UK ADVANCE

2025 Guidelines and Recommendations for Generative AI in Clinical Care

Executive Summary

- Since early 2023, the public availability of generative artificial intelligence (AI) tools has prompted extensive research and experimentation, particularly in clinical care. While these tools hold the potential to enhance various aspects of human endeavor, they also raise concerns regarding data privacy, security, accuracy, bias and the retention of human oversight and accountability.¹
- Clinical care settings demand careful attention to these issues. As Brainard, Tanden and Prabhakar note, "[w]ithout appropriate testing, risk mitigations, and human oversight, AI-enabled tools used for clinical decisions can make errors that are costly at best—and dangerous at worst."² The American Medical Association (AMA) highlights the need for informed guidance and policy on AI use in clinical care, noting the "lagging effort" around comprehensive oversight, especially in "clinical applications, such as some clinical decision support functions."³
- Machine learning (ML) and AI have been used in health care in various ways.⁴ These guidelines specifically address generative AI, a distinct AI technology with multimodal capabilities.⁵ According to the AMA, generative AI is "a type of AI that can recognize, summarize, translate, predict, and generate text and other content based on knowledge gained from large datasets."⁶ This includes images, audio, video and non-linguistic data, often combined with language. Since the release of OpenAI's ChatGPT in late 2022, stand-alone apps and interfaces have proliferated. Generative AI is now embedded within software from Microsoft, Google, Adobe and Epic.⁷
- In June 2023, the University of Kentucky established UK ADVANCE, a committee of experts to evaluate generative AI's implications for education, research and clinical care. The committee provides evidence-based recommendations and monitors developments locally and globally, incorporating stakeholder input.

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 "trained to create new data, rather than making a prediction about a specific dataset.

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).

- The guidelines for generative AI use, including large language models, images, audio, video and non-linguistic data, are based on emerging evidence and experiences.
- These guidelines are available on the UK ADVANCE <u>website</u> and may be updated as the technology evolves.
- Relevant UK HealthCare policies should also be consulted (see below).

Relevant UK HealthCare Policies

Links require UK VPN or on-site UK HealthCare 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
- <u>A06-045 Confidentiality</u>
- A08-025 UK HealthCare Core Values and Behavioral Standards
- <u>A08-370 Escalation of Issue</u>
- A13-075 Data Classifications
- <u>A13-080 Electronic Communications</u>

Areas of Caution

The rise of generative AI presents potential advancements for clinical care, but its implementation must adhere to UK HealthCare's legal, ethical and professional standards. This involves considering factors such as accountability, autonomy, equity, integrity, morality, non-maleficence, privacy, security, transparency and trust.⁸ The following areas of caution are critical for generative AI use in clinical settings:⁹

- **Privacy and security.** Generative AI tools that are public and available for use by anyone pose elevated risks to privacy and security; any data provided to a generative AI tool renders that data available in the AI tool and its use. Protected health information (PHI), personally identifiable information, other information protected by privacy laws and any proprietary information should not be provided to generative AI 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.
- 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.

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.

- **Black-box technology.** Transparency and explainability are important aspects of AI use in clinical care, yet it is difficult to explain how a generative AI tool arrived at its output from the given input.¹¹ Further, a generative AI tool can provide varying output from the same prompting without the user understanding the underlying processes at work.
- Accuracy and falsifications. Generative AI continues to become more sophisticated, but it
 has a well-documented history of producing "hallucinations," or fabricated, incorrect and
 misleading information.¹² 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.
- **Bias and impact.** 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 health disparities. When training a generative AI tool on local data, it is crucial to avoid introducing bias.

Recommendations

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 UK HealthCare systems. UK ADVANCE advises strongly against using generative AI that is not within Epic, UK HealthCare's EHR, or other secure systems such as 3M and Hyland OnBase (including any apps available in the Epic API Portal/Vendor Services Showroom), particularly in the following instances:

- 1. Clinical documentation like medical records or correspondence
- 2. Any protected health information, de-identified or otherwise
- 3. Data related to clinical or human subjects research, including de-identified data
- 4. Recordings or documents of internal meetings or private events
- 5. Clinical decisions without proper expert and human oversight

Use of generative AI within Epic EHR or other secure UK HealthCare systems. Any

integration of generative AI within Epic and other secure UK HealthCare systems such as 3M and Hyland OnBase (including any apps available in the Epic API Portal/Vendor Services Showroom) must be reviewed and approved by the appropriate UK HealthCare IT governance authorities for risk and compliance. Epic's <u>Generative AI Roadmap</u> can be accessed via UserWeb account linked to UK linkblue ID/password through single sign-on (SSO). Features announced in the roadmap are not necessarily approved for use in UK HealthCare. When using approved generative AI tools, consider the following:

- 1. Ensure expert and human oversight.
- 2. Evaluate the appropriateness of AI for each use case.

¹¹ Bjerring and Busch 2021; Franzoni 2023; Smith 2021.

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

- 3. Verify AI output for accuracy and appropriateness.
- 4. Maintain equitable and quality care for all patients.
- 5. Adhere to UK HealthCare policies and legal, ethical and professional standards.

For vendor requests and new options to enhance our work, consult UK HealthCare leadership. Specific requests for integrating third-party generative AI vendors (including third-party interfaces in Epic) should be submitted to the UK HealthCare Demand Management Committee for review of 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 <u>UKADVANCE@uky.edu</u>.

- Tim Slocum, Senior Vice President, Chief Operation Officer
- Gwen Moreland, Chief Nurse Executive
- Chris DeSimone, Executive Chief Medical Officer
- Katie Dickens, Chief Digital and Information Officer
- R. Brett Short, Chief Compliance and Privacy Officer

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