



# Does Use of Artificial Intelligence Impose Additional Informed Consent Obligations to Health Practitioners?

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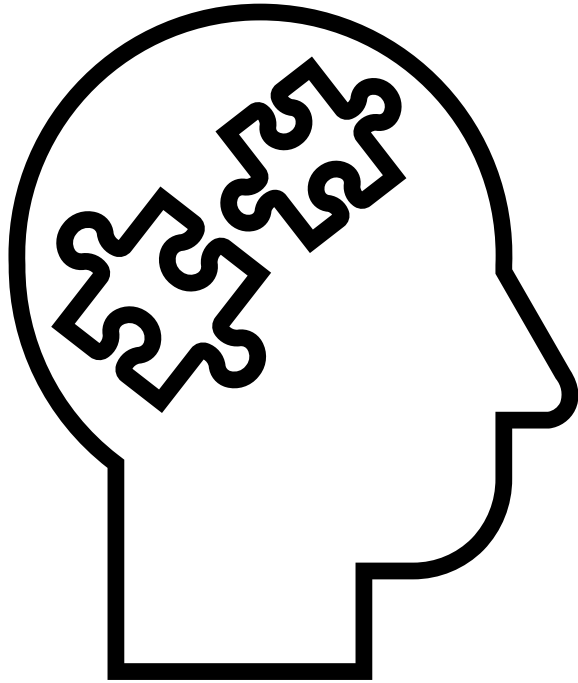
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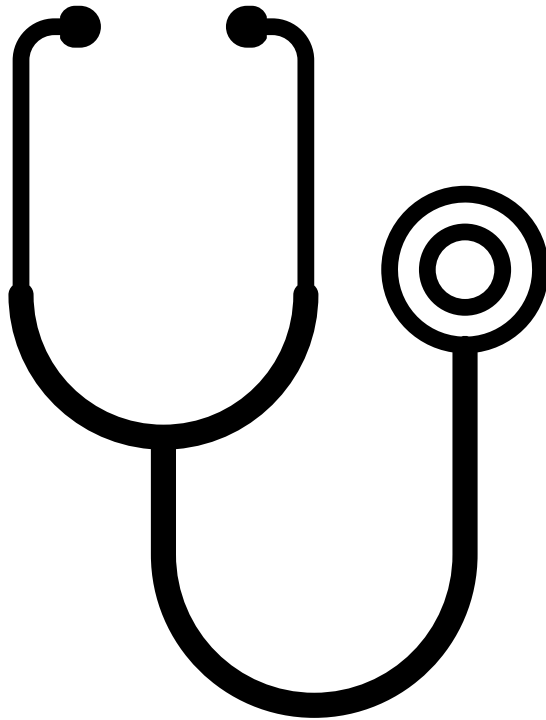
# Acknowledgement of Country

- I would like to acknowledge the Gadigal of the Eora Nation, the traditional custodians of this land, and pay my respects to the Elders past, present and emerging.



## Overview

- Case example
- Review of current situation
- Highlighting the policy/practice divergence
- Finding the middle ground

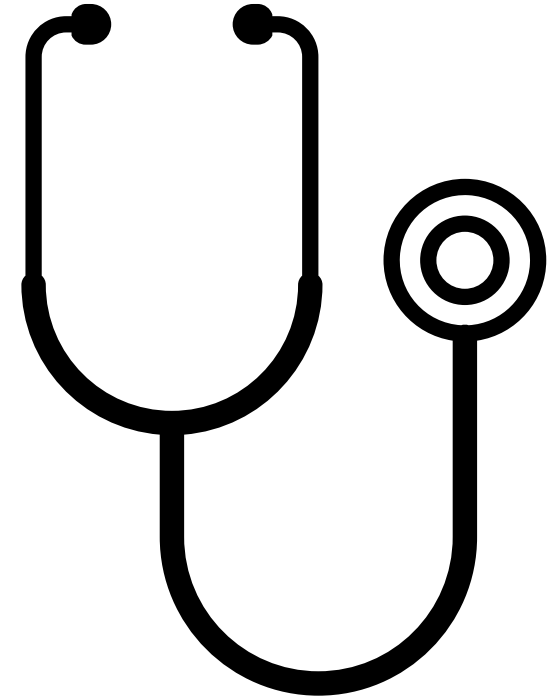


# Case

- Mr Case Example (CE) attends a telehealth appointment with Dr New Technology (NT) due to headaches
- Dr NT records the consult using a digital scribe
  - Clinic software includes diagnostic assistance AI that gives Dr NT recommendations about possible diagnoses and suggested investigations
- Dr NT sends Mr CE for a head CT
  - AI generated radiology request form
  - AI enabled software is used to optimise image collection
- Mr CE's results are screened by AI prior to the radiologist reporting
  - A brain bleed is identified and Mr CE scan is prioritised for reporting

# Case

- Lots of opportunities for AI – more efficient, safer care
  - Software currently in use
- When should Mr CE have been informed about the AI? When should Dr NT have sought his consent?
  - Digital Scribe
  - Diagnostic assistant
  - CT image preparation
  - Scan triage tool
- Would it be different if Dr NT was a bot?



# Position Statements

- *WHO Ethics and Governance of AI for Health (2021)*
  - “Physicians should be frank with patients from the onset and inform them of the use of AI rather than hiding the technology.” p. 48

ETHICS AND GOVERNANCE  
OF ARTIFICIAL INTELLIGENCE  
FOR HEALTH

WHO GUIDANCE



# Position Statements



- Australian Government Department of Industry, Science and Resources *Australia's AI Ethics Principles 2022*
  - “There should be **transparency and responsible disclosure** so people can understand when they are being **significantly impacted by AI**, and can find out when an AI system is engaging with them.”
- *AMA Artificial Intelligence in Healthcare – Position Statement 2023*
  - “Patients must be informed when a diagnosis or recommended course of treatment was **determined by an AI program.**”

# Australian Practitioner Guidelines



- Discussion about consent are conspicuously absent
  - Often reference the Privacy Act when discussing consent
    - NSW Government Mandatory Ethical Principles for the Use of AI
    - RANZCR Ethical Principles for AI in Medicine
    - AHPRA *Meeting your professional obligations when using Artificial Intelligence in healthcare (2024)*
      - “Health practitioners need to involve patients in the decision to use AI tools that require input of their personal patient data and if a patient’s data is required for care.

# Literature



- Pruski (2022) ‘AI-Enhanced Healthcare: Not a new Paradigm for Informed Consent’
  - AI does not pose new ethical challenges in healthcare therefore does not warrant special consent
- Sentiment echoed by Australian Commission on Safety and Quality in Health Care Report (2024) ‘AI Implementation in Hospitals’
  - “Patient consent for using AI in their care should build on existing consent requirements and practices for other medical procedures.”  
p.112

# Differing Standards

- Marked divergence between WHO recommendations and practice guidelines
  - “[There is] **no precedent** for seeking the consent of patients for diagnosis or treatment... the use of AI in medicine and failure to disclose its use could **challenge the core of informed consent** and wider public trust in health care.” P. 47 *WHO Ethics and Governance of AI for Health*
- Should we embrace a radical rethink of informed consent in clinical practice?

# What is the purpose of informed consent?

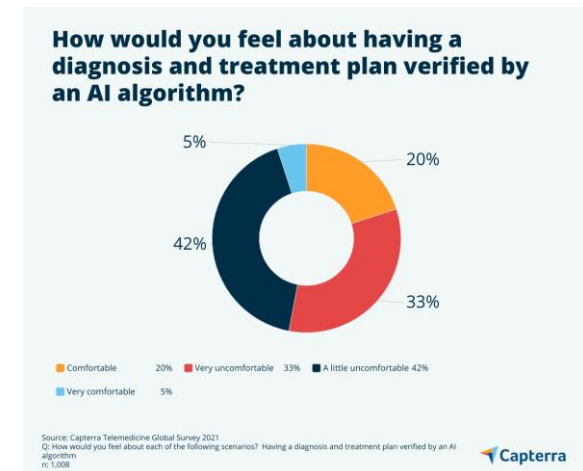
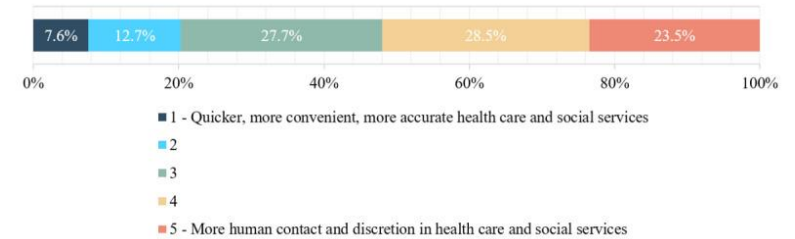
- Expression of respect for patient autonomy
- Facilitate shared decision making
- Transparency is key to the therapeutic relationship
  - Maintains trust and engagement with healthcare

# When is informed consent required?

- Eyal (2019) 'Informed Consent'
  - Consent requirements occur on a spectrum
  - Need for and formality of informed consent is influenced by:
    - Riskiness of the proposed treatment
    - Invasiveness
    - ★ ○ Controversy
    - Practitioner uncertainty
    - Degree of impact ('critical life choices')

# Public Views

- Survey of 1000 Australians about AI in healthcare (Capterra)
  - 33% felt uncomfortable
  - 20% felt very uncomfortable
- Monash Data Futures Institute survey of 2019 Australians
  - 38% uncertain or not supportive of AI development in Healthcare
- Survey of 4448 Australians (Isbanner)
  - 52% preferred human contact and discretion over speed, convenience and accuracy of AI
  - 28% undecided



# Downsides of rigorous informed consent requirements

- Time burden for clinicians
  - Processes that are not routinely discussed
- Limited patient and practitioner understanding of technology
  - Beyond scope of expertise
- Risk of harm to patients
  - Difficulty distinguishing between significant and insignificant risks
  - Anxiety disproportionate to risks

# Literature



- Cohen (2020) ‘Informed consent and medical artificial intelligence: What to tell the patient?’
  - Additional consent for AI if:
    - Specifically asked by the patient
    - The doctor is concerned about the reliability of the AI output
    - The intent of use is something other than optimising patient care
    - AI is central in decision-making/care

# Tool or Team Member?

- Balsano: “AI transforms the traditional therapeutic relationship between physicians and patients into a new triadic doctor-machine-patient relationship”
  - If we view AI as a tool to be used by our doctors?
  - If we view AI as a member of the treating team?
    - Human in the loop vs. Autonomous AI

# Conclusion

- Greater disclosure and consent requirements while technology is new
- Lesser requirements for human in the loop/doctor led decisions and interactions
- Informed consent not the answer for riskiness/practitioner uncertainty
  - Adequate regulation eg TGA

# Acknowledgements

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  - Dr Simon Coghlan
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