

# Healthtech Equilibrium: Balancing Innovation, Governance and Compliance

#### Prof Kee Yuan Ngiam

MBBS (Lond), MRCS (Glasg), Mmed (Surg), FRCS (Edin) Senior Consultant and Head, AI Office

Head, Division of Biomedical Informatics, NUS Division of Thyroid and Endocrine Surgery Department of Surgery National University Hospital Singapore

#### **Artificial Intelligence vs Augmented Intelligence**

"Artificial Intelligence is the capability of a machine to imitate intelligent human behaviour"

> "Augmented Intelligence refers to the effective use of information technology in augmenting human intelligence rather than to replace it."

# **Ethics and Healthcare Digitisation**

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# Ethics of Healthcare Digitisation : The Importance of Trust and Validation

## **Ethics and Healthcare Digitisation**

**Digitisation is required to solve the healthcare problems** 

- Digitisation of healthcare is inevitable to address efficiency and quality of care
- Availability of electronic health records have improved care coordination
- Telehealth is used to deliver care remotely, especially during the pandemic
- Data can also be used to build AI models that predict outcomes
- New large language models add novel capabilities that can be applied to healthcare use cases
- These technologies are met with new ethical challenges to their appropriate use
- These ethical challenges should be debated and encapsulated in guidelines and regulations issued by governments

## **Ethics of Healthcare Al**

The importance of trust and validation of Clinical AI tools

- AI tools are increasingly being used in healthcare
- Provides many benefits at the individual level and may be extrapolated to the population
- Doctors and patients need to know that these tools are rigorously tested and validated before deployment
- The medical fraternity relies on peer reviewed evidence before adopting AI methods to practice
- Regulatory requirements add to the safety of AI tools deployed in practice

#### Al-Assisted Decision Making in Healthcare

Key Principles in the Ethics framework for AI decision making

- Professional Integrity
- Justice
- Public Benefit
- Procedural Value
  - Transparency (explainability)
  - Accountability

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**ORIGINAL PAPER** 



AI-Assisted Decision-making in Healthcare

The Application of an Ethics Framework for Big Data in Health and Research

Tamra Lysaght<sup>1</sup> · Hannah Yeefen Lim<sup>2</sup> · Vicki Xafis<sup>1</sup> · Kee Yuan Ngiam<sup>3</sup>

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#### Abstract

Artificial intelligence (AI) is set to transform healthcare. Key ethical issues to emerge with this transformation encompass the accountability and transparency of the decisions made by AI-based systems, the potential for group harms arising from algorithmic bias and the professional roles and integrity of clinicians. These concerns must be balanced against the imperatives of generating public benefit with more efficient healthcare systems from the vastly higher and accurate computational power of AI. In weighing up these issues, this paper applies the deliberative balancing approach of the *Ethics Framework for Big Data in Health and Research* (Xafis et al. 2019). The analysis applies relevant values identified from the framework to demonstrate how decision-makers can draw on them to develop and implement AI-assisted support systems into healthcare and clinical practice ethically and responsibly. Please refer to Xafis et al. (2019) in this special issue of the Asian Bioethics Review for more information on how this framework is to be used, including a full explanation of the key values involved and the balancing approach used in the case study at the end of this paper.

Keywords Artificial intelligence  $\cdot$  Big data  $\cdot$  Clinical decision-making support systems  $\cdot$  Professional governance  $\cdot$  Bioethics

# Building Ethics into AI Through Addressing Data Bias

#### **Data Bias in Al**

**Biases reflect real world prevalence** 

- Accountability and transparency (explainability) of the decisions of Al-assisted systems
- The potential for group harms arising from 'biases' built into Al algorithms
- Al systems do not generate 'biases' independently, but instead, these are learnt from existing data with its inherent 'distributions'
- Public interest in generating more efficient healthcare from Alassisted systems vs individualised treatment
- Clinicians need to judge the use of AI suggestions viz the patient's condition to make a considered decision on the patient's care

# Doctors are <u>Still</u> Responsible: Al-based Clinical Decision support systems

## **Doctors are <u>Still</u> Responsible**

**AI-based clinical decision support systems** 

- Most AI tools in development and production are "clinician in the loop systems" (Clinician decision support systems)
- They support clinicians in making decisions but the ultimately, the responsibilities lie with the clinician
- Medicolegally, the responsibility of care is between the patient and the doctor, not AI tools
- Many parallels with assigning responsibility in case of accidents involving semi-autonomous driving cars

## Validation of AI Models

#### The importance of trust and validation of Clinical AI tools

- An understanding of the effort and precision in which AI tools are made needs to be fully appreciated by clinicians who use them
- Hence, robust validation and clinical trials are needed to establish the efficacy of these tools
- These AI tools should be treated as any other medical interventions in an evidence-based manner
- Leveraging well established critical review of evidence for new clinical practice, AI tools may be on-boarded onto clinical workflows
- Ethical tests need to be established to ensure effective AI tools indeed are beneficial in the long run to patients

Restricted, Non-Sensitive

## **Ensuring Safety: Guardrails and Compliance**

**Our Guiding Principles for Production LLMs** 

- NUHS GenAl policy for internal users
- MOH Circular No. 51/2023 (Use of Generative AI in the Public Healthcare Sector)
- NUHS AI Governance committee Stage gates promote and regulate AI projects
- HIM-ICT Security Policy (HIM-ISP)

\* Paper preprint download URL: https://preprints.jmir.org/preprint/50082



## **Regulatory Frameworks for AI**

#### **Regulatory Aspects of the Use of AI in Healthcare**

- Any device which claims to affect a medical outcome is subject to regulatory approvals
- Software, such as AI are subject to the same standards as medical devices: Software as a medical device (SaMD)
- Internationally, the FDA and CE marks are key regulatory bodies under which devices may be registered for medical use
- Provides framework and assurance of the safety, and efficacy of Al deployed in clinical practice
- In Singapore, HSA has issued guidance on SaMD
- MOH also issued AI in healthcare guidelines (AIHgle) 2021, revision this year

#### US FDA: Software as a Medical Device (SAMD) Guidelines 2017



Figure 15 - Change to SaMD category from continuous learning

#### **Singapore HSA - Regulatory Guidelines for Software Medical Devices**

#### **Artificial intelligence – Medical Device**



Source: "Regulatory Guidelines for Software Medical Devices – A Lifecycle Approach" https://www.hsa.gov.sg/docs/default-source/announcements/regulatoryupdates/regulatory-guidelines-for-software-medical-devices--a-lifecycle-approach.pdf.

#### Thank you.

