Overview of developments in AI guidance for primary care

including approaches for assurance and safe deployment of ambient scribes in general practice

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Content

- Regulatory landscape
- Guidance (?)
- Assurance approaches for general practice deployment of AI scribes

A bit of background

Changing regulatory landscape

UK MDR 2002

(law governing medical devices in the UK)

- UK MDR 2002 is currently being revised and will be published in Spring 2026
- MHRA is minded to align UK law with new EU MDR (stricter regulation)
- MHRA has indicated that the new law will follow IMDRF guidance on software classification (to align with EU MDR)

Digital clinical safety standards (DCB 0129 and DCB 0160)

- Undergoing consultation / review
- Ensure DCB standards remain practical and keep pace with rapid technological advancements in healthcare IT
- Align closely with the forthcoming UK Data (Use and Access) Bill
- DCB standards + UK Data (Use and Access) Bill → support a data-driven, trust-based healthcare system

AI specific governance in NHSE

- No specific policy which sets out governance for AI in NHSE (yet)
- AI specific policies are in discussion
- Considerations for new policy:
  - AI use in NHSE
  - AI use across NHS
  - Categorising AI
  - Intended uses and implications (clinical, HR, administrative)

On the regulatory horizon

UK National Commission on the Regulation of AI in Healthcare

- Primary objectives:
  - Reviewing current regulation
  - Accelerating AI adoption
  - Ensuring patient safety
- Publish new regulatory ‘rulebook’ for AI in healthcare in 2026

NHSE Medium Term Planning Framework (2026-27 to 2028-29)

- Providers should deploy AVT at pace, with due regard to the national AVT registry
- In *2026/27 all ICBs must…support primary care providers to deploy ambient voice technologies*
- NHS must begin move to unified access model, using AI-assisted triage (delivered via NHS App)

Shared learning

- Regular meetings of devolved nations stakeholders and NHSE for *UK Collaboration on AI Guidance for NHS Primary care*
- In consultation, Scottish Government’s (draft) policy *Framework for the safe, efficient and ethical application of Artificial Intelligence (AI) across health and social care*

Guidance (?)

Implementing AI-enabled ambient scribing products

For practices considering AVT, here is a 10-step plan to implementation:

1. Appoint a lead and get them CSO-trained if not already
2. Choose a supplier with due diligence, including ensuring Class I medical device registration
3. Contact your DPO for the latest approved DPIA, read, complete, and sign it
4. Ask the supplier for their DTAC
5. Complete DCB0160 documents
6. Write AI scribe practice policy
7. Update your privacy notice
8. Consider a pilot phase (many offer free versions and trials)
9. Support your team to understand the risks (mainly, over-reliance) and benefits
10. Engage and inform patients through various communication channels

For more information: NHS England » Guidance on the use of AI-enabled ambient scribing products in health and care settings

Adapted from:
https://www.linkedin.com/posts/wandsworth-gp-federation_navigating-ambient-voice-technology-in-nhs-activity-7384558217676374017-e31w/?utm_source=share&utm_medium=member_desktop&rcm=ACoAADvha58BYTVKEB1FtF9fnRz0lYeQhNChaxk

What does research suggest?

- Terms such as explainability, transparency and interpretability are not considered in MDR 2002 and remain under-specified in current regulatory guidance
- Existing standards and guidance on applying human factors do not fully address AI-specific challenges, such as explainability-driven, over-reliance, deskilling, or automation bias

[ref: AI_Airlock_Sandbox_Programme_Report_Final.pdf]

- In a typical NHS trust, 3 out of 4 digital tools influencing patient care do not demonstrate compliance with minimum legal or clinical safety requirements
- "...failure to assure digital technologies poses a significant risk to one of the core ambitions of the NHS 10-Year Health Plan for England; safely transitioning from analogue to digital care models"

[ref: https://www.jmir.org/2025/1/e80076/PDF]

- Newton's Tree awarded grant from AI Security Institute to develop CLIO, a tool designed to address the challenge of keeping LLM technologies safe by delivering real time tracking of how LLMs are used in clinical settings
- CLIO aims to develop proactive safety measures such as tools to flag performance drift and automation biases

[ref: AI Safety at Scale: a new frontier for LLM oversight in healthcare | Blogs | Newton's Tree]

Focus of CQC assessments for use of AI in GP services

Look for evidence in following areas:

- **Procurement and governance:** AI tools must have been procured in line with relevant evidence and regulatory standards
- **Risk assessment:** hazard log & risk assessments completed in relation to AI tools
- **Responsibilities:** identified responsible CSO & digital lead for AI technologies and related clinical governance, including completed relevant training
- **Human oversight:** demonstrate AI is used as a support tool – not a replacement for human oversight
- **Learning from errors**: established systems to report and investigate occurrences if something goes wrong
- **Data protection:** demonstrate how third-party venders have met assurances on how data is shared, stored or used
- **Consent:** type of consent required (implied or explicit) determined by AI technology and its intended use
- **Staff training:** staff should have received appropriate training to be competent to use AI tools
- **Equity in access:** take practical steps to reduce digital exclusion by looking at digital skills, connectivity and accessibility among the patient population
- **Managing bias:** should seek assurance on mitigating risk of bias in AI around certain population groups, based on the quality of data that was used to develop it

Ref: GP mythbuster 109: Use of artificial intelligence (AI) in GP services - Care Quality Commission

Approaches for assurance and safe deployment of ambient scribes in general practice

Approach 1:

Implementation and adoption of AI scribes – compliance checklist for GP Practices

- NEL (North East London) ICB approach for pilot of Heidi AI scribe and Accurx AI scribe
  - seeking 'higher level of assurance' from GP practices, within NEL ICB region, intending to use these tools
- ICB offer central support for:
  - Clinical safety process at scale –good governance and sharing of hazard risks across practices
  - Support and provide oversight with information and clinical governance requiring oversight
- Local GP practices need to seek the following assurances:
  - Socialise to their patients some information on "What is an AI scribe"
  - Update the practice privacy (transparency) notice
  - Inform NEL DPO that they wish to use the scribe and agree (NEL) DPIA
  - Complete DCB0160 for the tool and agree to collate hazards logs into NEL repository
  - Make staff aware of DPIA / clinical safety documentation, including hazards

Ref: [AI Scribes for Primary Care – NEL approach – North East London]

AI Transcription Scribes Enhancing Your Healthcare

How AI Scribes Work

Listening and Typing: The AI scribe listens to your conversation with your clinician and types up relevant notes. This allows your clinician to focus more on you, ensuring a more attentive and personalised consultation. The scribe is only interested in medical information relevant to your care.

Simple and Effective AI

Basic AI Technology: Built by a team led by doctors, the AI scribe uses basic artificial intelligence to transform your conversation into clear and concise notes. This supports your care and helps save time.

Your Clinician Reviews Everything

Oversight: Your clinician will review and edit all the notes before they are saved to your medical record. The AI scribe does not add anything directly to your medical record, ensuring that all decisions about your care are made by your healthcare professional.

Privacy and Security

Data Privacy: The AI scribe technology adheres to all necessary UK data privacy rules and NHS standards. Your voice recordings are not stored within the scribe. Only the information your GP deems necessary is saved to your medical record.

Your Choice Matters

Your Comfort: If you are not comfortable using an AI scribe, ask your clinician for more information on how it works. If at any point you feel uneasy, you can request your clinician not to use the scribe during your consultation.

Enhancing Your Care

AI scribes are designed to make your GP visits more efficient and focused on your needs. They are a tool to enhance the quality of care you receive while ensuring your privacy and comfort.

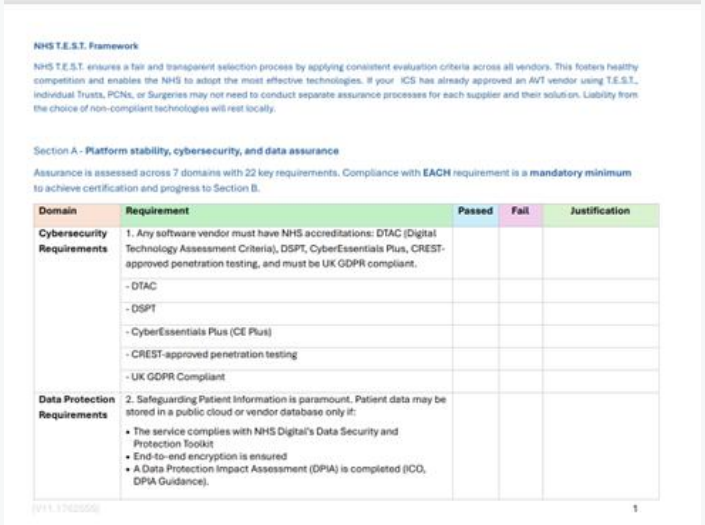
[AI Scribe – Patient Info Leaflet]

Approach 2:

NHS TEST (Technology Evaluation Safety Test)

- Developed at request of NHS England (London Region) - not guidance, but practical tool to assess if a technology is sufficiently assured and demonstrates proven benefit to justify scaling
- Framework employs a dual evaluation model, focusing on both platform assurance (foundational technical and regulatory compliance) and demonstrable benefits to support healthcare delivery:
    - Platform Assurance (Section A): assesses compliance across 7 key domains, including Cybersecurity, Data Governance, Clinical Safety, Bias and Inclusivity, Technical Requirements, Business Continuity, and Evolving Technology. Compliance with NHS DTAC accreditation, UK GDPR, and DCB 0129 clinical risk standards are fundamental requirements at this stage.
    - Benefits Assessment (Section B): evaluates measurable impact across 12 domains, including clinical effectiveness, operational efficiency, workforce impact, and environmental sustainability. Based on a scoring system, technologies are classified into certification tiers, determining their suitability for NHS-wide adoption.

Ref: NHS TEST: not every AI is intelligent, but we need an intelligent framework to choose new technologies - Health Innovation Network



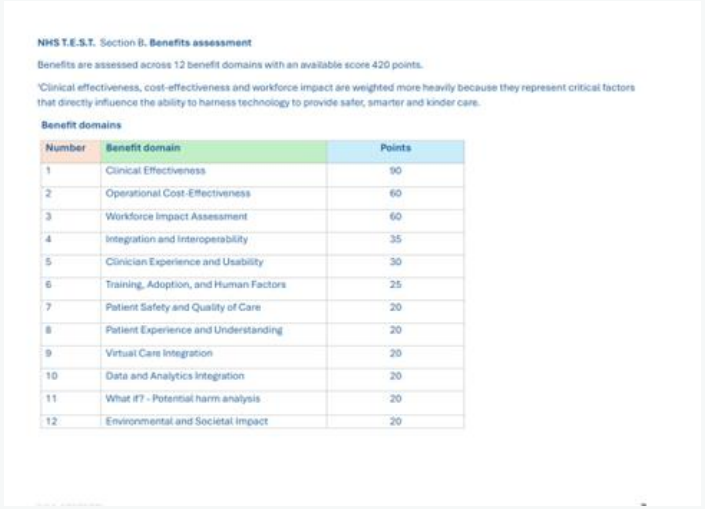
NHS T.E.S.T. Framework

NHS T.E.S.T. ensures a fair and transparent selection process by applying consistent evaluation criteria across all vendors. This fosters healthy competition and enables the NHS to adopt the most effective technologies. If your ICS has already approved an AVT vendor using T.E.S.T., individual Trusts, PCNs, or Surgeries may not need to conduct separate assurance processes for each supplier and their solution. Liability from the choice of non-compliant technologies will rest locally.

Section A - **Platform stability, cybersecurity, and data assurance**

Assurance is assessed across 7 domains with 22 key requirements. Compliance with **EACH** requirement is a **mandatory minimum** to achieve certification and progress to Section B.

Domain	Requirement	Passed	Fail	Justification
Cybersecurity Requirements	1. Any software vendor must have NHS accreditations: DTAC (Digital Technology Assessment Criteria), DSPT, CyberEssentials Plus, CREST-approved penetration testing, and must be UK GDPR compliant.			
	- DTAC			
	- DSPT			
	- CyberEssentials Plus (CE Plus)			
	- CREST-approved penetration testing			
	- UK GDPR Compliant			
Data Protection Requirements	2. Safeguarding Patient Information is paramount. Patient data may be stored in a public cloud or vendor database only if: • The service complies with NHS Digital's Data Security and Protection Toolkit • End-to-end encryption is ensured • A Data Protection Impact Assessment (DPIA) is completed (ICO, DPIA Guidance).			



NHS T.E.S.T. Section B. **Benefits assessment**

Benefits are assessed across 12 benefit domains with an available score 420 points.

'Clinical effectiveness, cost-effectiveness and workforce impact are weighted more heavily because they represent critical factors that directly influence the ability to harness technology to provide safer, smarter and kinder care.

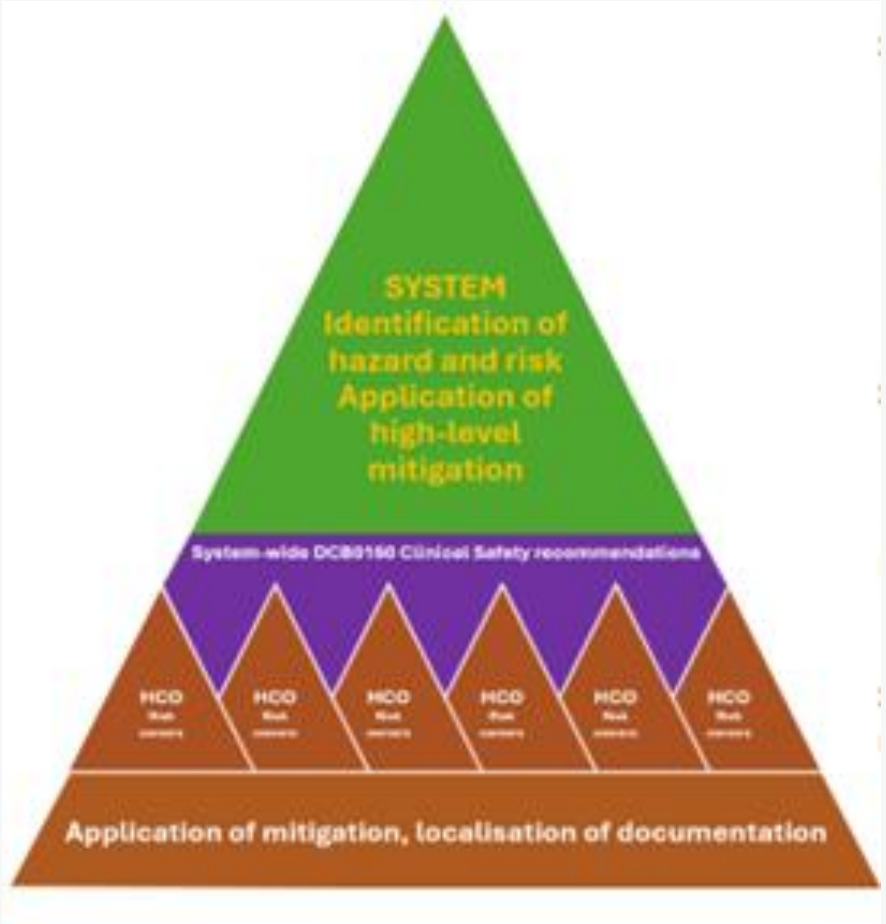
Benefit domains

Number	Benefit domain	Points
1	Clinical Effectiveness	90
2	Operational Cost-Effectiveness	60
3	Workforce Impact Assessment	60
4	Integration and Interoperability	35
5	Clinician Experience and Usability	30
6	Training, Adoption, and Human Factors	25
7	Patient Safety and Quality of Care	20
8	Patient Experience and Understanding	20
9	Virtual Care Integration	20
10	Data and Analytics Integration	20
11	What if? - Potential harm analysis	20
12	Environmental and Societal Impact	20

Approach 3:

AVT System-level Approach

- NHSE South-West region CRM pilot approach for primary care AVT deployments
- System-level Clinical Risk Management - system-level outputs, residual level of risk and recommendations communicated to stakeholders
    - System-level hazard workshops completed - mitigations for unacceptable levels of risk are proposed
    - System-level mitigations - applied and tested ahead of residual risk evaluation
    - Local-level (HCO) mitigations - documented and communicated to the HCOs
- Local-level Clinical Risk Management
    - Where system-level residual risk is assessed as acceptable:
        - Individual organisations signed up to the CRMS assured they need do nothing further.
    - Where mitigations must be applied at a local, organisational level:
        - Programme provides clear recommendations for those local mitigations.
        - Once mitigations have been applied, local risk owners are assured the residual level of risk is acceptable (following local scoring)



Ref: Wessex-LMC-AVT-Presentation-for-sharing.pdf

Thank You

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