Review Article

Changing Scope of Medical Writing in the Era of Artificial Intelligence — A Fresh Perspective

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Abstract

Background : Artificial Intelligence (AI) is considered useful for improving various functions in healthcare delivery and clinical decision-making, including its use as prognostic and a diagnostic aid, which ultimately decrease the healthcare delivery time.

Material and Methods : The effects of the recent disruption caused by Large Language Models (LLMs) and AI chatbots such as ChatGPT on the functions and roles in the pharma industry have received limited attention, despite the chatter regarding its safety. Multiple facets of medical AI include data analysis, using machine learning, deep learning, natural language processing, LLM training, chatbots, domain-specific LLM creation and Bidirectional Encoder Representations from Transformers (BERT) software development. These AI products aim to reduce productivity timelines and increase the utilities of large clinical datasets, especially in regulatory and clinical documentation support. The extent of assistance provided by AI-based literature survey tools and LLM based medical writing require discussion and vigilance. AI has disrupted research functions and boosted pharmaceutical product development timelines by a potential decrement of timeline costs, the utilization of AI is being probed in drug discovery, development, and regulatory submissions. Considering this disrupted scenario, this review throws light upon the advent of AI and the responses from regulators, publishers, and the EQUATOR NETWORK.

Discussion : The authors intend to inform the medical writing fraternity regarding the areas of risks and benefits of using AI tools in medicine.

Conclusions : The pharma industry grapples with a routine dependence on AI, a surge in the vigilance, ethical considerations and robust governance has been observed.

Key words : Artificial Intelligence, Language Learning Model, Machine Learning, Medical Writing.

Artificial Intelligence (AI) involves all processes using computers, data storage, and data processing devices that produce robust computer-generated outputs from analysing large volumes of data generally similar to the analytical tasks performed by humans. AI involves storage, processing, analysis, and critical scrutinizing of data and creating an AI system that begins with feeding existing data into the computer system and allowing it to “learn”.

Editor's Comment :

- It is mandatory to uphold the principles of transparency, inclusion, accountability, trust, and patient safety in all processes of the drug and medical device development lifecycle, as per the EMA and FDA directives.
- The EQUATOR NETWORK guidelines adequately assess AI in medicinal evaluation and reporting.

Material and Methods

For the literature review, open access articles were sourced from indexed databases like PubMed Central, EMBASE, JSTOR, Directory of Open Access Journals (DOAJ) and studied extensively.

From the initial 100 articles screened, a total of 50 were shortlisted for drawing insights on the practical use of AI in medical research and writing in the pharmaceutical industry.

In preclinical research, AI and Machine Learning (ML) systems are commonly used for data models that can replace, reduce, and/or refine the processes of testing, identification, re-evaluation, and other procedures. Across numerous medical specialties, AI aids in medical decision-making through expediting steps involved in molecular testing and reducing the

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costs of drug discovery[1].

ChatGPT enables the retrieval of preliminary molecular data/information regarding pertinent drug targets, setting off the discovery pathway for specific diseases that require further studies to be validated. A plug-in present in ChatGPT-4 is noted to be potentially helpful for these niche purposes[2]. Moreover, such AI platforms may help comprehend drug target proteins, molecular binding dynamics, antigen activity, three-dimensional and two-dimensional structural domains of proteins, and extract information of active sites of drug targets. In addition, ChatGPT is expected to assist in understanding the ADMET properties (absorption, distribution, metabolism, excretion, and toxicity) of investigational new drugs and be useful for toxicity assessments[2].

LLMs are large datasets of information stored in computers in conversational English language, which is different from machine language or programming languages. The development of LLMs has given rise to a new domain in information analytics known as Natural Language Processing (NLP), which involves algorithmic programming of the LLMs. These developments have been significant for the early-stage drug discovery researchers who may want to use LLMs like ChatGPT in retrieving information from large web databases using specific prompts. However, these approaches need testing and validation. A domain-specific LLM named "DrugChat" has been developed for the pharma and life sciences industry, which has an interface and user-friendliness as that of ChatGPT that can extract information on drug molecules.

Since there is currently minimal supervision of the application of rapidly developed AI tools in medicine it may affect the quality of medical documents. This in turn highlights the potential limitations of AI in medicine, including challenges spanning ethical, legal, regulatory, methodological, and technical domains. Hence, a powerful governance model has been proposed by the European Medicines Agency (EMA), under the European Commission.[3] These efforts of the EMA to control the use of AI are considered a small step as part of the BIG DATA Workplan 2022-2025, under development by the Big Data Steering Group, a functional collaborative under the EMA[4].

Application of AI Tools in Clinical Research :

Perspectives from the insiders of the pharmaceutical industry have highlighted pitfalls such as implicit bias, reproducibility, and clinical validity, which need to be addressed. Stricter methods for the validation and evaluation of AI development tools are necessary. Specific guidelines were thus developed to address all concerns raised by regulators and vigilantes using relevant research literature of biostatistics and data sciences. These were published alongside the guidance document published by the United States Food and Drug Administration (USFDA)[4] and the reflection paper given by the EMA[5,6]. Fourteen documents (Table 1)[7-20] are available : the Guidelines for Developing and Reporting framework[7], AI in Health Care[8], CONSORT-AI[9], SPIRIT-AI[10], DECIDE-AI[11] (Table 1). Among these frameworks, the Guidelines for Developing and Reporting framework by Luo W, *et al*[7] and AI in Health Care[8] publication elucidate the general guidance on the use of AI in medicine.

TRIPOD-AI and PROBAST-AI Statement :

In 2015, the "Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis (TRIPOD) Statement" was published[14]. While most items in the TRIPOD Statement are relevant to ML based prediction model studies and as most ML methods originate from statistical methods, two overlapping prediction modelling scenarios have emerged in the statistical and epidemiological domains. The relative novelty of applying ML methods to clinical prediction modelling had conferred some uncertainty regarding the credibility of these recent studies. Therefore, the TRIPOD group initiated the development of a consensus-based extension of the TRIPOD statement specifically focused on reporting of studies that undertake the development, validation or updating of a diagnostic or prognostic prediction model using ML techniques known as TRIPOD-AI[12].

The TRIPOD-AI extension comprises a checklist and an accompanying elaboration and explanation document, which informs regarding the minimal set of items to report with detailed examples of good reporting for each item.

In addition, the Prediction Risk of Bias Assessment Tool (PROBAST) was published in 2019 to critically appraise the study design, conduct and analysis of prediction modelling studies. PROBAST comprises four domains (participants, predictors, outcome and analysis) and contains 20 signalling questions to assess the risk of bias[15]. Clearly, the processes of "risk of bias" and reporting are intrinsically linked, as this is a predication made on primary data.

Table 1 — *All available audit frameworks established to control the usage of AI tools in clinical medicine, medical publishing, data analysis, and scientific reporting*[1]

Guideline/Framework	Summary	Intended user entities
Guidelines for Developing and Reporting	12-item guidance list for applying and reporting the medical AI Amodel specifications and results in biomedical research.	AI developers, investigators
AI in Healthcare	A general paper describing the challenges and opportunities for medical machine learning (MML) and AI.	AI developers, clinicians, patients, policymakers
CONSORT-AI	A structured reporting framework for specific clinical trials that evaluate medical treatments having an AI component (25 core and 15 AI-specific reporting items)	AI modelling software developers, investigators
Standard Protocol Items: Recommendations for Interventional Trials-AI Extension (SPIRIT-AI)	Guidance framework for writing clinical trial protocols for studies that evaluate medical AI interventions (25 core and 15 AI-specific reporting items).	Principal investigators, clinical researchers
DECIDE-AI	Guideline framework for clinical evaluations of early-stage decision support systems developed using AI (10 generic and 17 AI-specific reporting items).	Investigators, clinicians, patients, policymakers
Clinician Checklist	Describes recommendations on studies that evaluate the suitability of AI applications for clinical settings.	Clinicians
Reporting and Implementing Interventions	Describes barriers to the implementation of AI in medicine and provides solutions to address them.	Health care organizations
20 Critical Questions	Proposes 20 questions for evaluating the development and use of AI in research (20 reporting items)	Investigators, clinicians, patients, policymakers
Comprehensive Peer Review Checklist	Proposes a comprehensive checklist for the self-assessment and evaluation of medical papers (30 reporting items)	Investigators, editors and peer reviewers
PROBAST-AI and TRIPOD-AI	Guidelines on using AI/ML with sensitivity and precenting bias in data analysis and reporting	Researchers, investigators, peer reviewers
Ethical Considerations	Describes a roadmap for considering ethical aspects of AI with health care applications	AI developers, investigators, clinicians, policymakers
Users' Guide	Describes an approach for assessing published literature using AI for medical diagnoses	Clinicians
Clinical AI Research (CAIR) Checklist	Provides guidelines and an associated checklist for the reporting of AI research to clinicians (15 reporting items)	Investigators, developers, clinicians
Minimum Information on AI Reporting (MINIMAR)	Provides minimum reporting standards for AI in health care (16 reporting items)	AI developers, investigators

As per the original publications, TRIPOD-AI and PROBAST-AI guidelines aim to address the needs of prediction modelling studies from all public health domains (primary, secondary, tertiary and nursing home care) and all corresponding target populations (healthy individuals, suspected and diseased individuals)[12].

Clinical AI Research Checklist :

The Clinical AI Research (CAIR) guideline was documented to help clinicians, data collectors, and other clinical workers in assimilating, organizing, and appraising clinical tasks performed using AI. The guideline is meant for effectively supporting the use of AI in ensuring quality, maintaining timelines, streamlining data capture processes, and optimizing the precision of data collection[13].

Olczak, *et al* simplified the application of AI/ML systems with regard to classifying clinical data, image analysis, segmentation and localization, performing regression modelling, translating medical documents for wider dissemination, and clustering data for deeper analyses[13].

Additionally, Olczak, *et al* proposed the need for a guideline on managing missing data and scarcity of data, especially in handling new clinical data obtained from subjects that cannot be combined with existing data for interpretation or analysis. Next, the guideline is expected to explain how overfitting of data within models can be avoided and how model training and validations are to be performed for clinical trials. Olczak, *et al* have listed the calculation methods for assessing the consistency, accuracy, sensitivity, and optimal ML model performance[13].

Checklist for Artificial Intelligence in Medical Imaging :

The Checklist for Artificial Intelligence in Medical Imaging (CLAIM) guideline serves as a 'best practice' recommendation for reporting original work on AI-

supported medical imaging[18], providing a framework for systematic assessment of medical image analysis to peer reviewers in medicine. CLAIM has seven categories — each aspect addressing a manuscript's title, abstract, introduction, methods, results, discussion, and other parts together forming a 42-item checklist. The CLAIM guideline focuses on clear reporting of training procedures and hyperparameters to enable replicability and repeatability by other researchers.

AI Application in Clinical Decision Support Systems: DECIDE-AI Guideline :

Various AI-based clinical decision support systems have been used in preclinical, in silico, evaluation research phases, of which some have been handpicked for demonstrating benefits for patients. Although existing reporting guidelines exist for some of these study designs , none of them cover all the core aspects of AI system early-stage evaluation and none would fit all possible study designs; DECIDE-AI was therefore developed as a new independent clinical outcomes' data reporting guideline.

The DECIDE-AI statement provides a multistakeholder, consensus-based reporting guideline for the Developmental and Exploratory Clinical Investigations of DEcision support systems driven by Artificial Intelligence. The final guideline was determined at a virtual consensus meeting, and its checklist with the explanation and elaboration sections were refined based on feedback from a qualitative evaluation process.

Guidelines on Using AI for Clinical Trial Reporting: CONSORT-AI Extension and SPIRIT-AI Extension (Table 2).

The SPIRIT-AI extension includes 15 new items pertaining to clinical trial protocols of AI interventions[10], which should be routinely reported in addition to the core SPIRIT 2013 requirements. To comply with the SPIRIT-AI conventions, investigators should describe the AI intervention in articulate non-ambiguous language, including the instructions and skills required for use, the settings for integrating the novel AI intervention, considerations for the input and output data handling, human–AI interaction, and analysis of AI error cases. The SPIRIT-AI extension requires the compliance with existing SPIRIT 2013 items and additional 15 items in the trial protocols of AI interventions. It is necessary to fully describe the AI/ML intervention and specify the type of model, its intended use, version, exact algorithm necessary, and the exact role of the AI/ML for optimal results.

The SPIRIT-AI and CONSORT-AI Working Group published the CONSORT-AI extension for ensuring transparent reporting in clinical research, especially for new therapies[9,10]. The guideline is particularly meant for clinical trials evaluating interventions with an AI component[9]. It was developed in parallel with its companion statement for clinical trial protocols: SPIRIT-AI. The CONSORT-AI extension includes 14 new items relevant for AI interventions, which should be routinely reported in addition to the core

Table 2 — *Summary of existing mandatory guidelines for AI in medicine*

Name	Stage	Study design	Comment
CONSORT-AI	Comparative prospective evaluation	Randomised controlled trials*	Extension of CONSORT. Used to report randomised controlled trials evaluating AI systems as interventions (large scale, summative evaluation), independently of the AI system modality (diagnostic, prognostic, therapeutic). Focuses on effectiveness and safety
SPIRIT-AI	Comparative prospective evaluation	Randomised controlled trials (protocol)*	Extension of SPIRIT. Used to report the protocols of randomised controlled trials evaluating AI systems as interventions
DECIDE-AI	Early live clinical evaluation*	Various clinical studies (prospective cohort studies, non-randomised controlled trials, etc.) with additional features such as modification of intervention, analysis of prespecified subgroups, or learning curve analysis	Standalone guideline. Used to report the early evaluation of AI systems as an intervention in live clinical settings (small scale, formative evaluation), independently of the study design and AI system modality (diagnostic, prognostic, therapeutic). Focuses on clinical utility, safety, and human factors
TRIPOD-AI	Preclinical development	Prediction model evaluation*	Extension of TRIPOD. Used to report prediction models (diagnostic or prognostic) development, validation and updates. Focuses on model performance
STARD-AI	Preclinical development, offline validation	Diagnostic accuracy studies*	Extension of STARD. Used to report diagnostic accuracy studies, either at development stage or as an offline validation in clinical settings. Focuses on diagnostic accuracy

CONSORT 2010 items. In both CONSORT-AI and its companion project SPIRIT-AI, a major emphasis was the addition of several new items relating to the intervention itself and its application in the clinical context. Items 5(i)–(vi) were added to address AI-specific considerations when describing the intervention.

US-FDA Approach of Monitoring AI/ML Applications :

Digital health products have become a crucial field of interest for the US-FDA, especially AI. The federal agency advices that the indented use of a medical AI/ML product whether as a 'general wellness product' (consumer-grade) or as a 'medical device' (clinical-grade) needs to be determined prior to starting the marketing authorization application process[16].

Regarding AI/ML products that are listed under the Software as a Medical Device (SaMD) category, the US-FDA mandates that, if the AI/ML product is labelled, promoted, or used as per the definition of 'device' in section 201(h) of the Federal Food Drug & Cosmetic (FD & C) Act, it falls under the scope of FDA regulations as a SaMD and requires pre-marketing and post-marketing regulatory controls, including: (1) FDA establishment registration, device listing, and pre-market notification requirements (Title 21 CFR Part 807); (2) labelling requirements (Title 21 CFR Part 801 and 809.10; (3) current Good Manufacturing Practices (GMP) and quality system requirements (Title 21 CFR Part 820); and (4) medical device reporting requirements (Title 21 CFR Part 803)[17].

In the recent years, the FDA had published dedicated guidance documents on the use of AI in drug development and it recognizes its emergent role in improving the efficiency of clinical research. In its recently published 33-page guidance document, the FDA mentions that AI/ML applications are being used for individual case safety report submissions. Permissible AL/ML uses for event monitoring and recording, case validation, removing duplicate data, and quality control of MeDRA coding have been described.

Guidance from EMA for AI Use in Medicinal Product Lifecycle :

The European Medical Agency (EMA) has released draft guidelines in July, 2023, describing the length and breadth of the considerations for using AI and machine learning in every stage of medicinal product development[5], including the scientific principles for regulatory evaluation. Regarding the development lifecycles of medical devices, the EMA states that medical devices with AI/ML technology can be used for clinical development, evidence generation, and data evaluation in support of a marketing authorisation application as a sole medicinal product or as a combined (drug + device) therapy. In such cases, the EMA will assess the adequacy of device characteristics to generate evidence that supports an EU marketing authorisation and all other proposed combined uses.

EMA Guidance on Ethical Aspects and Trustworthiness on AI :

The EMA has shared fresh principles on the trustworthy use of AI tools and published the Assessment List for Trustworthy Artificial Intelligence (ALTAI) for self-assessment prepared by the independent High-Level Expert Group on AI that was established by the European Commission.[5]

The list is applicable for all bodies and includes the below 7 key aspects of ethics and safety:

(1) Human agency and oversight;

(2) Technical robustness and safety;

(3) Privacy and data governance;

(4) Transparency;

(5) Accountability;

(6) Societal and environmental well-being;

(7) Diversity, non-discrimination, and fairness.

Discussion

As of now, there is little clarity on the extent of using LLMs in clinical documentation. The draft reflection paper from the EMA does not have any directive regarding the use of chatbots or generative AI in medical writing.

Using LLM Chatbots in Medical Writing :

There has been increased curiosity and criticism in the aspect of using chatbots to compile medical documents. Ever since OpenAI launched ChatGPT in January, 2023, several researchers and medical writers conducted trial runs of retrieving information using this user-friendly chatbot[18]. Initially, as reported

by Salvagno, *et al*, the results and responses from the chatbot were factually incorrect; some attempts provided older information, hinting at the limited data fed into the databank that the chatbot depended on[19,20]. This sparked both more interest and massive scrutiny among members of the medical fraternity, as more trial runs led to the accumulation of readable, but not appreciable medical information.

Recently, the role of an AI chatbot in medical writing was fragmented to provide a refined understanding of the quality of the content generated by ChatGPT-4 depends largely on the prompts given by the user – thus enabling the dawn of a new domain called as "prompt engineering". Until now, some researchers have used ChatGPT versions and published the experiences of routine medical writing activities such as rewording sentences and paraphrasing, summarizing, copyediting, writing methods section, tabulating content, creating Abstracts, reference management, and complete tasks such as creating patient-facing medical content, suggesting peer reviewers, writing grants, recognizing research ideas, and finding gaps in literature, offering potentially useful manuscript titles and generating short titles.

Response from the ICJME :

The International Committee of Medical Journal Editors (ICJME) specifies that ChatGPT cannot be listed as an author in any ICJME-accredited journal. Moreover, it is mandatory to disclose the use of other AI tools including ML algorithms, LLMs, etc, in the preparation of study documents and medical publication materials, including the shorter content pieces facing patients. The exact details of the use of AI tools must be provided in the Disclosure section of the manuscript as well as the cover letter. The ICJME emphasized on the resounding principles of accountability, integrity, and originality of work and instructs that "Authors should carefully review and edit the result because AI can generate authoritative-sounding output that can be incorrect, incomplete, or biased."

Ethical Concerns with the Use of LLMs in Medical Documentation :

Beyond the misleading and unreadable text generation outputs, the need for assimilating information and feeding it into the LLM for appropriate output has been concerned with data breaches and unwarranted dissemination. There is also a risk of increasing the bias in research and publication. While clinicians can benefit from the text generation and summarization capabilities of AI chatbots, a word of caution and an eagle's eye on the data fed to the LLM is necessary to determine the correctness of the output...

Conclusion

Given that AI and its application in the healthcare industry are here to stay, medical writers need to arm up with a strong AI portfolio. With the regulatory oversight on medical AI increasing every day and achieving an encapsulated structure, it is imperative for medical writers to address the enormity of data. While the AI invasion is still a matter of debate, medical writers using AI are mandated to uphold the principles of transparency, inclusion, accountability, trust, and patient safety in all processes of the drug and medical device development lifecycle and design the routine SOPs as per the EMA and FDA directives on AI use in clinical and scientific documentation. Furthermore, publication writers are expected to brace up on the updated recommendations by the EQUATOR NETWORK and ICJME to ensure integrity and credibility of their scientific materials.

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