

Emerging Ethical Challenges of Healthcare Digitalisation

Associate Professor Ngiam Kee Yuan

MBBS (Lond), MRCS (Glasg), Mmed (Surg), FRCS (Edin)

Senior Consultant and Group Chief Technology Officer

Division of Thyroid and Endocrine Surgery

Department of Surgery

National University Hospital Singapore

Ethics and Healthcare Digitisation

Contents

- Ethics of Healthcare Digitisation: The Importance of Trust and Validation
- Artificial Intelligence vs Augmented Intelligence
- Building Ethics into AI Through Addressing Data Bias
- Doctors are Still Responsible
- Self-learning Machines

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 AI

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

AI-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



AI-Assisted Decision-making in Healthcare

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

Tamra Lysaght¹  · Hannah Yeefen Lim² · Vicki Xafis¹  · Kee Yuan Ngiam³ 

Received: 31 July 2019 / Revised: 27 August 2019 / Accepted: 28 August 2019 /
Published online: 12 September 2019
© The Author(s) 2019

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 · Big data · Clinical decision-making support systems · Professional governance · Bioethics

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.”

Building Ethics into AI Through Addressing Data Bias

Data Bias in AI

Biases reflect real world prevalence

- Accountability and transparency (explainability) of the decisions of AI-assisted systems
- The potential for group harms arising from 'biases' built into AI algorithms
- AI 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 AI-assisted 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 Still Responsible: AI-based Clinical Decision support systems

Doctors are Still 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

Large Language Models in Healthcare

LLMs will change healthcare fundamentally

- The use of LLMs have revolutionized the way we use AI
- Out of the box capabilities uses natural language and some intelligence based on pre-trained models
- However, the original LLM, ChatGPT has significant ethical and technical issues – privacy, legal, inaccuracy and hallucination
- The use of LLMs the context of the healthcare amplifies these issues, making it difficult to use LLMs in production for healthcare purposes
- To use LLMs effectively in healthcare, a secure technical architecture, with a robust validation process is required

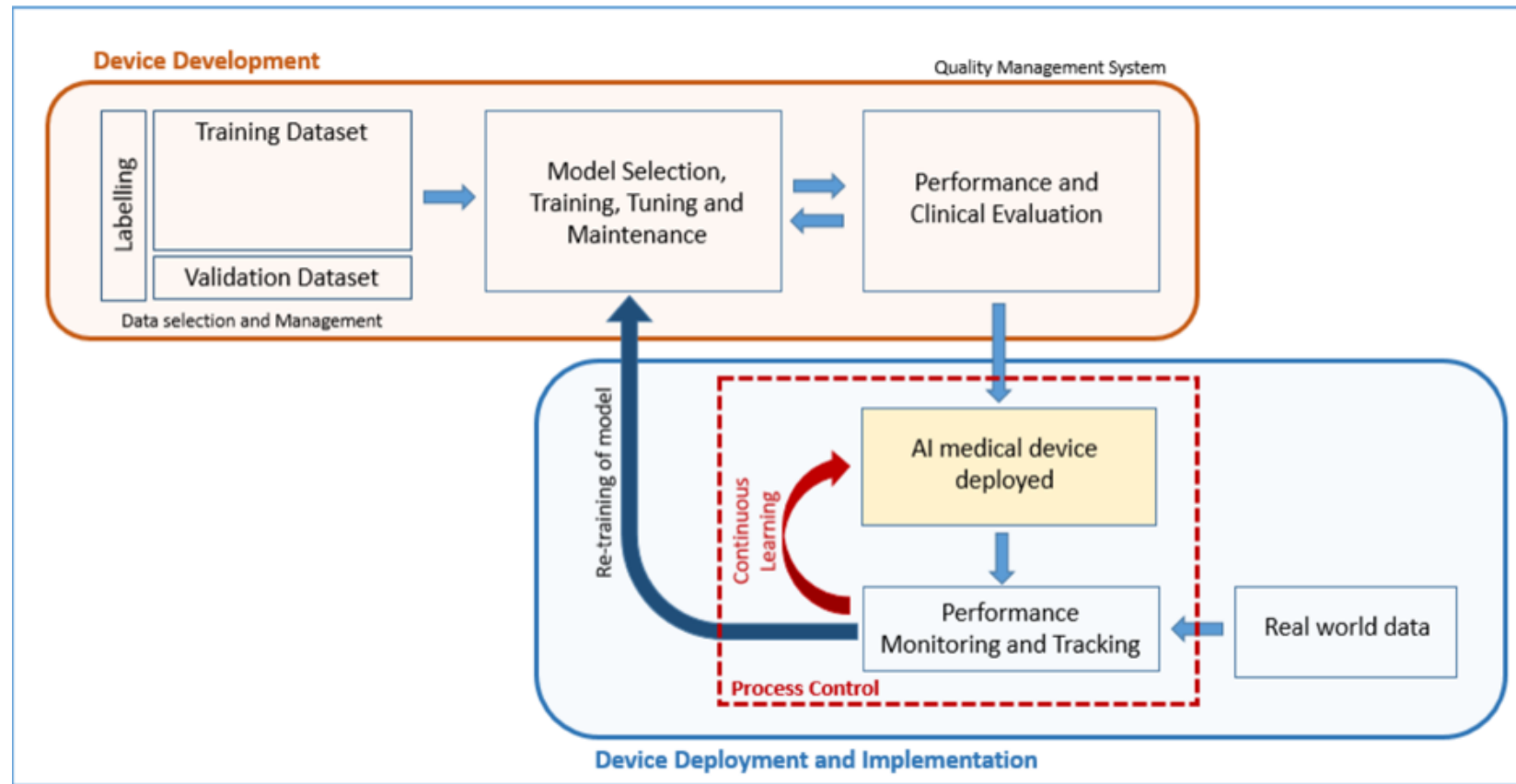
Regulatory Frameworks for AI

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 AI deployed in clinical practice
- In Singapore, HSA has issued guidance on SaMD
- MOH also issued AI in healthcare guidelines (AIHgle) 2021

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/regulatory-updates/regulatory-guidelines-for-software-medical-devices--a-lifecycle-approach.pdf>.

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

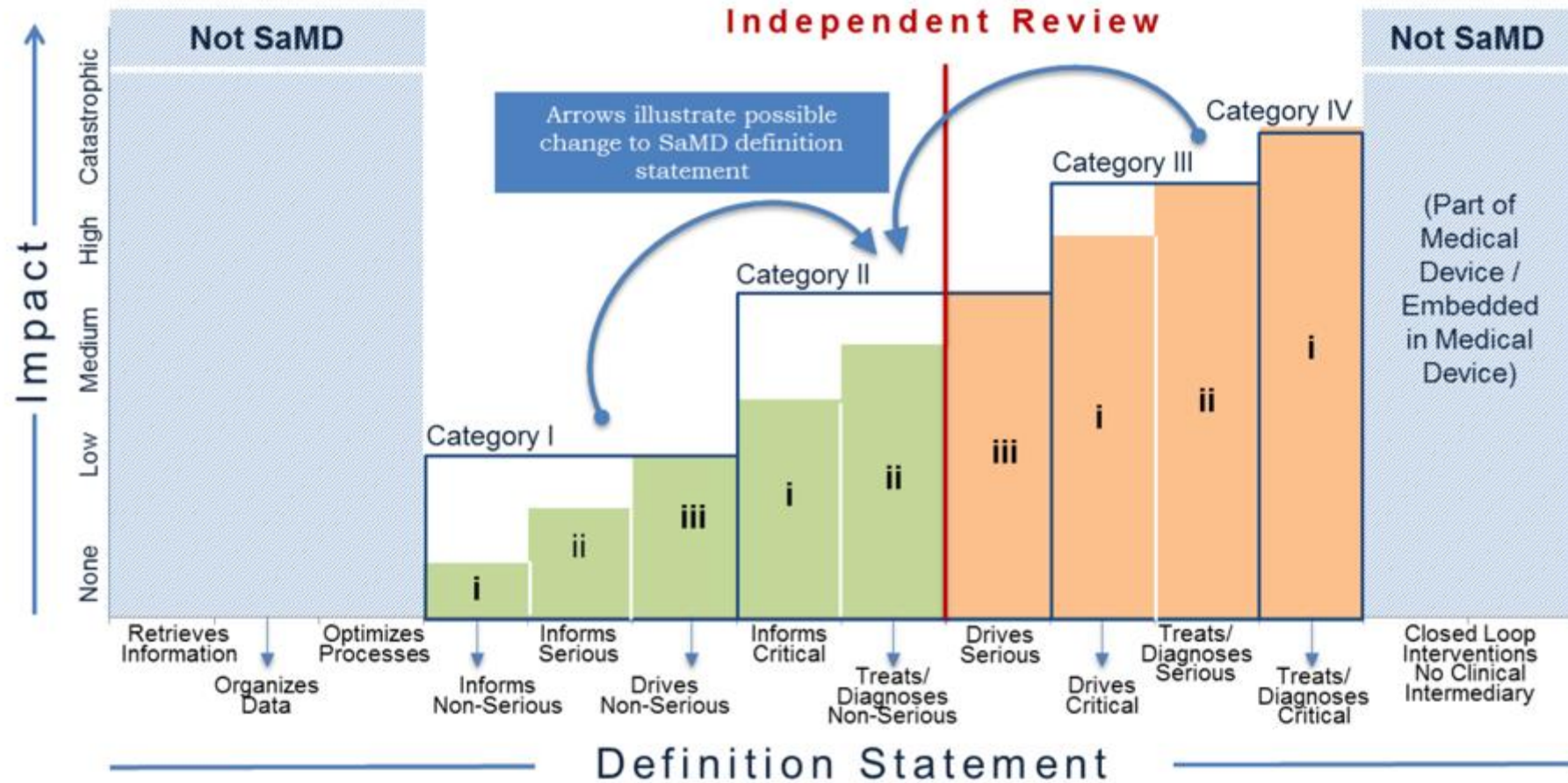


Figure 15 - Change to SaMD category from continuous learning

Self-learning Machines

Self-learning AI Machines

Future directions of AI development

- Self learning AI tools presents a great opportunity, as well as risks in healthcare
- Most neural network AI models are capable of ‘incremental’ learning with new data
- Some ‘reinforcement learning’ AI models can also be improved through ‘self-learning’
- An example is AlphaGo Zero vs AlphaGo Lee
- Hypothetical ‘Gödel machines’ are far from being practical in healthcare
- Key is to ensure strict versioning for each ‘improved version’ without features of continuous recursive self-improvement

**“Artificial intelligence is not the problem,
it’s the intelligent use of it, that is.”**

Thank you.

