Australian Commission on Safety and Quality in Health Care

Australian Government
Department of Health, Disability and Ageing

AI Safety Scenario

Ambient scribe

This safety and quality scenario provides clinicians with an example application of tools which use generative Artificial Intelligence (AI) in clinical note taking to demonstrate safe and responsible use.

The example is the use of ambient AI scribes to generate clinical records. The scenario should be read in conjunction with the Commission's *AI Clinical Use Guide*. Also review the Australian Health Practitioner Regulation Agency (Ahpra) and the National Boards guidance and information from your professional association or college for example The Royal Australian College of General Practice.

Unlike verbatim transcription, ambient AI scribes are intended to record and then use generative AI to summarise a consultation, which is then added to the heath care record. Like any clinical innovation you will need to understand the potential benefits, limitations, and risks; obtain consent; and monitor outcomes and performance, as outlined in the *AI Clinical Use Guide*.

The rapid evolution of these tools may mean current or future features meet the Therapeutic Goods Administration (TGA) definition of a medical device and require subsequent inclusion in the Australian Register of Therapeutic Goods (ARTG).
For example, an ambient AI scribe suggesting a diagnosis or further treatment that was not mentioned to the patient (even if this was not the original intent of the software) may trigger the requirement for inclusion in the ARTG. If in doubt, contact the TGA through your organisation's channels.

Before using an ambient AI scribe

Review the evidence

Generally, and depending on specific functionality, AI tools used to assist administrative processes, such as ambient AI scribes are not regulated as a medical device by the TGA, nor does ambient AI scribe software have rigorous supporting evidence on safety and performance. It is critical that you review the available information supporting the use of the tool and its intended use to determine if it is appropriate for you and your patients. Example assessment considerations used in Radiology[1] are:

- **Relevance:** Confirm the problems that the AI tool is intended to solve through published literature and AI developer information, potential clinical or operational benefits, and clinical risks.
- **Performance and validation:** Confirm the tool is trained and tested on data aligned to the target patient population and data quality requirements.

- **Usability and integration:** Understand how the AI tool will be used in your workflow and where you are responsible for final record authorisation. Understand and mitigate automation bias and how the AI tool is integrated with other systems you use.
- **Monitoring:** Know how to identify poor performance, for example, hallucinations.

If the ambient AI scribe is included in the ARTG as a medical device, there will be accompanying documentation providing evidence of its intended purpose.

Establish transparency and informed consent procedures

Clinicians are responsible for the safe and appropriate use of ambient AI scribes, their impacts on patient care, and discussing their use with patients.

Be prepared to:

- Explain the benefits to patients, for example, more focused consultation with reduced typing
- Review risks to the patient including AI bias and how those risks are managed, for example, timely review of all AI summaries for accuracy and quality
- Disclose the use of the ambient AI scribe, for example, posters in waiting room, information on registration forms or during the appointment booking process (online or in person).

The audio recording and summarising of a consultation by an ambient AI scribe will contain personal and sensitive information under the Privacy Act 1988 (Cth). These data must be stored and processed in Australia unless the patient has provided explicit consent for their data to be managed offshore.

Refer to the *AI Clinical Use Guide* for consent requirements. The recording of a conversation without consent may also be subject to national and/or jurisdictional device surveillance Acts. The nature of consent will be situational and largely determined by your organisation.

- If you are responsible for decisions on implementing an ambient AI scribe, consider undertaking a privacy impact assessment to assist in determining privacy and consent requirements. See Office of the Australia Information Commissioner.
- Understand how consent will be documented, for example, on registration forms (paper or electronic), as part of online booking terms and conditions, through privacy collection notices with opt out options or in the healthcare record.
- Determine how circumstances where consent is not given will be managed consistently across all clinicians in the organisation.

Understand common limitations and risks

The underlying data used to train the ambient AI scribe may introduce bias in outputs due to differences in ethnicity, sexuality, disability and age characteristics of the training data and that of the local population. The underlying models may not use health specific data and may leverage openly available generic commercial models.

- Confirm with your organisation and/or AI developer that the ambient AI scribe has been trained and tested on data consistent with the population in which the AI scribe will be used.

Ambient AI scribes can make mistakes and provide inaccurate or nonsensical outputs known as 'hallucinations'.[2] This is an intrinsic characteristic of generative AI tools, for example, they can fabricate diagnosis, omit or add steps in treatment plans, and confuse similar words like 'medication' and 'mediation'. Also see RACGP information.

The evolving nature of the underlying computational models means there will be differences in summaries produced from the same inputs.

- Confirm with your organisation what governance and management structures are or will be put in place to assess the performance of the ambient AI scribe.

Clinicians are susceptible to automation bias when they accept ambient AI scribe outputs as being accurate and complete.[3] All ambient AI scribe outputs must be reviewed for accuracy and quality (refer to the *AI Clinical Use Guide* and ACSQHC 'Communicating for Safety' standard).

When using an ambient AI scribe

Continue being transparent with patients

At the start of the consultation discuss the use of the ambient AI scribe with the patient, ensuring microphones can easily record voices and highlight how the ambient AI scribe:

- Supports care for example, the opportunity for a more focused conversation with the reduced need to type on the computer.
- Records and summarises the consultation and review by the clinician for accuracy and completeness before completing the medical record. Outline the risks and limitations of the ambient AI scribe, how these issues are managed, and provide an opportunity for the patient to discuss the use of AI and their alternatives.

Be satisfied with consent

- You and your patient should be satisfied that appropriate and proportionate consent procedures have been followed and appropriately documented, including the patient having sufficient time to make their decision.
- Where applicable, ensure consent covers the disclosure of personal information to third parties and the purpose of sharing.
- If consent is withdrawn, stop the recording and delete any data and outputs.

Review ambient AI scribe summaries

Responsibility for the quality and accuracy of ambient AI scribe information and summaries included in healthcare records remains with the clinician.

- Review the accuracy and quality of the ambient AI scribe summary, ideally at the completion of the interaction with the patient as outlined in the *AI Clinical Use Guide*. Review for bias based on the patient's characteristics, as well as hallucinations, over-summarisation and missing information.
- Consultation summaries in healthcare records must meet medico-legal requirements.
- Be aware that AI generated information may be included in healthcare records provided to other organisation and clinicians. Privacy and accuracy are paramount.
- Take notes on positive and negative observations of ambient AI scribe summaries for discussion at forums where AI performance is reviewed.
- Label records indicating AI was involved in its creation.
- Report adverse events or near misses resulting from the ambient AI scribe to your organisation and appropriate external organisation (see 'Ensure ongoing support for safe and secure use' section in *AI Clinical Use Guide*).

After using an ambient AI scribe

Monitor and evaluate performance for safety and quality

Undertake regular reviews of how the ambient AI scribe is performing. Refer to the *AI Clinical Use Guide* and '*Understand common limitations and risks*' section above.

- Discuss with your colleagues and in clinical governance and/or management forums common observations both positive and negative.
- Where the accuracy and quality of AI generated summaries is deteriorating, report to your organisation and AI developer to provide opportunities for improved performance.

References

1. European Radiology (2021) 31:3786–96 To buy or not to buy – evaluating commercial AI solutions in radiology (the ECLAIR guidelines)
2. Coiera E, Fraile-Navarro D. AI as an Ecosystem – Ensuring Generative AI Is Safe and Effective. NEJM AI. 2024;1(9):AIp2400611.
3. Coiera E. (2015). Guide to health informatics. Taylor & Francis.

For more information

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