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Priority Notification: Ensuring Safe and Assured Adoption of AI Scribe Technology

The adoption of ambient scribing products and Ambient Voice Technology (AVT) solutions hold transformative potential for any care setting. Their adoption, when used safely and securely, is to be encouraged to improve both the quality of patient care and operational efficiency. However, since NHS England published AVT guidance on 27th April 2025, we have received an increasing number of requests to clarify their deployment and use.

We are now aware of a number of AVT solutions which, despite being non-compliant with our published guidance, are still being widely used in clinical practice as free trials or through direct commissioning, both by individuals and organisations. Irrespective of care setting, all NHS organisations must ensure that any AVT solutions being used meets the specified NHS standards as the use of non-compliant solutions poses a risk to clinical safety and data security.

Key points you need to follow:

1. Do not use AVT solutions that are not compliant with NHS standards.
2. All AVT solutions that generate summarisation require, at least, MHRA Class 1 medical device status.
3. Providers need to complete a clinical safety risk assessment and data protection impact assessment (DPIA) before using these tools as part of your legal responsibilities as set out in the DCB0160.
4. Liability for using a non-compliant solutions sits with the deploying organisation (e.g. general practice or trust) or individual user.

A full breakdown of the assurance requirements is detailed below. It is essential that any NHS organisation reads the guidance (https://tinyurl.com/7s3vmtw2) and checks with their ICB digital team before proceeding.

Several AVT suppliers are approaching NHS organisations, including Primary and Secondary Care, offering AI-driven ambient scribe solutions. While the opportunity for efficiency and workflow enhancement is emerging at pace, many of these vendors have not complied with basic NHS governance standards, such as seeking ICB approval, providing MHRA clinical safety and technical/cyber platform assurance, and evidencing proven benefit within the NHS.

Proceeding with non-compliant solutions risks clinical safety, data protection breaches, financial exposure, and fragmentation of broader NHS digital strategy. It is a requirement to check that your AVT solution meets the requirements below. Liability for the use of non-compliant AVT solutions will be held by the local NHS Trust, Primary Care practice or individual clinicians.

An NHS England national delivery proposal is in development to support all care settings to roll out assured and standardised AVT solutions across England in a safe and compliant way to deliver efficiency and productivity benefits across the system. This will include a common and consistent approach to documentation and broader assurance requirements. Further communications will be issued shortly outlining more information on this work.

NHS position on AVT deployment

NHS England has published guidance on how digital technologies should be approved for use in the NHS. Additional National Guidance explains how AVT solutions should be selected, deployed, and scaled. These standards are required for any AVT solution to be considered safe, effective, and eligible for NHS adoption (https://tinyurl.com/7s3vmtw2).

Minimum Requirements for AVT adoption

It is the responsibility of all NHS organisations to ensure that AVT suppliers demonstrate compliance with the requirements listed below. Any engagement with AVT suppliers that are not compliant must cease until such time as compliance has been formally signed off by the ICB. Local and regional governance oversight should be followed as standard. This applies to any health and care organisation or professional.

It is the responsibility of all AVT suppliers to demonstrate compliance with these requirements.

1. **Core platform assurance requirements**
    a. Digital Technology Assessment Criteria (DTAC), Data Security and Protection Toolkit (DSPT,) Cyber Essentials Plus, CREST-approved pen testing
    b. Data Protection Requirements as set by ICO - Local ICB / Trust governance approval including DPIA completion
    c. Clinical Safety Officer(s) named and accountable
    d. End-to-end encryption and GDPR compliance
    e. No unsafe functionality e.g. prompt injection access
    f. Appropriate NHS clinical system integration (API or FHIR/HL7 compliance and write-back capability).
    g. The responsibility for translation accuracy remains with the AVT supplier.

2. **Enhanced Requirements**
    a. **Medical Device Classification –** All AVT solutions that undertake summarisation require, at least, MHRA Class 1 medical device status. Companies must NOT extend system capabilities to produce generative diagnoses, management plans, or other medical referrals and calculations without seeking at least MHRA Class 2a approval.
    b. **Data Protection –** Safeguarding Patient Information is paramount. Patient data from clinical sessions (e.g. immediate inference) should be automatically deleted unless legally or operationally required, in line with UK GDPR and DPA 2018 principles on data minimisation and storage limitation. Further guidance on this will be published shortly.
    c. **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).

3. **Clinical and Operational Benefits Thresholds**
    a. Evidence of real-world clinical validation of benefits in the NHS care setting proposed (e.g. enhancing clinical efficiency and workflow, reducing administrative burden; improving patient care by increasing face to face time with patients; improving accuracy of documentation;

improving data quality and capture of structured data recorded in electronic patient record systems)

b. Clear economic justification and workforce impact.

Immediate Required actions

1. Pause, reject or stop engagement with any AVT supplier that is not able to meet the published assurance standards above.
2. Pause or stop any implementation or use of AVT by an organisation / individual that is not able to meet the published assurance standards above.
3. Engage with your ICB and regional teams for assurance.