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From:

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To:

Digital Health Leads
Clinical Digital Health Leads
Primary Care Leads

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Dear Colleagues

Use of Ambient Voice Technologies ('AI Scribes') in NHS Scotland– Interim position

Artificial Intelligence (AI) presents unprecedented opportunities to transform healthcare. There are promising examples of AI being developed to improve the accuracy and speed of diagnosis, enhance decision support tools, increase access to personalised and community-based care and facilitate the shift towards prevention. As part of the long-term health and social care data strategy and work to improve innovation adoption pathways the Scottish Government are working to develop more consistent approaches to the use of AI technologies in NHS Scotland.

Ambient Voice Technologies are an emerging category of AI that is starting to be used across NHS and social care settings. These tools take an audio recording of a consultation or interaction and transcribe this to text often summarising the most useful and relevant information based on templates. This has the potential to reduce workload and cognitive burden and improve the quality of record keeping. However the evidence base is still building, not all AVT tools are equal and they create significant digital, information and clinical governance challenges. Several suppliers are approaching NHS organisations, including Primary and Secondary Care, offering AI-driven ambient scribe solutions. Many clinicians have asked for guidance on whether they can use these technologies and if so, which tools to access.

In light of recent guidance from NHS England, advice from the British Medical Association General Practitioners Committee England ('BMA GPCE') and from territorial Health Boards we are writing to set out an interim position on the use of AVT in NHS Scotland. Whilst this position applies irrespective of care setting, given the level of interest in primary care settings, this approach has been endorsed by the Royal College of General Practitioners as well as BMA Scottish General Practitioners Committee. This is expressed as an interim position due to the fast-moving nature of these developments and recognising the need for more detailed guidance and support. It is intended to provide a more consistent approach within Scotland and should not supersede local policies already in place or in development which are likely to be more detailed and specific to the local context.

Our position is that **the use of AVT, when used safely and securely, has the *potential* to improve both the quality of care, enhance the experience of staff and create operational efficiencies.** In order to demonstrate safety and security of these tools, all NHS organisations must ensure that the following steps are taken:

1. Engage with your local Information Governance (IG) team, Cybersecurity team and your Caldicott Guardian (CG) early to understand legal and regulatory requirements and to ensure the use of AVT is ethical, safe, transparent and inclusive. For example:
 - patient data from clinical sessions should be automatically deleted unless legally or operationally required, in line with UK GDPR and DPA 2018 principles on data minimisation and storage limitation.
 - Patients should be informed about how AVT are being used and what happens to their data in line with the 8th Caldicott principle.
2. Ensure evidence of MHRA approval i.e. A UK Conformity Assessed (UKCA) certificate or a valid CE mark (until 30th June 2028.) MHRA advice is that all AVT solutions that generate summarisation should be classified as at least a Class I medical device, and in many cases Class II. Be aware that when capabilities are added (e.g. producing management plans, creating referrals or generating diagnoses) this changes the classification.
3. Ensure that the following have occurred
 - the manufacturers have provided a clinical safety risk assessment
 - the deploying organisation has undertaken a formal clinical safety risk assessment around the use of the product ,
 - a data protection impact assessment (DPIA) has been undertaken
 - a System Security Plan (SSP) is in place
4. Specify requirements for integration with IT infrastructure, systems and workflows. This should refer to standards like FHIR, HL7, and SNOMED CT for efficient data exchange and accurate documentation and ensure the system supports future compatibility with other technologies and platforms.
5. Define performance metrics for accuracy and reliability and ongoing monitoring arrangements. This should include clear responsibilities and processes for sense checking the information created before onward use, bias mitigation, audits of clinical documentation and incident reporting (in line with advice from IG, Cyber and Caldicott guardians as mentioned in (1)). The manufacturer needs to comply with post-market surveillance requirements under Medical Device Regulations, but there should be independent analysis of monitoring data.
6. Provide appropriate training to users including on responsibility for review and revising outputs.
7. Ensure that there are clear and comprehensive contracting arrangements in place with suppliers to set out roles, responsibilities and liability. Seek legal advice from NSS CLO and/ or Medical Defence Organisations where there is any doubt.

Proceeding with AVT solutions without taking these steps presents risks to patient safety, data protection principles, legal liability, and fragmentation of the broader NHS Scotland digital strategy. Any engagement with AVT suppliers that are not compliant should stop and local territorial board IG teams should be engaged.

National guidance is being developed to support GPs. This will include supporting common approaches to assurance documentation and key roles within NHS Scotland territorial boards that can support further understanding and delivery of AVT solutions. Relevant stakeholders are currently being engaged to ensure there is a wide representation of experts

from NHS Scotland, the Scottish Government and professional bodies in drafting this guidance, supporting a 'Once for Scotland' approach.

Kind regards,



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