



# *Regulatory silence in the clinic:*

## The case for oversight of AI scribes in Australian healthcare

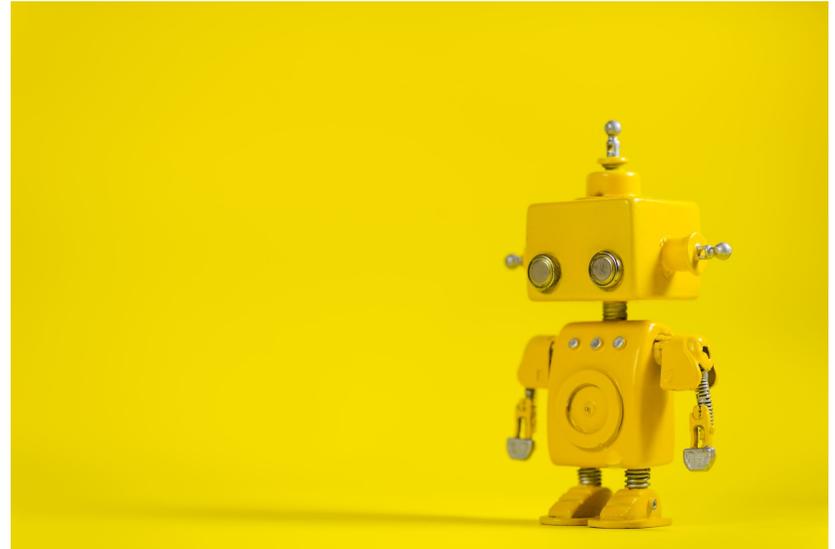
Dr. Megan Pricor ([megan.pricor@unimelb.edu.au](mailto:megan.pricor@unimelb.edu.au))

Melbourne Law School



# Overview

- What are AI scribes and who creates them?
- Who uses them?
- What are their risks and benefits?
- How are they regulated?
- How should the regulatory gap (software as a medical device) be addressed?





# What are AI scribes?



**Dusty Swendson, DO**  
Internal Medicine

**“As close to magic as it gets.”**

“Using the AI scribe was as close to magic as I have ever seen. I was able to listen to my patient and engage with them while not worrying about remembering to note down every piece of information. I leave the room and the note is nearly perfect with just a few edits.”

<https://chartnote.com/aiScribe>, 27/11/2025



# Commercial interests



 3M M*Modal Fluency Align	 Abridge	 accel-EQ	 Ambience	 Athelas Scribe	 Augmedix Go	 Augnito	 Beam Health Shine AI
 Chartnote	 Contrast	 Corti	 DeepScribe	 DeepCura	 Eleos Health	 Freed	 Fusion Narrate + SOAP Health
 Heidi Health	 Innovaccer InScribe	 iScribeHealth	 Knowtix	 Mariana AI	 mdhub	 Mentalyc	 Mutuo Health
 Nabla Copilot	 Nuance DAX Copilot	 Overnight Scribe	 Playback Health	 QiiQ	 SIO.AI	 ScribeAmerica Speke	 Scribeberry
 ScribeMD	 Simbo AI	 Suki	 Sully.ai	 Sunoh	 Tali AI	 Tortus	 Upheal



# Usage rapidly accelerating

Used by  $\approx$  40% to 50% of GPs in Australia and NZ

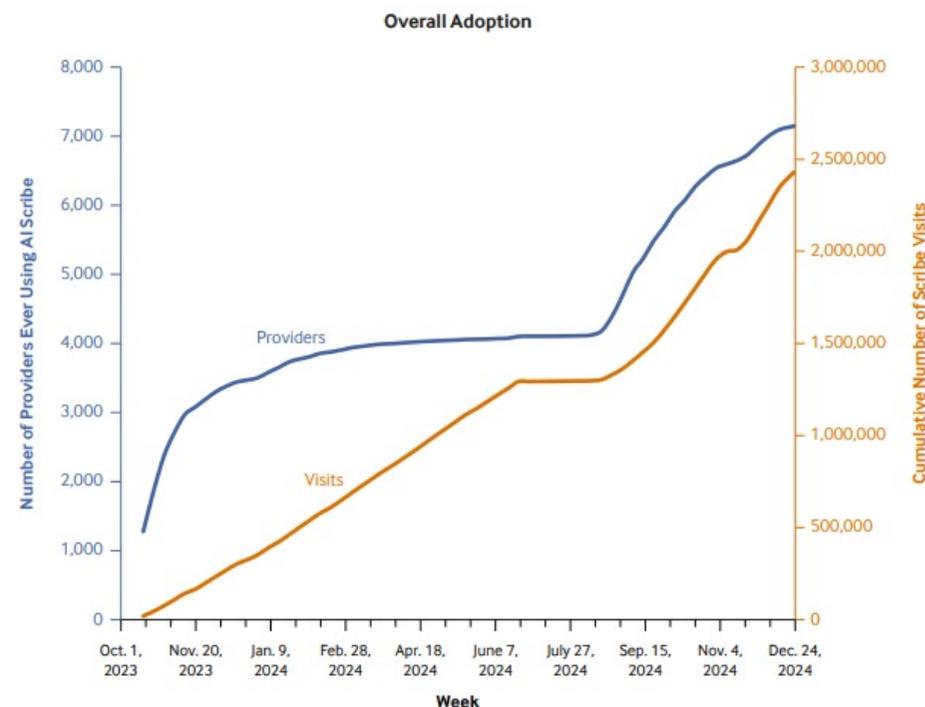
In the Permanente Medical Group (USA), use of AI scribes over 2023 grew from 34% to 72%. (Tierney et al DOI 10.1056/CAT.25.0040)

## 6 GP INSIGHTS

'I have adopted an intelligence tool for consultations and it has been a great consultation. It folds naturally into editible notes, so I don't have to look at the patient's history or a great consultation unfolds naturally. It's easy, as I no longer have to interrupt for consultations or try to make sense of their history. Quite often in the consultation, I'm editing the notes. Medications are more detailed, and my work is more structured. I have a GP and I'm even planning to retire.'

### Growth in AI Scribe Usage

This chart shows the overall adoption of providers using an AI scribe and the cumulative number of AI scribe visits, from October 2023 through December 2024.



Source: The authors  
NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

trying to capture a description as part of the medical record. This is a challenge because it has been difficult to increase the adoption of using embedded



2024



## Benefits and risks

- *Maybe* reduced ‘burnout’
  - *Maybe not* time savings (although a selling point is – see more patients!)
  - *Perhaps* accuracy and completeness of record (including reduced med neg claims)
  - *Perhaps* greater attention to patient and better communication and information provision
- Data quality – omissions, inaccuracies, hallucinations
  - Data security (hacking)
  - Unanticipated secondary data use including training AI models
  - Biases
  - Lack of patient knowledge, consent
  - Overreliance by clinician (automation bias)
  - Something intangible...



## Are scribes currently ‘unregulated’?

No

Surveillance/ listening devices laws

Professional obligations: accuracy, respect for patient

Privacy laws (collection, use, disclosure, deletion)

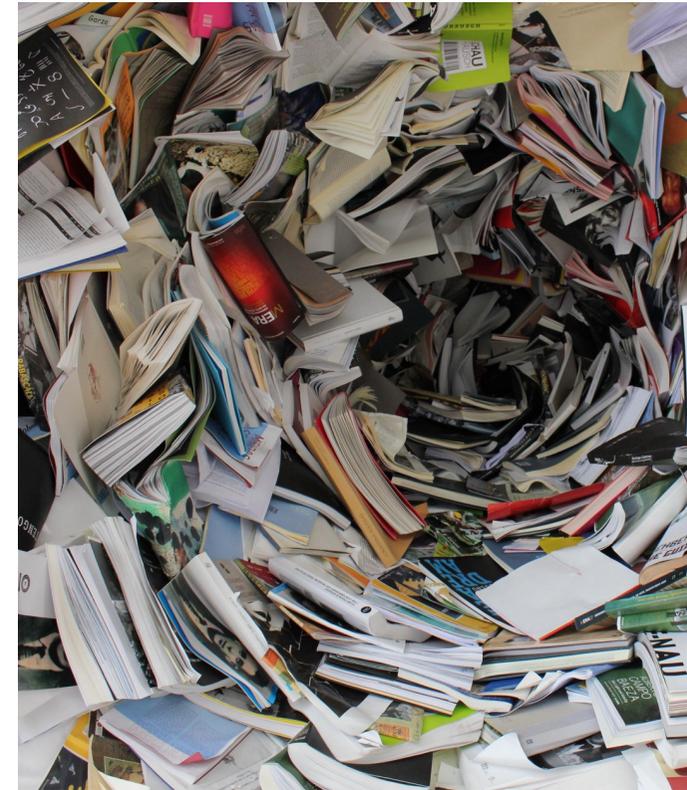
Medical negligence claims if patient suffers harm

Product safety and quality – consumer law



## What else do we have? Guidelines

- Avant, *AI Scribes – a checklist of things to consider* (2024)
- Avant, *Artificial Intelligence for medical documentation* (2024)
- MDA National, *Using Artificial Intelligence (AI) tools for record management in doctor consultations* (2024)
- Australian Health Practitioner Regulation Agency and National Boards, *Meeting your professional obligations when using Artificial Intelligence in healthcare* (2024)
- RACGP, *Artificial intelligence (AI) scribes* (2025)
- Victorian Department of Health, *Ambient AI Scribes: Sector Advisory* (2025)
- Medical Council of New Zealand (MCNZ), *Draft statement: Using artificial intelligence in patient care* (2025)



Overwhelmingly, the obligation for safe & appropriate use of AI scribes is placed on healthcare providers & services



# Current position of Therapeutic Goods Administration

- ‘Digital’ scribes are simply record keeping tools.
- Explicitly excluded from regulation - *unless* they incorporate diagnostic or treatment advice. (If so, they must be included in ARTG)

**PROBLEM:** This suggests a misunderstanding.

AI scribes **do** analyse and interpret clinical conversations, but might **not** generate diagnostic or treatment advice

## Our regulatory approach

Digital scribes intended only to transcribe and translate clinical conversations into written records without performing analysis or interpretation are not considered medical devices. These products do not have a therapeutic use under the Act.

However, if a digital scribe analyses or interprets clinical conversations – for example by generating a diagnosis, differential diagnosis or treatment recommendation not explicitly stated by the healthcare practitioner – it is considered a medical device. These products must:

- meet all relevant regulatory requirements
- be included in the ARTG before they can be imported, exported, or supplied in Australia.

Source: TGA, <https://go.unimelb.edu.au/yca2>



## This is insufficient.

- AI scribes are *not without risk* – currently borne by the healthcare provider and patient (including errors, opacity, commercial interests, automation bias)
- Software developers themselves, and other experts, are calling for regulation
- Other countries are moving to regulate





# The changing position overseas

## England:

- **April 2025:** New NHS England guidance that scribes generating summaries (not simply transcribing) must be registered as medical devices (MHRA).
- **June 2025:** NHS England wrote to NHS organisations requiring immediate halt on use of AI scribes that are not registered for medical use

## NZ:

- Health NZ National Artificial Intelligence (AI) and Algorithm Expert Advisory Group (NAIAEAG) advises and endorses entities developing healthcare AI.
- Recently endorsed Heidi AI Scribes, conditionally endorsed three other scribe products.





# Australia – regulatory options

Retain exclusion	Light touch – ‘exempt’ classification  <i>Amend Therapeutic Goods (Medical Devices) Regulations 2002 (Cth) to incorporate AI scribes as ‘exempt’</i>	Full regulation and registration on ARTG – as new category
<p>There is a ‘human in the loop’ and it’s not a medical device</p> <ul style="list-style-type: none"> <li>• <i>No impact on regulator or software developers</i></li> <li>• <i>No oversight of products</i></li> <li>• <i>Places obligations almost entirely on health professionals, patients</i></li> <li>• <i>The ‘market’ will regulate...</i></li> </ul>	<p>No need to list on Australian Register of Therapeutic Goods, but must notify TGA, meet TGA ‘Essential Principles’ and report compliance on request, and report adverse events.</p> <ul style="list-style-type: none"> <li>• <i>Low burden on regulator</i></li> <li>• <i>Enables data collection, insight (including into adverse events)</i></li> <li>• <i>Comparatively low burden on software developers (consistent minimum standards)</i></li> <li>• <i>Gives users some confidence</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Aligns with English developments</i></li> <li>• <i>Prioritises patient safety, transparency and strict data governance</i></li> <li>• <i>Significantly reduces burden on health professionals/services, improves confidence</i></li> <li>• <i>Places significant obligations on software developers (market impacts)</i></li> </ul>



## Closing reflections

- AI scribe use skyrocketing
- Current patchwork of regulation mostly burdens healthcare professionals and services
- In Australia, TGA should rapidly reconsider current exclusion of AI scribes from regulatory regime
- Assessment of risk (based on emerging evidence) should guide classification





THE UNIVERSITY OF  
MELBOURNE

# Thank you

Megan Pictor

---

[megan.pictor@unimelb.edu.au](mailto:megan.pictor@unimelb.edu.au)

