Date published: 27 April, 2025
Date last updated: 29 April, 2025

Guidance on the use of AI-enabled ambient scribing products in health and care settings

Version 1
For England only

Publication (/publication)

Content

Purpose

This guidance offers high-level information to assist those adopting ambient scribing products that feature Generative Artificial Intelligence (AI), for use across health and care settings in England. These products are sometimes referred to as ambient scribes or AI scribes and include advanced ambient voice technologies (AVTs) used for clinical or patient documentation and workflow support.

The guidance is intended for settings aiming to implement a specific product or function of an existing product. It is not meant for individuals seeking to use tools outside the supervision of their setting, such as through unauthorised applications.

Scope

The guidance provides an overview of ambient scribing products and key considerations for Chief Information Officers (CIOs) and Chief Clinical Information Officers (CCIOs) leading AI adoption in health settings.

The Appendix offers an in-depth exploration of these considerations, providing further actions for technical and product teams leading AI adoption.

Further support

This is the first in a series of documents to be published over the next six months to support the adoption of ambient scribing products. These documents will be aimed at a broader system audience and will include:

- support templates and tools; for example, a business case development template, and example templates for risk assessments like hazard logs and safety cases
- guidance on further information governance considerations including a template for a data protection impact assessment (DPIA)
- guidance to support evaluation and monitoring of ambient scribing products.

A community of practice will be established to facilitate the sharing of insights and best practices among sites implementing ambient scribing products. The AI Ambassadors (https://forms.office.com/Pages/ResponsePage.aspx?id=zwd49LyvhEGleYZ4vqMBmgJmsKj78UdPiNHdaZ67ZbVURUU2TFZJM0JBV0hXT05JSzNHUFZHNklDRy4u&origin=QRC network will support this community.

1. Quick implementation guide

This section outlines critical high-level actions to support the safe adoption of ambient scribing products at your setting.

1.1 Assign a Clinical Safety Officer and identify key risks

- technical risks may include output errors, system unavailability, integration failures or data loss. Clinical hazards may include missing critical information, incorrect information or context, or delayed outputs
- be mindful that products that use Generative Artificial Intelligence (AI) and Large Language Models (LLMs) may introduce new functions unintentionally or through user-provided instructions

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

(Note: Example templates are in development and will be published separately).

- 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 can seek help from your local ICB

1.3 Plan for appropriate integration

- ensure integration with your IT infrastructure, systems and workflows. For example, in most general practitioner settings ambient scribing products will require integration with the principal electronic patient record system

1.4 Ensure appropriate controls

- ensure legal and regulatory requirements are factored into the procurement and implementation of your chosen products. Products should comply 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 on the appropriate and approved use of your ambient scribing products

1.5 Implement your monitoring framework

- ensure output accuracy, including through ongoing audits of clinical documentation, and reviews of incident reports and system performance

2. Product details

2.1 What is an ambient scribing product?

Ambient scribing products involve tools that use advanced speech technologies to automatically convert spoken words into text and other outputs, requiring minimal user intervention. They are designed to support clinical or patient documentation and workflows.

Earlier versions of ambient scribing products, such as traditional speech recognition and automated digital dictation tools, have already been used in health and care settings in England for some time, but the technology is evolving rapidly.

The latest generation of ambient scribing products integrates powerful capabilities driven by Generative Artificial Intelligence (AI) and Large Language Models (LLMs). One major subgroup of ambient scribing products involves Ambient Voice Technologies (AVTs).

2.2 Product functions

Ambient scribing products used for documentation and workflow support can perform a variety of functions that are likely to include AI, as detailed below.

Input information functions:

- capture/record speech interactions
- incorporate other secondary information, provided directly by the user or otherwise, for example, extra context or external information from health records.

Output information functions:

- convert speech interaction recordings into text transcripts
- generate summaries based on text transcripts. These can be driven and structured according to templates, which can sometimes be customised
- format outputs according to a particular style or structure
- extract and link terms to clinical codes
- generate outputs in the form of medical letters or other documentation
- populate information in health records
- suggest actions or other tasks like scheduling or referrals

2.3 Benefits

The adoption of ambient scribing products and AVTs can transform any care setting by reducing clinician workload, addressing the challenges of poor data quality, and enhancing patient care:

- these technologies can reduce the administrative burden, enabling caregivers to dedicate more time to providing care rather than documenting it
- accurate documentation is achieved by capturing detailed and accurate notes in real-time, ensuring that patient records are comprehensive and up-to-date, which supports better clinical decision-making
- consistent data capture standardises the way clinical information is recorded, reducing variability and errors in data entry within electronic patient record (EPR) systems. This can result in higher quality, real-time data that can improve patient outcomes
- reducing the administrative workload and improving data quality could lead to significant cost savings and improvements in operational efficiency

By integrating with existing EPRs and being adaptable to diverse environments, ambient scribing products support a wide range of use cases, from primary, community, and care home settings to specialised hospital settings, and can intelligently automate workflow, promoting scalability and interoperability.

3. Key Considerations

The following outline key considerations when adopting ambient scribing products. These are detailed further in the Appendix.

3.1 Risk identification and assessment (see also A2.1)

- complete the DCB0160 documentations (including related safety case, hazard log, and monitoring frameworks) and a Data Protection Impact Assessment (DPIA). Ensure the supplier has completed the DCB0129
- be mindful that:
  - products that use Generative AI and LLMs may introduce new functions unintentionally, and can introduce unique cybersecurity challenges
  - a user might be able to provide instructions to get the product to generate an output that goes beyond the product's intended purpose, even if this is not the user's intent
  - some users may use products outside the supervision of their setting, circumventing related policies and approvals

3.2 Regulatory compliance (see also A2.2)

- ensure that the ambient scribing product has been correctly considered under medical device regulation
- 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
- an ambient scribing product that is deemed to be a medical device needs to be registered with the Medicines and Healthcare products Regulatory Agency (MHRA) and regulated proportional to its risk classification. A UK Conformity Assessed (UKCA) certificate is needed for clinical use of medical devices in the NHS. A valid CE mark is equally acceptable until 30th June 2028
- for medical devices, training must be provided to intended users if the manufacturer determined that such training is necessary to meet safety requirements when registering their product with the MHRA

3.3 Data compliance and security (see also A2.3 (http://a2-3-data-compliance-and-security))

- engage with Information Governance (IG) and cybersecurity support early to ensure legal and regulatory requirements are factored into the procurement and implementation of your chosen product. You can seek help from your local ICB if needed
- data security measures can include end-to-end encryption and access controls. Ensure that you and your supplier comply with the Data Security and Protection Toolkit (DSPT), as well as Cyber Essentials Plus certification
- ensure the product complies with UK General Data Protection Regulation (UK GDPR) and relevant healthcare regulations, outlining data handling, access, and third-party involvement
- be transparent about how information is used and shared in your setting in relation to ambient scribing products

3.4 Integration and performance (see also A2.4)

- specify the integration requirements with your existing Electronic Health Records (EHR) systems, for example by supporting standards like FHIR, HL7, and SNOMED CT for efficient data exchange and accurate documentation
- define performance metrics for accuracy, reliability, and uptime, and set clear expectations for error correction and customisation needs
- ensure the supplier has satisfactorily completed onboarding to any required national infrastructure and remains compliant with terms of access; for example, the NHS Personal Demographics Service (PDS)

3.5 Portability, scalability and flexibility (see also A2.5)

- ensure the system supports data portability and is designed for long-term integration, allowing for easy migration and future compatibility with other healthcare technologies and platforms
- consider a product with modular architecture that can scale to handle increasing data volumes and adapt to evolving healthcare needs across multiple departments and sites

3.6 Support and maintenance (see also A2.6)

- ensure appropriate planning and resourcing for the ongoing maintenance of ambient scribing products. This includes clarifying responsibilities for data storage and access, as well as costs for storing, subject access requests, lifecycle management and security updates
- include detailed Service Level Agreements (SLAs) for system uptime, response times, ongoing training, and technical support, along with post-deployment maintenance and software updates

3.7 Supplier engagement and procurement (see also A2.7)

- as a first step, you should develop a clear picture of what it is you want to buy and undertake an assessment of interoperability considerations between ambient scribing products and your critical systems, such as Electronic Patient Records (EPRs)
- use the NHS England's system guidance to help you understand procurement via nationally accredited frameworks. In brief, when selecting procurement frameworks as your purchasing route for a product, you should only procure through a framework operated by the accredited framework hosts

3.8 Monitoring and bias mitigation (see also A2.8)

- ensure that the ambient scribing product's performance is maintained over time once in use. This will necessitate actions from the product's manufacturer as part of post-market surveillance requirements, as well as your own ongoing quality assurance and monitoring (i.e. your monitoring data should be collected and analysed independently from the manufacturer's). Your ongoing monitoring can consist of error reporting processes, service usage monitoring, and comparison between reported and observed metrics
- AI-enabled products have high potential for bias due to limitations in the data and processes used for training AI models
- AVTs particularly may have varying success with some accents or regional dialects, and where the participants speak English as a second language, or are affected by speech disorders or impairments.
- confirm that the product works well for users and patients with different accents and monitor whether any patient groups hesitate to seek your services due to opposing the use of ambient scribing products

3.9 User training (see also A2.9)

- provide appropriate training to users. Specifically, you can consider providing guidance on appropriate dictation regarding voice and words used, and reinforcing ongoing responsibility for practitioners to review and revise the outputs

3.10 Liability (see also A2.10)

- NHS organisations 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 financial exposure can be mitigated by clear and comprehensive contracting arrangements with suppliers setting out their roles, responsibilities and liability appropriately

Appendix – in-depth considerations and actions

This Appendix provides further considerations and actions to support technical and product teams leading AI adoption in health settings.

A1. Product details

A1.1 What is an ambient scribing product?

- note that LLM-powered plug-ins to existing documentation and workflow applications can also be used for ambient scribing
- if you are new to AI, the NHS AI Lab's AI dictionary (https://nhsx.github.io/ai-dictionary) and the Parliamentary Office of Science and Technology's glossary (https://post.parliament.uk/artificial-intelligence-ai-glossary/) provide an overview of related terms, including Generative Artificial Intelligence (AI) and Large Language Models (LLMs)

A1.2 Product functions

- note that due to their flexibility, LLMs can allow for additional functionalities by utilising the transcript outputs and summaries. These may include the user providing a specific brief for these tasks; for example, users may be able to further adapt outputs to a particular style
- due to the free-text nature of this briefing functionality, users might unintentionally produce outputs beyond the product's intended purpose, such as 'call for action' prompts or feedback on a practitioner's performance
- the product supplier should detail guardrails in place and clearly outline intended use in their usage policy to minimise the risk of users instructing products to suggest diagnoses or identify missing consultation components, especially if the product is not registered as a medical device
- the questions in Box 1 can help you further clarify the specific features and functionalities of ambient scribing products. You can seek information to answer these from your supplier, technical experts, and your clinical safety, IG and IT teams

Box 1: Questions to clarify product functionality

Clarifying inputs for capturing speech:

- is the device passively recording ('listening' or recording 'in the background') or does it actively feature in the interaction (for example, being directly addressed by the user)?
- does the recording need to be started manually by the user?
- is the audio captured through dedicated devices (via single, or multiple microphones) or through a device with a microphone (for example, a smartphone)?
- can speech be captured from more than one party (for example, from a healthcare professional and their patient as well as others that may be present as part of the interaction, such as a family member, guardian, children and young people)?
- to improve intelligibility in the transcription process, does the audio processing:
  - reduce background noise?
  - boost weak signals?
  - filter out unwanted frequencies?
  - remove parts of the recording not relevant to the interaction (such as interruptions) or extended silences?

Clarifying outputs for transcription:

- as part of the interaction transcript, are different individuals tagged to their speech?
- does the transcription support the correct identification of clinical and colloquial medical discussions with necessary alignment to UK specific terminology where required?
- can the transcription handle a variety of speaker characteristics, such as age, gender, variations in speakers' accents and dialects, as well as any disorders (for example, aphasia)

- can the user:
  - review the transcript?
  - make updates to the transcript to fix errors, realign incorrect allocations of speaker (if relevant) and improve quality where required?
- does the product allow secondary vocal interactions through the capture device(s) to make edits (during or after the interaction)?

Clarifying outputs for downstream tasks:

- are the outputs (for example, the interaction summary note being generated from the transcript) presented back to the primary user or to others involved in the interaction?
- when, in what format, and for how long are the outputs presented to the user?
- does the product generate summarised outputs from the transcription directly *(*extractive), or combine information to create new outputs from the transcript (abstractive)?
- can the user review the transcription once processing and downstream outputs are complete?
- can the user review generated clinical codes allocated to the downstream output?
- does the interface feature 'call to action' prompts (for example, recommending treatment or next steps) for the user?
- does the user have control over the downstream task final output (for example, through templating, direct editing, or editing via a conversational interface)?
- does the user have manual control over the finalised information being written into any other downstream systems?
- can the outputs be integrated into Electronic Health Records and, if so, how is this done?

Clarifying data and system considerations:

- how long is each type of data kept for reviewing, monitoring, and audit processes (for example, the interaction audio, generated transcripts, user interactions, and any final outputs)?
- where is data being accessed from, shared and stored?
- what is the legal basis for using and/or retaining the data? Is patient consent needed to use and/or retain the data?
- what are the hardware requirements for the product?
- does its use affect other systems like Electronic Health Records?
- will the product lead to increased costs in relation to the amount of data used, transferred or how it is stored or retained?
- can the product be integrated with other existing products and providers like telephony?
- does the product meet secure by design principles (https://www.ncsc.gov.uk/collection/machine-learning-principles) and has it been securely configured?

A2. In-depth considerations and actions

A2.1 Risk identification and assessment

A2.1.1 Risks relating to safety

- specific safety considerations for ambient scribing products can include:
  - clarifying the level of evidence from the product supplier on the accuracy of their product, including validation from prospective user groups (for example, clinicians) on rate of errors, omissions and other dysfunctions
  - clarifying the key safety process for detecting, reporting, and managing serious incidents that may result from product errors
  - asking for the supplier's DCB0129 documentation (i.e. the clinical safety case report).
- be aware of the following challenges regarding outputs from ambient scribing products:
  - **accuracy:** Products may struggle with complex clinical terminology, abbreviations, or rapidly spoken dialogue. Some accents or regional dialects, and factors affecting speech such as disorders or impairments can impact the transcription's accuracy
  - **contextual understanding:** Misinterpretation of clinical context, such as mistaking a patient's hypothetical statement for a confirmed diagnosis, could lead to critical documentation errors
  - **completeness**: Gaps in documentation could lead to misunderstandings, incomplete medical records, and compromised patient care
- the following may pose risks that will need to be mitigated:
  - errors in outputs like inaccurate or incomplete documentation

- overreliance or automation bias from users
- poor integration with clinical workflows
- any effect on the dynamics and quality of patient-clinician interactions due to the presence of ambient scribing.

A2.1.2 Risks relating to data and cybersecurity

- AI-enabled products and systems could entail the following risks:
  - data leakage, integrity and compromised confidentiality of content and user data in hosted supplier environment
  - inability to govern privacy and data protection policies in externally hosted environments
  - difficulty conducting privacy impact assessments and complying with regulations due to the black-box nature of third-party AI-enabled products.
- engage with IG support early to ensure that any processing of personal data (including invisible processing) is subject to rigorous controls and considered in the Data Protection Impact Assessment (DPIA) and transparency materials to data subjects (such as patients).This should include how and why personal data is processed, what the legal basis is, and how it accords with data protection principles and laws, including data security, purpose limitation, data minimisation and necessity and proportionality among others
- AI-enabled systems can introduce unique security challenges due to the often large-size requirements of the training dataset, opaque internal workings of the AI model, and use of natural language for input prompting (in the case of LLMs). For example, indirect prompt injection attacks can be used to extract a user's personal data from LLMs. For high-level descriptions of different attacks on AI-enabled systems (including adversarial attaches) and their possible effects see What are attacks on AI (https://atlas.mitre.org/resources/ai-security-101#what-are-attacks-on-ai%3F)
- externally hosted AI models pose risks due to lack of control over their application processes and data handling. On-premises models also carry risks, so manage these with appropriate security and risk controls

A2.2 Regulatory compliance

This section has been developed in collaboration with Medicines and Healthcare products Regulatory Agency (MHRA) and Care Quality Commission (CQC).

- the AI and Digital Regulations Service (https://www.digitalregulations.innovation.nhs.uk/regulations-and-guidance-for-adopters/) for health and social care provides comprehensive guidance to adopters of AI technologies, including in relation to regulatory considerations
- software products with a 'medical purpose' for individual patients may qualify as a medical device. The Medicines and Healthcare products Regulatory Agency (MHRA) has published guidance to assist with this determination (https://www.gov.uk/government/publications/medical-devices-software-applications-apps) and how to tell if a software product falls within the UK Medical Devices Regulations 2002
- the individuals responsible for the due diligence process during procurement of new digital products at any healthcare organisation should ensure that the product has been correctly considered under the medical device regulation and whether the product is registered with the MHRA (https://pard.mhra.gov.uk/). This assessment should be independently conducted, rather than based on any self-declarations from industry suppliers about these technologies

Box 2: Is an ambient scribing product a medical device or not?

A product's intended purpose and level of functionality determine its medical device status.

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.

Manufacturers should seek regulatory approval for including these functions in their ambient scribing products or when extending the existing capabilities of their products to include these functions.

Some Generative AI models may incorporate these functions in their outputs unintentionally, or without prompt. If you don't intend for these functions, you should minimise their occurrence and potential impact through appropriate design of the outputs (for example generating outputs in restrictive formats) and through arrangements for appropriate user oversight and training.

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.

Further, functions that involve providing ‘call for action’ prompts or feedback/suggestions on the consultation (including on the practitioner’s performance or treatment suggestions), functions that generate clinical codes, letters or health records that inform clinical decisions, and any related processes that complicate the user’s ability to verify the product’s outputs may qualify it as a medical device.

- safety requirements apply to all digital products to be used in the NHS, regardless of whether it is considered a medical device. The DCB0129 clinical safety standard requires suppliers of digital health solutions to verify the safety of their products in England
- information in Box 3 and the AIDRS (https://www.digitalregulations.innovation.nhs.uk/regulations-and-guidance-for-adopters/all-adopters-guidance/understanding-how-the-care-quality-commission-cqc-regulates-health-and-social-care-services/) can help you understand how the Care Quality Commission (CQC) regulates health and social care services. In brief, CQC uses different methods and sources of evidence to assess the quality of care, depending on the type of service provided. This is to understand if services are safe, effective, caring, responsive and well-led
- the Network and Information System (NIS) Regulations (https://www.gov.uk/government/collections/nis-directive-and-nis-regulations-2018) are the established cyber security regulatory framework, applying to organisations known as operators of essential services or relevant digital service providers. Those organisations are required to take technical and organisational measures to manage risks, and prevent and minimise incidents concerning networks and information systems on which their essential service relies, which may include ambient scribing products. Further information is available on the AIDRS (https://www.digitalregulations.innovation.nhs.uk/regulations-and-guidance-for-adopters/all-adopters-guidance/cyber-security-and-resilience-for-health-or-care-services/)

Box 3: CQC’s role and remit

CQC is the independent regulator of health and social care in England. CQC makes sure health and social care services provide people with safe, effective, compassionate and high-quality care. CQC also encourages care services to improve.

You may need to register with CQC if you provide or intend to provide health or social care activities in England. The CQC website provides further information on regulated activities and registration (https://www.cqc.org.uk/guidance-regulation/providers/scope-registration). When applying for CQC registration, you must show that you will be able to meet the regulations in the Health and Social Care Act (https://www.legislation.gov.uk/ukdsi/2014/9780111117613/contents) 2008. Once registered, you must show that you will continue to meet them. Further information on the regulations and standards you must meet:

- the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (https://www.legislation.gov.uk/ukdsi/2014/9780111117613/contents) (including the fundamental standards)
- the Care Quality Commission Registration Regulations 2009 (https://www.legislation.gov.uk/uksi/2009/3112/contents/made)

Following registration, CQC uses different methods and sources of evidence, including on-site inspection activity to assess the quality of care you provide. This is to understand if services are safe, effective, caring, responsive and well-led.

When do the regulations apply?

If the use of digital technology constitutes an activity regulated by CQC, and you are not already registered to provide that activity, you may need to register and demonstrate that you can meet the regulations and standards. If you continue to carry on regulated activity that you are already registered for, the above regulations and standards continue to apply. This includes Regulation 10: Dignity and Respect (https://www.cqc.org.uk/guidance-providers/regulations/regulation-10-dignity-respect). All the above regulations and standards apply irrespective of whether regulated activity is supported by/delivered with or without technology including AVTs.

Where technology is deployed, CQC inspection teams may consider areas including (but not limited to):

- checking whether technologies are safely and effectively deployed in the care pathway (completing a data protection impact assessment (https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/accountability-and-governance/data-protection-impact-assessments) before deployment may help demonstrate how data protection risks were considered and mitigated)
- looking for evidence that relevant staff have been appropriately trained in using any new technologies
- identifying that processes are in place for appropriate reporting of any issues or incidents relating to new technologies

- identifying good, innovative practice, particularly where technology is delivering improvements in care for people using a service

A2.3 Data compliance and security

- NHS England has developed guidance for IG professionals (https://transform.england.nhs.uk/information-governance/guidance/artificial-intelligence/#ig_professional) to assist with meeting the requirements of data protection legislation when implementing AI-enabled technologies or sharing data for AI-based research in a health and care setting. Further guidance on this topic is in development and expected to be released in 2025. You can also seek further guidance from the NHS England IG Policy Engagement team using their query form (https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fnhsplatform.corestream.co.uk%2Fpublic%2Fform%2FIGPolicyQuery&data=05%7C02%7Cg.onis
- you should be aware that people have the right under UK GDPR Article 22 (https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/artificial-intelligence/guidance-on-ai-and-data-protection/how-do-we-ensure-fairness-in-ai/what-is-the-impact-of-article-22-of-the-uk-gdpr-on-fairness/) not to be subject to automated decision making, where the outcome produces a legal or similarly significant effect on them
- the Information Commissioner's Office provides further guidance (https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/artificial-intelligence/) for data protection and compliance with UK GDPR for those adopting AI technologies, and specific guidance (https://ico.org.uk/about-the-ico/media-centre/blog-generative-ai-eight-questions-that-developers-and-users-need-to-ask) on using Generative AI that processes personal data
- you should be transparent about how information is used and shared in your setting, including in relation to ambient scribing products. This can involve updating your privacy notices and explaining how their information will be used before the processing takes place, giving them the chance to object. Provided information can include:
  - what is being recorded
  - what the output will be
  - who will use that output and how it will be stored
  - any related information governance statements.
- as well as having direct conversations with patients, information can also be made available to patients in public areas and published on your website and social media channels
- generally, you should implement robust measures to protect any patient data, including encryption, access controls, and regular security audits. Ensure that you and your supplier comply with the Data Security and Protection Toolkit (https://www.dsptoolkit.nhs.uk/) (DSPT), as well as CREST (https://www.crest-approved.org/) and Cyber Essentials (https://www.ncsc.gov.uk/cyberessentials/overview) Plus certifications or similar ISO standards

A2.4 Integration and performance

Box 4: Key actions for successful integration and adoption

1. **Evaluate vendor capabilities:** Assess the vendor's experience with Electronic Health Record (EHR) integration and their ability to deliver scalable, interoperable solutions compliant with NHS standards like Fast Healthcare Interoperability Resources (FHIR), HL7, and SNOMED CT.
2. **Develop an integration plan:** Create a roadmap for seamless bidirectional integration with the EHR, allocating resources for custom development and testing.
3. **Analyse clinical workflows:** Map current workflows to identify areas where ambient scribing can add value and ensure the technology aligns with operational needs across specialties and departments.
4. **Customise the solution:** Work with the vendor to tailor the system to meet the requirements of different clinical settings and workflows.
5. **Establish error-handling processes:** Define straightforward methods for clinicians to identify and correct transcription errors without disrupting workflows.
6. **Plan for scalability and futureproofing:** Ensure the solution can scale across multiple sites, integrate with future system updates, and align with long-term NHS digital transformation objectives

- to support seamless integration with Electronic Health Records (EHRs) consider:
  - **bidirectional integration:** Ambient scribing solutions must enable seamless communication with the EHR, ensuring that notes generated are accurate, structured, and automatically aligned with the clinical documentation standards of the organisation
  - **standardised terminologies:** Integration with standardised clinical terminologies like SNOMED CT, ICD-10, and others, to ensure consistency in medical coding and documentation

    - **technical challenges:** Integration may involve significant technical complexity, particularly if the vendor's solution is immature or lacks pre-established interfaces with the provider's EHR system. Healthcare organisations should evaluate the vendor's experience with similar integrations and the level of support offered
    - **cost implications:** The financial and resource investments required for integration can be substantial, especially for custom development or interfaces. Organisations must balance these costs against anticipated efficiencies and clinical benefits
- to enhance workflow compatibility, consider:
    - **ease of use:** The technology must align with clinicians' workflows, minimising disruption and avoiding additional administrative burdens. Accurate voice recognition and features such as real-time transcription, and context-aware automation are essential
    - **customisation:** The ability to tailor the solution to the unique workflows of various specialties or departments within the NHS is critical to ensuring it adds value across diverse clinical settings
    - **error handling:** Clinicians must be able to use straightforward methods to identify and correct errors in the outputs without significantly slowing their workflow
- any product with functions that require integration with patient records may need significant support from your IT team. This is especially the case where outputs from ambient scribing products do not support industry standards and protocols such as HL7, FHIR and IHE, which may result in manual transcribing or the adoption of Robotic Process Automation (RPA) tools
- you should consider whether the product can support in-context launch (via protocols such as SMART on FHIR) and direct integration of summaries back to the consultation to maximise end user usability and minimise opportunities for transcription errors

A2.5 Portability, scalability and flexibility

- to ensure scalability and futureproofing, consider:
    - **scalable solutions:** Providers must evaluate whether the technology can scale across multiple sites or departments and integrate with future EHR updates or system changes
    - **interoperability:** Ensuring compatibility with other NHS digital systems and frameworks (for example, FHIR standards and SNOMED CT) is essential for long-term viability
    - **support large volumes of data:** Ensure that the infrastructure can handle the large volumes of patient data generated in a healthcare setting, with the capability to scale up as usage increases
    - **modular architecture:** Incorporate a modular approach that allows for easy upgrades, the addition of new features, and adaptation to future healthcare technologies or evolving standards

A2.6 Support and maintenance

- effective support and maintenance services are crucial to ensure that the ambient scribe technology operates efficiently in a clinical environment. Your product contract should include:
    - **Service Level Agreements (SLAs) for uptime and response times**: Set clear expectations for system uptime (e.g., 99.9% availability) and response times for resolving technical issues
    - **training and user support**: Specify the training that will be provided to clinicians and IT staff, as well as ongoing support services to address any technical challenges that may arise. For medical devices, training must be provided to intended users if the manufacturer determined that such training is necessary to meet safety requirements when registering their product with the MHRA
    - **post-deployment maintenance**: Define terms for ongoing maintenance, including software updates, bug fixes, and enhancements

A2.7 Supplier engagement and procurement

- there is no single route to follow when considering procuring ambient scribing products. This should be considered on a case-by-case basis through a sourcing strategy and will be dependent on the procurement size, scale and exact requirements
- key points to consider:
    - you should undertake assessment of interoperability considerations between ambient scribing products and your critical systems such as Electronic Patient Records (EPRs) and understand whether your required deliverables might be satisfied by a pre-developed complete-off-the-shelf (COTS) software (implying limited configurability and customisation for NHS use), or whether you may need to develop something bespoke (in such case, the NHS would retain the IPR)
    - you should link your plan for market engagement to a related ICB strategy
    - you should be aware that there are at least two separate and distinct markets for ambient scribing products and related AVTs; one which is via an existing EPR supplier and another where a product is procured as an add on, direct from another supplier. You should remain cognisant of these different markets when undertaking market analysis, drafting Request for Information (RFI) documentation, considering responses, developing sourcing strategies and specification

    - ensure that your product assessment and implementation considerations (including the use case and involved data) inform your planned contracting structure and related terms in any end user agreements
- following this initial analysis, you should share your intentions with the market and seek feedback. Expressions of interest from suppliers can be coordinated via a preliminary market engagement notice (https://assets.publishing.service.gov.uk/media/66b24baf0808eaf43b50de08/CCS0524204542-001_Transforming_public_procurement_Combined__3_.pdf) advertised on the Find a Tender Service website (https://www.gov.uk/find-tender) (to be replaced by the Central Digital Platform)
- you can then make a more informed decision about procurement routes, considering factors such as which suppliers responded to the market engagement and their appointment to frameworks and how closely your requirements align to those that have been defined, specified and tested under each framework, its statement of requirements and evaluated selection and award criteria
- NHS England's system guidance (https://www.england.nhs.uk/publication/system-guidance-for-the-implementation-of-framework-host-management/) can help you understand procurement via nationally accredited frameworks
- you can encourage procurement of products supplied by small and medium sized enterprises (SMEs) by publishing your pipelines and allowing sufficient time for bid responses

A2.8 Monitoring and bias mitigation

- you should regularly monitor system performance metrics to identify and address emerging safety risks and mitigate potential biases in the product's outputs
- this should involve clarifying appropriate governance and clearly defined roles, responsibilities, and accountability for the product's deployment, maintaining appropriate human oversight of its outputs and related auditing and record-keeping
- ensure that ambient scribing products are incorporated into your system-wide processes for reviewing and responding to relevant safety recommendations and alerts, including those from NHS England (https://digital.nhs.uk/services/respond-to-an-nhs-cyber-alert), the MHRA, and the Health Services Safety Investigations Body (https://www.hssib.org.uk/) (HSSIB)
- for medical devices, the product manufacturer has legal responsibility to conduct post-market surveillance. Please note that the deploying organisation should still report any concerns relating to a medical device to the MHRA via the Yellow Card (https://yellowcard.mhra.gov.uk/) reporting portal, and report any safety concerns through local incident management systems feeding into the Learn from Patient Safety Events Service (LFPSE) (https://www.england.nhs.uk/patient-safety/patient-safety-insight/learning-from-patient-safety-events/learn-from-patient-safety-events-service/)

A2.9 User training

- the AIDRS (https://www.digitalregulations.innovation.nhs.uk/regulations-and-guidance-for-adopters/all-adopters-guidance/general-staff-training-and-product-specific-user-training-for-digital-healthcare-technologies/) outlines how you can develop product-specific user training. Depending on the specific product and user setting, you may need to consider:
    - providing guidance on appropriate dictation and procedures, for example regarding consultation behaviour and required speech patterns and words used
    - educating practitioners on how to gain permission from patients to use ambient scribing
    - reinforce ongoing responsibility for practitioners to review and revise the outputs given potential errors
    - planning for any anticipated retraining needed for any updates or new functionalities
    - establishing dedicated support channels for addressing user queries and resolving technical issues.
- this case study (https://www.chcpcic.org.uk/articles/integrating-ai-scribe-into-the-frailty-team) highlights how a team at City Health Care Partnership used a trial of an AVT product to create and strengthen product-specific training for their staff, which is now supporting its wider roll out. Time gained from using these products is reclaimed as protected time for broader structured education and training.

A2.10 Liability

- liability for any claims associated with the use of AI-enabled products in NHS settings remains complex and largely uncharted, with limited case law to provide clarity
- as such, engage your legal teams before procuring ambient scribing and AVT products, particularly to assess specific functionalities, intended use, and levels of human oversight. Legal consultations can help mitigate liability risks by addressing these factors as part of comprehensive risk management
- within NHS organisations, liability (particularly liability for clinical negligence claims) can ultimately lead to a non-delegable duty on the part of the Trust or primary care provider if a specific liable party cannot be established. This may also apply in cases where the party that would ordinarily bear liability (for example, the product supplier) lacks sufficient coverage or does not fully assume responsibility. In such situations, following an initial assessment, the liability may default to the Trust, which retains a non-delegable duty to ensure patient safety and quality of care. This is based on the understanding that the Trust or primary care provider retains control and responsibility for the treatment

provided to the patient, and the duty of care arising from this personal relationship is non-delegable and remains with the Trust or primary care provider. This is unlikely to prevent the Trust or primary care provider from taking legal action against the product supplier

- clear and comprehensive contracting arrangements with suppliers and stakeholders are essential to appropriately delineate responsibility and liability. This should include any implications that may arise from your organisation customising or developing new aspects of the ambient scribing product; for example, developing templates to be used for its outputs
- it is crucial that processes involving AI-enabled products are designed with transparency and traceability in mind to aid in establishing accountability and liability when required

Publication reference: PRN01734_i

Date published: 27 April, 2025
Date last updated: 29 April, 2025

▲Back to top