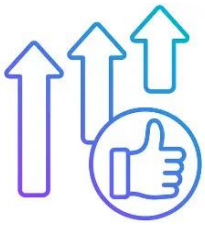
Ambient Transcription

Ambient scribing products are tools that use advanced speech technology to turn spoken words into text with little effort from the user. They help with tasks like writing patient notes and supporting healthcare work-flows.

Older versions, like speech recognition and digital dictation tools, have been used in England's health and care system for a while. But the technology is now improving quickly.

For example, an ambient scribing product can listen to the consultation between a patient and a healthcare professional and create clinical notes and referrals.



Key Benefits include:

1. Enhance clinical efficiency by reducing administrative tasks.
2. Improve patient care through increased face-to-face interaction.
3. Address data quality with consistent documentation practices.
4. Promote cost savings by minimising workloads and errors.
5. Support scalability and interoperability in various care settings.

However, such products can cause privacy concerns with patients who ultimately:

- Must be made aware that your practice is using such a product AND
- Have the choice of whether the product is used in their consultation or not

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Before you start using an ambient transcription product, <u>you</u> will need to:

- ✓ Engage with your Data Protection Officer
- ✓ Ensure a Data Protection Impact Assessment (DPIA) is completed
- ✓ Ensure an Artificial Intelligence Assessment is completed
- ✓ Both assessments need to be approved by your Data Protection Officer
- ✓ Your practice will need to sign a Data Processing Agreement – please let the DPO Service check this for you before signing

Before you start using an ambient transcription product, <u>we</u> will need to:

- ✓ Check the supplier is registered with the Information Commissioner's Office
- ✓ Check the supplier has completed the Data Security and Protection Toolkit to a 'Standards Met' or above level
- ✓ Check the supplier has got an up to date Cyber Essentials Plus Certification
- ✓ Ensure the provider is compliant with the Digital Technology Assessment Criteria (DTAC)
- ✓ Ensure the DPIA is complete and that there are no concerns
- ✓ Ensure that the Artificial Intelligence Assessment is complete and that there are no concerns
- ✓ Check the Data Processing Agreement is compliant with Article 28 regulations
- ✓ If medical device registration is needed, check registration is appropriate and in place
- ✓ Ensure that the DCB0129 is provided by the supplier and indicates no concerns
- ✓ Ensure that a suitably qualified Clinical Safety Officer has approved the DCB0160

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Medical Devices

NHS England have also mandated that we consider whether an AI Scribe must be registered as a medical device or not. Ambient scribing products that inform medical decisions and have simple/low functionality (for example, products that solely generate text transcriptions that are easily verified by qualified users) are likely not medical devices. However, the use of Generative AI for further processing, such as summarisation, would be treated as high functionality and likely would qualify as a medical device. In this case the supplier must register the product with the Medicines and Healthcare products Regulatory Agency (MHRA). You can check if they have done so on the public register - PARD. Please note that there are different classes of medical device. It is likely that such technology will need a higher class registration of medical device as it advances and regulations change.

NHS England Information Standards

You will also need to be compliant with the following NHS standards:

DCB0129: Clinical Risk Management in the Manufacture of Health IT Systems

DCB0129 sets out the clinical risk management requirements for manufacturers of health IT systems. Its primary aim is to ensure that digital health solutions—such as electronic patient records, diagnostic tools, and clinical decision support systems—are developed with patient safety at the forefront. This involves maintaining a hazard log and implementing risk controls. This should be completed by the supplier.

DCB0160: Clinical Risk Management in the Deployment and Use of Health IT Systems

DCB0160 outlines the requirements for healthcare organisations to manage clinical risks associated with the deployment and use of health IT systems. It complements DCB0129, which focuses on the manufacture of health IT systems, ensuring a comprehensive approach to clinical safety across the entire lifecycle of digital health technologies. A qualified CSO should be designated to oversee the clinical safety aspects of health IT systems, ensuring compliance with clinical safety standards. This could be a CSO trained within your practice, or SNEEICBs CSO.

System Integration

Ensure appropriate integration with your IT infrastructure, systems and workflows. For example, in most general practice and hospital settings, AVT solutions will require integration with the principal electronic record system. This will enable automated workflow (e.g. diagnostic test requesting or prescribing presented within the system being used, for clinician validation and submission).

Why is so much due diligence necessary?

Due diligence ensures the AI scribe is safe, effective, compliant, and worth the investment. It protects your organisation from legal liability, operational risk, and reputational harm.

The Chief Clinical Information Officer at NHS England issued a priority notification on the 9th June 2025 regarding how to ensure the safe and assured adoption of AI Scribe Technology. The letter added stricter guidance to that which they had previously published on their website. NHS England are adding and amending this guidance going forward.

Proceeding with non-compliant solutions risks clinical safety, data protection breaches, financial exposure, and fragmentation of broader NHS digital strategy.

Remember that liability for using a non-compliant solution sits with the deploying organisation.

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Transparency Action Plan

1. Practices must insert an **AI and Your Practice** banner on to their website as a permanent fixture that links to this site: Artificial intelligence (AI) use in primary care - NHS Suffolk and North East Essex ICB (or their own drafted materials providing comparable information)
2. Practices must display this poster in the practice (or a poster of their own, providing comparable information).
3. Patients can use this video in their waiting room display screens: https://youtu.be/rxXg50J_Gw0
4. Clinicians should display this desk sign to provide every opportunity to opt out of the use of the tool: Desk Sign 1.pdf
5. The patient information guide should be made available to patients who are interested in finding out more about the use of the system.
6. Practice staff must have a general awareness of the system and be prepared to acknowledge any opt outs in a positive and accommodating way.
7. The practice must consider how they will notify the clinician if a patient raises an objection at reception, on arrival for their appointment (clinical system task, physically popping into the consult room etc).
8. The practice must set the retention period for the draft notes at a suitable length (would recommend no more than 28 days). They should request that this is set to automatic deletion by the provider.
9. Practices must treat these recordings like CCTV or telephone recordings, meaning that when a subject access request (SAR) is made, they should immediately draw the draft notes down to avoid them being automatically deleted.
10. Practices must fully train existing **and all newly inducted** staff on the use of the system and alert clinicians that they must;
    - Carefully check the output for accuracy and avoid the temptation for cognitive drift which would compromise their ability to scrutinise the resulting transcript.
    - Carefully check the output for excessive references to third parties (family members etc) and anonymise as appropriate, retaining only the information *necessary* to support that patient's care.
    - If it is clear that a patient lacks capacity or cannot understand the implications, the default will be to deactivate the tool and revert to manual note-taking. This means that the tool will not be used for children under 12 or patients that do not have capacity unless clear additional safeguards (i.e. care-giver provides consent) are in place and professionally justified.

    It is noted that this may create an inequality, potentially resulting in these patients not being subject to the allocative benefits identified earlier in this assessment. As a result, this item will be revisited as the project progresses.
11. Practices must ensure that all objections are recorded (perhaps as a front screen alert) to ensure that patient preferences are respected in future consultations.
12. The practice must take steps to monitor and report on whether the system works well for users and patients with different accents or speech patterns and monitor whether any patient groups are hesitant to seek your services due to opposing the use of ambient scribing products.

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13. Practices should work with their IT and Clinical Safety staff to ensure that all the recommendations made by NHS England in relation to AI scribes have been implemented. NHS England » Guidance on the use of AI-enabled ambient scribing products in health and care settings