is most often observed with pharmacological treatments, especially in cancer applications[7]. Post-market follow-up, research, and guideline modification currently lack these two vital components: customization and response-based modifications[8]. The only feedback comes from anecdotal and fragmented data or studies fashioned after the original protocols[4]. None of these efforts have resulted (nor can they result) in customizable guidelines needed to address the differences between clinical studies and clinical practice[9]. This gap between study protocols and customizable guidelines for post-market application has frustrated physicians, left at least one-third of the treated patients with bad results and contributed to added complications and expense[10]. This costly gap between clinical research and practice should be bridged using a different approach[11].

To bridge this gap, recent research has shown the benefits of adopting an algorithmic custom-designed approach instead of the study protocol(s) as the preferred treatment guideline, as documented by our "Custom-Designed Approach to Treatment with Algorithms" (C-DATA)[12]. Algorithms are increasingly used instead of or alongside traditional, rigid protocols as treatment guidelines because they offer more dynamic, data-driven, and personalized care, translating evidence-based data into actionable, often visual, step-by-step guides (like flowcharts) that improve accuracy and efficiency and reduce variability, although they require careful design to avoid bias and ensure clinical flexibility.[13,14] The challenges to such a model include the ability to develop a responsive, reliable, and user-friendly system to construct and continually modify said algorithms as well as quantify responses in an objective and usable fashion to populate the algorithms seamlessly. In addition, there are challenges with implementation, training, modification and feedback[11]. All these challenges can be addressed with the proper use of artificial intelligence (AI).

AI presents the opportunity of machine learning to augment (not replace) our ability to develop and implement the needed algorithmic approach; however, it also presents unique challenges and threats.

The purpose of this editorial is to explore the Strengths, Weaknesses, Opportunities and Threats (SWOT) of both C-DATA and AI to strategically map out ways AI can improve our ability to build custom-designed adaptable algorithms with reliable feedback while avoiding the pitfalls inherent to both, AI and C-DATA. We will start with C-DATA, then AI, and finally analyze the value of combining them.

C-DATA

The custom-designed Approach to Treatment with Algorithms (C-DATA) refers to a novel solution to bridge the gap between clinical studies and clinical practice, as detailed in the above-referenced studies.[7,11,12] While protocols are rigid, rule-based instructions for specific, well-defined problems, sometimes criticized for inflexibility, algorithms are presented as graphic or logical representations (flowcharts, decision trees) that guide decision-making, offering more personalized recommendations by incorporating patient-specific data.

STRENGTHS

The main strengths of C-DATA as a treatment guideline can be summarized in four benefits.

1. Simplicity: The entire approach of C-DATA is built on the simple concept of response-based action: if a certain treatment option resulted in resolution, the action would be to observe for recurrence and then use the same treatment. If the treatment fails to produce the desired response, a different treatment should be used. If the treatment results in partial resolution, then it should be repeated and further evaluated. This simple formula can incorporate the knowledge gained in clinical trials into an easy-to-follow custom-designed treatment guideline, bypassing the complexities and guesswork inherent to the application of the "cookie-cutter" guidelines of clinical trials. [7,11,12]
2. Adaptability: Once constructed, the most basic algorithm can be expanded, updated and amended based on individual and collective responses as well as new research findings.[11]
3. Reliability: Using response-based data to formulate the recommendations takes the subjective bias as well as the guess work out of trying to apply the general study protocol's recommendations in the setting of uniquely varied clinical situations.[7] Using data from clinical studies as the backbone of the algorithmic approach assures efficacy and safety.[12]
4. Accessibility: The ability to be cloud- or web-based, with or without the use of a mobile application.

WEAKNESSES

The weaknesses of C-DATA are mainly in the development process and implementation, not in the basic concept itself. These weaknesses can be summarized as follows:

1. Successful development requires competency in at least three areas. A full comprehension of the data produced by the clinical studies, the proper choice and reproducible quantification of response parameters (Diagnostic Data), and finally fluency in constructing a user-friendly algorithm that informs treatment choices (agent, dose, frequency, and combination treatments; as well as timing for reevaluation).
2. Successful implementation requires adaptability as well as a balance between adherence to guidelines and modifications deemed necessary for individual clinical situations.

OPPORTUNITIES

The opportunities presented by our algorithmic approach are very promising theoretically and practically (evidence-based).[7,12] The most important benefit of the algorithmic approach is better results for more cases, especially for the "forgotten third" who end up with poor results under the protocol construct. In addition, the decrease in treatment burden results in less side effects and resistance as well as in less cost.[7,12,14]

THREATS

The threats that C-DATA could present are directly tied to weaknesses stemming from improper development and/or implementation.

AI

"Artificial intelligence (AI) refers to computational models and algorithms designed to perform tasks that historically required human intelligence, such as pattern recognition, decision-making, language comprehension, and predictive analytics. In medicine, AI has rapidly evolved from theoretical frameworks to clinical tools influencing diagnostics, treatment planning, administration, research, and patient engagement."[15] AI and machine learning (ML) have received considerable attention lately, most of it deserved and appropriate, but some not. Understanding what AI can and cannot do is essential for maximizing its benefits. This is true in medicine as well as in other sectors.

STRENGTHS

The strengths of AI are many and continue to develop over time. For the purposes of our discussion, we highlight the six most relevant:

1. Enhanced efficiency and performance with Machine Learning (ML), automating repetitive tasks, accelerating data processing, and supporting decision-making based on complex patterns, thus boosting productivity with algorithms that learn patterns from data without explicit programming.
2. Deep Learning (DL) and data-driven insights with neural networks, especially Convolutional Neural Networks (CNNs), highly effective in image and signal interpretation, as well as predictive capabilities.
3. Scalability and adaptability across different applications.
4. Natural Language Processing (NLP) enables the extraction of insights from text.
5. Multimodal AI can combine heterogeneous data (e.g., imaging, text, and genomics) for a richer context and analysis.
6. Enhancing and driving innovation by expanding research capabilities, enabling new products and services, and integrating with emerging technologies.[15-19]

WEAKNESSES

The weaknesses of AI, like its strengths, continue to unfold with usage. These limitations stem from inherent internal limitations and areas where AI may not perform optimally. We summarize the five most relevant concerns.

1. Data quality and bias: The quality of AI outputs strongly depends on the quality of the data. Biased or incomplete data can lead to flawed predictions and undesirable outcomes.
2. Algorithmic Bias: Biased training data can lead to inequitable performance across populations, raising equity and fairness concerns. This problem is accentuated in healthcare, especially across diverse cohorts. Advocacy groups have called for equity-first AI standards to avoid worsening health disparities.[16]
3. Ethical and privacy concerns: The use of personal data and opaque algorithmic decision-making raises privacy, accountability, and fairness issues, particularly in sensitive domains such as healthcare and education.
4. High Implementation Costs: Initial deployment of AI systems, including infrastructure and talent acquisition, can be expensive and resource-intensive.
5. Technical and Trust Limitations: As mentioned in #3 above, AI systems may lack transparency or explainability, they seem like "black boxes" leading to user distrust and resistance to adoption.[15-20]

OPPORTUNITIES

Globally, opportunities for leveraging AI to produce better outcomes and growth are rapidly developing. The most relevant aspects to our topic are AI's ability to improve healthcare delivery, accelerate drug development and enhance educational outcomes. In addition, AI can facilitate global collaboration among academia, industry, and public sectors and open pathways for innovation and scalable solutions.[15-20]

THREATS

This is a complex topic, since AI may suffer from internal or external threats. Internally, some of the weaknesses mentioned above can easily morph from minor concerns to catastrophes in the absence of proper guardrails. Externally, there are at least four major relevant threats affecting AI.

1. Regulatory uncertainties and compliance issues can slow down adoption or lead to legal risks for the implementers.
2. Security and cyber challenges are major concerns because of their vulnerability to cyber-attacks or adversarial manipulation, which threaten data integrity and system reliability.
3. Ethical and trust erosion from misuse of AI or lack of transparency.[15-20]
4. Allowing AI to replace rather than augment clinical judgement and practice could result in a vicious cycle of disastrous outcomes.

Utilizing AI for the Development and Implementation of C-DATA

In clinical medicine, both algorithms and protocols are used to standardize care, but they serve different functions. Algorithms are increasingly favored as the primary decision-making framework, while protocols serve as detailed operational instructions for executing those decisions, especially in the pre-market phases of drug development.[13,14] Considering the SWOT analysis of C-DATA and AI (above) leads to an obvious strategic conclusion: By utilizing AI to help develop and implement C-DATA, we can leverage the strengths and promise of

AI to maximize the strengths and opportunities of C-DATA while mitigating the weaknesses and minimizing the threats. This has the potential to revolutionize healthcare delivery. Therefore, the next logical question is: How do we do that?

To answer that question, we need to summarize the established role of AI in healthcare, then apply that to the steps outlined in our paper (*The Missing Link…*), detailing how to develop, implement, update and safeguard C-DATA.[11]
First, a summary of AI in healthcare is provided.

AI's development is trending toward multimodal integrations, combining rich data sources for enhanced predictive power as well as explainable outputs to improve transparency and clinician trust.[21-23]

Algorithms powered by Artificial Intelligence and Machine Learning can analyze vast datasets to find patterns, improve predictions, and automate aspects of decision support. Web-based algorithms allow clinicians to input patient parameters and receive real-time tailored recommendations. The rise of AI introduces "algorithm change protocols," which manage updates to adaptive AI tools to ensure safety and effectiveness, shifting regulations from static rules to ongoing oversight.[21,22]

There are many areas where AI and the algorithmic approach intersect; the three most relevant areas for our purposes are as follows:

1. Analyzing and quantifying outcome results, especially medical images[23-24], has great potential for fast improvement with progressive training, which is inherent to the automatic feedback required by our application. Thus, the AI output will produce simple data that the algorithm can use more effectively. For example, looking at tumor size in the lung over a period of treatment, a conventional text report would use qualitative descriptors, such as smaller, larger, or unchanged, whereas AI can use a digital scale, such as 17% smaller, 67% larger, or 1% change". These numbers can be automatically plugged into the algorithm to trigger the next step (treatment choice), such as "same treatment and same dose," "same treatment with a higher or lower dose," "combination treatment," or a different treatment altogether.
2. Algorithm feedback with response-guided decisions would be easier to make with AI, given proper training. For example, if the result after three months of treatment was 80% growth, the recommendation by rigid protocols may be to continue the treatment. However, with AI-driven algorithms, the decision may be to alternate between one more month of the same treatment and dose, one more month of the same treatment with a higher dose, or changing the treatment altogether. Because AI can provide better feedback to educate the system in real time regarding which decision was best for most people in that category, it becomes possible to provide customized feedback and recommendations.
3. The development process for algorithms (creation and updating) is made more user-friendly, more reliable and seamless with AI. Unlike conventional human efforts, multimodal feedback and changes do not frustrate or overwhelm AI; rather, they contribute to better "learning" resulting in better outcomes.

This whole process of AI training, of course, has to be developed under the mentorship of skilled clinicians/scientists along with IT support.[21-25]

Applying all the above-mentioned possibilities of AI and human partnership to our C-DATA road map[11] yields the following synergistic opportunities:

1. *Comprehensive review of all relevant studies leading to licensure.* AI can make this step faster, more comprehensive, up to date, and interactive.
2. *Adaptation of general information to design the treatment matrix.* AI can produce better visual flowcharts and step-by-step logic trees.
3. *Creation of a Preference List for treatment options.* AI can help clinicians create this list more objectively based on a more comprehensive analysis of published research and collective clinical feedback. The latter objective is accomplished by replacing manually managed local registries with AI-driven, collective registries.
4. *Finalization of the desired case-specific outcome parameters.* Similar to #3 above, AI can help C-DATA creators choose these parameters more objectively based on a more comprehensive analysis of published research and collective clinical feedback.
5. *Development of a prototype, custom-designed treatment algorithm.* Perhaps, this is the step where supervised AI would shine the most. By facilitating the construction of an actual flow chart (matrix) from logical choices based on treatment responses (evidence-based), as measured by quantifiable (digital) outcome parameters.
6. *Interactive use, evaluation, and modification of algorithms.* The information that is automatically gathered from collective registry feedback can be collated and integrated much better by AI than by conventional means.
7. *Education and training of healthcare providers in the use and evaluation of Custom-Designed Algorithms (CDAs) to maximize benefits and minimize risks.* This is where the partnership between AI and conventional methods could significantly enhance the implementation of an actively responsive and adaptive guideline to enhance clinical practice.[20,22]
8. *Ongoing prospective data collection and analysis are required to continuously evaluate and modify the matrix based on new scientific and clinical information.* As mentioned above, AI can make this step seamless and automatic, answering difficult questions such as "loading," "resistance," "recurrence," "failure" and "partial responses." However, all these promises hinge on close human supervision before final adoption.[26]

Conclusion

In this article, we have analyzed the emerging role of algorithmic treatment guidelines, as described by our C-DATA. We have also affirmed the benefits of bridging the gap between the "cookie-cutter" approach dictated by protocols from clinical studies and "real-life" clinical practice using custom-designed algorithmic approaches. Finally, we showed how the responsible use of AI in healthcare can provide a great strategic advantage in the goal of constructing, implementing, actively modifying, and supervising such algorithmic approaches. The synergy of this combination holds promise for revolutionizing treatment approaches in healthcare.

Conflict of Interest: The author has no conflicts of interest to declare

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