Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

PWYLLGOR DIGIDOL, DATA AC ARLOESI
DIGITAL, DATA AND INNOVATION COMMITTEE

DYDDIAD Y CYFARFOD: DATE OF MEETING:	22 July 2025
TEITL YR ADRODDIAD: TITLE OF REPORT:	Proposal of Ambient AI within the Health Board
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Huw Thomas, Executive Director of Finance
SWYDDOG ADRODD: REPORTING OFFICER:	Anthony Tracey, Digital Director Gareth Beynon, Head of Information Services

Pwrpas yr Adroddiad (dewiswch fel yn addas) **Purpose of the Report** (select as appropriate)
Er Sicrwydd/For Assurance

ADRODDIAD SCAA
SBAR REPORT

Sefyllfa / Situation

This report provides an overview of the current opportunities, challenges and recommendations regarding the use of Ambient Artificial Intelligence (AI) in the Health Board. AI scribes offer significant benefits in reducing administrative burden and clinician burnout. These benefits have to be weighed against potential clinical and data / information governance risks and lessons must be learned from previous AI model implementation experiences.

Cefndir / Background

AI scribes are advanced tools that utilise machine learning and natural language processing (NLP) to transcribe and summarise clinical encounters in real-time. By capturing conversations between healthcare providers and patients, these systems aim to automate the documentation process, thereby reducing the administrative burden on clinicians and allowing them to focus more on patient care whilst also improving clinical wellbeing

Asesiad / Assessment

Ambient AI scribes represent a promising advancement in healthcare, offering potential benefits in reducing documentation burdens and enhancing clinician-patient interactions. However, careful implementation, continuous monitoring, and addressing challenges related to accuracy, privacy, and integration are essential to fully realise their potential in clinical practice.

Benefits of AI Scribes:

- Reduction in Documentation Time: AI scribes have been shown to decrease the time clinicians spend on documentation, improving operational efficiency and reducing administrative workload.
- Improved Physician Well-being: Reduced clerical workload has been linked to lower levels of burnout and increased job satisfaction among clinicians.
- Enhanced clinician - patient Interaction: With less focus on note-taking during consultations, clinicians can engage more meaningfully with patients, improving the quality of care.

Challenges and Considerations:

- Accuracy and Reliability: AI scribes can misinterpret context or generate inaccurate information (hallucinations). Errors such as transposing positive and negative statements (e.g., "does" vs. "does not") have been reported and could impact clinical decision-making.
- Furthermore, OpenAI's terms of use explicitly prohibit medical applications, meaning developers should instead consider fine-tuning an open-source large language models with controlled version management or, ideally, developing their own model.
- Data Privacy and Security: AI scribes rely on handling sensitive patient data, raising concerns about data protection and confidentiality. Even if AI scribes claim to be General Data Protection Regulation (GDPR)-compliant, practices / health boards should remain aware that some models (e.g. Heidi and Tortus) use OpenAI infrastructure, which introduces the involvement of a third party.
- Integration with Electronic Medical Records: Effective use of AI scribes requires seamless integration with existing health records systems to avoid workflow disruptions and ensure consistency in clinical documentation.
- Consent: While some clinicians inform patients that their consultations are being recorded for documentation purposes, others do not disclose this, arguing that no audio file is retained. The ethics of this practice remain unclear.

Health Boards and Trusts are uniquely positioned to inform decisions by Welsh government regarding development and deployment of AI technologies, including AI scribes. Strategic alignment with national AI frameworks and ongoing engagement with stakeholders are critical to ensuring AI adoption is both safe and effective. Links and working relationships are already established with colleagues across the four nations including other partners within Wales such as Digital Health and Care Wales (DHCW) and Welsh Government.

Building on the approach outlined in the previous meeting, this proposal seeks to enable safe and practical engagement with AI technologies among clinicians. This will be achieved through the establishment of working groups, the implementation of educational pilots—such as the development and evaluation of non-patient-facing custom Generative Pre-trained Transformer (GPTs) (e.g., for summarising clinical guidelines or generating draft documentation)—and research into real-world barriers to AI adoption within the Health Board. Specific technologies under consideration include large language models (LLMs) like OpenAI's GPT-4, clinical decision support tools powered by machine learning, and AI-driven image analysis platforms for radiology and pathology. In collaboration with our strategic partner, the aim is to position the organisation as a leader in the application of AI in both clinical workflows and patient-facing services.

Workforce Readiness

A lack of AI literacy and confidence among staff poses a significant barrier to digital transformation, with potential consequences for both patient care and operational efficiency. Tools such as AI scribes — alongside other AI applications — introduce complex challenges, including hallucinations, algorithmic bias, and the risk of misinterpreting clinical data. It is essential that staff are equipped to recognise and manage these risks. Without targeted education and training, NHS Wales may struggle to fully realise the benefits of AI while navigating its ethical and safety implications, increasing the risk of inaccurate documentation and potential patient harm.

To mitigate these risks, a structured programme of engagement and training is required. This should begin with a foundational 'Basics in AI' module, complemented by the development of an AI-powered 'Healthcare AI Mentor' to support ongoing learning. Collaboration with our

university partners and Health Education and Improvement Wales (HEIW) will be key to designing and delivering these initiatives effectively.

Is it a medical device?
There is ongoing debate about whether ambient scribes and clinical summarisers powered by LLMs should be classified as medical devices. According to the Medicines and Healthcare products Regulatory Agency (MHRA), software is generally considered a medical device if it performs calculations or interprets data used for diagnosis, treatment, or monitoring — rather than simply presenting reference information.

LLM-based summarisers go beyond basic transcription by generating structured summaries and selectively including or omitting clinical information. This interpretive function aligns with the MHRA's criteria for software as a medical device (SaMD), and similar interpretations are emerging under EU regulations. In the U.S., the Food and Drug Administration (FDA)'s Clinical Decision Support (CDS) guidance indicates that LLM-based summarisers may not meet key 'non-device' criteria, suggesting they could also fall under medical device regulation.

Consequently, these systems may require formal certification—such as UK Conformity Assessed (UKCA) marking, CE marking, or FDA approval—before they can be deployed in clinical settings. This introduces a significant risk: if procurement contracts are signed before regulatory classification is confirmed, these tools could become unusable until certified, delaying implementation and potentially incurring financial and operational costs.

Additionally, OpenAI's terms of service explicitly state: 'You must not use any Output relating to a person for any purpose that could have a legal or material impact on that person, such as making … medical, or other important decisions about them.' Given that clinical documentation directly influences patient care—especially when reviewed by clinicians other than the author—this clause raises serious concerns about the current use of OpenAI-powered ambient AI solutions, many of which rely on Whisper and GPT APIs.

To ensure compliance and patient safety, it is essential that NHS Wales and other healthcare organisations proceed cautiously, seeking legal and regulatory clarity before widespread deployment of these technologies.

Data Privacy and Security
It is important to recognise that even if an AI scribe claims to comply with GDPR, the underlying infrastructure (e.g., OpenAI) may still share data with third parties. While not likely to breach confidentiality, healthcare providers need to be aware of this potential risk. In April 2025, NHS England published comprehensive implementation guidance for AI-enabled ambient scribing products, aimed primarily at Chief Information Officers (CIOs), Chief Clinical Information Officers (CCIOs), clinical safety officers, and digital transformation leads within health and care organisations in England (NHSE guidance). This guidance complements this document by providing detailed operational frameworks for procurement, risk management, clinical safety (DCB0129/0160), and post-deployment monitoring. It introduces structured tools such as DPIA templates, hazard logs, and service-level agreements, and offers clarity on regulatory classification under MHRA rules; particularly where summarisation or decision-support functionalities may render products medical devices. Importantly, it emphasises patient transparency, user training, and liability considerations, offering a valuable resource for organisations preparing to procure or deploy these technologies. While specific to England, many of the principles and tools are equally applicable and useful for planning in Wales.

Lessons learned from current implementations

The implementation of Brainomix for stroke imaging in NHS Wales highlights critical lessons for future AI scribe rollouts. A significant challenge was the variation in local Information Governance (IG) requirements across Health Boards, which led to delays and duplication effort, despite the existence of centralised approvals. Procurement took over 12 months due to complex processes and slow contract adjustments, emphasising the need for streamlined frameworks. A lack of consistent engagement with key stakeholders, firewall challenges, and delays in securing funding further complicated implementation. The absence of a standardised patient safety assurance process also poses significant risks. For AI scribes, these challenges underscore the importance of establishing a clear, standardised governance framework, engaging stakeholders early, and ensuring sufficient resourcing for IG and clinical safety reviews to avoid similar delays and risks.

Financial Constraints

AI scribe implementation would require initial investment in technology, training, and ongoing support. However, this investment could be offset by increased clinical efficiency and reduced workload and burnout of clinical and administrative staff. Evidence from other healthcare systems suggests potential for a positive return on investment through improved operational efficiency and reduced staff turnover.

Financial constraints also pose a challenge for AI scribe implementation, as the cost of licensing, training, and integration into existing NHS Wales systems could be substantial. Establishing a clear funding strategy and ensuring early alignment with Integrated Medium Term Plan (IMTP) priorities will be essential to prevent similar challenges. Strategic investment in the Clinical lead for AI will support the successful delivery of future AI projects across the Health Board.

Argymhelliad / Recommendation

The Committee are requested to :

- **RECEIVE ASSURANCE** that the Health Board will continue to explore the potential application of Ambient AI (e.g. Radiology or Outpatients), and will actively engage with Welsh Government to clarify the strategic direction and policy position on ambient scribe in order to understand its implications for the wider NHS Wales roadmap.
- **NOTE** the ongoing pilot studies across Wales and subject to approval through the appropriate governance, consider supporting future studies to evaluate the performance, accuracy, and clinician acceptance of AI scribes in the Hywel Dda.

Amcanion: (rhaid cwblhau) **Objectives: (must be completed)**	
Committee ToR Reference: Cyfeirnod Cylch Gorchwyl y Pwyllgor:	3.1.3 Seek assurance that the digital, data and information governance implications and risks arising from the development of the Health Board's corporate strategies and plans or those of its stakeholders and partners are considered and mitigated.
Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol: Datix Risk Register Reference and Score:	Not applicable
Parthau Ansawdd: Domains of Quality	7. All apply

Quality and Engagement Act (sharepoint.com)	
Galluogwyr Ansawdd: Enablers of Quality: Quality and Engagement Act (sharepoint.com)	6. All Apply
Amcanion Strategol y BIP: UHB Strategic Objectives:	All Strategic Objectives are applicable
Amcanion Cynllunio Planning Objectives	9 Digital plan All Planning Objectives Apply
Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Objectives Annual Report 2021-2022	9. All HDdUHB Well-being Objectives apply

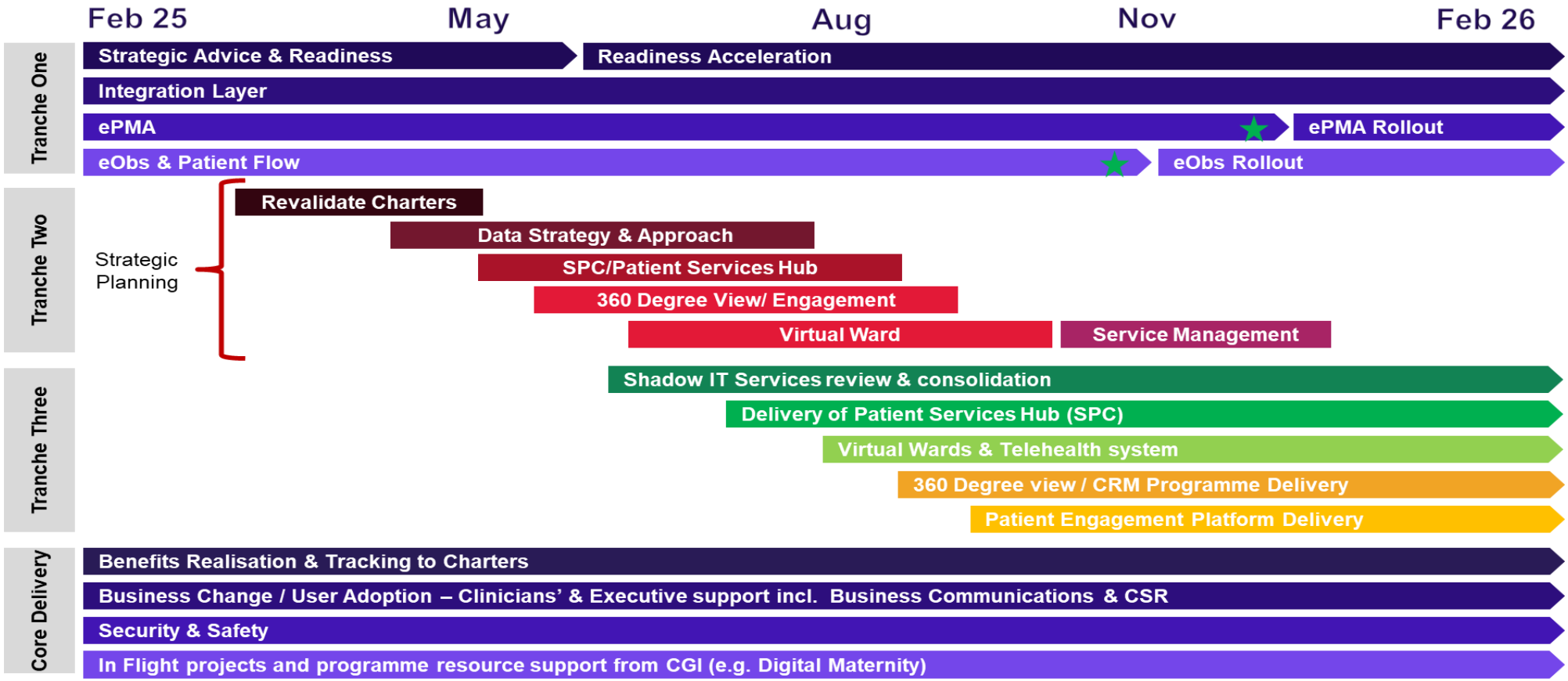
Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	Not applicable
Rhestr Termau: Glossary of Terms:	Contained within the report
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Pwyllgor Digidol, Data ac Arloesi Parties / Committees consulted prior to Digital, Data and Innovation Committee:	Not applicable

Effaith: (rhaid cwblhau) Impact: (must be completed)	
Ariannol / Gwerth am Arian: Financial / Service:	The financial impact of AI use within the Health Board includes both significant initial investments and potential long-term savings, from an efficiency and cash releasing perspective.
Ansawdd / Gofal Claf: Quality / Patient Care:	The use of AI within the Health Board has a profound impact on quality and patient care. Internally, AI enhances service delivery, reduces clinician workloads, and improves patient outcomes through continuous observation and effective management of conditions. Externally, AI fosters innovative medical treatments, enhances clinical workflows, and ensures equitable and transparent patient care

Gweithlu: **Workforce:**	The use of AI within the Health Board has a significant impact on the workforce. Internally, AI initiatives focus on educating and upskilling the workforce, automating content creation, and maintaining data quality for informed decision-making. Externally, AI addresses workforce shortages, enhances diagnostic accuracy, and improves treatment planning, ultimately leading to a more efficient and effective healthcare workforce.
Risg: **Risk:**	Outlined within the paper
Cyfreithiol: **Legal:**	Not applicable
Enw Da: **Reputational:**	The use of AI within the Health Board has a significant impact on its reputation. Internally, the adoption of trusted AI frameworks, robust data protection measures, and ethical clinical practices ensures transparency, trust, and compliance with regulatory standards. Externally, aligning with best practices in AI transparency, informed consent, and health equity can further enhance the Health Board's reputation as a leader in ethical and innovative healthcare
Gyfrinachedd: **Privacy:**	Not applicable
Cydraddoldeb: **Equality:**	This will be included within the review, and will be a crucial element of the outputs

Appendix 1

High Level Programme 12-month view



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