Guidance on the use of AI-enabled ambient scribing products in health and care settings – A summary for LMCs

Comment from GPCE Executive Officers:

Use of Artificial Intelligence (AI) software in General Practice

We recognise the importance evolving technologies can play in our day-to-day work, and with the recent availability of AI software tools being able to interface with our clinical systems, this has never been more apparent. However, we feel it is important to make it clear that there are risks associated with the use of technologies, especially if they are to be considered medical devices, and appropriate regulatory approval must be in place before clinical use occurs. It is important to have absolute clarity around the use of confidential patient data, where it is transferred, when being processed, and where it may later be stored, and if it is made available for secondary purposes. We must maintain our patients' trust in us as GPs and so must take the utmost care in the processing of their medical data.

There are also obligations on suppliers and practices to comply with the Health and Social Care Act 2012, with regard to the application of standards such as DCB0129 and DCB0160. Data protection legislation must also be complied with by practices and Data Protection Impact Assessments (DPIAs) constructed before any processing that is considered 'high risk' occurs. (cf. https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/accountability-andgovernance/data-protection-impact-assessments-dpias/when-do-we-need-to-do-a-dpia/).

*Practices should ensure they have appropriate indemnity. For technologies that are medical devices the Yellow Card Reporting System (https://yellowcard.mhra.gov.uk/) should be used if the outputs of an AI technology adversely affect the diagnosis or treatment of a patient. NHS England published advice on the use of AI scribes earlier this week (https://www.england.nhs.uk/publication/guidance-on-the-use-of-ai-enabled-ambient-scribingproducts/) which we would recommend you review (**this has been summarised for you below).***

In summary, practices, as data controllers, need to understand the risks they may be taking on if using such AI technologies, particularly at this early stage when the regulatory landscape is in a state of flux.

In the coming months we will be working with external bodies to ensure any necessary regulation occurs at a national level and that GPs have the protections they require if these tools are to be adopted more widely, ensuring at all times that patients maintain their high level of trust in their GP. We will also be publishing more detailed guidance to inform and support practices to utilise AI driven software the in the delivery of care.

Dr Mark Coley, GPC England Policy Lead for Digital, IT and Data

Dr David Wrigley, Deputy Chair of GPC England and Officer Lead Digital, IT and Data

Overview

This document, published by NHS England on 27th April, provides guidance on the deployment of AI-enabled ambient scribing products including advanced ambient voice technologies (AVTs) used for clinical or patient documentation and workflow support in health and care settings. It is of relevance to GPs aiming to implement a specific product. This is the first in a series of documents to be published over the next six months. An AI Ambassadors network will be established to support best practice and sharing of insights.

What are AI-enabled Ambient Scribing Products?

These are speech recognition and natural language processing (NLP) systems that:

- Record and transcribe conversations between clinicians and patients during consultations.
- Use AI algorithms to generate structured clinical notes, such as SNOMED-coded entries.
- Can auto-populate sections of the patient record, with clinician approval.
- Can generate outputs in the form of medical letters or other documentation.
- Can recommend actions such as onward referral.

Some tools include features such as:

- Automatic summarisation of discussions based on text transcripts.
- Intelligent prompts for missing clinical information.
- Real-time transcription during the consultation.

Potential **Benefits for GPs**

Reduced Clinician workload

- Save time otherwise spent on typing or dictation.
- Potential to reduce burnout related to administrative overload.

Improved Patient Engagement

- Enable GPs to dedicate more time to providing care rather than documenting it.
- May enhance rapport and patient satisfaction with the GP solely focused on the patient not the computer screen during consultations.

Improved Consistency and Quality

- Potentially more comprehensive and standardised notes improving the quality of the patient record and supporting clinical decision making by having up to date, detailed, real-time accurate records.
- Assists with clinical coding and claiming for work carried out.

- Improvements in operational efficiency and potential cost savings by reducing administrative workload and improving data quality.
- Intelligently automating workflow, promoting scalability and interoperability across health care settings.

Key Governance and Safety Considerations

Clinical Responsibility and Legal Liability

- NHS organisations (including GP practices) may still be liable for any claims arising out of the use of AI products particularly if it concerns a non-delegable duty of care between the practitioner and the patient. This is a complex and largely uncharted area, with limited case law to provide clarity. Clear and comprehensive contracting arrangements with suppliers setting out their roles, responsibilities and liability can mitigate this risk.
- Even though AI creates the draft, GPs must validate, correct, and sign off on all content as the final output is legally and clinically attributable to the practitioner.
- Practices must complete the DCB0160 documentations (including related safety case, hazard log, and monitoring frameworks) and a Data Protection Impact Assessment (DPIA) and ensure that the supplier has completed the DCB0129.
- If a product is registered with the MHRA, training for intended users may be necessary to meet safety requirements.
- The Yellow Card reporting mechanism **needs to be used every time** a medical device does something unexpected or gets something wrong. Most AI scribe products will be classed as medical devices.
- CQC inspection teams will consider if:

  - Technologies are safely deployed (practices need a DPIA).

  - Staff have been trained.

  - There are reporting processes for incidents.

  - There is innovative practice which improves patient care.

Patient Consent and Information

- Consent must be explicit and informed. Key points to explain to patients:
    - What the AI is recording and why.
    - How their data is stored and for how long.
    - Their right to refuse recording or withdraw consent.
- Consider using visual signage or digital consent forms. Make information available to patients in public areas, on practice websites and social media channels.

- Notes and recordings may need to be disclosed to the patient in case of a SAR. What the AI scribe records may diverge from what was actually said by the GP/ healthcare professional. At the current time, it is unclear who will be responsible for what if full records are not maintained. The practice should familiarise itself with the document retention policy, privacy notices and DPNs of the potential providers.

Data Protection (UK GDPR) Compliance

- Engage with information governance and cybersecurity support early to ensure legal and regulatory requirements are met. Seek help from your local ICB to ensure tools are compliant with:
    - UK GDPR and Data Protection Act 2018.
    - NHS Data Security and Protection Toolkit, CREST and Cyber Essentials Plus certification.
- Use the least amount of data necessary to deliver the function.
- Be transparent around how information is used and shared in relation to ambient scribing products including data storage, encryption, and retention.
- NHS England has developed guidance for IG professionals to assist with meeting the requirements of data protection legislation when implementing AI-enabled technologies. Further guidance will be released in 2025.
- The ICO provides guidance for data protection and compliance with UK GDPR for those adopting AI technologies, and specific guidance on using Generative AI that processes personal data.

Digital Technology Assessment Criteria (DTAC)

The use of Generative AI for further processing, such as summarisation would likely qualify as a medical device (requiring it to be registered with MHRA). A product is a medical device if its intended purpose falls under the definition of a medical device, for example if it informs or drives medical decisions and care. This includes incorporating a diagnosis or prognosis within its outputs, triaging and stratifying, or carrying a prescriptive function like managing or recommending treatments. Products that solely generate text transcriptions are not likely to be classed as medical devices.

Ambient scribing tools must meet DTAC standards for medical device regulation, including:

- Clinical safety (compliant with DCB0129/0160).
- Technical security.
- Interoperability with existing systems (e.g., EMIS, SystmOne).
- Accessibility and usability.

Bias and Inaccuracy Risks

- AI tools may generate inaccurate or fabricated content.
- Risk of embedded algorithmic bias (e.g., misinterpretation of accents or clinical context such as mistaking a patient's hypothetical statement for a confirmed diagnosis, misgendering, gaps in documentation leading to compromised care).
- Products that use Generative AI can introduce unique cybersecurity challenges.
- Clinical staff must identify and correct errors before notes are committed to record.
- Ensure ongoing quality assurance and monitoring such as error reporting processes, service usage monitoring, and comparison between reported and observed metrics.

Quick **Implementation Guide**

1. Assign a Clinical Safety Officer and identify key risks

- Consider technical risks (e.g. output errors, system unavailability) and clinical hazards (e.g. incorrect context or information).
- Be aware that new functions may be introduced unintentionally or through user-provided instructions.
- An Appendix to the guidance provides actions for technical and product teams leading AI adoption. A series of detailed questions are offered to aid in clarifying the specific features and functionalities of ambient scribing products. The answers should be sought from the supplier, technical experts, clinical safety, IG and IT teams before implementation.

2. Complete the DCB0160 documentation and a Data Protection Impact Assessment (DPIA)

- Develop a safety case, hazard log, and monitoring framework. If you do not have the right tools and capabilities to comply with these standards you should seek help from your local ICB.

3. Plan for appropriate integration

- Ensure integration with your IT infrastructure, systems and workflows.

4. **Ensure appropriate controls**

- Consider legal and regulatory requirements. Ensure compliance with all applicable information law, the Data Security and Protection Toolkit (DSPT), and Medical Device regulations if applicable.

- Ensure users review any product outputs prior to further actions.

- Train staff to use the product.

5. Implement your monitoring framework

- Ensure ongoing audits of clinical documentation, and reviews of incident reports and system performance.