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Guidelines and Recommendations for the Use of Generative AI in Clinical Care

UK ADVANCE

Overview

For over a year, the public availability of generative artificial intelligence (AI) tools has elicited a great deal of research, experimentation, and speculation as to how this new technology can enhance and transform all aspects of human endeavor from the future of work and education broadly to specific settings such as clinical care. At the same time, generative AI presents many areas of caution when it comes to data security and privacy, the effectiveness and accuracy of the tools, bias or inequity in how the technology impacts different groups of people, and the degree to which human agency and accountability is retained when generative AI is deployed.

Clinical care settings in particular demand careful attention to these issues.¹ As Brainard, Tanden, and Prabhakar note in a White House briefing room release, "[w]ithout appropriate testing, risk mitigations, and human oversight, Al-enabled tools used for clinical decisions can make errors that are costly at best—and dangerous at worst."² The American Medical Association further notes the importance of informed guidance and policy on the use of Al in clinical care settings given the "lagging effort" around comprehensive oversight of novel Al technologies in areas not already explicitly regulated—particularly, in "clinical applications, such as some clinical decision support functions."³

Machine learning (ML) and Al have been used in healthcare settings in many ways.⁴ These guidelines and recommendations specifically address *generative Al* as a particular type of Al technology and a growing set of tools with increasingly multimodal capabilities.⁵ The AMA defines generative Al as "a type of Al that can recognize, summarize, translate, predict, and generate text and other content based on knowledge gained from large datasets."⁶ This 'other content' has increasingly involved images, audio, video, and non-linguistic data often in

¹ Meskó and Topol 2023

² Brainard, Tanden, and Prabhakar 2023

³ AMA 2023

⁴ ANA Center for Ethics and Human Rights 2022; Clipper, et al. 2018; Jiang, et al. 2017; Kaul, Enslin, and Gross 2020; Kavasidis, et al. 2023

⁵ Topol 2023

⁶ AMA 2023. Ning, et al. (2023) write that "the capability of generative AI to generate realistic content differentiates it from other general AI technology." The critical difference between generative AI and other kinds of AI, adds Zewe (2023), is that generative AI "is trained to create new data, rather than making a prediction about a specific dataset."

combination with written or spoken language. Since the release of OpenAl's ChatGPT in late 2022 the number of stand-alone apps and interfaces has proliferated, including both proprietary and open-source tools. In addition to these, generative Al is increasingly embedded within other software including Microsoft, Google, Adobe, and Epic.⁷

In June 2023, the University of Kentucky empaneled <u>UK ADVANCE</u>, a broad-based committee of experts to examine generative AI and make recommendations to the UK campus and community regarding the implications of this rapidly evolving technology for higher education, research, clinical care, and beyond. UK ADVANCE is taking an evidence-based approach with experts from many disciplines and continues to monitor experiences among our local campus and community as well as national and global developments. For these guidelines, UK ADVANCE has sought input from multiple stakeholders.

After reviewing emerging evidence, experiences, and policies related to generative AI in clinical care, UK ADVANCE offers the following guidelines and recommendations concerning the use of all generative AI technologies and tools, including large language models (LLMs) as well as other modes such as images, audio, video, and non-linguistic data. Guidelines for the use of generative AI in both instruction and research are currently available on the UK ADVANCE website.

Generative AI is a rapidly evolving technology. These guidelines reflect our best understanding at the current time and may be updated to reflect the nature of the field as it continues to change.

Relevant UK HealthCare Policies

Beyond these guidelines and recommendations specifically concerning the use of generative AI in clinical care, the following UK HealthCare policies should be consulted. (Links require UK VPN or on-site UKHC access.)

- A05-200 Photography, Video Imaging, and Audio Recording in Health Care
- A06-100 Privacy Investigations and Breach Notification
- A06-035 Patient Safety Evaluation System
- A06-045 Confidentiality
- A08-025 UK HealthCare Core Values and Behavioral Standards
- A08-370 Escalation of Issue
- A13-075 Data Classification
- A13-080 Electronic Communications

⁷ Diaz 2023. Because generative AI will increasingly be integrated into other digital tools, a critical component of AI literacy is "being capable of recognizing when it is being used" in the first place (Watkins 2024).

Areas of Caution

The emergence of generative AI suggests many possible innovations and enhancements for clinical care, but its use must align with legal, ethical, and professional frameworks that govern UK HealthCare. This alignment involves many factors, including accountability, autonomy, equity, integrity, morality, non-maleficence, privacy, security, transparency, and trust.⁸ The following areas of caution are particularly significant for the use of generative AI in clinical care.⁹

- 1. Privacy and security. Generative Al tools that are public and available for use by anyone pose elevated risks to privacy and security; any data provided to a generative Al tool renders that data available in the Al tool and its use. Protected health information, personally identifiable information, other information protected by privacy laws, and any proprietary information should not be provided to generative Al tools unless they have been vetted for data privacy and other governance issues and approved by the University and UK HealthCare for the proposed use.
- 2. **Human agency and accountability.** Researchers continue to examine the degree to which generative AI can support and potentially enhance clinical decision-making.¹⁰ At the same time, centering human agency and accountability is a critical component of informed and ethical use. Decisions about clinical care ultimately lie with the provider and patient.
- 3. **Black-box technology.** Transparency and explainability are important aspects of Al use in clinical care, yet it is difficult to explain how a generative Al tool arrived at its output from the given input. Further, a generative Al tool can provide varying output from the same prompting without the user understanding the underlying processes at work.
- 4. **Accuracy and falsifications.** Generative Al continues to become more sophisticated, but it has a well-documented history of producing 'hallucinations': fabricated, incorrect, and misleading information. Hallucinations are a type of forecasting error similar to what we see in other predictive technologies and may involve a range of information such as facts, data, evidence, claims, summaries, reviews, assessments, and sources.
- 5. **Bias and equity**. Generative AI may inherit and perpetuate biases from its training data. Clinical care in particular demands the evaluation of generative AI output for accuracy and appropriateness. Generative AI may also be deployed in ways that exacerbate inequities

⁸ Ning, et al. 2023

⁹ See also AMA 2023; ANA Center for Ethics and Human Rights 2022; WHO 2024.

¹⁰ Braun, et al. 2020; Goh, et al. 2023; Haim, et al. 2024; McDuff, et al. 2023; Sezgin, et al. 2023

¹¹ Bjerring and Busch 2021; Franzoni 2023; Smith 2021

¹² Alkaissi and McFarlane 2023; Siontis, et al. 2024

or health disparities. Should there be occasion to train a generative AI tool on local data, it is likewise critical to ensure that this does not introduce bias or inequity.

Recommendations

Following from the areas of caution outlined in the previous section, UK ADVANCE offers the following recommendations for the use of generative AI in clinical care environments.

Use of generative AI outside Epic EHR or other secure UKHC systems. UK ADVANCE recommends *against* using generative AI that is not housed within Epic, UK HealthCare's electronic health record management system, as well as other secure UKHC systems such as 3M and Hyland OnBase, especially in the following ways:¹³

- 1. Creating clinical documentation such as medical record notes or correspondence
- 2. Providing protected health information, including de-identified information, or any other information protected by law
- 3. Providing data, including de-identified data, related to clinical or human subjects research
- 4. Recording or uploading recordings of internal meetings or other private events, including any related documentation of those meetings or events
- 5. Making clinical decisions without appropriate expert and human oversight

Use of generative AI within Epic EHR or other secure UKHC systems. Any rollout or integration of a generative AI tool within Epic and other secure UKHC systems such as 3M and Hyland OnBase will be reviewed and approved by the appropriate IT governance authorities in UKHC regarding risk and regulatory compliance. Epic has laid out its Generative AI Roadmap, and users must make a UserWeb account to access it. The account merges with our UK LinkBlue ID/password via single sign-on (SSO). Features announced in the roadmap have not necessarily been reviewed or rolled out for use in UK HealthCare. Even when using a generative AI tool that has been approved for clinical practice, it is important to keep the following in mind:

- 1. Maintaining expert and human oversight over the uses and impact of generative Al tools
- 2. Evaluating the appropriateness of generative AI in the context of each use case
- 3. Verifying all output from generative AI in terms of both accuracy and appropriateness
- 4. Ensuring equity and quality of care for all patients
- 5. Following UKHC policies as well as other legal, ethical, and professional requirements

Vendor requests. As there are many new options becoming available to enhance our day-to-day work, please reach out to UKHC leadership for general questions and ideas. Any specific

¹³ This category includes any apps that are available in the Epic API Portal/Vendor Services Showroom.

requests to integrate or interface with a third-party generative AI vendor (including a third-party interface in Epic) should be sent to the UKHC Demand Management Committee where it will be reviewed for security, safety, architecture, data, and privacy.

Further Questions

Should you have any questions about these guidelines, please contact one of the following UK HealthCare leaders or UK ADVANCE at UKADVANCE@uky.edu.

- Colleen Swartz, Acting Chief Operation Officer
- Gwen Moreland, Chief Nurse Executive
- Chris Desimone, Acting Executive Chief Medical Officer
- Michael O'Rourke, Interim Chief Information Officer
- R. Brett Short, Chief Compliance Officer

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