IKIGAI LAW

THE UNIVERSITY OF MELBOURNE

NALSAR HYDERABAD

PROJECT BUILD

SUPPLEMENTARY MATERIALS

Building Inclusivity by Design in AI/ML Powered Healthtech funded by a grant under Australia India Cyber & Critical Technology Partnership

TABLE OF CONTENTS

CONCEPT NOTE FOR PROJECT BUILD

INTRODUCTION

The National Academy of Legal Studies and Research (**NALSAR**) with Ikigai Law (**Ikigai**) and Centre for Digital Ethics and AI at the University of Melbourne (**CAIDE**) is currently undertaking an 18-month research project. It is titled 'BUILD: BUilding IncLusivity by Design in AI/ML Powered Healthtech: an Indo-Australian Partnership for International Policy Making (**Project BUILD**). NALSAR was awarded the grant for the project by the Commonwealth of Australia, as a part of the Australia-India Cyber and Critical Technology Partnership. Project BUILD has five milestones and will lead to recommendations for Australia and India to jointly spearhead for an open, safe, inclusive technology in the Asia Pacific.

This document outlines the scope and limitations of Project BUILD (Concept Note) in identifying the barriers to inclusive AI research and development (**R&D**) in healthcare. The Concept Note is part of milestone 1 of Project BUILD and will serve as the basis for activities in the subsequent milestones.

LITERATURE SURVEY

RISKS OF EXCLUSION:

In India, the Rights of Persons with Disabilities Act, 2016 recognises 21 disabilities, and regulates the certification of such disabilities.[1] However, the certification process is marred by inconsistencies in assessment procedures across states, leading to disparities in the support individuals receive.[2] This issue is compounded by outdated data on disabilities; for instance, the National Family Health Survey's last disability data collection was in 2011, leaving a gap in current understanding and policy adaptation.[3] The lack of uniformity in disability assessment not only affects the allocation of resources but also impedes the effective inclusion of persons with disabilities in societal frameworks.[4] Recognizing and addressing these challenges are crucial for ensuring the appropriate populations are included in innovation of AI in healthcare.

RISKS WITH AI:

Digital tools such as AI are transforming healthcare in areas such as clinical decision support, medical detection and diagnostics, patient and population monitoring, information sharing, and drug development.[5]

There has been increasing interest in socially just use of Artificial Intelligence (AI) and Machine Learning (ML) in the development of technology that may be extended to marginalised people. However, the exploration of such technologies entails the development of an understanding of how they may increase and/or counter marginalisation.

[1] See schedule of The Rights of Persons with Disabilities Act 2016

[2] See here, here, and here for examples of the difficulties faced in obtaining a disability certificate.

[3] Indiaspent, Abhishek Anicca, Data Gaps: Undercounting Disability in India (20 July 2022)

[4] Scroll, Nivedia Krishna and Upasana Nath, India has axed queries on disability from key survey – and there's no easy way to fill the data gap (01 July 2023)

[5] World Health Organization, Regulatory considerations on artificial intelligence for health (2023), "Introduction" (see page 1) and "Key AI applications in health care and therapeutic development" (see figure 1 on page 4).

The use of AI/ML algorithms can lead to several challenges, such as privacy and security concerns, biases, unfairness, and lack of cultural awareness, which especially affect marginalised people. Marginalised people can include "children, older adults, people with disabilities, racial and ethnic minorities (in a country or region), low-income, gender, or general marginalised populations."[6]

However, experts have flagged issues with using AI in healthcare. Broadly, AI comes with risks around privacy, security breaches, lack of clear accountability, safety concerns, biased algorithms, poor accessibility, and dehumanisation of care.[7] Similarly, the quality of an AI tool in healthcare depends on the data sets with which it was trained. The creation of training data sets, and their assimilation to make the AI algorithms function as intended, are not straightforward processes. The AI tool may still generate anomalies, which could for instance, translate to incorrect diagnosis.[8] And there are challenges with getting access to data sets[9] that are unbiased and representative of diverse populations, for training the AI tools.[10] Biased AI tools raise ethical issues around the use of AI in healthcare, such as the risk of exclusion of certain segments of the population or discriminatory outcomes.[11] For instance, one study found that an AI algorithm (unnamed in the study) inaccurately assessed the healthcare risk to African Americans in the US.[12] The study found that the algorithm tended to assign lower risk scores to African Americans than their Caucasian counterparts, despite them having a higher need for access to special healthcare programs.[13] Similar errors have been reported along lines of gender and disability, and other forms of socio-economic status.[14] Additionally, access to the internet or hardware such as smartphones, and the ability of people to understand and navigate technologies used for healthcare (e.g., the Co-WIN platform for booking COVID vaccination appointments or the ABHA app to access one's electronic health records under India's Ayushman Bharat Digital Health Mission), also determine how effectively AI is harnessed for public health objectives.[15]

[6] Yuan, Xiaojun & Bennett Gayle, DeeDee & Knight, Thora & Dubois, Elisabeth. (2023). Adoption of Artificial Intelligence Technologies by Often Marginalized Populations. 10.1007/978-3-031-06897-3_3.

[7] Observer Research Foundation, Laura Sallstrom, Olive Morris and Halak Mehta, "Artificial Intelligence in Africa's Healthcare: Ethical Considerations", ORF, Issue Brief No. 312 (September 2019)

[8] Anomaly detection

[9] McKinsey & Co, Top ten observations from 2022 in life sciences digital and analytics, 31 January 2023.

[10] Arora, A., Alderman, J.E., Palmer, J. et al. The value of standards for health datasets in artificial intelligence-based applications. Nat Med (2023). https://doi.org/10.1038/s41591-023-02608-w

[11] Norori N, Hu Q, Aellen FM, Faraci FD, Tzovara A. Addressing bias in big data and AI for health care: A call for open science. Patterns (N Y). 2021 Oct 8;2(10):100347.

[12] Ziad Obermeyer et al., "Dissecting racial bias in an algorithm used to manage the health of populations", Science (2019)

[13] Ziad Obermeyer et al., "Dissecting racial bias in an algorithm used to manage the health of populations", Science (2019)

[14] Meredith Broussard, More than a Glitch: Confronting Race, Gender, and Ability Bias in Tech (MIT Press, 2023).

[15] Abhinav Verma, Krisstina Rao, Vivek Eluri, and Yukti Sharma, "Building a collaborative ecosystem for AI in healthcare in Low and Middle Income Economies", Atlantic Council (2020)

Representative and high-quality datasets will be important in some instances, but discrimination may also be perpetuated by human systems and institutions using data concerning health. Examples might include insurance companies discriminating[16] against people based on data showing that they accessed particular health services at one time, or employers or financial aid agencies discriminating against people based on data concerning an individual's engagement with mental health services.[17]

AI tools need to be designed keeping the realities of marginalised communities at the forefront, to avoid harms, and exclusion from access to healthcare. People with disabilities may not fall into the 'formulaic structure' of how AI tools are designed.[18] Additionally, because AI tools treat 'outlier data' as 'noise', they may exclude conclusions that actually help include people with disabilities.[19] For instance, in 2019, AI-powered autonomous food driving robots on college campuses failed to sense people in wheelchairs, thus obstructing their movement and creating traumatic moments of indignity.[20] Based on months of research, including feedback and role-play scripts, Google created 'Riley' a genderqueer AI persona struggling to reveal their gender and sexual orientation, to support the training of volunteers in The Trevor Project (an initiative to provide mental health support to LGBTQIA+ youth in distress). Google will add more personas so that volunteers are trained in a variety of crisis situations faced by LGBTQIA+ youth.[21] AI tools such as personas for training in mental healthcare, can be designed to account for specific challenges faced by marginalised communities.

GLOBAL RECOGNITION FOR A HUMAN-CENTRED APPROACH TO AI REGULATION FOR INCLUSIVE AI R&D AND USE:

The call for a more human-centred approach to AI R&D is growing globally. One study called for the need to include persons with disabilities in the design of AI tools citing various examples of how a speech-software produced errors when converting speech to text, and in failing to perform commands such as ending a call.[22] The United Nations Special Rapporteur on the rights of persons with disabilities called for countries to include people with disabilities in their digital inclusion policies and ensuring technology does not exclude persons with disabilities.[23]

[16]For example, see this class action suit filed against UnitedHealth and NaviHealth in the United States of America, where 2 elderly plaintiffs alleged discrimination in access to healthcare because of an AI tool aiding in the insurance claims decision.
[17] Bondre, Ameya, Soumitra Pathare and John A Naslund, 'Protecting Mental Health Data Privacy in India: The Case of Data Linkage With Aadhaar' (2021) 9(3) Global Health: Science and Practice 467
[18]Cat Noone, Flawed data is putting people with disabilities at risk, (2019). See TechCrunch article here.
[19]Cat Noone, Flawed data is putting people with disabilities at risk, (2019). See TechCrunch article here. See testimony from a person affected by these AI-powered food delivery robots, here.
[20]See reporting here.
[21]Google's Crisis Contact Simulator for The Trevor Project
[22]Smith, P., Smith, L. Artificial intelligence and disability: too much promise, yet too little substance?. AI Ethics 1, 81–86 (2021).
[23]A/HRC/49/52, Report of the Special Rapporteur on the rights of persons with disabilities on Artificial Intelligence and the rights of persons with disabilities (28 December 2021)

The Commission for Human Rights in the Council of Europe called for a human rights approach to AI oversight and highlighted the role that member-nations' and human rights government bodies can play in oversight.[24] The Australian Commission for Human Rights also submitted a similar call to the Department of Industry, Science, and Resources in July 2023.[25]

Conversations from the recent HeforShe Summit by United Nations Women reveal a global awareness of how AI can perpetuate existing gender biases and stereotypes, resulting from biased training data sets (e.g., a generative AI showing images of men only in response to the search "judge").[26]

The global policy discourse is picking up to ensure that AI is safe for use. However, there is a need to test and implement policies for AI oversight, to mitigate its risks and harness its rewards.

GLOBAL PRINCIPLES FOR RESPONSIBLE AI - A WORK IN PROGRESS:

The World Health Organisation (**WHO**), for instance, released six guiding principles for AI regulation and governance in healthcare: (a) protecting human autonomy; (b) promoting human well-being, safety, and the public interest; (c) ensuring transparency, explainability, and intelligibility' (d) fostering responsibility and accountability (e) ensuring inclusiveness and equity; and (f) promoting responsive and sustainable AI. The WHO aims to maximise the benefits of AI for healthcare while safeguarding human rights and ethical considerations, with these principles.[27] The United Nations Educational, Scientific and Cultural Organization (**UNESCO**) echoes the human rights approach to harnessing the power of AI ethically. UNESCO recommends similar principles as the WHO, to guide the evaluation of ethical questions posed by AI.[28] The International Medical Device Regulators Forum, an international organisation for global harmonisation medical device regulations (which includes the Therapeutic Goods Authority), Australia's medical devices' regulator), is currently working on 'Good Machine Learning Practices' for AI/ML enabled[29]

Government of India's think tank, the NITI Aayog developed a set of seven responsible AI principles,[30] which include safety and dependability, equality, inclusivity and non-discrimination, privacy and security, transparency, accountability, and the protection and reinforcement of positive human values. The NITI Aayog also issued approach documents[31] for developing responsible AI in India. The approach documents included principles for managing AI, exploring legal and regulatory approaches to manage AI and technology-based approaches to manage AI.

[24]"Human rights by design – future-proofing human rights protection in the era of AI", May 2023 (read summary and full report).
[25]See submission here.
[26]UN Women, HeForShe summit discusses gender bias in AI and how to encourage male feminist allies, (September 2023)
[27]WHO, Ethics and governance of artificial intelligence for health, 2021, (see here)
[28]UNESCO, Recommendation on the Ethics of Artificial Intelligence (2022), See recommendations here.
[29]See here for more.
[30]NITI Aayog, Responsible AI, Adopting the Framework: A Use Case Approach on Facial Recognition Technology (2022).
[31]NITI Aayog, Approach Document for India Part 1 – Principles for Responsible AI (Part 1) and Approach Document for India: Part 2 - Operationalizing Principles for Responsible AI (Part 2)

Australia has a voluntary framework of 8 "AI Ethics Principles", namely- (a) human, societal and environmental wellbeing; (b) human-centred values; (c) fairness; (d) privacy protection and security; (e) reliability and safety; (f) transparency and explainability: (g) contestability; and (h) accountability.[32] Australia also has an "AI Action Plan" that identifies four key focus areas: (a) transforming businesses by supporting businesses to adopt AI technologies, creating jobs and enhancing productivity; (b) growing AI talent for ensuring access to world-class AI expertise; (c) solving national challenges for utilising AI research to address national issues and promote AI benefits for all; and (d) global leadership in Responsible AI for ensuring AI inclusivity and alignment with Australian values.[33]

In 2022, a study by the European Parliamentary Research Service called for AI traceability and explainability,[34] in line with requirements of the European Union's General Data Protection Regulation, 2016 (**GDPR**)[35] and the European Union's Medical Devices Regulation, 2017 (**MDR**)[36]. The Organisation for Economic Co-operation and Development (**OECD**) also adopted the "OECD AI principles" in 2019, which calls for inclusive growth and sustainable development, human-centred values and fairness, investing in AI research and development, fostering a digital ecosystem, providing an enabling policy environment, building human capacity, and promoting international cooperation for trustworthy AI.[37]

EXAMPLES OF IMPLEMENTATION OF AI OVERSIGHT:

Singapore's Personal Data Protection Commission (**PDPC**) released the 2nd edition of its Model AI Governance Framework in 2020,[38] which creates a 'Responsible AI framework'. The PDPC's voluntary framework is based on two principles: (a) prioritise explainability, transparency, and fairness in AI decision-making, and (b) focus on being human-centric. The PDPC's framework also provides examples of how relevant stakeholders can be part of the design and oversight of AI tools. For instance, the PDPC's frameworks cites Cujo AI (a US-based company), which has a "Research Board" and an "Architecture Steering Board" to ensure that relevant experts guide R&D. The Architecture Steering Board at Cujo evaluates the company's research team's findings on the ML models and AI algorithms (e.g., data, approach, and assumptions), before they are deployed.[39]

[32]See Australia's 8 AI Ethics Principles here.
[33]Government of Australia, Australia's AI Action Plan (2021).
[34]European Parliamentary Research Service, Artificial intelligence in healthcare: Applications, risks, and ethical and societal impacts, 2022
[35]See text of GDPR here.
[36]See text of MDR here.
[37]OECD AI Principles (2019)
[38]See text of PDPC's Model AI framework here.
[39] PDPC's Model AI Governance Framework (2020), page 25.

The PDPC's framework also calls for organisations to provide information on where they use AI tools and how and develop policies on how organisations can consistently communicate this to customers, and other relevant organisations.[40]

In Canada, through its "Directive on Automated Decision-Making", it mandates Algorithmic Impact Assessments for federal agencies using automated decision systems (**DADM**).[41] Canadian federal agencies also collaborate with the private sector to develop assessment tools and review the DADM every 6 months, to account for technological advancements.[42] This demonstrates an innovative approach to AI governance.

The President of the United States (**US**) issued an executive order for the safe use of AI in October 2023 (**Order**).[43] The Order, among other things, calls for the US' Department of Justice (**DoJ**) and Federal Civil Rights offices to create best practices for investigating and prosecuting civil rights violations related to AI. The Order also calls for the National Institute of Standards and Technology to develop standards, tools, and tests, that ensure that AI systems are safe and trustworthy. The DoJ and the US' Equal Employment Opportunity Commission have warned[44] that AI tools used for employment purposes may discriminate against persons with disabilities. The DoJ guidance[45] clarifies that employers should consider the impact of AI tools on different disabilities, connecting this consideration to obligations under the Americans with Disabilities Act, 1990. Similarly, the US Department of Health and Human Services' Secretary's Advisory Committee on Human Research Protections, recommended that US government consider establishing fora and mechanisms to facilitate dialogue, and ultimately, regulatory guidance, about how the interests of groups predictably affected by AI research might be considered and protected, consistent with maintaining scientific integrity".[46] This recommendation was in relation to tackling biases and inclusion (e.g., of tribal people) in AI research.

The Therapeutic Goods Administration – Australia's medical devices regulator – considers some AI tools as part of 'software as medical devices' including situations where large language models are used to provide chat based services.[47] The developers of such tools therefore are regulated under the Therapeutic Goods Act 1989. [48]

[40]PDPC's Model AI Governance Framework (2020), at page 53.
[41]Directive on Automated Decision-Making, 2019 (updated 25.04.2023)
[42]ITU and the World Bank, Digital Platform Regulation, Transformative technologies (AI) challenges and principles of regulation, (2023). See full report here.
[43]Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence (30 October 2023), White House Fact Sheet
[44]GIP Digital Watch Observatory, US government issues warning about disability discrimination caused by AI tools used for employment decisions, 13 May 2022
[45]DoJ, ADA, Algorithms, Artificial Intelligence, and Disability Discrimination in Hiring (12 May 2022)
[46]HHS, Considerations for IRB Review of Research Involving Artificial Intelligence, (21 July 2022)
[47]See Therapeutic Goods Administration guidance here.
[48]Read text of Therapeutic Goods Act 1989 (as amended in 2023) here

Medical devices regulators in the United States (i.e., the Food and Drug Administration (**FDA**)), Canada (i.e., Health Canada, and the United Kingdom (i.e., the Medicines and Healthcare products Regulatory Agency (**MHRA**)) identified 10 guiding principles that can inform the development of 'Good Machine Learning Practice' (**GMLP**)[49]. The GMLP include: (a) ensuring clinical study participants and data sets are representative of the intended patient population; and (b) ensuring the training data set and the testing data set are independent of each other.

The Group of Seven nations (**G7**) have arrived at the "Hiroshima Process International Code of Conduct for Organizations Developing Advanced AI Systems (**Hiroshima Code**)".[50] The Hiroshima Code calls for organisations to take appropriate measures to be taken through the lifecycle of an AI tool to identify, evaluate, and mitigate risks associated with the tool. The Hiroshima Code also calls for organisations to work with stakeholders to identify and mitigate 'vulnerabilities' and for organisations to publicly report advanced AI systems' capabilities, risks, use cases of the tool that are inappropriate, and limitations of the tool. For instance, details of safety evaluations should be made public. The Hiroshima Code also calls for incident reporting and responsible information sharing on AI between academia, civil society, government, and industry.

The work of the G7, the IMDRF, and the joint efforts of the US FDA, UK's MHRA, and Canada's Health Canada to harmonise standards are great examples of countries collaborating to create uniform standards for AI. However, testing some of these efforts is key to their effective implementation, and refinement based on needs/ issues faced in different countries. India and Australia are countries with diverse populations, with both countries keen on robust foreign relations and knowledge partnership, especially in the Indo-Pacific region.[51] These ingredients create a favourable environment for an Indo-Australian exchange of learnings (e.g., AI technical know-how in India and Australia's frameworks for AI oversight); namely, Project BUILD.

RESEARCH GAP:

The literature survey reveals that countries are discussing how best to regulate AI, to harness its power for healthcare safely. Many countries have opted for principles that guide the use, monitoring, and regulation of AI. However, greater clarity is needed on how to implement these principles for regulating AI in the healthcare context in particular, and for ensuring that AI R&D is inclusive. The research reveals the need for greater depth in how to implement oversight in AI R&D. This includes codification of principles, assessment frameworks for adherence to the principles, and assessment frameworks for measuring the effectiveness of the principles.

[49]Read the guiding principles here.

[50]See text here.

[51]Observer Researcher Foundation, Premesha Saha, The growing centrality of India in Australia's Indo-Pacific policy (13 March 2023).

The perspectives of various stakeholders on the actual implementation of these principles that are emerging globally to regulate or exercise oversight on AI, could prove to be useful for achieving that depth. Industry perspectives would help in simplifying complex technological architecture/ concepts in AI tools. Civil society and academic perspectives would help identify issues such as exclusions in the data sets used to train AI tools and how they impact patients. Similarly, as the Université de Montréal Declaration for a Responsible Development of Artificial Intelligence notes, professionals have a clear role in *'exercis[ing] caution by anticipating, as far as possible, the adverse consequences of AI by taking the appropriate measures to avoid them.'*[52] In many cases, medical professionals appear to perform the role of 'human-in-the-loop' for R&D and use of AI tools in healthcare, and their perspectives would help in guiding how regulatory authorities evaluate such tools, (e.g., based on what clinical evidence should regulators assess 'fairness' or 'explainability' while reviewing the clinical investigation of novel AI medical device?).

Project BUILD will facilitate discussions around such questions. These multi stakeholder perspectives can be the foundation for international policymaking on AI, as global discussions continue to evolve over time. And can help to arrive at harmonised implementation strategies for these principles, that may be adopted regionally, or even globally, when there is AI R&D in healthcare. The perspectives to such questions can enable creation of standard operating procedures and model documents, which governments can use to harmonise implementation of the globally evolving AI principles.

SCOPE AND LIMITATIONS OF PROJECT BUILD:

Scope:
Project BUILD will be limited to analysing how to enable inclusive AI when AI is used in the clinical setting (i.e., where healthcare is provided directly to patients). AI can pose risks to human life when used in healthcare.[53] For instance, one study in 2020 found that racial biases in pulse oximeters lead to more African American patients not receiving treatment for hypoxia, than their Caucasian counterparts.[54] Similarly, there may be risks arising from using facial recognition software (e.g., for diagnosis of dermatological conditions).

[52]University of Montreal, 'Montreal Declaration for a Responsible Development of Artificial Intelligence' (2018), Principle 8.

[53]Federspiel F, Mitchell R, Asokan A, et al, Threats by artificial intelligence to human health and human existence, BMJ Global Health, 2023;8:e010435.

[54]Sjoding MW, Dickson RP, Iwashyna TJ, Gay SE, Valley TS. Racial Bias in Pulse Oximetry Measurement. N Engl J Med. 2020 Dec 17;383(25):2477-2478.

There are studies that show such facial recognition software can mis-gender people of darker skin complexions.[55] Access to healthcare is a human right according to international conventions.[56] Indian and Australian laws and policies also seek to protect and expand access to healthcare.[57] Additionally, promoting good health and well-being is one of the United Nations' 'Sustainable Development Goals'.[58] As digital tools advance access to healthcare and the capabilities of doctors to provide quality care, exercising oversight of such technologies, based on global principles, is imperative.

Limitations:
NALSAR, CAIDE, and Ikigai (**Partners**) were awarded the AICCTP grant to study inclusion of typically marginalised communities, in the R&D of AI in healthcare. As such, the scope of Project BUILD is guided by the milestones and activities listed in the Grant Agreement with the Australian government. Therefore, while AI is used in allied aspects of healthcare, such as insurance claims processing and clinical trials, Project BUILD focusses on the use of AI in healthcare delivery (e.g., through medical devices or mobile health applications).

RESEARCH QUESTIONS FOR PROJECT BUILD:

1. In India and Australia, what should "inclusive design" entail to ensure AI in healthcare includes persons with disability or mental illnesses, women, indigenous populations, and the LGBTQIA+ community ?
2. What are the barriers faced by industry/academia in their AI R&D for healthcare, in Australia and India?
3. How can the Australian and Indian governments enable inclusive AI R&D for healthcare? For example, how can the two governments approach codification of principles, assessment frameworks for adherence to the principles, and assessment frameworks for measuring the effectiveness of the principles?

[55]Buolamwini J, Gebru T. Gender shades: intersectional accuracy disparities in commercial gender classification. Proc Mach Learn Res 2018;81:1–15.
[56]Article 25 of the Universal Declaration of Human Rights | Article 12(1) of the International Covenant on Economic Social and Cultural Rights
[57]For India – Observer Researcher Foundation, Declaring the right to health a fundamental right, 14 July 2020 | For Australia- Attorney General's Department, Right to Health
[58]United Nations, Sustainable Development Goal 3 – Ensure healthy lives and promote well-being at all ages (see here).

BRIEFING PAPER ON AUSTRALIA'S LEGAL AND POLICY LANDSCAPE FOR AI, INCLUSION, AND HEALTH-TECHNOLOGY

BRIEFING PAPER ON AUSTRALIA'S LEGAL AND POLICY LANDSCAPE FOR AI, INCLUSION, AND HEALTH-TECHNOLOGY

ABOUT THE AUTHOR AND PROJECT BUILD

This Briefing Paper has been authored by Ikigai Law for Project BUILD.

Ikigai Law along with its project partners - India's NALSAR University of Law, Hyderabad and Australia's Centre for AI and Digital Ethics (CAIDE) at the University of Melbourne are executing this project.

Funded under the AICCTP grant by the Australian government, the objective of **Project BUILD: BUilding IncLusivity by Design in AI/ML Powered Healthtech** is to explore policy recommendations on building inclusive approaches to AI enabled healthcare. It has the potential to be a part of future collaboration between the two nations and help guide the conversation in the Asia Pacific region around AI and healthcare.

This paper is based on desk and secondary research conducted by Ikigai Law and does not constitute specialized legal advice on Australian regulatory, legal and policy frameworks.

Ikigai Law is an award-winning public policy and law firm with a sharp focus on technology and innovation. The firm advises a wide range of stakeholders including the government, start-ups, industry associations, think thanks and multi-national companies. The firm is the project execution partner for Project BUILD.

I. EXECUTIVE SUMMARY

This paper (**Paper**) provides an overview of:

- The Australian healthcare system and the role of technology within it
- Legislation and regulatory bodies governing:
  - Healthcare delivery and products
  - Information technology
  - Matters related to inclusion
- The Australian government's approach to:
  - AI Governance and Adoption
  - AI applications in healthcare
  - AI powered assistive technology

The Paper serves as a foundation for identifying challenges in the governance and regulation of inclusivity within AI and healthcare. The issues will be examined by a cohort of experts, as part of "Project BUILD: Building Inclusivity by Design in AI/ML Powered Healthtech" (**Project BUILD**).

Project BUILD aims to - (a) articulate a clear definition of 'inclusivity' in the context of AI and healthcare; (b) identify the barriers to inclusivity and inclusive design; (c) explore mitigation strategies for overcoming barriers to inclusivity; (d) propose a high-level governance framework/best practices guide that can bring inclusivity in healthcare; and (e) foster policy and partnership discussions using actionable insights on inclusivity in AI in healthcare at the Indo-Aus bi-lateral level.

This paper is to be read along with the Briefing Paper on India, which provides an overview of India's healthcare system and the regulatory and policy framework around technology and healthcare.

II. OVERVIEW OF AUSTRALIA'S HEALTHCARE LANDSCAPE

A. Structure of healthcare governance in Australia

1. Central versus state government:

Similar to India, Australia is a common-law jurisdiction substantially derived from the English legal system. Australia has a dual system of government. There is a federal level government. Six states have separate jurisdictions with their own system of courts and parliaments, and two territories are granted a regional legislature by the federal government. The day-to-day running of health, welfare and disability services occurs at the state-level.[1] Broadly, here is the work allocation:

[1] Australian Government, Department of Health and Aged Care, The Australian Health System, https://health.gov.au/about-us/the-australian-health-system; See also, Australian Institute of Health and Welfare's "Health System Overview", https://www.aihw.gov.au/reports/australias-health/health-system-overview.

Federal government	State/ territory government	Both federal and state/ territory
• Maintain doctors across the country and ensure equitable distribution • Support and regulate both Medicare and private insurance • Regulate medical devices through the Therapeutics Goods Administration • Collect and publish health informatics through the Australian Institute of Health and Welfare[2] • Funding for medical research through the Medical Research Future Fund[3] and the National Health and Medical Research Council.[4]	• Manage and administer public hospitals • Regulate, inspect, license and monitor health facilities • Deliver preventative services (e.g., screening for diseases) • Fund and manage community and mental healthcare. • Patient transport and subsidy schemes.	• Funding public hospitals • Registering/ accrediting healthcare professionals • Responding to national emergencies Funding palliative care.

2. Healthcare system in Australia

In Australia, healthcare is provided through a mix of professionals and institutions who are funded by federal government, state/ territory governments, and non-government or private institutions.[5] There are also 31 Primary Health Networks across the country which- (i) support community health centres, hospitals, general practitioners, and other healthcare professionals to improve the care system; (ii) assess local health needs; (iii) coordinate between different parts of the health ecosystem (e.g., a hospital and the general practitioner); and (iv) provide extra services (e.g., after hours services, mental health services).[6]

B. Healthcare challenges in Australia and the role of technology

The Australian government is presently grappling with the following challenges: (i) increasing demand on health services and an aging population; (ii) increasing

[2] Australian Institute of Health and Welfare, https://www.aihw.gov.au/.
[3] Medical Research Future Fund, https://www.health.gov.au/our-work/mrff.
[4] National Health and Medical Research Council, https://www.nhmrc.gov.au/.
[5] Australian Government, Department of Health and Aged Care, The Australian Health System, https://health.gov.au/about-us/the-australian-health-system; See also, Australian Institute of Health and Welfare's "Health System Overview", https://www.aihw.gov.au/reports/australias-health/health-system-overview.
[6] Australian Government, Department of Health and Aged Care, The Australian Health System, https://health.gov.au/about-us/the-australian-health-system; See also, Australian Institute of Health and Welfare's "Health System Overview", https://www.aihw.gov.au/reports/australias-health/health-system-overview.

incidence of chronic diseases; (iii) increasing costs of healthcare; (iv) harnessing emerging health technologies; and (v) harnessing health data.[7]

The National Digital Health Strategy 2023-2028 (covered in section V of this Paper) lists strategies to use technology for addressing these challenges, including AI and data-driven healthcare that is personalised for each patient.

III. OVERVIEW OF HEALTH GOVERNANCE AND LAWS

A. Health governance:

1. Australian Institute of Health and Welfare (AIHW)
As a pivotal national[8] agency, AIHW provides essential health and welfare information and statistics, supporting informed decision-making for better Australian well-being. Its work includes reporting[9] on Australia's Disability Strategy 2021−2031, aiming to enhance inclusivity and improve life for people with disabilities, aligning with the project's focus on creating more accessible health technologies.

2. Department of Health and Aged Care (DHAC)
Oversees[10] Australia's health policies, medical research, health emergencies, and aged care. It actively promotes care for individuals with intellectual disabilities through initiatives[11] like curriculum development and the establishment of a national centre of excellence, reflecting a focus on inclusive health technology. Mr Blair Comley, PSM, is the Secretary to the DHAC.

3. National Health and Medical Research Council (NHMRC)
NHMRC sets the benchmark[12] for health and medical research in Australia, also offering guidance on clinical ethics and health privacy. Their work, especially on ethical review and research involving[13] indigenous peoples, supports emphasis on ethical AI development and inclusivity in health technologies. Simon Mair[14] is the Executive Director, Technology and Data.

4. Therapeutic Goods Administration (TGA)

---

7 Australian Government, Department of Health and Aged Care, The Australian Health System, https://health.gov.au/about-us/the-australian-health-system.
8 'Our Role & Strategic Goals' (Australian Institute of Health and Welfare, 15 August 2023) https://www.aihw.gov.au/about-us/what-we-do> accessed 13 May 2024.
9 'Australia's Disability Strategy' (Australian Institute of Health and Welfare, 25 January 2024) <https://www.aihw.gov.au/australias-disability-strategy> accessed 13 May 2024.
10 Australian Government Department of Health and Aged Care, 'What We Do' (27 October 2023) <https://www.health.gov.au/about-us/what-we-do> accessed 13 May 2024.
11 Australian Government Department of Health and Aged Care, 'Our Work' (5 April 2024) <https://www.health.gov.au/our-work> accessed 13 May 2024.
12 ibid.
13 'Ethics and Integrity | NHMRC' <https://www.nhmrc.gov.au/research-policy/ethics-and-integrity> accessed 13 May 2024.
14 'Who We Are | NHMRC' <https://www.nhmrc.gov.au/about-us/who-we-are> accessed 13 May 2024.

TGA oversees[15] the regulation of therapeutic goods to guarantee safety and efficacy within Australia. Their commitment to making information accessible aligns with Project BUILD's goals of ensuring[16] health technologies are inclusive and meet the diverse needs of the community, particularly for those with disabilities.

5. **Australian Commission on Safety and Quality in Health Care (ACSQHC)**
Tasked[17] with enhancing safety and quality across Australia's healthcare system, ACSQHC sets benchmarks and provides resources for better patient care. Their focus[18] on equitable healthcare for individuals with intellectual disabilities, through structured approaches like planning and communication, mirrors Project BUILD's commitment to inclusivity in health technologies. Conjoint Professor Anne Duggan is the Chief Executive Officer of the ACSQHC.[19]

6. **Australian Health Practitioner Regulation Agency (AHPRA)**
The Australian Health Practitioner Regulation Agency is the regulator that ensures Australia's registered health practitioners are suitably trained, qualified and safe to practise. National Boards represent each health profession within AHPRA, to apply the National Registration and Accreditation Scheme. Some Boards have issued specific statements on the use of AI/ML in medical practice,[20] and AHPRA has undertaken some research on the potential role of AI/ML in regulatory activity.[21] Mr Martin Fletcher, is the Chief Executive Officer of AHPRA.

7. **Australian Digital Health Agency (ADHA)**
Spearheads[22] the integration of digital health technologies to improve healthcare delivery, including the My Health Record system[23] for secure health information sharing and initiatives[24] for telehealth and digital prescriptions, supporting the principles of accessibility and security in health tech development. Dr Steve Hambleton,[25] is the Chief Clinical Adviser for the ADHA.

B. Health laws:

15 ibid.
16 Therapeutic Goods Administration (TGA), 'Accessibility | Therapeutic Goods Administration (TGA)' (21 July 2022) <https://www.tga.gov.au/accessibility> accessed 13 May 2024.
17 'Our Work | Australian Commission on Safety and Quality in Health Care' <https://www.safetyandquality.gov.au/our-work> accessed 13 May 2024.
18 'Intellectual Disability and Inclusive Health Care | Australian Commission on Safety and Quality in Health Care' <https://www.safetyandquality.gov.au/our-work/intellectual-disability-and-inclusive-health-care> accessed 13 May 2024.
19 'Chief Executive Officer | Australian Commission on Safety and Quality in Health Care' <https://www.safetyandquality.gov.au/about-us/our-people/chief-executive-officer> accessed 13 May 2024.
20 Medical Radiation Practice Board, 'Statement on Artificial Intelligence (AI)' <https://www.medicalradiationpracticeboard.gov.au/Registration-Standards/Statement-on-Artificial-Intelligence.aspx> (accessed 17/05/2024).
21 See, eg, Biggar, S, Lobigs, LM and Fletcher, M (2020) 'How can we make health regulation more humane? A quality improvement approach to understanding complainant and practitioner experiences' Journal of Medical Regulation, 106(1) pp. 7–15.
22 'About Us' <https://www.digitalhealth.gov.au/about-us> accessed 13 May 2024.
23 'My Health Record' <https://www.digitalhealth.gov.au/initiatives-and-programs/my-health-record> accessed 13 May 2024.
24 'National Digital Health Strategy' <https://www.digitalhealth.gov.au/national-digital-health-strategy> accessed 13 May 2024.
25 'Organisational Structure' <https://www.digitalhealth.gov.au/about-us/organisational-structure> accessed 13 May 2024.

1. **Therapeutic Goods Act 1989 (Cth)**
   The TGA[26] provides a national framework for the regulation, assessment, and monitoring of therapeutic goods, including medicines, medical devices and Software as a Medical Device **(SaMD),**[27] in Australia to ensure their safety and efficacy. The Therapeutic Goods Amendment (Medical Devices) Act 2002 (the Amendment Act), inserts a new part into the Act to provide for the creation of a new regulatory system for medical devices, harmonising[28] Australia's requirements with the recommendations of the Medical Devices Global Harmonisation Task Force (the five key global regulators of medical devices, Japan, USA, EU, Canada and Australia), which are based on those of the European Community.

   a. ***Mandate for Medical Devices*:** The Act classifies medical devices into different risk categories, from low to high, and sets out the requirements for their approval, manufacture, importation, supply, and post-market monitoring. It requires that medical devices must be included in the Australian Register of Therapeutic Goods before they can be legally supplied in Australia, except in specific circumstances such as for clinical trials or under special access schemes. The Australian Regulatory Guidelines for Medical Devices released updated guidance on 19 August 2022, which provides information on the import into, export from and supply of medical devices within Australia and explains the legislative requirements that govern medical devices.[29]
   b. ***Mandate for SaMD***: SaMD is software intended to be used for one or more medical purposes without being part of a hardware medical device. The TGA has been actively working to clarify the regulatory requirements for SaMD, recognizing its growing importance in healthcare. This includes guidance on how SaMD is defined, classified, and the evidence required to demonstrate its safety, quality, and efficacy for its intended purpose.

2. **Health Insurance Act 1973 (Cth)**
   While primarily governing Medicare and the Pharmaceutical Benefits Scheme, this Act also impacts digital health services by setting standards for what constitutes a reimbursable health service, which can influence the design and delivery of healthtech solutions.[30]

3. **My Health Records Act 2012 (Cth)**

---

[26] 'AU Therapeutic Goods Act 1989,' <https://www.vertic.org/media/National%20Legislation/Australia/AU_Therapeutic_Goods_Act_1989.pdf>vaccessed 13 May 2024.

[27] The term "software-based medical device" refers to software that fit the definition of a medical device under one of two circumstances: either it is integrated into, or depends on, specific hardware to operate as intended, or it is a standalone piece of software that is also referred to as a medical device (SaMD). In Australia, the Therapeutic Goods Administration (TGA) is in charge of regulating both. Software, including mobile apps, is classified as a medical device under section "41BD of the Therapeutic Goods Act of 1989", unless an exception applies.

[28] 'THERAPEUTIC GOODS AMENDMENT (MEDICAL DEVICES) BILL 2002 Explanatory Memorandum' <https://classic.austlii.edu.au/au/legis/cth/bill_em/tgadb2002381/memo1.html> accessed 13 May 2024.

[29] Therapeutic Goods Administration (TGA), 'Australian Regulatory Guidelines for Medical Devices (ARGMD) | Therapeutic Goods Administration (TGA)' (21 June 2022) <https://www.tga.gov.au/resources/resource/guidance/australian-regulatory-guidelines-medical-devices-argmd> accessed 13 May 2024.

[30] Health and Aged Care, 'Health Insurance Act 1973' <https://www.legislation.gov.au/C2004A00101/2022-06-13> accessed 13 May 2024.

Governs the My Health Record system, an online platform for storing individuals' health information, crucial for projects aiming to integrate with or complement this digital health infrastructure. This is critical for Project BUILD as it highlights the importance of secure and accessible digital health records, facilitating the sharing and access of health data between patients and healthcare providers in a digital health ecosystem.[31]

4. Australian Consumer Law (Schedule 2 of the Competition and Consumer Act 2010 (Cth)

Protects consumers of health tech products and services, ensuring they are safe, fit for purpose, and free from misleading information. Consumer awareness of laws to protect their basic consumer rights is almost universal, consistently[32] above 90% across all states, territories and geographic remoteness levels across Australia (as derived from the Accessibility/Remoteness Index of Australia Plus) and 92% nationwide.[33]

This law is crucial for health tech consumers, ensuring that digital health products and services are safe, effective, and as described by the provider. In the context of telemedicine, it provides a legal basis for patients to seek redress if a digital health service fails to meet quality standards or if the health data is mishandled, misleading, or incorrect, thereby impacting the patient's care and treatment outcomes.

There are other laws[34] which govern other facets of healthcare which we have not included for the sake of brevity.

IV. OVERVIEW OF SCIENCE AND TECHNOLOGY GOVERNANCE AND LAWS

A. Science and Technology governance

1. Office of the Australian Information Commissioner (OAIC)

Mandated[35] to protect privacy and information access rights, the OAIC addresses[36] complaints on the mishandling of health data by providers and advocates[37] for 'privacy by design' in health data sharing, aligning with Project BUILD's focus on secure and

---

31 Health and Aged Care, 'My Health Records Act 2012' <https://www.legislation.gov.au/C2012A00063/2017-09-20> accessed 13 May 2024.

32 Australian Consumer Survey Report 2023, <https://www.google.com/search?q=acl-aust-consumer-survey-2023+(1).docx&rlz=1C1CHBF_enIN1101IN1101&oq=acl-aust-consumer-survey-2023+(1).docx&gs_lcrp=EgZjaHJvbWUyBggAEEUYOTIKCAEQABiABBiiBNIBBzQ2OWowajeoAgiwAgE&sourceid=chrome&ie=UTF-8> accessed 13 May 2024.

33 'COMPETITION AND CONSUMER ACT 2010 - SCHEDULE 2 - TABLE OF CONTENTS' <https://classic.austlii.edu.au/au/legis/cth/consol_act/caca2010265/toc-sch2.html> accessed 13 May 2024.

34 Health and Aged Care, 'Legislation we Administer' < https://www.health.gov.au/about-us/what-we-do/legislation-we-administer> accessed 09 October 2024

35 Office of the Australian Information Commissioner, 'What We Do' (OAIC, 10 March 2023) <https://www.oaic.gov.au/about-the-OAIC/what-we-do> accessed 13 May 2024.

36 Office of the Australian Information Commissioner, 'Health Information' (OAIC, 10 March 2023) <https://www.oaic.gov.au/privacy/your-privacy-rights/health-information> accessed 13 May 2024.

37 Office of the Australian Information Commissioner, 'The Importance of Privacy by Design in the Sharing of Health Data for Domestic or International Travel Requirements' (OAIC, 10 March 2023) <https://www.oaic.gov.au/newsroom/the-importance-of-privacy-by-design-in-the-sharing-of-health-data-for-domestic-or-international-travel-requirements> accessed 13 May 2024.

inclusive health tech practices. Ms. Angelene Falk,[38] is the Australian Information Commissioner, and Privacy Commissioner.[39]

2. **Commonwealth Scientific and Industrial Research Organisation (CSIRO)**
The CSIRO is the national science agency is responsible for scientific research and any commercial or industrial applications of this research.[40] CSIRO oversees a national digital health programme through the Australian e-Health Research Centre (AEHRC).[41] AEHRC works on AI, precision medicine, interoperability, and virtual care.[42] Dr Doug Hilton AO, is the Chief Executive Officer of CSIRO.[43]

3. **Digital Transformation Agency (DTA)**
Guides[44] the digital transformation of government services in Australia,[45] ensuring they are accessible and efficient. Its Data and Digital Government Strategy, emphasizing[46] best practices in data collection and use, supports inclusive policy development, including gender-disaggregated data analysis to advance gender equality initiatives. Mr. Chris Fechner[47] is the Chief Executive Officer.

4. **Department of Industry, Science and Resources (DISR)**
The DISR works towards creating an enabling productive economy, that is enriched by science and technology for all Australians.[48] The DISR oversees organisations like the Office of the Chief Economist, Office of the Chief Scientist, and Industry Innovation and Science Australia (a statutory body that advises the DISR on science and research matters),[49] the National Artificial Intelligence Centre (set up in 2021 to accelerate Australia's AI industry).[50] The Hon. Ed Husic MP is the Minister for Industry and Science.[51]

---

38 Office of the Australian Information Commissioner, 'Who We Are' (OAIC, 19 September 2023) <https://www.oaic.gov.au/about-the-OAIC/who-we-are> accessed 13 May 2024.
39 Office of the Australian Information Commissioner, 'OAIC' (OAIC, 20 September 2023) <https://www.oaic.gov.au> accessed 13 May 2024.
40 CSIRO, About, https://www.csiro.au/en/about.
41 CSIRO, the Australian e-Health Research Centre, https://aehrc.csiro.au/.
42 CSIRO, the Australian e-Health Research Centre, https://aehrc.csiro.au/.
43 CSIRO, Executive Team, https://www.csiro.au/en/about/Corporate-governance/Chief-Executive-and-Executive-Team/Chief-Executive-and-Executive-Team.
44 Digital Transformation Agency, 'About Us' (8 April 2024) <https://www.dta.gov.au/about-us> accessed 13 May 2024.
45 Digital Transformation Agency, 'Digital Transformation Agency' (2024) <https://www.dta.gov.au/> accessed 13 May 2024.
46 'Data and Digital Government Strategy', https://www.dataanddigital.gov.au/sites/default/files/2023-12/Data%20and%20Digital%20Government%20Strategy%20v1.0.pdf.
47 Digital Transformation Agency, 'Chris Fechner CEO' (2 February 2023) <https://www.dta.gov.au/about-us/our-people/chris-fechner-ceo> accessed 13 May 2024.
48 DISR website main page, https://www.industry.gov.au/.
49 Industry Innovation and Science Australia, What we do, https://www.industry.gov.au/science-technology-and-innovation/industry-innovation/industry-innovation-and-science-australia.
50 National Artificial Intelligence Centre, What we do, https://www.industry.gov.au/science-technology-and-innovation/technology/national-artificial-intelligence-centre.
51 DISR, Minister of Industry and Science, https://www.minister.industry.gov.au/ministers/husic.

5. **Department of Home Affairs (DHA)**
Oversees[52] Australia's cyber and critical infrastructure security, with the 2023-2030 Cyber Security Strategy aiming[53] to position Australia as a global leader in cyber security and advocating for the protection of datasets and the development of a voluntary data classification model. Hon Clare O'Neil MP,[54] is the Minister for Home Affairs and Minister for Cyber Security.

B. Technology Laws:

1. Privacy Act 1988 (Cth)

This law[55] is fundamental for any project dealing with personal information, as it sets out the standards, rights, and obligations for the collection, use, and disclosure of personal information, including health data. According to the Notifiable data breaches report[56] by OAIF, the health service providers is the top sector to notify data breaches-reported 104 breaches (22% of all notifications). There are 13 Australian Privacy Principles **(APPs)**[57] and they govern standards, rights, and obligations around: (i) the collection, use and disclosure of personal information; (ii) an organisation or agency's governance and accountability; (iii) integrity and correction of personal information; (iv) the rights of individuals to access their personal information. The 13 privacy principles are highlighted below:

a. Open and transparent management of personal information - Ensures that APP entities manage personal information in an open and transparent way. This includes having a clearly expressed and up to date APP privacy policy.
b. Anonymity and pseudonymity - Requires APP entities to give individuals the option of not identifying themselves, or of using a pseudonym. Limited exceptions apply.
c. Collection of solicited personal information - Outlines when an APP entity can collect personal information that is solicited. It applies higher standards to the collection of sensitive information.
d. Dealing with unsolicited personal information - Outlines how APP entities must deal with unsolicited personal information.

52 Who we are | 'Department of Home Affairs Website' https://www.homeaffairs.gov.au/about-us/who-we-are.
53 '2023-2030 Australian Cyber Security Strategy' Security Strategy.
54 'Ministers for the of Home Affairs Website' (Ministers for the Department of Home Affairs Website) <https://minister.homeaffairs.gov.Departmentau/> accessed 13 May 2024.
55 Privacy Act 1988, https://www.oaic.gov.au/_old/assets/about-us/access-our-information/foi-disclosure-log/foireq20-00051.pdf, accessed 13 May 2024.
56 Australian Government, Office of the Australian Information Commissioner, 'Notifiable Data Breaches Report July to December 2023', https://www.oaic.gov.au/__data/assets/pdf_file/0021/156531/Notifiable-data-breaches-report-July-to-December-2023.pdf
57 'The Australian Privacy Principles', https://www.oaic.gov.au/__data/assets/pdf_file/0006/2004/the-australian-privacy-principles.pdf.

e. Notification of the collection of personal information - Outlines when and in what circumstances an APP entity that collects personal information must tell an individual about certain matters.
f. Use or disclosure of personal information - Outlines the circumstances in which an APP entity may use or disclose personal information that it holds.
g. Direct marketing - An organisation may only use or disclose personal information for direct marketing purposes if certain conditions are met.
h. Cross-border disclosure of personal information - Outlines the steps an APP entity must take to protect personal information before it is disclosed overseas.
i. Adoption, use or disclosure of government related identifiers - Outlines the limited circumstances when an organisation may adopt a government related identifier of an individual as its own identifier, or use or disclose a government related identifier of an individual.
j. Quality of personal information - An APP entity must take reasonable steps to ensure the personal information it collects is accurate, up to date and complete. An entity must also take reasonable steps to ensure the personal information it uses or discloses is accurate, up to date, complete and relevant, having regard to the purpose of the use or disclosure.
k. Security of personal information - An APP entity must take reasonable steps to protect personal information it holds from misuse, interference and loss, and from unauthorised access, modification or disclosure. An entity has obligations to destroy or de-identify personal information in certain circumstances.
l. Access to personal information - Outlines an APP entity's obligations when an individual requests to be given access to personal information held about them by the entity. This includes a requirement to provide access unless a specific exception applies.
m. Correction of personal information - Outlines an APP entity's obligations in relation to correcting the personal information it holds about individuals.[58]

2. Data Breach Notification Law (Part of the Privacy Amendment (Notifiable Data Breaches) Act 2017)

Requires entities to notify individuals affected by data breaches that are likely to result in serious harm, critical for maintaining user trust in digital health services. According to the OAIC Australian Community Attitudes to Privacy Survey (ACAPS)[59] 2023, three-quarters (74%) of Australians feel data breaches are one of the biggest privacy risks they face today. Three-quarters (76%) of those whose data was involved in a

[58] As noted in the introduction, federal laws often have state-level counterparts. Some of these principles appear at the state level in relevant law. For example, in Victoria, the following laws echo the APPs: Health Practitioner Regulation National Law (Victoria) Act 2009; Health Services Act 1988 (Vic); Health Records Act 2001 (Vic); Health Privacy Principles (HPPs); Privacy and Data Protection Act 2014 (Vic); Health Complaints Act 2016 (Vic).
[59] 'Notifiable Data Breaches Report: January to June 2023 | OAIC' <https://www.oaic.gov.au/privacy/notifiable-data-breaches/notifiable-data-breaches-publications/notifiable-data-breaches-report-january-to-june-2023> accessed 13 May 2024.

breach said they experienced harm as a result. More than half (52%) reported an increase in scams or spam texts or emails.[60]

This legislation is directly relevant to the management of health data, requiring health service providers to notify individuals of data breaches that could potentially cause them serious harm. This is critical in the health sector, where a data breach could lead to the unauthorized disclosure of sensitive health information, affecting patient privacy and trust in digital health services. It underscores the importance of robust data security measures and transparent communication with patients regarding their data.

V. OVERVIEW OF FEDERAL GOVERNMENT POLICIES, REPORTS AND CONSULTATIONS ON AI REGULATION RELEVANT TO HEALTHCARE/ PERSONS WITH DISABILITIES

A. Current health technology strategies:

1. National Digital Health Strategy 2023 – 2028 (February 2024)

The National Digital Health Strategy and the accompanying strategy delivery roadmap was released by the Australian Digital Health Agency to drive the digital transformation of healthcare in Australia.[61] The strategy envisions an inclusive, sustainable and healthier future for all Australians through a connected and digitally enabled health system.[62] It is structured around four 'change enablers':[63] (a) policy and regulatory settings to support innovation and adoption of digital health; (b) secure, fit-for-purpose digital solutions that enhance service delivery and clinical workflows: (c) a digitally enabled workforce to meet evolving healthcare demands, and (d) informed, confident consumers with strong digital health literacy. The strategy recognises:

a. *Potential of AI in healthcare and the need for healthcare specific governance*: The strategy highlights AI's potential in healthcare to improve healthcare outcomes through advanced analytics, predictive diagnostics, and improved resource management. The strategy highlights the need for strong ethical frameworks and high clinical standards, for taking the advantages of AI in healthcare.[64] The strategy notes that non-regulatory frameworks could help unlock the benefits of AI in healthcare delivery, harness opportunities for innovation, and promote safer and more secure data sharing practices.[65] The strategy highlights the need for healthcare-specific governance of AI to address its potential risks, challenges and opportunities.[66]
b. *Cultural change, strong ethical frameworks for harnessing AI*: The strategy notes that to take advantage of AI and other technologies, cultural change, individual

[60] Attorney-General's, 'Privacy Amendment (Notifiable Data Breaches) Act 2017' <https://www.legislation.gov.au/C2017A00012/asmade> accessed 13 May 2024.
[61] See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024. Available at: https://nqphn.com.au/sites/default/files/2024-02/national-digital-health-strategy-2023-2028.pdf.
[62] See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 5.
[63] See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 18.
[64] See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 14.
[65] See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 14.
[66] See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 24.

digital competency and capacity, strong ethical frameworks and high clinical standards are required.[67]

c. *AI's potential to provide data driven personalised care*: Noting the value of health information and data analytics, the strategy notes that on combining data analytics with emerging medical science and technologies such as AI, data analytics can deliver a more personalized treatment and care.[68]

The strategy outlines 4 key health system outcomes[69] and their priority areas for strategy delivery –

Key health outcomes	Priority areas for strategy delivery
Digitally enabled – Health and wellbeing services are connected, safe, secure and sustainable.[70]	Priority areas:[71] i. Connect Care: Enhancing the integration of digital solutions. ii. Enable a digitally ready workforce: Supporting a digitally enabled healthcare workforce. iii. Enhance and maintain modern and integrated digital solutions: Maintaining modern, secure digital health platforms.
Person-centered - Australians are empowered to look after their health and wellbeing, equipped with the right information and tools.[72]	Priority areas:[73] i. Support strong consumer digital health literacy: Improving consumer understanding of digital health. ii. Increase availability of health information: Increasing availability of personal health information. iii. Enhance consent management and flexible health information exchange: Enhancing consent mechanisms for information exchange.
Inclusive and accessible AI – Australians have equitable access to health services when and where they need them.[74]	Priority areas[75]: i. Improve and expand virtual care: Enabling virtual care including email, messaging, notifications, telehealth, video conferencing, and sharing information between consumers and multiple healthcare providers. ii. Integrate personal devices: Enabling consumers of personal medical devices to connect with their respective healthcare teams

67 See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 14.
68 See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 37.
69 See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 9.
70 See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 32.
71 See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 39.
72 See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 40.
73 See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 43.
74 See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 44.
75 See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 45.

	for data sharing, with appropriate safeguards for privacy, security and consent. iii. Support equitable health access: Ensuring vulnerable populations are supported in using digital health systems.
Data-driven and integrated decision making - Readily available data informs decision making at the individual, community and national levels, contributing to a sustainable health system.[76]	Priority areas include:[77] i. Use health information for research and public health purposes: Leverage high-quality health data for research, policy development, and improving clinical practices. ii. Plan for emerging data sources and technology such as artificial intelligence, spatial data, genomics: Planning for innovations such as AI, genomics, and big data analytics to enhance system efficiency and early intervention, adhering to regulatory and ethical standards. iii. Monitor and evaluate outcomes and progress: Using digital tools to track progress, optimize resource allocation, and improve patient-cantered outcomes.

2. Action Plan for the Digital Health Blueprint 2023-2033 (December 2023)

The Action Plan for Digital Health Blueprint was released by the DHAC, outlines Australia's vision for digital health capabilities to deliver a more person-centered and sustainable health system by 2033.[78] The plan aims to complement existing frameworks and the National Digital Health Strategy, aligning with the Australian Government's broader digital transformation agenda.[79]

The key vision of the Action Plan is that the trusted, timely and accessible use of digital and data underpins a personalised and connected health and wellbeing experience for all Australians.[80] The plan takes a principles-led approach for developing initiatives for supporting the vision, with the principles being – (a) person-centred, (b) collaborative, (c) trusted, and (d) enduring.[81] The plan is structured around four main outcomes:

a. Australians have choice in managing their health and wellbeing, navigating the health system with their information following them.
b. Australia's health workforce is digitally empowered to provide connected care confidently, whenever or wherever needed.
c. Modern digital foundations underpin and strengthen a collaborative, standards-based health system that is safe and secure.

[76] See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 47.
[77] See The National Digital Health Strategy 2023-2028, Australian Digital Health Agency, February 2024, page 49.
[78] See Action Plan for the Digital Health Blueprint 2023-2033, Australian Government, Department of Health and Aged Care, page 4. Available at: https://www.health.gov.au/sites/default/files/2023-12/the_action_plan_for_the_digital_health_blueprint_2023-2033.pdf.
[79] See Action Plan for the Digital Health Blueprint 2023-2033, Australian Government, Department of Health and Aged Care, page 4.
[80] See Action Plan for the Digital Health Blueprint 2023-2033, Australian Government, Department of Health and Aged Care, page 4.
[81] See Action Plan for the Digital Health Blueprint 2023-2033, Australian Government, Department of Health and Aged Care, page 7.

d. Data and information are shared and reused securely to deliver a sustainable learning health system.

The Action Plan specifically highlights the potential of AI technologies for boosting Australia's competitiveness, drive industry transformation and create local jobs and economic growth, especially for the healthcare sector.[82] The plan notes that the rise of generative AI will introduce new challenges for healthcare such as unguided development of algorithms given the public access to consumer-grade AI tools, concerns about unknown quality, accuracy and risk understanding, and role of clinical governance in the use of generative AI.[83]

B. Current standards, or principles for using AI generally

1. Artificial Intelligence Ethics Principles (2019)

Australia has 8[84] AI Ethics Principles, designed to ensure AI is safe, secure and reliable. These principles are:

a. Human, societal and environmental wellbeing: AI systems should benefit individuals, society and the environment.
b. Human-centred values: AI systems should respect human rights, diversity, and the autonomy of individuals.
c. Fairness: AI systems should be inclusive and accessible and should not involve or result in unfair discrimination against individuals, communities or groups.
d. Privacy protection and security: AI systems should respect and uphold privacy rights and data protection and ensure the security of data.
e. Reliability and safety: AI systems should reliably operate in accordance with their intended purpose.
f. Transparency and explainability: 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.
g. Contestability: When an AI system significantly impacts a person, community, group or environment, there should be a timely process to allow people to challenge the use or outcomes of the AI system.
h. Accountability: People responsible for the different phases of the AI system lifecycle should be identifiable and accountable for the outcomes of the AI systems, and human oversight of AI systems should be enabled.

2. Voluntary AI Safety Standard (September 2024)

[82] See Action Plan for the Digital Health Blueprint 2023-2033, Australian Government, Department of Health and Aged Care, page 34.
[83] See Action Plan for the Digital Health Blueprint 2023-2033, Australian Government, Department of Health and Aged Care, page 34.
[84] See Australia's Artificial Intelligence Ethics Principles, Australian Government, Department of Industry, Science and Resources. Available at: https://architecture.digital.gov.au/australias-artificial-intelligence-ethics-principles-0#:~:text=Australia's%208%20Artificial%20Intelligence%20(AI,is%20safe%2C%20secure%20and%20reliable.&text=Contestability%3A%20When%20an%20AI%20system,outcomes%20of%20the%20AI%20system.

The Australian Government, Department of Industry, Science and Resources has also released Voluntary AI Safety Standards,[85] which provide guidance to organizations regarding safe and responsible development and deployment of AI systems, in line with existing international standards.[86] The standard is structured around 10 voluntary guardrails, with the aim of mitigating risks, ensuring transparency, and promoting ethical AI usage throughout the supply chain. The 10 voluntary guardrails are –

a. Establishing accountability and governance processes for AI deployment,[87]
b. Implementing risk management to identify and mitigate potential harms,[88]
c. Ensuring data governance, protecting AI systems, and managing data quality and provenance,[89]
d. Testing and monitoring AI systems post-deployment to assess performance,[90]
e. Enabling human oversight to maintain control over AI systems,[91]
f. Informing end-users about AI-generated decisions or content,[92]
g. Providing avenues for those impacted by AI systems to challenge use or outcomes,[93]
h. Ensuring transparency across the AI supply chain,[94]
i. Maintaining records to demonstrate compliance,[95] and
j. Engaging stakeholders to focus on safety, diversity, and fairness.[96]

C. AI in healthcare proposals and consultations

1. Public consultation on Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review (September 2024)

The Public consultation has been released by the Australian Government, Department of Health and Aged Care regarding regulating AI use in healthcare, as part of its

85 See Voluntary AI Safety Standards, Australian Government, Department of Industry, Science and Resources, August 2024. Available at: https://www.industry.gov.au/sites/default/files/2024-09/voluntary-ai-safety-standard.pdf.
86 See Voluntary AI Safety Standards, Australian Government, Department of Industry, Science and Resources, August 2024.
87 See Voluntary AI Safety Standards, Australian Government, Department of Industry, Science and Resources, August 2024, page 16.
88 See Voluntary AI Safety Standards, Australian Government, Department of Industry, Science and Resources, August 2024, page 19.
89 See Voluntary AI Safety Standards, Australian Government, Department of Industry, Science and Resources, August 2024, page 22.
90 See Voluntary AI Safety Standards, Australian Government, Department of Industry, Science and Resources, August 2024, page 25.
91 See Voluntary AI Safety Standards, Australian Government, Department of Industry, Science and Resources, August 2024, page 29.
92 See Voluntary AI Safety Standards, Australian Government, Department of Industry, Science and Resources, August 2024, page 31.
93 See Voluntary AI Safety Standards, Australian Government, Department of Industry, Science and Resources, August 2024, page 34.
94 See Voluntary AI Safety Standards, Australian Government, Department of Industry, Science and Resources, August 2024, page 36.
95 See Voluntary AI Safety Standards, Australian Government, Department of Industry, Science and Resources, August 2024, page 39.
96 See Voluntary AI Safety Standards, Australian Government, Department of Industry, Science and Resources, August 2024, page 42.

broader efforts to establish a safe and responsible AI environment in high-risk settings, focusing on the potential risks and benefits of AI in healthcare.[97]

Building on the previous consultations of the Department of Industry, Science and Resources (**DISR**) for introducing mandatory guardrails for AI in high-risk settings and the complementary proposal paper, the consultation aims to address risks associated with AI use in healthcare settings in Australia.[98]

The consultation paper:

a. Identifies certain AI benefits for healthcare professionals such as supporting the provision of quality health care by reducing the human factors which can impact patient safety, like fatigue, burn-out and cognitive biases. Also identifies certain AI benefits for consumers or patients, such as navigating complex healthcare system, real time language translation, etc.[99]

b. Explains AI risks, especially in high-risk areas like AI systems prioritising emergency health care services and use of AI-enabled robots for medical surgery. Also highlights low risk uses of AI such as navigating patients through hospitals, chatbots for content finding on websites, etc.[100]

c. Highlights that AI can potentially perpetuate societal injustices and have a disproportionate impact on vulnerable and underrepresented groups, such as those based on age, disability, race, sex, gender identity, and sexual orientation.[101] It also highlights that the potential risks of AI could be reduced by promoting AI literacy among healthcare providers.[102]

d. Assess how existing regulations need to evolve to address AI-specific challenges, noting that a combination of different regulatory tools will likely be needed to adequately support the safe use of AI in health and aged care settings.[103]

e. Provides regulatory options of – (a) updating existing laws, (b) introducing new laws, and (c) creating a regulatory body to monitor and enforce AI rules or performance in health and aged care settings.[104]

---

97 See Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review, Public Consultation, Australian Government, Department of Health and Aged Care, September 2024, page 2-3. Available at: https://consultations.health.gov.au/medicare-benefits-and-digital-health-division/safe-and-responsible-artificial-intelligence-in-he/supporting_documents/Consultation%20on%20Safe%20and%20Responsible%20AI%20in%20Health%20Care.pdf.

98 See Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review, Public Consultation, Australian Government, Department of Health and Aged Care, September 2024, page 2-3.

99 See Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review, Public Consultation, Australian Government, Department of Health and Aged Care, September 2024, page 5

100 See Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review, Public Consultation, Australian Government, Department of Health and Aged Care, September 2024, page 6.

101 See Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review, Public Consultation, Australian Government, Department of Health and Aged Care, September 2024, page 6.

102 See Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review, Public Consultation, Australian Government, Department of Health and Aged Care, September 2024, page 6.

103 See Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review, Public Consultation, Australian Government, Department of Health and Aged Care, September 2024, page 7.

104 See Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review, Public Consultation, Australian Government, Department of Health and Aged Care, September 2024, page 7.

f. Provides certain non-regulatory changes such as[105] –

i. Creating a new certification scheme for AI-based products which can be used in health and aged care settings,
ii. Developing non-legislative policies, procedures and standards for ensuring AI tools are safe, effective and secure,
iii. Publishing guidelines for the use of AI in certain health or aged care settings,
iv. Developing guidance resources for the AI product developing technology companies,
v. Providing education and training programs for healthcare professionals; and
vi. Boosting public AI information to help patients and healthcare consumers engage with AI safely and effectively.

The consultation paper poses 19 questions to stakeholders such as, AI benefits, regulatory changes needed to healthcare laws, any specific safety considerations, etc.[106]

D. General AI proposals and consultations

1. Safe and responsible AI in Australia: Proposals paper for introducing mandatory guardrails for AI in high-risk settings (September 2024)

The proposal paper[107] was released by the federal Department of Industry, Science and Resources in September, and forms part of Australia's ongoing efforts to regulate artificial intelligence (**AI**) and ensure its safe and responsible use, particularly in high-risk settings. The paper was open for public consultation until 4 October 2024.[108]

The paper focuses on three main areas: (i) defining high-risk AI, (ii) establishing mandatory guardrails for high-risk AI systems, and (iii) considering regulatory mechanisms for implementation of the proposed guardrails. The key highlights of the proposal paper are below:

a. *Defining high risk AI*: The paper proposes two categories – systems with foreseeable and unforeseeable uses. It outlines consideration of the following principles for classification, based on the risk of adverse impacts to[109] – (a) individual's rights, (b) individual's physical or mental health or safety, (c) legal effects, such as defamation or similarly significant effects on an individual's legal rights; (d) collective rights of cultural

105 See Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review, Public Consultation, Australian Government, Department of Health and Aged Care, September 2024, page 7.
106 See Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review, Public Consultation, Australian Government, Department of Health and Aged Care, September 2024, page 11.
107 See Safe and responsible AI in Australia: Proposals paper for introducing mandatory guardrails for AI in high-risk settings, Department of Industry, Science and Resources, Australian Government, September 2024. Available at: https://storage.googleapis.com/converlens-au-industry/industry/p/prj2f6f02ebfe6a8190c7bdc/page/proposals_paper_for_introducing_mandatory_guardrails_for_ai_in_high_risk_settings.pdf.
108 See Introducing mandatory guardrails for AI in high-risk settings: proposals paper, Department of Industry, Science and Resources, Australian Government, 5 September 2024. Available at: https://consult.industry.gov.au/ai-mandatory-guardrails.
109 See Safe and responsible AI in Australia: Proposals paper for introducing mandatory guardrails for AI in high-risk settings, Department of Industry, Science and Resources, Australian Government, September 2024, page 19.

groups, or groups of individuals; (e) broader Australian economy, society, environment and rule of law; and (f) severity and extent of the adverse impacts.

b. *General-purpose AI (**GPAI**) models as high risk*: Notably, the proposal paper proposes treating all GPAI models, such as ChatGPT and Claude, as high-risk due to their versatility and unpredictable uses.[110] The paper proposes to apply the mandatory guardrails to GPAI models, which would require developers and deployers of such models, to take specific steps across AI lifecycle.

c. *Mandatory guardrails*: The proposal introduces 10 mandatory guardrails, emphasized to apply across the entire AI supply chain. These include[111]:

   i. establishing robust accountability and governance processes,
   ii. implementing risk management frameworks,
   iii. implementing data governance measures for ensuring data quality and provenance,
   iv. conducting testing and evaluation of AI models with monitoring the systems once deployed,
   v. enabling human control or intervention for meaningful oversight,
   vi. informing end-users regarding AI-enabled decision making,
   vii. establishing processes for challenging AI use or outcomes for impacted individuals,
   viii. ensuring transparency across AI supply chain on data, models and systems,
   ix. keeping and maintaining records allowing third-parties to assess compliance with guardrails, and
   x. undertaking conformity assessments for demonstrating and certifying compliance with the guardrails.

d. *Regulatory options for introducing guardrails*: The paper also proposes three regulatory options: (i) domain specific approach of adapting existing regulatory frameworks to include guardrails, (ii) framework approach of introducing a new legislative framework to adapt existing regulatory frameworks across the economy, or (iii) a whole-economy approach, introducing cross-economy AI specific legislation.[112]

E. Guidance for inclusive innovation

1. Framework for Artificial Intelligence-enabled Assistive Technology as supported under the National Disability Insurance Scheme (November 2022)

Australia's National Disability Insurance Scheme (**NDIS**) in collaboration with CSIRO's Australian e-Health Research Centre (**AEHRC**), developed and released a framework promoting innovation and development of safe and effective AI-enabled Assistive

[110] See Safe and responsible AI in Australia: Proposals paper for introducing mandatory guardrails for AI in high-risk settings, Department of Industry, Science and Resources, Australian Government, September 2024, page 29.
[111] See Safe and responsible AI in Australia: Proposals paper for introducing mandatory guardrails for AI in high-risk settings, Department of Industry, Science and Resources, Australian Government, September 2024, page 35.
[112] See Safe and responsible AI in Australia: Proposals paper for introducing mandatory guardrails for AI in high-risk settings, Department of Industry, Science and Resources, Australian Government, September 2024, page 43.

Technologies (**AT**).[113] The framework aims to encourage innovation, build consumer confidence, and increase the uptake of AI-enabled AT by people with disability.[114] The framework supports a person-centric approach for assessing AI-enabled AT, considering the context in which it is to be used and acknowledging the unique capabilities, preferences, and goals of end-users and their environment.[115] The report also provides a roadmap which will consider the contexts and settings of use of AI-enabled AT, driven by key considerations identified during the framework development process.[116]

The framework focuses on six key principles with specific measures under each principle:

a. User experience: AI-enabled AT should provide a productive and positive experience to people with disabilities, with measures such as usability, usefulness, and functional accessibility.[117]
b. Privacy and security: AI-enabled AT should ensure robust data protection of users, with measures such as ensuring best cybersecurity practices, data protection ensuring confidentiality and data usage for consented purposes.[118]
c. Quality: AI-enabled AT should reliably produce desired or intended results, and quality should be sustained. Measures include ensuring credibility, validation of the AI-enabled AT functionalities, and ensuring data quality such as accuracy, relevance and representativeness.[119]
d. Safety: AI-enabled AT should do no harm, minimize negative outcomes, and not deceive people. Measures include providing comprehensive information regarding risks and reliability of AI-enabled AT.[120]
e. Relative value: AI-enabled AT should provide a better benefit-to-cost ratio compared to alternate options, with measures like ensuring total cost and cost consequences associated are considered, the outcomes of these systems should benefit individuals, and should generate greater benefits relative to costs.[121]

---

113 See AEHRC - Framework and Roadmap for Artificial Intelligence-enabled Assistive Technology, Australian e-Health Research Centre, Australia National Science Agency, and National Disability Insurance Agency, November 2022. Available at: https://dataresearch.ndis.gov.au/media/3712/download?attachment.
114 See AEHRC - Framework and Roadmap for Artificial Intelligence-enabled Assistive Technology, Australian e-Health Research Centre, Australia National Science Agency, and National Disability Insurance Agency, November 2022, page 6.
115 See AEHRC - Framework and Roadmap for Artificial Intelligence-enabled Assistive Technology, Australian e-Health Research Centre, Australia National Science Agency, and National Disability Insurance Agency, November 2022, page 9.
116 See AEHRC - Framework and Roadmap for Artificial Intelligence-enabled Assistive Technology, Australian e-Health Research Centre, Australia National Science Agency, and National Disability Insurance Agency, November 2022, page 17.
117 See AEHRC - Framework and Roadmap for Artificial Intelligence-enabled Assistive Technology, Australian e-Health Research Centre, Australia National Science Agency, and National Disability Insurance Agency, November 2022, page 10-11.
118 See AEHRC - Framework and Roadmap for Artificial Intelligence-enabled Assistive Technology, Australian e-Health Research Centre, Australia National Science Agency, and National Disability Insurance Agency, November 2022, page 11-12.
119 See AEHRC - Framework and Roadmap for Artificial Intelligence-enabled Assistive Technology, Australian e-Health Research Centre, Australia National Science Agency, and National Disability Insurance Agency, November 2022, page 12-13.
120 See AEHRC - Framework and Roadmap for Artificial Intelligence-enabled Assistive Technology, Australian e-Health Research Centre, Australia National Science Agency, and National Disability Insurance Agency, November 2022, page 13-14.
121 See AEHRC - Framework and Roadmap for Artificial Intelligence-enabled Assistive Technology, Australian e-Health Research Centre, Australia National Science Agency, and National Disability Insurance Agency, November 2022, page 14.

f. Human rights: AI-enabled AT must protect human rights and fundamental freedoms. Measures include ensuring legal compliance, fairness, transparency and ethical compliances.[122]

F. Reports of AI in healthcare

1. AI Implementation in Hospitals: Legislation, Policy, Guidelines and Principles, and Evidence about Quality and Safety – Literature Review and Environment Scan Report (May 2024)

The Report has been prepared for the Australian Commission on Safety and Quality in Health Care by Australian Institute of Health Innovation, Macquarie University and Australian Centre for Health Engagement, Evidence and Values University of Wollongong. The Report aims to identify principles that enable the safe and responsible implementation of AI in healthcare for future development of resources to assist healthcare organisations in evaluating and implementing AI.[123]

The key findings of the Report[124] are –

a. AI governance in healthcare spans not only AI-specific laws but also existing privacy, human rights, and data protection laws;
b. Similar to Australia, countries like the US, rely on national ethics frameworks to guide AI in healthcare, including establishing dedicated regulatory and oversight authorities (including healthcare-specific bodies), risk-based assessments, transparency requirements, and regulatory sandboxes;
c. Australia's National Ethics Framework guide AI governance in healthcare, with the Australian government developing a national risk-based approach to cross-sectoral AI regulation based on four principles – (a) balanced and proportionate (achieved via risk-based assessment); (b) collaborative and transparent (achieved via public engagement and expert involvement); (c) consistent with international requirements; and (d) putting community first.
d. Current developments in Australian governance and regulation of AI in healthcare include governance via existing cross-sectoral approaches (e.g. privacy and consumer law), regulation of software as a medical device, and specific health governance proposals from research and health organisations.
e. The key issues for health organisations and clinicians, highlighted in the Report[125] are:

i. *Quality*: Ensure high-quality, local evidence of AI system performance before use.

---

122 See AEHRC - Framework and Roadmap for Artificial Intelligence-enabled Assistive Technology, Australian e-Health Research Centre, Australia National Science Agency, and National Disability Insurance Agency, November 2022, page 14-15.

123 See AI Implementation in Hospitals: Legislation, Policy, Guidelines and Principles, and Evidence about Quality and Safety – Literature Review and Environment Scan Report, May 2024, page 9. Available at: https://www.safetyandquality.gov.au/sites/default/files/2024-08/artificial_intelligence_-_literature_review_and_environmental_scan.pdf.

124 See AI Implementation in Hospitals: Legislation, Policy, Guidelines and Principles, and Evidence about Quality and Safety – Literature Review and Environment Scan Report, May 2024, page 9.

125 See AI Implementation in Hospitals: Legislation, Policy, Guidelines and Principles, and Evidence about Quality and Safety – Literature Review and Environment Scan Report, May 2024, page 10-11.

ii. *Training*: Significant training is required for clinicians, including skills in AI use, ethical considerations, cybersecurity, and patient communication.
iii. *Compliance*: Ensure AI systems comply with existing laws, such as data privacy and AI ethics frameworks.
iv. *AI governance*: Build on existing governance processes for patient safety and ethics.
v. *Engagement*: Engage with communities to build trust and ensure responsible AI use in healthcare, including consumer-facing AI.
vi. *Indigenous governance*: AI governance should connect with existing Aboriginal and Torres Strait Islander governance structures, adhering to Indigenous Data Sovereignty principles.
vii. *Transparency and consent*: Establish governance for transparency, including informing patients about AI use and ensuring traditional consent requirements are maintained in clinical contexts.
viii. *Risk assessment*: Implement frameworks to monitor bias, discrimination, and AI incidents. Use existing systems for patient safety and AI monitoring.
ix. *Monitoring*: Ensure monitoring AI incidents and safety events as well as post-market safety monitoring so that cases of AI-related patient risk and harm are rapidly detected, reported and managed.

f. The key findings and principles for implementing AI systems at the health service level provided by the Report are as follows:[126]

Issue	Findings of the report	Principle(s) for implementing AI systems
AI in acute care settings	AI technologies are applied in various clinical areas, primarily for diagnosis and procedures. No studies have evaluated AI in hospital operations or clinical use of generative AI	AI should address specific clinical needs and use cases before implementation.
Approach to AI implementation	AI systems are developed in-house, co-developed, or purchased. Engagement with ethics committees was poorly reported.	i. Involve stakeholders across governance and clinical roles. ii. Test AI systems locally before full deployment.

[126] See AI Implementation in Hospitals: Legislation, Policy, Guidelines and Principles, and Evidence about Quality and Safety – Literature Review and Environment Scan Report, May 2024, page 12-14.

AI system performance	i. AI performance is typically evaluated against comparators like human experts. ii. studies lacked post-deployment monitoring and performance reviews.	i. Ensure AI performance evaluation in the local context. ii. Post-deployment monitoring should detect performance shifts.
Safety of AI in healthcare	AI-related safety concerns are emerging, with misuse leading to more patient harm than technical issues.	Integrate AI into existing IT infrastructure and ensure data quality to prevent risks.
Role of AI in clinical task, clinical workflow, usability, and safe use	AI systems are often assistive, requiring clinician oversight. Misuse is more likely to harm patients.	i. Ensure training on AI use and safety. ii. Integrate AI into clinical workflows and adjust as needed during pilot implementation.
Clinical utility and effects on decision-making	AI impacts decision-making, including decision velocity and confidence.	i. Clearly communicate AI limitations to users. ii. Use studies to evaluate AI's clinical utility before and after implementation.
Effects on care delivery and patient outcomes	Care process changes were underreported, but clinical outcomes are frequently used to measure AI effectiveness.	Use formative evaluations during AI implementation to ensure AI's utility before assessing its impact on patient care.

2. AI trends for healthcare (March 2024)

a. The report AI trends[127] for healthcare, by Australia's National Science Agency (**CSIRO**) highlights the growing adoption of AI technologies in healthcare, driven by increased data availability, computational power, and the widespread use of AI tools.[128] It notes that the use of AI in healthcare for decision making for diagnosis, prevention, prediction, prognosis, monitoring or treatment, is regulated as 'software as a medical device' (**SaMD**), with emergence of AI growing in the past couple of years.

b. The report notes four key trends in AI use in healthcare: (i) *Interoperability*: Facilitating safe data exchange across systems to improve patient care and healthcare system performance; (ii) *Cloud computing*: Increasingly used for secure data storage and high-performance computing in healthcare; (iii) *Apps and personalisation*: The availability of patient data fostering personalized healthcare solutions; (iv) *Data analytics as a*

[127] See AI trends for healthcare, Australia National Science Agency, March 2024. Available at: https://aehrc.csiro.au/wp-content/uploads/2024/03/AI-Trends-for-Healthcare.pdf.
[128] See AI trends for healthcare, Australia National Science Agency, March 2024, page 2.

service: Cloud-based analytics enabling algorithms to be 'brought to the data' rather than the data being shared.

c. The report delves into AI-driven software tools developed by CSIRO's Australian e-Health Research Centre (**AEHRC**) to optimize patient flows, improve safety, and support clinical decision-making.[129] AI is also being integrated into genomics and biomedical informatics to enable precision medicine and data-driven healthcare.[130]

d. The report provides an overview of key AI techniques such as predictive analytics and data-driven intelligence, computer vision and image processing, natural language processing, and knowledge representation and reasoning, which play crucial roles in clinical decision-making, image analysis, and data processing.[131]

e. Emphasising the necessity for ensuring responsible and ethical implementation of AI systems in healthcare,[132] the report underscores the need for responsible AI governance, citing frameworks like the Australian Government's AI Ethics Framework, comprising 8 principles to help ensure AI is safe, secure, and reliable.[133] The report notes that responsible AI includes the development, deployment and operation of AI systems which adhere to ethical standards, promote transparency, and establish governance and accountability.[134]

f. The report notes that the convergence of chatbots and voice assistants powered by AI represents a significant opportunity for clinical decision support and patient engagement.[135] However, it also notes the challenges before AI, such as the need for significant investments for computational power, which may result in disparities between institutions.[136]

g. The report notes that AI is revolutionizing medical imaging through tasks like image acquisition, segmentation, and quantification, improving diagnostic accuracy and treatment.[137] It further notes that AI also supports clinicians by reducing administrative burdens, enhancing data-driven decision-making, and improving workforce efficiency.[138]

h. The report highlights AI's potential in aged care by supporting independent living and clinical decision-making through wearables and assistive technologies.[139] However, it also notes the challenges like the lack of evidence on AI's impact including physical, emotional, and ethical considerations; education of users to know what they are engaging with and how to use it appropriately and safely.[140]

---

129 See AI trends for healthcare, Australia National Science Agency, March 2024, page 6.
130 See AI trends for healthcare, Australia National Science Agency, March 2024, page 6.
131 See AI trends for healthcare, Australia National Science Agency, March 2024, page 10.
132 See AI trends for healthcare, Australia National Science Agency, March 2024, page 18.
133 See AI trends for healthcare, Australia National Science Agency, March 2024, page 20.
134 See AI trends for healthcare, Australia National Science Agency, March 2024, page 20
135 See AI trends for healthcare, Australia National Science Agency, March 2024, page 24.
136 See AI trends for healthcare, Australia National Science Agency, March 2024, page 25.
137 See AI trends for healthcare, Australia National Science Agency, March 2024, page 26.
138 See AI trends for healthcare, Australia National Science Agency, March 2024, page 28-29.
139 See AI trends for healthcare, Australia National Science Agency, March 2024, page 30.
140 See AI trends for healthcare, Australia National Science Agency, March 2024, page 30.

i. Noting that the key for all future-ready consent platforms is putting a human at the centre of AI designs, with considerations for sociocultural angle of molecular and medical data management.[141] Another challenge highlighted by the report is the challenge of ensuring that AI-enabled products and services are fit for purpose for the people who use them.[142] It notes the challenge of using AI technologies by persons with disabilities, and that the expansion of assistive technology space needs to be informed by the people with lived experiences of disabilities, ensuring that the tools are safe, appropriate and beneficial for individuals.[143]

VI. OVERVIEW OF INCLUSIVITY GOVERNANCE AND LAWS

A. Inclusion governance

1. National Disability Insurance Agency (NDIA)
The NDIA is responsible[144] for implementing the National Disability Insurance Scheme, which provides support to Australians with a significant and permanent disability. The NDIA's mission is to empower people with disabilities to achieve their individual goals and to participate in the community and employment.

2. Department of Social Services (DSS):
Dedicated[145] to enhancing the welfare of Australian communities, DSS focuses on supporting individuals in need and fostering community cohesion. It launched Australia's Disability Strategy 2021-2031 to promote the rights and participation of people with disabilities, alongside the Disability Gateway for easier access to services nationwide. Hon Bill Shorten MP,[146] is the Minister for the National Disability Insurance Scheme.

3. Australian Human Rights Commission (AHRC)
As an independent[147] body, AHRC champions human rights, addressing issues like discrimination and advocating for the rights of diverse groups including those with disabilities. Its Disability Discrimination Commissioner focuses[148] on mitigating discrimination and enhancing rights for individuals with disabilities. Ms. Lorraine Finlay is the Human Rights Commissioner and Ms. Rosemary Kayess,[149]is the Disability Discrimination Commissioner.

4. Department of Education, Skills and Employment (DESE)

141 See AI trends for healthcare, Australia National Science Agency, March 2024, page 31.
142 See AI trends for healthcare, Australia National Science Agency, March 2024, page 33.
143 See AI trends for healthcare, Australia National Science Agency, March 2024, page 33.
144 'About Us | NDIS' <https://www.ndis.gov.au/about-us> accessed 13 May 2024.
145 'About the Department | Department of Social Services, Australian Government' <https://www.dss.gov.au/about-the-department> accessed 13 May 2024.
146 Canberra, 'Hon Bill Shorten MP' <https://www.aph.gov.au/Senators_and_Members/Parliamentarian?MPID=00ATG> accessed 13 May 2024.
147 'About | Australian Human Rights Commission' <https://humanrights.gov.au/about> accessed 13 May 2024.
148 'Current Projects | Australian Human Rights Commission' (9 May 2022) <https://humanrights.gov.au/our-work/disability-rights/projects/current> accessed 13 May 2024.
149 'Disability Rights' (1 April 2024) <https://humanrights.gov.au/our-work/disability-rights> accessed 13 May 2024.

DESE oversees[150] national policies for accessible and affordable education and job training, emphasizing inclusivity through programs like the Higher Education Disability Support Program.[151] Hon Jason Clare MP[152], is the Minister for Education.

5. National Mental Health Commission (NMHC)

Tasked[153] with enhancing Australia's mental health and suicide prevention strategies, the Commission emphasizes the use of digital and telehealth technologies to improve care. Their initiatives, such as the National Stigma and Discrimination Reduction Strategy[154] and Vision 2030[155], focus on reducing stigma and leveraging technology in mental health care. Professor Ngiare Brown,[156] is the Chair of the NHMC.

B. Inclusion Laws

1. Disability Discrimination Act 1992 (Cth)

Essential for ensuring that digital health solutions are accessible to and inclusive of people with disabilities, prohibiting discrimination and promoting equal rights and opportunities. In the context of health technology, this means that apps, websites, and other digital tools must be designed to be usable for people with a wide range of physical, sensory, and cognitive disabilities. Compliance with this act ensures that digital health solutions contribute to equitable healthcare access, promoting inclusivity and preventing discrimination in the rapidly evolving digital health landscape.[157]

2. Sex Discrimination Act 1984

This act is crucial for ensuring that digital health technologies and services are developed and implemented without bias or discrimination based on sex, gender identity, intersex status, sexual orientation, marital or relationship status, pregnancy, or breastfeeding status.

3. The Age Discrimination Act 2004

This legislation is significant for the development of inclusive digital health solutions that cater to individuals of all ages. It ensures that older adults and the young are not unfairly excluded from accessing or benefiting from digital health innovation.

---

150 Canberra City, Department of Education; Marcus Clarke St, 'About the Department' (4 April 2024) <https://www.education.gov.au/about-department> accessed 13 May 2024.

151 Canberra City, Department of Education; Marcus Clarke St, 'Higher Education Disability Support Program' (30 May 2023) <https://www.education.gov.au/higher-education-disability-support-program> accessed 13 May 2024.

152 'Hon Jason Clare MP' <https://www.aph.gov.au/Senators_and_Members/Parliamentarian?MPID=HWL> accessed 13 May 2024.

153 National Mental Health Commission, 'About' (20 February 2024) <https://www.mentalhealthcommission.gov.au/about> accessed 13 May 2024.

154 National Mental Health Commission, 'National Stigma and Discrimination Reduction Strategy' (3 April 2024) <https://www.mentalhealthcommission.gov.au/projects/stigma-and-discrimination-reduction-strategy> accessed 13 May 2024.

155 National Mental Health Commission, 'National Mental Health Commission' (13 May 2024) <https://www.mentalhealthcommission.gov.au/> accessed 13 May 2024.

156 National Mental Health Commission, 'Professor Ngiare Brown' (27 March 2024) <https://www.mentalhealthcommission.gov.au/about/our-people/chair-and-commissioners/prof-ngiare-brown> accessed 13 May 2024.

157 Attorney-General's, 'Disability Discrimination Act 1992' <https://www.legislation.gov.au/C2004A04426/2018-04-12> accessed 13 May 2024.

4. **Racial Discrimination Act 1975**
   This act is essential for ensuring that digital health services and technologies are free from racial biases and discrimination. It mandates that health technologies must be developed and deployed in a manner that respects racial, ethnic, and cultural diversity.

VII. ISSUES FOR DISCUSSION IN PROJECT BUILD

This section provides a suggested list of issues for discussion by the cohort, based on the landscape captured in this Paper.

A. Concluding remarks

The Australian government has been working extensively to understand the challenges and opportunities posed by AI for healthcare and inclusion. The National Digital Health Strategy 2023-2028 and the Framework for Artificial Intelligence-enabled Assistive Technology are examples of how the government wants to harness the power of AI for improving access to healthcare.

Inclusion appears to be a key consideration across the policies, frameworks, consultations and reports covered in section V of this Paper. However, 'inclusion' itself must be dissected to properly ensure that policies and innovation truly promote and protect inclusion.

B. Issues for discussion

Defining and Operationalizing "Inclusivity" in Healthcare AI:

- What specific criteria should be used to evaluate the inclusivity of an AI healthcare tool?
- How can inclusivity be measured and demonstrated empirically?
- What minimum standards of inclusivity should be required for regulatory approval?
- How might we assess the inclusivity of an AI-driven diagnostic tool for rural populations with limited healthcare access and low digital literacy?

Barriers to Inclusive AI Development and Deployment:

- How can we address data limitations and biases in training datasets?
- What strategies can increase diversity in AI/ML teams and decision-makers?
- How can we improve engagement with marginalized communities in AI development?
- What solutions can overcome economic and infrastructural constraints in accessing AI-enabled healthcare?

Lifecycle Approach to Inclusive AI:

- At what stages of the AI lifecycle should inclusivity be addressed?

- How can we manage potential tensions between rapid AI adoption and thorough inclusivity assessments?
- What ethical considerations arise in data collection and algorithm transparency?

Regulatory and Governance Challenges:

- How can existing regulatory frameworks be adapted for AI-driven healthcare?
- What new governance structures might be needed to oversee inclusive AI in healthcare?
- How can we create accountability mechanisms and incentive structures to prioritize inclusivity?

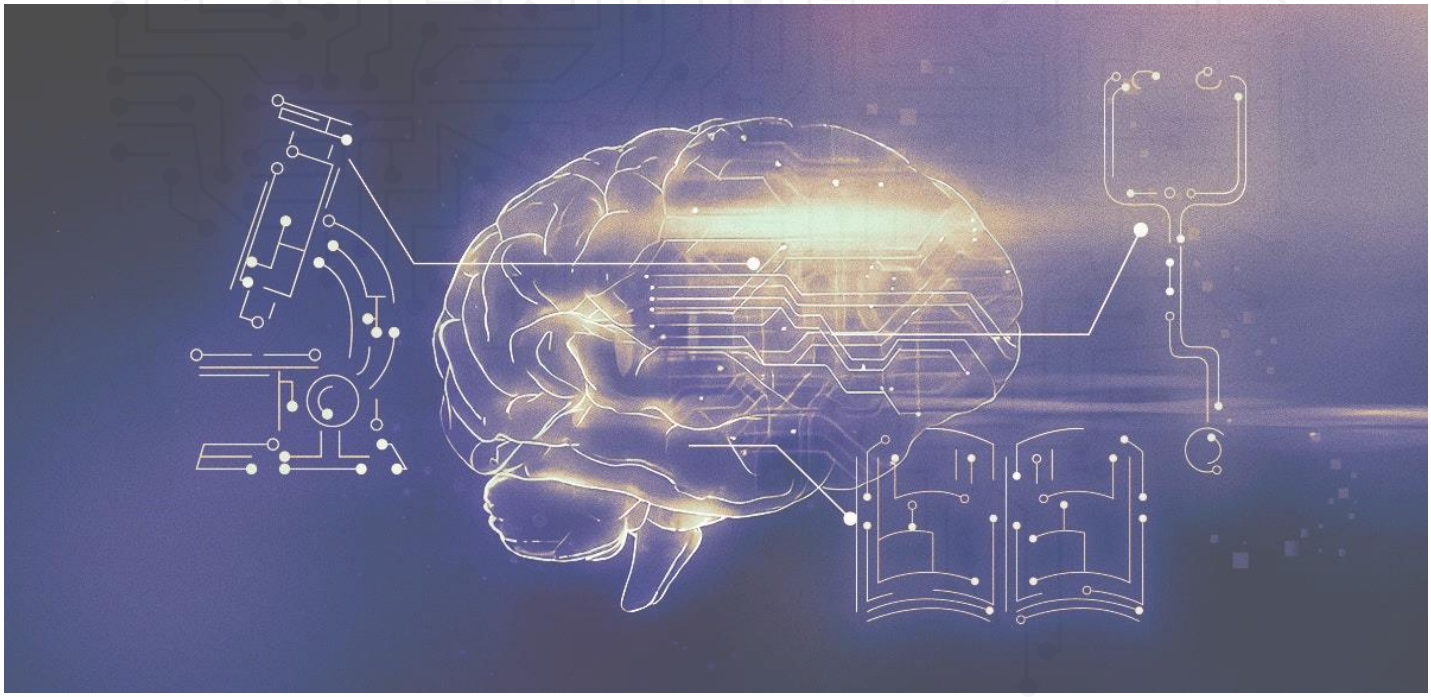
Capacity Building for Inclusive AI:

- How can we develop inclusivity-focused AI curricula and training programs?
- What strategies can help build multidisciplinary teams with diverse perspectives?
- How can we improve AI/ML literacy among healthcare providers and policymakers?

Implementation and Best Practices:

- How can we develop comprehensive guidelines and assessment frameworks for inclusive AI in healthcare?
- What should standardised inclusivity impact assessment tools for AI healthcare applications look like?
- What should inclusivity-focused procurement policies for public health AI systems entail?
- How can we design targeted funding programs for inclusive AI research and startups addressing health disparities?
- What inclusivity considerations should be mandated in regulatory approval processes for AI-enabled medical devices?
- What are the best practices for community engagement in AI healthcare tool development?
- How can we create public datasets representative of India's diverse population to enable more inclusive AI training?
- How should multistakeholder working groups be structured to address specific inclusivity challenges?
- What should inclusivity modules in medical and public health curricula cover?

BRIEFING PAPER ON INDIA'S LEGAL AND POLICY LANDSCAPE FOR AI, INCLUSION, AND HEALTH-TECHNOLOGY



BRIEFING PAPER ON INDIA'S LEGAL AND POLICY LANDSCAPE FOR AI, INCLUSION, AND HEALTH-TECHNOLOGY

About the Author and Project Build

This Briefing Paper has been authored by Ikigai Law for Project BUILD.

Ikigai Law along with its project partners - India's NALSAR University of Law, Hyderabad and Australia's Centre for AI and Digital Ethics (CAIDE) at the University of Melbourne are executing this project.

Funded under the AICCTP grant by the Australian government, the objective of **Project BUILD: BUilding IncLusivity by Design in AI/ML Powered Healthtech** is to explore policy recommendations on building inclusive approaches to AI enabled healthcare. It has the potential to be a part of future collaboration between the two nations and help guide the conversation in the Asia Pacific region around AI and healthcare.

Ikigai Law is an award-winning public policy and law firm with a sharp focus on technology and innovation. The firm advises a wide range of stakeholders including the government, start-ups, industry associations, think thanks and multi-national companies. The firm is the project execution partner for Project BUILD.

I. EXECUTIVE SUMMARY

This Briefing Paper provides a comprehensive overview of the following key areas:

- The Indian healthcare system and the role of technology within it
- Legislation and regulatory bodies governing:
  - Healthcare delivery and products
  - Information technology
  - Matters related to inclusion
- The Indian government's approach to:
  - AI Governance and Adoption
  - AI applications in healthcare
  - AI's role in promoting inclusion
- Key issues for further study and discussion, based on the above healthcare, legal, policy, and governance landscape

The Briefing Paper serves as a foundation for identifying challenges in the governance and regulation of inclusivity within AI and healthcare. The issues will be examined by a cohort of experts, as part of "Project BUILD: Building Inclusivity by Design in AI/ML Powered Healthtech" (**Project BUILD**).

Project BUILD aims to - (a) articulate a clear definition of 'inclusivity' in the context of AI and healthcare; (b) identify the barriers to inclusivity and inclusive design; (c) explore mitigation strategies for overcoming barriers to inclusivity; (d) propose a high-level governance framework/best practices guide that can bring inclusivity in healthcare; and (e) foster policy and partnership discussions using actionable insights on inclusivity in AI in healthcare at the Indo-Aus bi-lateral level.

II. OVERVIEW OF INDIA'S HEALTHCARE SYSTEM

A. Structure of healthcare governance in India

1. Central vs. State responsibilities

India follows a quasi-federal system, with a federal – level government (**Union**) and state governments (**state**) for each state. The Constitution of India provides the Union government and state governments different subjects to regulate on.

- Healthcare is a state-subject (i.e., a subject that may be regulated differently across states in India).
- Both Union and state governments can make laws on medical education and the medical profession.[1]
- The Union government law prevails in the case of a conflict with a state government enacted law.[2]

[1] Entries 25 and 26, List III – Concurrent List, Seventh Schedule, Constitution of India.
[2] Article 254, Constitution of India.

- State governments can make laws for 'public health and sanitation; hospitals and dispensaries' in their state.[3]
- Therefore, while health is a state-subject, policies for integration of AI in healthcare can be driven at the central level by the Union government. National level autonomous bodies have been working over policies for integrating emerging technologies such as AI, ensuring standardized frameworks for cross-cutting issues of data protection, infrastructure, health and governance.

The right to health has been recognised by the Supreme Court of India, as part of the fundamental right to life enshrined in the Constitution of India.[4] By recognizing this, the Supreme Court has effectively mandated that healthcare, including its technological advancements, must be accessible and inclusive for all citizens. This underscores the importance of ensuring that AI-powered healthcare solutions are designed to be inclusive and accessible, aligning with the constitutional obligation to protect and promote the right to health for all Indians, regardless of their socio-economic status, disability, or other factors.

2. Healthcare system in India:

India has a mix of public and private healthcare facilities. Public healthcare facilities are typically government funded and comprise of government hospitals, Sub Health Centres, Primary Health Centres, and Community Health Centres. Both the Union and state government have various schemes for providing healthcare coverage for Indians based on their socio-economic status. For instance, the Pradhan Mantri Jan Arogya Yojana (**PM-JAY**) launched in 2018, is part of the Union government's mission to achieve universal health coverage in India. PM-JAY provides INR 5 lakhs per family per year for secondary and tertiary care hospitalization.[5]

B. Key Challenges and role of technology in Indian healthcare

The Indian healthcare system struggles with- (i) shortage of healthcare professionals; (ii) urban-rural disparities in accessing quality and affordable healthcare; (iii) health insurance coverage is limited; (iv) government funding to public health infrastructure is inadequate; and (v) inadequate infrastructure.[6] The role of technology in tackling some of these challenges has long been floated across government policy documents (see section VII of the Briefing Paper for a sampling of these policy documents). In January 2024, the Prime Minister of India, Shri Narendra Modi highlighted the role technology plays in providing equitable and affordable access to healthcare.[7]

[3] Entry 6, List II – State List, Seventh Schedule, Constitution of India.
[4] *Consumer Education and Research Centre v. Union of India* AIR 1995 SC 922.
[5] PMJAY.
[6] Kumar A. The Transformation of The Indian Healthcare System. Cureus. 2023 May 16;15(5):e39079. doi: 10.7759/cureus.39079. PMID: 37378105; PMCID: PMC10292032.
[7] Press Information Bureau, Revolutionizing Healthcare: Digital Innovations in India's Health Sector, 15 January 2024.

The Union government's reliance on technology for healthcare includes:

- *National digital health push:* The National Health Authority (**NHA**) rolled out India's flagship digital health drive, the Ayushman Bharat Digital Health Mission (**ABDM**) in 2020.[8] ABDM is aimed at creating digital highways to connect doctors, patients, hospitals and other relevant stakeholders,[9] to enhance access to healthcare. In May 2024, the Union Health Secretary, Shri. Apurva Chandra discussed further collaboration opportunities between the NHA and Google Research in AI/ML.[10] ABDM is covered in greater detail in III of this Briefing Paper.
- *Providing telemedicine:* In November 2019, prior to the COVID-19 pandemic, the Union Health Ministry launched "e-sanjeevani" for providing telemedicine.[11] In March 2022 the Union Health Ministry stated that the Health Informatics Group in the Centre for Development of Advanced Computing[12] was strengthening e-sanjeevani and that AI powered solutions were in the offing.[13]
- *COVID-19 management:* During the COVID-19 pandemic, the Union Health Ministry had employed a range of digital tools for healthcare including applications such as Aarogya Setu (for contact tracing)[14] and Co-WIN platform (for managing the national vaccination drive).[15] Similarly, the Union Health Ministry allowed online sale of medicines for continuity of care during the pandemic.[16]
- *National mental health service:* The National Tele-mental Health Programme (**NTMHP**) was announced in February 2022[17] and launched as the "Tele Mental Health Assistance and Networking Across States (**Tele-MANAS**)".[18] Tele-MANAS is being run jointly by the Union Health Ministry, National Institute of Mental Health & Neuro Sciences (**NIMHANS**) and International Institute of Information Technology-Bangalore (**IIIT-B**). Tele-MANAS is a two-tiered system. Tier 1 has state-level Tele-MANAS cells with trained counsellors and mental health specialists.[19] Tier 2 has specialists at the District Mental Health Programme or from medical colleges for

[8] National Digital Health Mission launched in 2020. See also the rebranding of the NDHM to ABDM and the ABDM's formal launch.
[9] National Health Authority, Ayushman Bharat Digital Health Mission, About the ABDM.
[10] Medianama, India to Enhance Digital Healthcare with Google's AI Tools via Ayushman Bharat Digital Mission, 29 May 2024
[11] Ministry of Health and Family Welfare, e-sanjeevani portal.
[12] C-DAC is the premier research and development society of the Department of Electronics and Information Technology under the Ministry of Electronics and Information Technology.
[13] Press Information Bureau, Health Ministry's flagship telemedicine service - "eSanjeevani" records 3 Crore tele-consultations, 25 March 2022.
[14] Aarogya Setu app.
[15] Co-WIN platform.
[16] CDSCO, Door step delivery notification, (March 2020).
[17] Economic Times, National Tele Mental Health programme to be launched, (01 February 2022).
[18] Press Information Bureau, Tele Mental Health Assistance and Networking Across States (Tele-MANAS) initiative launched on occasion of World Mental Health Day, 10 October 2022.
[19] Press Information Bureau, Tele Mental Health Assistance and Networking Across States (Tele-MANAS) initiative launched on occasion of World Mental Health Day, 10 October 2022.

physical consultation or e-sanjeevani for teleconsultation.[20] Tier 1 comprises state-level Tele-MANAS cells with trained counsellors and mental health specialists. Tier 2 will comprise specialists at District Mental Health Programme or medical college resources for physical consultation and/or e-Sanjeevani for audio-visual consultation.[21] The Union Health Ministry was also considering linking Tele-MANAS to the ABDM.[22] 36 states have set up 53 Tele-MANAS cells and commenced providing services as of July 2024. Over 11,76,000 calls have been handled on the helpline number.[23] Jammu and Kashmir was the first state to introduce an AI-powered chatbot in Tele-MANAS, in July 2023.[24]

The Union government is also shaping global use of digital public health through its leadership in launching the Global Initiative on Digital Health with the World Health Organisation[25] during its presidency of the Global Partnership on AI. The initiative is a platform to support implementation of the Global Strategy on Digital Health 2020–2025.

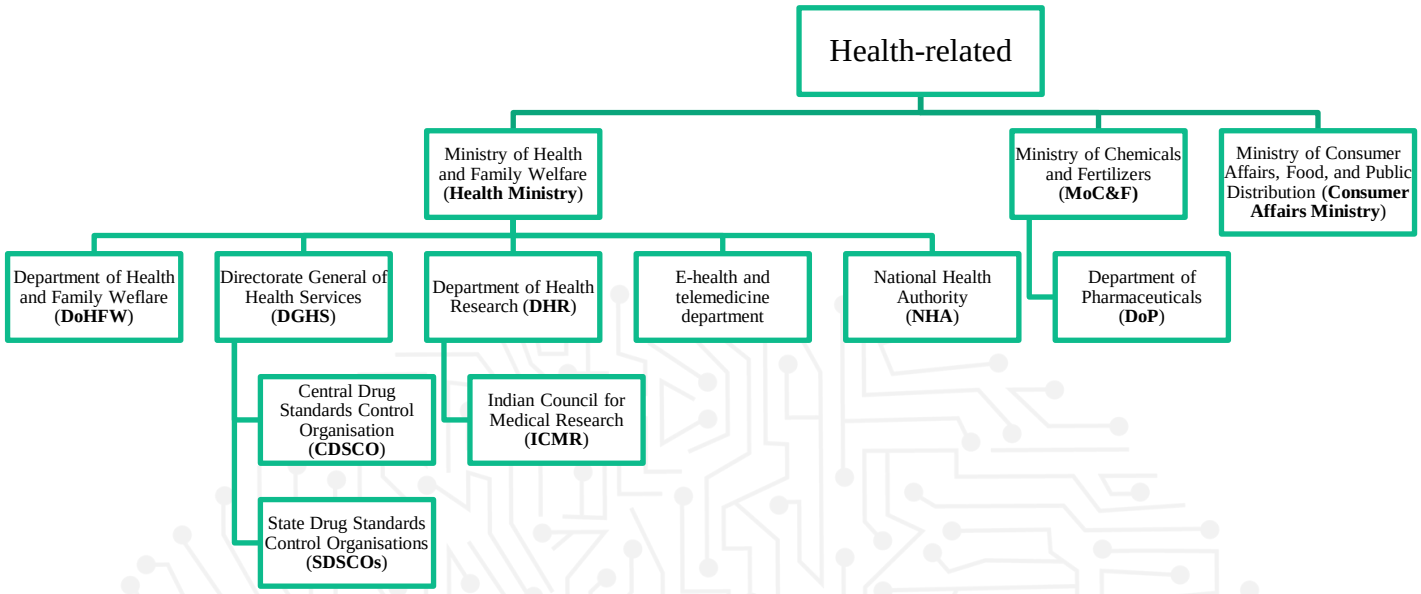
III. OVERVIEW OF HEALTH GOVERNANCE AND LAWS

This section provides a comprehensive snapshot of India's health governance framework and the legal landscape shaping healthcare delivery. The section first delves into the role of key government bodies such as the Ministry of Health and Family Welfare, including its key departments and bodies like the Department of Health and Family Welfare (**DoHFW**), the Directorate General of Health Services (**DGHS**), and the Central Drugs Standard Control Organisation (**CDSCO**). The section also discusses the Department of Health Research (**DHR**) along with its associated bodies like the Indian Council of Medical Research (**ICMR**), the E-health and Telemedicine department, and the National Health Authority (**NHA**). Additionally, the section covers allied ministries such as the Ministry of Chemicals and Fertilizers, particularly its Department of Pharmaceuticals (**DoP**), and the Ministry of Consumer Affairs, Food, and Public Distribution, with a focus on the Department of Consumer Affairs (**DoCA**) and the Bureau of Indian Standards (**BIS**).

The section further explores key healthcare laws such as the Medical Devices Rules 2017, the National Medical Commission Act 2019, the Telemedicine Practice Guidelines 2020, and patient protection laws under the Consumer Protection Act 2019.

[20] Press Information Bureau, Tele Mental Health Assistance and Networking Across States (Tele-MANAS) initiative launched on occasion of World Mental Health Day, 10 October 2022.
[21] Press Information Bureau, Tele Mental Health Assistance and Networking Across States (Tele-MANAS) initiative launched on occasion of World Mental Health Day, 10 October 2022.
[22] Press Information Bureau, Tele Mental Health Assistance and Networking Across States (Tele-MANAS) initiative launched on occasion of World Mental Health Day, 10 October 2022.
[23] Press Information Bureau, Steps Taken to Strengthen Mental Healthcare Services, 9 August 2024.
[24] The Hindu Bureau, J&K launches India's first chatbot for people in mental distress, July 2023.
[25] WHO launches a new Global Initiative on Digital Health supported by the G20 Presidency (19 August 2023)..

A. Health governance:



1. Ministry of Health and Family Welfare

Department of Health and Family Welfare (DoHFW): The department coordinates implementation of public health schemes and programmes with state governments. It also serves as a technical knowledge hub and plays a crucial role in enhancing India's healthcare infrastructure and policy implementation. Programmes include the National Mental Health Programme,[26] whose digital arm is the Tele Mental Health Assistance and Networking Across States (**Tele-MANAS**).[27] The DoHFW also oversees implementation of the Mental Healthcare Act 2017.[28] In 2023, the Health Ministry notified India's legislative body, the Union Parliament, that AIIMS Delhi, PGIMER Chandigarh and AIIMS Rishikesh (government hospitals) were designated as Centre of Excellence for Artificial Intelligence to promote creation and use of AI based solutions in health.[29]

2. Directorate General of Health Services (DGHS)

Central Drug Standards Control Organisation of India (CDSCO): The CDSCO functions under the DGHS[30] and implements the Drugs and Cosmetics Act 1940 (**DCA**) and Medical Devices Rules 2017. It sets standards, evaluates, licenses, and conducts post-market surveillance, ensuring the safety and efficacy of medical devices and drugs.[31]

[26] DoHFW work allocation, (accessed 26 February 2024).
[27] Tele-MANAS operational guidelines, (accessed 26 February 2024).
[28] DoHFW website on the National Mental Health Programme and the Mental Healthcare (Central Mental Authority and Mental Health Review Boards) Rules 2018, (accessed 26 February 2024).
[29] Press Information Bureau of India, AIIMS Delhi, PGIMER Chandigarh and AIIMS Rishikesh as Centre of Excellence for Artificial Intelligence (17 March 2024).
[30] CDSCO website, functions, (accessed 26 February 2024).
[31] CDSCO website, (accessed 9 February 2024).

The CDSCO[32] has adopted various digital initiatives to aid its activities and support the medical devices ecosystem. For example, the CDSCO has jointly launched MedTech Mitra an online portal for MedTech startups to get end-to-end regulatory support.[33] The CDSCO coordinates with State Drugs Standards Control Organisations across India for implementation of the DCA.

3. Department of Health Research (DHR)

DHR fosters health research, product translation, and public-private synergy, aiming to advance modern health technologies through innovation in diagnostics, treatment, and preventive vaccines.[34] The department has signed an agreement for a project collaboration with the World Health Organisation in 2022 to promote access to high-quality affordable assistive technology mainly through fostering research, innovation, and capacity building.[35]

i. **Indian Council for Medical Research (ICMR):** ICMR promotes biomedical research to address public health challenges, playing a pivotal role in India's healthcare research landscape.[36] It sets standards for ethical biomedical and health research,[37] including where AI is used.[38]

ii. **E-health and telemedicine department:** This department spearheads the integration of technology in public health,[39] promoting digital health initiatives like eSanjeevani for telemedicine,[40] and enhancing healthcare accessibility, especially in remote areas. Initiatives like the Online Registration System (to provide online access to hospital services for patients, integrated with Ayushman Bharat Health Account)[41] and 'Mera Aspataal' (an IT-based feedback application) highlight its commitment to achieving Universal Health Coverage.[42]

iii. **National Health Authority (NHA):** The NHA drives the implementation of the Ayushman Bharat Digital Health Mission (**ABDM**), a digital infrastructure mission to enhance adoption of digital healthcare.[43] Under the ABDM, individuals are given a unique health ID (ABHA ID), that is linked to their electronic health records. The ABDM also has registries for healthcare professionals and facilities and wants to

[32] CDSCO Notice on software as medical device (accessed 9 February 2024).
[33] Business Standard, Sanket Kaul, MedTech Mitra: Health minister launches online portal for medtech startups (accessed 9 February 2024). See the MedTech Mitra portal here.
[34] DHR website, (accessed 9 February 2024).
[35] Economic Times, Union Cabinet approves collaboration between Department of Health Research, WHO on assistive technology, (accessed 9 February 2024).
[36] ICMR website (accessed 9 February 2024).
[37] ICMR, National Ethical Guidelines For Biomedical And Health Research Involving Human Participants, 2017.
[38] Indian Council of Medical Research, Ethical Guidelines for Artificial Intelligence in Healthcare (2023), (accessed 9 February 2024).
[39] Telemedicine Practice Guidelines 2020, (accessed 9 February 2024).
[40] E-sanjeevani, (accessed 9 February 2024).
[41] Online Registration System (accessed 9 February 2024).
[42] E-health and telemedicine department website, (accessed 9 February 2024).
[43] NHA website, (accessed 9 February 2024).

enable health information exchange and consent management through a 'unified health interface'. The NHA operates a sandbox for healthtech tools to integrate into the ABDM and encourages participation through the Digital Health Incentives Scheme.[44] NHA has also launched 100 microsites to offer ABDM-enabled digital health services to patients.[45] The NHA runs India's health insurance scheme, the Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana (**AB-PMJAY**), where it uses AI/ML to detect fraud (e.g., suspicious transactions).[46] The NHA periodically releases papers about the ABDM's various features and building blocks to get public feedback. In its Consultation Paper on the Unified Health Interface, NHA discusses the use of health bots to support patients in their care management. The bot could look at their medical history, send reminders, support their doctors to provide chronic care, and provide advice based on the patient's trends.[47] In February 2022, Shri. Dr. R. S. Sharma, the former Chief Executive Officer of the NHA noted that AI technologies will be provided to health providers as a software as a service, through the ABDM.[48]

4. Ministry of Chemicals and Fertilizers (MoC&F)

i. **Department of Pharmaceuticals (DoP):** DoP oversees the pricing, availability of medicines, IP protection, and adheres to international commitments, playing a crucial role in the pharmaceutical sector's regulation and development.[49] It launched the Strengthening of Pharmaceutical Industry scheme (**SPI Scheme**) with a focus on enhancing infrastructure and innovation with a budget of INR 5 billion.[50] Initiatives like the Scheme for Promotion of Research and Innovation in the Pharma and Medtech Sector (**PRIP**)[51] and the National Medical Device Policy, 2023,[52] underline DoP's commitment to creating an ecosystem conducive to the growth of healthtech innovations. The PRIP scheme has various components that the government will use to encourage the MedTech sector, including evaluating startups with academia-industry linkages favourably for funding.

[44] The Hindu Bureau, National Health Authority announces extension of its Digital Health Incentives Scheme till December 31, 2023 (accessed 9 February 2024).
[45] Live Mint, NHA launches 100 microsites project to accelerate digital health adoption (accessed 9 February 2024). See also ABDM Microsite page for operational guidelines and a dashboard with a sampling of the work so far.
[46] Press Information Bureau, Use of AI for checking frauds under AB-PMJAY, (accessed 9 February 2024).
[47] National Health Authority, Consultation Paper on the Unified Health Interface, see the table in para 3.7 (Re-Thinking Digital Health Services with UHI), at p.24
[48] Medianama, Anushka Jain, AI to be deployed through Ayushman Bharat, RS Sharma reveals in post-budget webinar, March 2022.
[49] DoP website, (accessed 9 February 2024).
[50] SPI Scheme, (accessed 9 February 2024).
[51] PRIP Scheme, accessed (9 February 2024)
[52] National Medical Devices Policy 2023, (accessed 9 February 2024)

5. Ministry of Consumer Affairs, Food, and Public Distribution (Consumer Affairs Ministry)

i. **Department of Consumer Affairs (DoCA):** DoCA, established to bolster the consumer movement in India, oversees consumer cooperatives, price monitoring, and ensures the availability of essential commodities while administering policies and controlling statutory bodies like Bureau of Indian Standards.[53] In recent years, the Bureau of Indian Standards has adopted and worked on international standards for AI, such as the *Process Management Framework for Big Data Analytics*[54], the *Overview of Computational Approaches for AI Systems*[55], the *Governance Implications of AI Use by Organizations*[56], and the *Overview of Ethical and Societal Concerns*.[57] The proactive engagement of DoCA is also exemplified by the 2023 workshop on "Artificial Intelligence and Consumers," to explore issues around safeguarding consumer interests while reaping the benefits of AI.[58]

B. Healthcare laws:

1. Medical devices

Hardware and software medical devices are regulated under the Medical Devices Rules 2017 (**MDR**) by the CDSCO. The MDR classifies medical devices based on risk and regulates their manufacture, import, and sale based on that risk.[59] Together, the CDSCO and state drugs regulators exercise oversight on the quality of medical devices by- (a) granting licenses for the clinical investigation, import, sale, and manufacturing of medical devices;[60] (b) inspecting medical devices manufacturing and testing facilities;[61] and (c) post-market surveillance[62] and standard setting for medical devices regulation.

- ***Standalone software as medical device*:** In February 2020, the CDSCO expanded the definition of 'medical devices' to include software components and software using medical devices.[63] The CDSCO has also risk classified 60 software functions as medical devices[64] (e.g., computerized behavioural therapy device for psychiatric disorders - which is a software downloaded on a mobile phone).[65] Software

[53] DoCA website, (accessed 9 February 2024).
[54] IS/ISO/IEC 24668:2022.
[55] IS/ISO/IEC/TR 24372:2021.
[56] IS/ISO/IEC 38507:2022.
[57] IS/ISO/IEC/TR 24368:2022.
[58] Press Information Bureau, Artificial Intelligence to be harnessed to safeguard the interests of consumers: Secretary, Department of Consumer Affairs, (accessed 9 February 2024).
[59] Rules 8(1) and (2), MDR.
[60] Rules 8(1) and (2), MDR.
[61] Rules 42, 56(m), and 70, MDR.
[62] Rule 3(zl), MDR.
[63] S.O.E.648(E), 11 February 2020. See here for the expanded definition.
[64] See list here.
[65] Computerized behavioural therapy device for psychiatric disorders is a Class C medical device as per the CDSCO notice. It is a device intended to provide cognitive behavioural therapy to treat substance use disorder. The device is a software-based mobile app downloaded onto a smartphone.

functioning as medical devices will be 'validated'[66] before being approved by the CDSCO or state drugs authorities.

- ***Essential Principles for safety and performance of medical devices guidelines' 2018*:** The guidelines lay out principles for safety and efficacy of software components and standalone software.[67] They include (a) repeatability, reliability, and performance based on the intended use of the software; and (b) using principles of development lifecycle, risk management, verification, and validation of software.[68] The guidelines aid in licensing and approval processes of the CDSCO/ state drug authorities (depending on the risk classification of the software medical device).

2. Healthcare professionals:

- ***The National Medical Commission Act, 2019 (NMC 2019)*:** The NMC 2019 regulates the study and practice of medicine by "registered medical practitioners" (i.e., doctors). It creates a National Medical Commission (**NMC**) and State Medical Councils (**SMC**). The NMC oversees the Telemedicine Practice Guidelines 2020 which aims to facilitate telemedicine in India.

- ***Telemedicine Practice Guidelines 2020 (TPG)*:**
  - *Doctors' obligations*: Doctors can consult with patients remotely through text, audio call, email, and video.[69] Appropriateness of remote consultation is left to the doctor's judgement on a case-by-case bases.[70] Remote consultation in emergencies is excluded.[71] Doctors need to maintain records of the consultation provided,[72] and they cannot prescribe drugs and narcotics under Schedule X of the Drugs and Cosmetics Act, 1940.[73]
  - *Technology platforms obligations*: Such platforms need to (a) conduct due diligence before listing any RMP on its platform;[74] (b) notify the Board of Governors in the event of non-compliance by an RMP;[75] and (c) establish mechanism for grievance redressal.[76] Technology platforms that do not abide by the TPG can be blacklisted.[77]

[66] First Schedule, Part I (iii), MDR.
[67] Para 5.8 of the Essential Principles for safety and performance of medical devices guidelines,19 April 2018.
[68] Para 5.8 of the Essential Principles for safety and performance of medical devices guidelines,19 April 2018.
[69] Chapter II, technology used and modes of communication, TPG, at p.14-15.
[70] Para 3.1.1., TPG, at p. 16.
[71] Para 4.5., TPG, at p. 32.
[72] Para 3.5.1. TPG, at p. 18.
[73] Para 3.7.1., 'Prohibited List', TPG, at p. 20-21.
[74] Para 5.2., TPG, at p. 33.
[75] Para 5.3., TPG, at p. 33.
[76] Para 5.6., TPG, at p. 33.
[77] Para 5.7., TPG, 2020, at p. 33.

- *Use of AI/ML*: Doctors can use new technologies to assist them with patient evaluation and diagnosis. However, the doctor provides the final diagnosis/ prescription.[78]

3. Patient protections:

The Consumer Protection Act, 2019 (**CPA 2019**) protects consumers' interests by enabling their grievance redressal for goods and services they purchase.

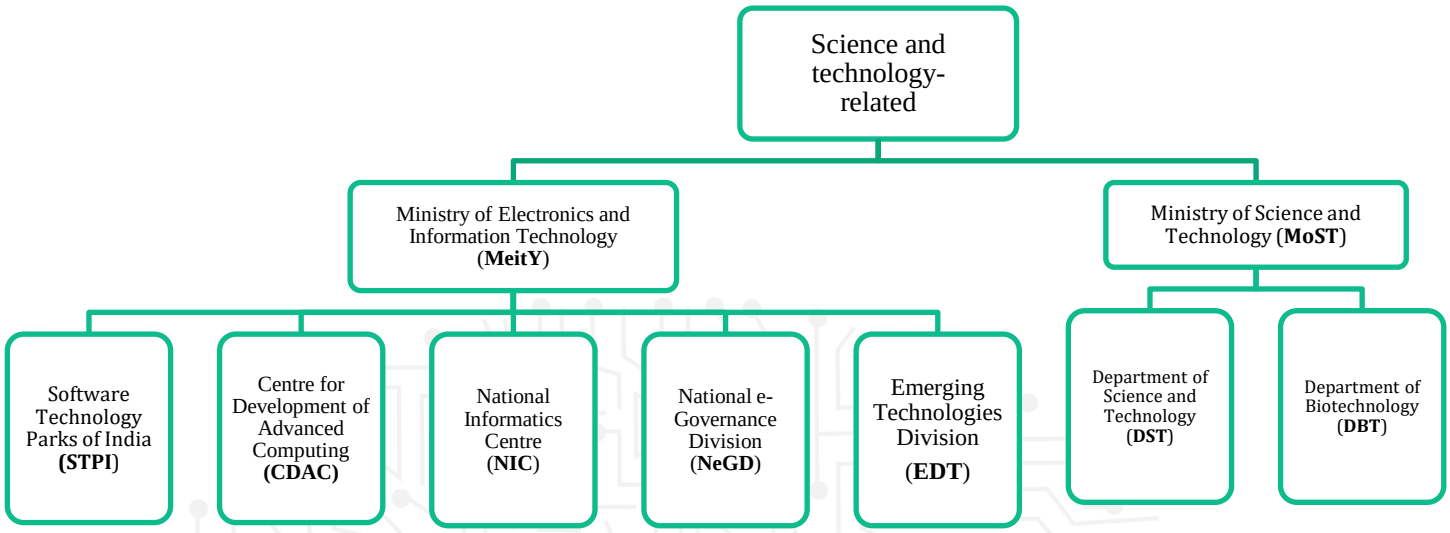
- ***Goods:*** It imposes product liability on manufacturers,[79] sellers,[80] and product service providers[81] even in the absence of fault or negligence. No-fault liability provision of the CPA 2019 may be applicable on manufacturers of medical devices, including hardware supporting AI/ML functions and assistive devices.
- ***Services:*** The consumer can file a complaint against deficiency of services[82] which includes negligence resulting in harm and withholding relevant information.[83] Healthcare services provided by doctors come under the purview of the CPA 2019.[84]

IV. Overview of Science and Technology Governance and Laws

This section provides a comprehensive overview of the key government ministries, departments, and autonomous bodies responsible for governing science and technology in India, with a particular focus on emerging technologies like AI. It outlines the roles and initiatives of crucial entities such as the Ministry of Electronics and Information Technology (**MeitY**) and the Ministry of Science and Technology (**MoST**), along with their various divisions and affiliated organizations. Additionally, it summarizes relevant technology laws, including data privacy regulations and intermediary liability rules, that shape the regulatory landscape for digital innovations in healthcare and other sectors. The section also highlights autonomous bodies like the Bureau of Indian Standards (**BIS**) and NITI Aayog, which play significant roles in policy-making, standard-setting, and fostering innovation in the intersection of technology and healthcare.

[78] Para 5.4., TPG, at p. 33.
[79] Section 84, CPA 2019.
[80] Section 86, CPA 2019.
[81] Section 85, CPA 2019.
[82] Section 2(6)(iii), CPA 2019.
[83] Section 2(11)(i) and (ii), CPA 2019.
[84] Medicos Legal Action Group v Union of India| SLP (Civil) 19374/2021.

A. Science and technology governance:



1. Ministry of Electronics and Information Technology (MeitY)

i. **Emerging Technologies Division (ETD):** ETD leads policy development for AI/ML, VR, blockchain, and IoTs, is crucial in sculpting India's digital landscape, and has established the Centre of Excellence on Virtual & Augmented Reality (**VARCoE**) at IIT Bhubaneswar to propel VR/AR innovation.[85] Additionally, the National Program on Artificial Intelligence (**IndiaAI Program**) is also under them and one of its pillars includes AI ethics and governance among others. Hence, the department pushes to ensure ethical, secure, and responsible use of emerging technologies. MeitY set up working groups under the IndiaAI Program (covered in section VII of the Briefing Paper) which recommended setting up centres of excellence in sectors like health, education and agriculture in a report on encouraging AI in India (2023).[86] In her Union Budget Announcement 2023-24, the Finance Minister of India announced the setting up of three centres for excellence for "Make AI in India and Make AI Work for India"[87] Later in 2023, the Ministry of Education and the Indian Institute of Technology Jammu (**IIT Jammu**) floated a call for proposals for higher education institutions to set up the centres of excellence (**CoEs**). In Phase 1, 11 institutions participated (**Cohorts**) with the intention of being shortlisted to establish CoEs in healthcare, agriculture, or sustainable cities.[88] In April 2024, IIT-Jammu announced that the 11 Cohorts had progressed in Phase 1 to show proof of concept of setting up the CoEs.[89] Phase 1 ended in September 2024.[90]

[85] ETD website, (accessed 9 February 2024).
[86] MeitY, IndiaAI 2023: First Edition by Expert Group.
[87] Para 60, Union Budget Announcement Speech 2023-24, 1 February 2023.
[88] Ministry of Education, AICoE, Call for Proposals.
[89] Indian Institute of Technology, Jammu's LinkedIn announcement.
[90] Indian Institute of Technology, Jammu's LinkedIn announcement.

ii. **National Informatics Centre (NIC):** The NIC is the technology partner of the union and state governments,[91] developing key government dashboards and portals,[92] including public health initiatives like 'e-Hospital' and the 'National Health Mission.[93]

iii. **National e-Governance Division (NeGD):** NeGD is tasked with implementing the Digital India Programpme,[94] along with developing and managing key digital platforms like the IndiaAI[95], DigiLocker[96], UMANG[97], and the National AI Portal[98], enhancing India's digital infrastructure.[99]

iv. **Centre for Development of Advanced Computing (CDAC):** CDAC, a premier R&D organization under MeitY, specializes in AI, focusing on sectors like health, education, and agriculture.[100] The recent transfer of three indigenously developed technologies to 12 industries in India, highlights CDAC's capability in bridging research and practical application, ensuring that innovative solutions reach the market and contribute to societal advancement.[101]

v. **Software Technology Parks of India (STPI**): STPI, established to promote software exports from India,[102] has evolved to establish Centres of Excellence focusing on AI/ML, computer vision, and automation across various sectors.[103] Recently, STPI launched a three-month incubation programme aimed at identifying and nurturing tech startups looking to scale,[104] diversify their product range, or expand to new geographies.

2. Ministry of Science and Technology (MoST)

i. **Department of Science and Technology (DST):** DST, dedicated to making India a global leader in science and technology, significantly promotes scientific research and innovation across the country.[105] The Technology Interventions for Disabled and Elderly (**TIDE**) program by DST, focusing on inclusiveness for the elderly and disabled,[106] offers funding for assistive technology R&D and initiatives that enhance daily life.

ii. **Department of Biotechnology (DBT):** DBT plays a critical role in healthcare, focusing on biomedical sciences, health and wellness initiatives, and biotechnology applications, including significant contributions to vaccine research and development

[91] NIC website, (accessed 26 February 2024).
[92] NIC website, (accessed 9 February 2024).
[93] NIC projects, (accessed 9 February 2024).
[94] Emerging Technologies Division, AI and Emerging Technologies Group, India AI Mission.
[95] IndiaAI website, (accessed 9 February 2024).
[96] DigiLocker website, (accessed 9 February 2024).
[97] UMANG portal, (accessed 9 February 2024).
[98] IndiaAI website, (accessed 9 February 2024).
[99] NeGD website, (accessed 9 February 2024).
[100] CDAC website, (accessed 9 February 2024).
[101] Press Information Bureau, Three indigenous developed technologies transferred to Industries as a step towards innovation, science and technology theme of Vikshit Bharat @2047, (accessed 9 February 2024).
[102] STPI website, (accessed 9 February 2024).
[103] STPI website, (accessed 9 February 2024).
[104] See here for more, (accessed 9 February 2024).
[105] DST website, (accessed 9 February 2024).
[106] DST programmes, accessed 9 February 2024.

and regulatory oversight in healthcare biotechnology.[107] The DBT also oversees collaborative research funds like the Indo-Australian Biotechnology Fund (**IABF**).[108]

B. Technology laws

1. Data privacy:

India enacted the Digital Personal Data Protection Act 2023 (DPDP) to protect individuals' personal data while also allowing for lawful processing of that data.

- ***What does the DPDP regulate?*** It regulates the processing[109] of digital personal data[110] (i.e., personal data about an individual that can identify them including usage or profiling data).[111]
- ***Whom does the DPDP apply to?*** The law applies to data fiduciaries (i.e., businesses/ government bodies that determine the process and means of processing personal data)[112] and data processors (i.e., businesses that process personal data based on the instructions of the data fiduciary).[113] MeitY is empowered to classify data fiduciaries as 'significant data fiduciaries' (**SDF**),[114] based on criteria including the volume and sensitivity of the personal data being processed.[115] It is possible that health data may be considered for its volume and sensitivity, and businesses processing health data could attract an SDF classification.
- ***How can businesses/ government process personal data?*** Businesses wishing to process an individual's personal data must provide certain information (i.e., notice) to the individual either before or while asking for their consent.[116] The information required for notice are-[117] (a) what personal data is needed and the purpose for which the data will be processed (e.g., electronic health records of the individual to provide healthcare); (b) how the individual can exercise their rights under the DPDP; and (c) how the individual can complain to the Data Protection Board set up under the DPDP.
- ***What are the exemptions?*** The government can be exempt from application of certain parts of the DPDP.[118] There are 'legitimate use cases'[119] where companies/

[107] DBT website, accessed 9 February 2024.
[108] DBT, Revised IABF Round 15 (Government of India 2021), (accessed 9 February 2024).
[109] Section 2(x) "processing" in relation to personal data, means a wholly or partly automated operation or set of operations performed on digital personal data, and includes operations such as collection, recording, organisation, structuring, storage, adaptation, retrieval, use, alignment or combination, indexing, sharing, disclosure by transmission, dissemination or otherwise making available, restriction, erasure or destruction, DPDP.
[110] Section 2(n), DPDP.
[111] Section 2(t), DPDP.
[112] Section 2(i) - "Data Fiduciary" means any person who alone or in conjunction with other persons determines the purpose and means of processing of personal data. DPDP.
[113] Section 2(k), DPDP.
[114] Sections 2(z) and 10, DPDP.
[115] Section 10(1)(a), DPDP.
[116] Section 5(1), DPDP.
[117] Section 5(1), DPDP.
[118] Section 17, DPDP.
[119] Section 7, DPDP.

the government can process personal data without consent (e.g., to provide healthcare to the individual during an epidemic).

- ***What other obligations do businesses have?***
  - Business that are data fiduciaries[120] – they must adopt reasonable security safeguards and organisational and technical measures to comply with the DPDP. They must also report data breaches to the Data Protection Board and the affected individuals. And erase personal data if the individual withdraws consent or when the purpose the data was collected for is met. Finally, they can contract with other businesses to aid in the processing of the personal data (i.e., data processors).
  - Businesses that are classified SDF[121] – Along with complying with the obligation of data fiduciaries, SDFs must also appoint a data protection officer based in India, appoint an independent auditor to conduct periodic audits, and carry out data protection impact assessments periodically.
  - The DPDP provides penalties for non-compliance as high as INR 2.5 billion.[122]
- ***What rights do individuals have?*** Individuals providing personal data (i.e., data principals)[123] have the rights to- (a) access information about their personal data (e.g., a summary of how it is used);[124] (b) correct, completion, updating and erasure of their personal data;[125] (c) grievance redressal;[126] and (d) nominate a person to exercise their rights if they die or become incapacitated.[127]

2. Intermediary liability

- ***Information Technology Act, 2000 (IT Act)*:** The IT Act regulates electronic communication and commerce. Technology platforms enabling telemedicine, may be considered as 'intermediaries'. Such platforms will have additional obligations to avoid intermediary liability.[128] These obligations include:
  - Due diligence obligations- The Information Technology (Intermediary Guidelines and Digital Media Ethics) Rules, 2021 (**IT Rules**) lists various obligations for intermediaries including publishing privacy policies and terms of use;[129] informing users (e.g., doctors) to publish certain kinds of content;[130] having grievance redressal mechanisms;[131] and reporting cyber incidents to the 'Indian Computer Emergency Response Team'.[132]

[120] Section 8, DPDP.
[121] Section 10, DPDP.
[122] Section 33 read with the Schedule of the DPDP.
[123] Section 2(j), DPDP.
[124] Section 11, DPDP.
[125] Section 12, DPDP.
[126] Section 13, DPDP.
[127] Section 14, DPDP.
[128] S. 79-A, Information Technology Act, 2000.
[129] Rule 3(1)(a), IT Rules.
[130] Rule 3(1)(b), IT Rules.
[131] Rule 3(2), IT Rules.
[132] Rule 3(1)(l), IT Rules.

- Content takedown obligations- The IT Rules require intermediaries to adhere to requests to take down content from the Union government[133] and ensure that such telemedicine technology providers do not knowingly transmit certain kinds of content (e.g., sexually explicit content).[134]

The Indian government is currently working to modernize its technology regulations, with efforts focused on updating the 25-year-old IT Act to address challenges posed by rapid technological advancements, particularly in artificial intelligence. For the past four years, the Union government has been working on the Digital India Bill (**DIB**), a comprehensive piece of legislation aimed at addressing these new challenges. However, recent reports indicate that the DIB may face further delays. MeitY is reportedly considering an alternative approach: introducing smaller, issue-specific legislations instead of a complete overhaul of the tech regulatory framework. In the interim, however, MeitY has issued advisories[135] on AI, providing guidance on AI-generated content (e.g., such as labelling of AI-generated content and consent-popups for informing users on the possible biases or unreliable output),[136] and tackling deepfakes.[137] The first advisory by MeitY was issued targeting the growing concerns around misinformation from AI-deepfakes. The advisory mandated that intermediaries clearly communicated what was prohibited content, particularly those specified under the IT Rules. Largely flowing from Google's Gemini controversy, where inaccuracies and biases were observed in AI generated result,[138] MeitY issued another advisory on AI, asking for intermediaries and platforms to obtain approval from the government before launching AI products.[139] However, this advisory was replaced with another advisory by the government, wherein this requirement of government approval before launching AI products was removed.

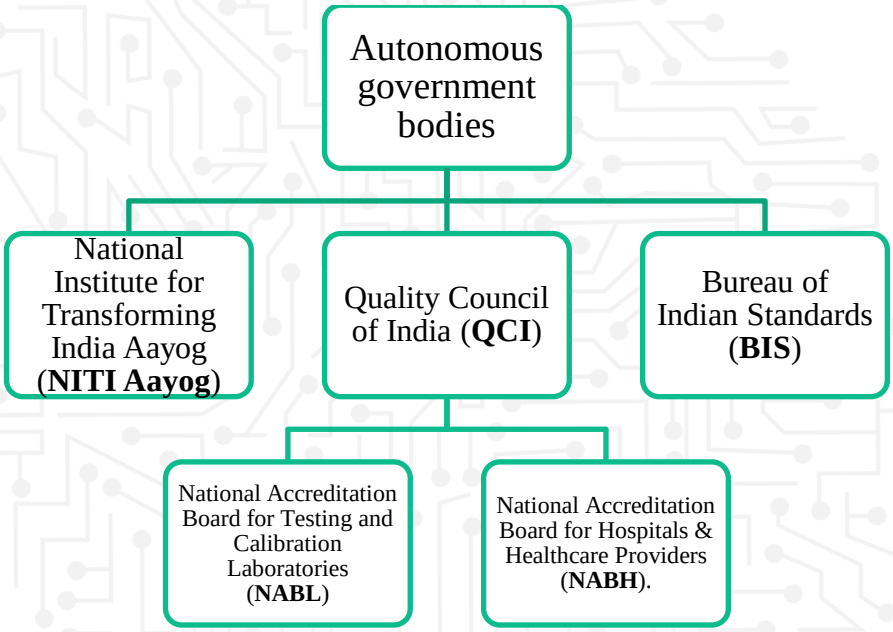
- ***Consumer Protection (E-Commerce) Rules, 2020 (E-Commerce Rules):*** It regulates digital platforms for electronic commerce, such as telemedicine platforms and health aggregating services. Nodal officers need to be appointed to ensure compliance with the rules[140] and establish a grievance redressal mechanism.[141] Further, sellers need to adhere to the E-Commerce Rules' disclosure requirements on quality, warranty etc.[142] The rules require mandatory disclosures under other

[133] Section 69A, Information Technology Act, 2000.
[134] Section 67, 67A, and 67B, Information Technology Act, 2000.
[135] eNo.2(4)/2023-CyberLaws-3, Government of India, MeitY, Cyber Laws and Data Governance Group, Due Diligence by Intermediaries/ Platforms under IT Rules 2021, 15 March 2024.
[136] *See* Ashutosh Mishra, MeitY's fresh advisory on AI does away with govt approval for AI platforms, Business Standard, 16 March 2024.
[137] No. 2(4)/2023-Cyber Laws – 2, Government of India, MeitY, Due Diligence by Intermediaries and Grievance Reporting Mechanism under IT Rules 2021, 26 December 2023.
[138] *See* Vasudha Mukherjee, Google apologises for Gemini results on PM, calls AI platform 'unreliable', Business Standard, 04 March 2024.
[139] *See* Ashutosh Mishra, MeitY's fresh advisory on AI does away with govt approval for AI platforms, Business Standard, 16 March 2024.
[140] Rule 4(1)(b), E-Commerce Rules.
[141] Rule 4(2)(d) and Rule 4(4), E-Commerce Rules.
[142] Rule 6(5)(g), E-Commerce Rules.

applicable laws must be made on the e-commerce platform. For example, telemedicine platforms or e-pharmacies must ensure that all requirements under the various healthcare laws, should be disclosed.[143]

V. OVERVIEW OF RELEVANT AUTONOMOUS GOVERNMENT BODIES:

This section provides an overview of the autonomous government bodies that play a role in policy making or standard setting for technology and/or healthcare sectors. These bodies, including the Bureau of Indian Standards, NITI Aayog, and the Quality Council of India, play crucial roles in shaping the policies on the development and implementation of emerging technologies, like AI.



1. Bureau of Indian Standards (BIS):

BIS is instrumental in standardization and quality control across various sectors, including healthcare products, ensuring the safety and efficacy of goods through rigorous standards and conformity assessments.[144] Initiatives like the Standards National Action Plan **(SNAP)** 2022-27 and collaborations with technical institutions for standardization in AI, can help get guidance on the specific standards applicable to AI/ML technologies in healthcare, including data privacy, interoperability, and device safety.[145] BIS has a specific technical department - Electronics and Information Technology Department (**LITD**), with the Artificial Intelligence Sectional Committee (**LITD 30**) under the department dedicated towards setting standards on AI. Recently, the Artificial Intelligence Sectional Committee has adopted and worked on international standards for AI, such as

[143] Rule 6(5)(c) of the E-commerce Rules.
[144] BIS website, accessed (9 February 2024).
[145] BIS SNAP, (accessed 9 February 2024).

the "Process Management Framework for Big Data Analytics",[146] providing guidelines for handling and analyzing large-scale data using AI systems; the "Overview of Computational Approaches for AI Systems",[147] outlining various computational methods used in AI, offering a comprehensive view of different approaches; the "Governance Implications of AI Use by Organizations",[148] addressing the broader governance and risk management issues AI introduces; and the "Overview of Ethical and Societal Concerns,"[149] delving into the ethical implications of AI adoption, emphasizing the need for responsible and socially aware AI deployment.

2. **National Institute for Transforming India Aayog (NITI Aayog):**

As the Indian government's premier think tank, NITI Aayog plays a pivotal role[150] in formulating policy initiatives, focusing on the integration of frontier technologies like AI across various sectors. This includes healthcare through initiatives like the Ayushman Bharat Digital Health Mission[151]. NITI Aayog[152] has also put forth policy documents namely- (a) National Strategy for AI, (b) Approach Document for India Part 1, Principles for Responsible AI, and (c) Approach Document for India Part 2, Responsible AI: operationalising principles for responsible AI, providing guidance on how AI use should be regulated and encouraged in India. (We discuss these policy documents in greater detail in the later sections of this paper.)

3. **Quality Council of India (QCI):**

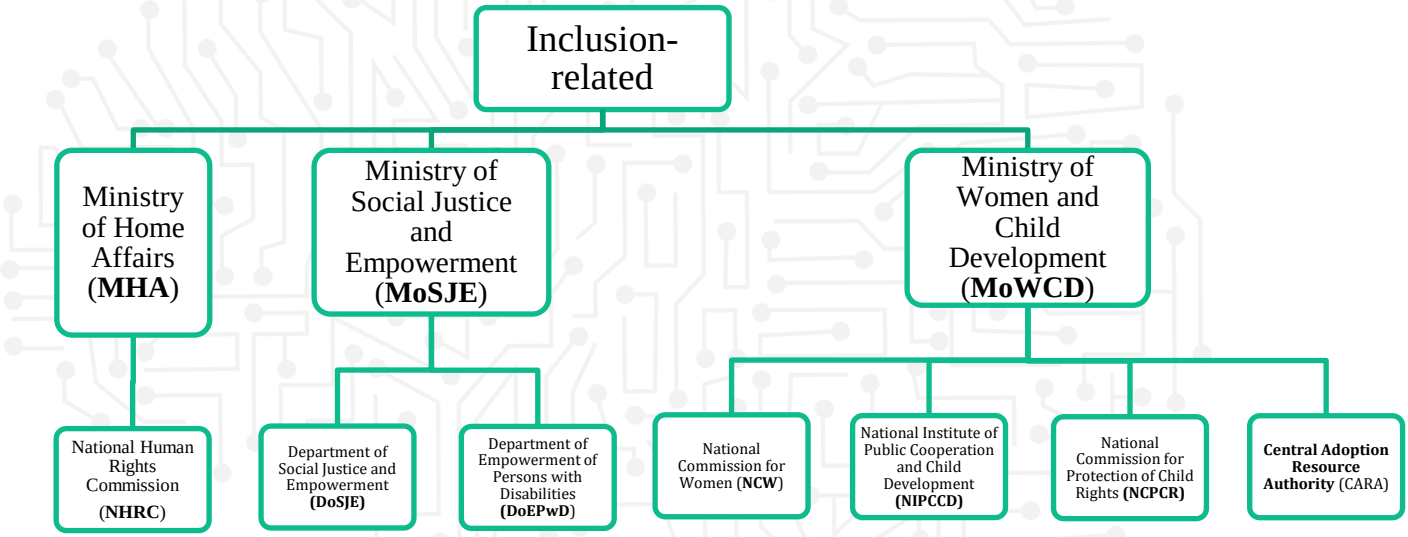
The National Accreditation Board for Testing and Calibration Laboratories (NABL), under the Quality Council of India (QCI), accredits testing and calibration laboratories across various fields, including medical and environmental, ensuring high standards of technical competence.[153] The National Accreditation Board for Hospitals & Healthcare Providers (NABH), also a part of the Quality Council of India, accredits healthcare organizations, setting benchmarks for the healthcare industry and addressing consumer needs through comprehensive assessment standards.[154] NABH released the Digital Health Standards for Hospitals 2023[155] which sets out standards (e.g., for privacy and security and patient safety) for quality digital health in hospitals. NABH will ensure hospitals adopting digital health are accredited based on those standards.

[146] IS/ISO/IEC 24668:2022.
[147] IS/ISO/IEC/TR 24372:2021.
[148] IS/ISO/IEC 38507:2022.
[149] IS/ISO/IEC/TR 24368:2022.
[150] NITI Aayog website, (accessed 9 February 2024).
[151] National Health Authority, National Digital Health Mission Strategy Overview, July 2020 – The National Digital Health Mission was rebranded to be called Ayushman Bharat Digital Health Mission in 2021.
[152] NITI Aayog, Principles for Responsible AI, (February 2021), and National Strategy for AI, (June 2018) .
[153] NABL website, (accessed 9 February 2024).
[154] NABH website, (accessed 9 February 2024).
[155] NABH Digital Health Standards for Hospitals 2023.

VI. OVERVIEW OF INCLUSION GOVERNANCE AND LAWS

This section provides an overview of key governance bodies and legal frameworks dedicated to promoting social inclusion and protecting the rights of marginalized groups, including persons with disabilities and women. The Ministry of Social Justice and Empowerment (**MoSJE**) and the Ministry of Women and Child Development (**MoWCD**) play pivotal roles in shaping inclusion policies, supported by bodies like the Department of Social Justice and Empowerment (**DoSJE**), Department of Empowerment of Persons with Disabilities (**DoEPwD**) and the National Commission for Women. This section delves into their functions and initiatives, providing an overview of the regulatory landscape regarding inclusion.

A. Inclusion governance:



1. Ministry of Social Justice and Empowerment (MoSJE)

i. **Department of Social Justice and Empowerment (DoSJE):** The department is tasked with empowering underprivileged sections including Scheduled Castes, Scheduled Tribes, Other Backward Classes, Economically Backward Classes, and various minority groups. This department implements crucial programs for social upliftment and inclusion.[156] The department recently launched the Purple Festival to celebrate and empower persons with disabilities and also discuss the importance of inclusivity.[157]

[156] DoSJE website, (accessed 9 February 2024).
[157] See here for more, (accessed 9 February 2024).

ii. **Department of Empowerment of Persons with Disabilities (DePWD**): The department is dedicated to the socio-economic development of persons with disabilities. The Office of the Chief Commissioner for Persons with Disabilities (**CCPD**)[158] has the powers of a civil court to exercise its functions. It can either on its own, or on being petitioned, take up matters of violation of the Rights of Persons with Disabilities Act 2016 and related rules/ guidelines. For example, in 2022, the CCPD ordered Practo, a health-tech platform to make its platform digitally accessible for persons with disabilities.[159]

2. Ministry of Women and Child Development (MoWCD)

i. **National Institute of Public Cooperation and Child Development (NIPCCD):** The NIPCCD is a central institution dedicated to research, training, and documentation[160] in the fields of women empowerment and child development.[161] Its key functions include conducting and sponsoring research on voluntary action and child development, reviewing national policies affecting children and women, and facilitating collaborations with other institutions and universities engaged in social development.[162] It also organizes training programs and workshops for government, corporate, and voluntary sector personnel working on women and child development.[163]

ii. **National Commission for Women (NCW):** NCW focuses on reviewing legal safeguards for women, recommending legislative measures, addressing grievances, and advising the government on policies affecting women, working towards their empowerment and improved status.[164] NCW has been in an active stakeholder in discussions involving the security of women in the digital space.[165]

iii. **National Commission for Protection of Child Rights (NCPCR):** NCPCR is a statutory body constituted under the Commission for Protection of Child Rights Act, 2005, tasked with ensuring the effective implementation of safeguards for child rights in India.[166] It examines laws and policies affecting children, inquiries into violations of child rights, and recommends necessary actions, addressing issues affecting children.[167]

iv. **Central Adoption Resource Authority (CARA):** The CARA is a statutory body set up in 1990 (i.e., functions according to the Juvenile Justice Act, 2015),[168] as the nodal body for adoption of children. CARA is designated as the Central Authority to deal with inter-country and in-country adoptions.[169]

[158] Section 74 of the RPwD. See here for more on the CCPD's predecessor.
[159] Read a summary of the order here.
[160] See Documentation Centre on Women and Children.
[161] See Objective, NIPCCD (accessed 03 October 2024).
[162] See Functions, NIPCCD (accessed 03 October 2024).
[163] See Functions, NIPCCD (accessed 03 October 2024).
[164] See here for more, (accessed 9 February 2024).
[165] See here for more, (accessed 9 February 2024).
[166] See About the Commission, NCPCR (accessed 03 October 2024).
[167] See Functions and Powers, NCPRC (accessed 03 October 2024).
[168] CARA Citizen Charter.
[169] See About CARA, CARA (accessed 03 October 2024) .

The MoWCD has also been pioneering initiatives in the domain of female child education and skilling, having launched initiatives in collaboration with the Ministry for Skill Development and Entrepreneurship for the skilling of women and children.[170] Recently, the MoWCD has been awarded the National e-Governance Award 2024 for its innovative Poshan Tracker initiative for monitoring the growth and nutritional health of millions of children.[171]

3. Ministry of Home Affairs (MHA)

i. **National Human Rights Commission (NHRC):** The NHRC is a statutory body constituted under the Protection of Human Rights (PHRA), 1993.[172] The NHRC is empowered to examine and investigate issues that affect human rights, makes recommendations on various policy issues surrounding human rights, and reviews different safeguards and mechanisms provided under the Constitution of India to protect human rights principles. The NHRC Chairperson looks into issues of business and human rights, rights of LGBTQI+ members' rights, right to mental health, right to privacy, digital space and human rights.[173] The NHRC held an event in 2022 on the impact of AI on persons with disabilities. Justice M.M Kumar[174], a former NHRC Member, noted that AI should leave no one behind, while acknowledging the various ways AI can help people with disabilities. Dr. Ben Gauntlett from the Australian Human Rights Commission also spoke at the event on the barriers to inclusion.[175] The NHRC has appointed a Special Monitor for Artificial Intelligence, wherein complaints around human rights issues related to AI can be specifically raised.[176]

B. Inclusion laws:

1. Disability rights

Scope: The Rights of Persons with Disabilities Act 2016 (**RPwD**) aims to protect and promote the rights of persons with disabilities (**PwD**),[177] and lists 'specified disabilities' such as multiple sclerosis, cerebral palsy, muscular dystrophy, visual and hearing impairments, speech and language disabilities, and mental illnesses such as autism

[170] See PIB, WCD Ministry partners with Ministry of Skill Development & Entrepreneurship for Skilling of Women & Children, 14 February 2020.
[171] See Ministry of Women and Child Development Wins National Award for e-Governance 2024 for Poshan Tracker Initiative, VoH.
[172] See About the Organisation, NHRC (accessed 08 October 2024).
[173] See Allocation of Subjects, NHRC (accessed 08 October 2024).
[174] See Justice Shri MM Kumar, NHRC (accessed 08 October 2024).
[175] See "Leave no one behind" says NHRC, NHRC (accessed 08 October 2024).
[176] See Dr. Muktesh Chander, NHRC (accessed 08 October 2024).
[177] Section 2(s) – 'person with disability' means a person with long term physical, mental, intellectual or sensory impairment which, in interaction with barriers, hinders his full and effective participation in society equally with others. RPwD.

spectrum disorder or specific learning disabilities.[178] The RPwD applies to both government and private establishments.[179]

Digital accessibility: The Union government is empowered to set standards of accessibility[180] and to take measures to ensure access to 'information and communication'[181] for PwDs.[182] The RPwD provides time limits for establishments to make their premises/ infrastructure (five years from the notification of rules)[183] and services (two years from the notification of rules)[184] accessible. The Rights of Persons with Disabilities Rules, 2017 made it mandatory for 'establishments' to comply with the digital accessibility standards set out by the central government for information and communication.[185] The Ministry of Information and Broadcasting (**MIB**) recently proposed the Broadcasting Services (Regulations) Bill 2023, which would empower the MIB to issue Accessibility Guidelines.[186] These Accessibility Guidelines could mandate measures such as supplementing video content with audio-descriptions for the blind, translating audio content into sign language (where appropriate), using applications which are accessible to persons with disabilities, etc.[187] Such regulatory proposals also promote greater accessibility of digital platforms and services for persons with disabilities.

2. Mental health

The Mental Healthcare Act 2017 (**MHA**) aims to provide mental healthcare[188] and services for people with mental illnesses[189] and protect their rights.[190] MHA protects rights of people living with mental illnesses including the right to (a) access mental health services funded by the government;[191] (b) equality and non-discrimination;[192] (c) protection from cruel inhuman and degrading treatment;[193] (d) access medical records;[194]

[178] Section 2(zc) read with the Schedule of the RPwD.
[179] Section 2(i) – definition of 'establishment' includes a Government establishment and private establishment - RPwD
[180] Section 40 of the RPwD.
[181] Section 2(n), RPwD.– "information and communication technology" includes all services and innovations relating to information and communication, including telecom services, web based services, electronic and print services, digital and virtual services.
[182] Section 42 of the RPwD.
[183] Section 45 of the RPwD.
[184] Section 46 of the RPwD.
[185] Rule 15, Rights of Persons with Disabilities Rules, 2017.
[186] Clause 23(1), Broadcasting Services (Regulations) Bill, 2023.
[187] Clause 23(2), Broadcasting Services (Regulations) Bill, 2023.
[188] Section 2(1)(o) "mental healthcare includes analysis and diagnosis of a person's mental condition and treatment as well as care and rehabilitation of such person for his mental illness or suspected mental illness." MHA.
[189] Section 2(1)(s) "mental illness means a substantial disorder of thinking, mood, perception, orientation or memory that grossly impairs judgment, behaviour, capacity to recognise reality or ability to meet the ordinary demands of life, mental conditions associated with the abuse of alcohol and drugs, but does not include mental retardation which is a condition of arrested or incomplete development of mind of a person, specially characterised by subnormality of intelligence." MHA.
[190] Preamble to the MHA.
[191] Section 18, MHA.
[192] Section 21, MHA.
[193] Section 20, MHA.
[194] Section 25, MHA.

and (e) make complaints about deficiencies in provision of services.[195] The MHA also sets up the Central Mental Health Authority,[196] which has various functions including maintaining a register of all mental health establishments, and national register of clinical psychologists, mental health nurses and psychiatric social workers in India.[197]

VII. OVERVIEW OF UNION GOVERNMENT POLICIES AND PAPERS ON AI REGULATION RELEVANT TO HEALTHCARE/ PERSONS WITH DISABILITIES

Since 2018, various government bodies have studied the Indian context to suggest ways to safely and ethically harness AI for social good (e.g., in sectors like healthcare). This section captures the Indian government's AI journey, both generally and with specific reference to healthcare or people with disabilities.

1. NITI Aayog's three papers on AI

NITI Aayog[198] has put forth policy documents on how AI use should be regulated and encouraged in India, namely- (a) National Strategy for AI (**2018 paper**); (b) 'Approach Document for India Part 1, Principles for Responsible AI' (**February 2021 paper**); (c) 'Approach Document for India Part 2, Responsible AI: operationalising principles for responsible AI' (**August 2021 paper**).

National Strategy for AI (**2018 paper**)	National Strategy for AI (**2018 paper**) identified five barriers to the growth of AI/ML use in India- (a) lack of expertise in research and use of AI; (b) absence of data ecosystems; (c) low public awareness and high resource cost for adoption of AI; (d) privacy and security related concerns; and (e) the lack of a collaborative approach for AI adoption and use. It proposed setting up Centre of Research Excellence or 'CORE' and International Centres of Transformational AI or 'ICTAI' to improve AI-related research in India. CORE would focus on improving AI understanding and research, while ICTAI would develop and deploy research.[199]
Approach Document for India Part 1, Principles for Responsible AI'	The paper identifies 'system considerations' such as privacy risks, security risks, and risks of exclusion of users of AI/ML tools. It also covers 'societal considerations', such as the impact of use of AI/ML on society, and job creation.[200] The paper invokes the fundamental rights listed in the Constitution of India, as the foundation for principles to

[195] Section 28, MHA.
[196] Section 33, MHA.
[197] Section 43, MHA.
[198] NITI Aayog, Principles for Responsible AI, (February 2021), and National Strategy for AI, (June 2018).
[199] NITI Aayog, National Strategy for AI, (June 2018), at p. 7-8.
[200] NITI Aayog, Principles for Responsible AI (February 2021).

(**February 2021 paper**):	guide the use of AI/ML in India.[201] And sets out seven guiding principles to guide the use and research in AI such as principles on:[202] (a) safety and reliability; (b) equality; (c) inclusivity and non-discrimination; (c) privacy and security; (d) transparency; (e) accountability; and (f) protection and reinforcement of positive human values (**RAI principles**).
Responsible AI: operationalizing principles for responsible AI (**August 2021 paper**):[203]	Operationalising the principles for responsible AI can be done through education, training, and various compliance mechanisms. For instance, for start-ups, the August 2021 paper suggests that assigning accountability to a member of the leadership team would help ensuring responsible AI use. Similarly, the August 2021 paper also suggested training and education on the RAI principles and leveraging.[204] It calls for 'ethics-by-design' which can be implemented by mandating the use of the RAI principles by public sector procurement. The paper suggests that the RAI principles will consequently permeate into the private sector's product and approaches.[205] The paper calls for setting up the Council for Ethics and Technology, to be an independent think-tank that interfaces with all ministries and departments.[206]

2. NHA's digital health blueprint (2019) and strategy (2020):

The ABDM is based on the health stack approach suggested in the NITI Aayog and Union Health Ministry's National Digital Health Blueprint (**NDHB 2019**)[207] and the National Digital Health Mission Strategy (**NDHMS 2020**).[208] The NDHB 2019, called for the creation of a Unified Health Communication Centre to be the single point of contact for managing public health emergencies, where AI/ML would be deployed.[209] The NDHB 2019 also called for the adoption of AI/ML and other emerging technologies as quickly as possible.[210] The NDHMS 2020 reiterates the need to adopt AI/ML for a holistic digital health ecosystem,[211] including for extraction of information from existing electronic health records.[212]

[201] NITI Aayog, Principles for Responsible AI (February 2021) at p. 38-39.
[202] NITI Aayog, Principles for Responsible AI (February 2021) at p. 41-42.
[203] NITI Aayog, Operationalising principles for Responsible AI (August 2021).
[204] NITI Aayog, Operationalising principles for Responsible AI (August 2021) at p. 27.
[205] Para 4.1.7., NITI Aayog, Operationalising principles for Responsible AI (August 2021), at p. 27.
[206] Para 3.52-3.55, NITI Aayog, Operationalising principles for Responsible AI (August 2021), at p. 22.
[207] Union Health Ministry, National Digital Health Blueprint.
[208] Union Health Ministry, National Health Authority, and the Ministry of Electronics and Information Technology, National Digital Health Mission Strategy Overview.
[209] Union Health Ministry, National Digital Health Blueprint at. p. 27.
[210] Union Health Ministry, National Digital Health Blueprint at p. 45.
[211] Union Health Ministry, National Health Authority, and the Ministry of Electronics and Information Technology, National Digital Health Mission Strategy Overview at p. 6.
[212] Union Health Ministry, National Health Authority, and the Ministry of Electronics and Information Technology, National Digital Health Mission Strategy Overview at p. 11.

3. MeitY's AI committees' four reports (2019):

In 2018, MeitY constituted four committees to promote AI and create a policy framework, namely- (a) Platform and data for AI; (b) Leveraging AI for identifying national missions in key sectors, (c) Mapping technological capabilities key policy enablers required across sectors, skilling and re-skilling R&D; and (d) Cyber security, safety, legal and ethical issues.[213] Relevant recommendations from the four committees are captured below (published in 2019):[214]

Report of Committee –A "on platform and data for AI" (**Committee A's Report**)	Relevant recommendations include- (a) creating an 'Open National Artificial Intelligence Resource Platform (**NAIRP**)' as a central hub for knowledge integration and dissemination in AI/ML; (b) Develop a generalized meta-data standard; (c) Create mechanisms for data and meta-data harvesting and integration across partners; (d) Encourage unbiased, reliable, safe, open by default, inclusive data sharing; (e) Conduct gap analysis to help stakeholders provide quality data; (f) create a technical committee to oversee NAIRP; (g) create a data monitoring committee for data standards; and (h) create ethical committee to monitor ethical aspects of NAIRP and their interplay with security, privacy and other laws.[215]
Report of Committee - B "on leveraging AI for identifying national missions in key sectors" (**Committee B's Report**)	AI can be used for problems that are important and are amenable to AI technology and calls for special attention in involving relevant sector stakeholders to develop the ecosystem.[216] For health, AI can be used for (a) identifying patterns (e.g., interaction between treatment and age or gender); (b) low cost MRI screening solutions; (c) prediction of disease outbreaks; (d) clinical decision support systems to support medical professionals in low resource settings (e.g., for better screening of patients); (d) micro planning to support health workers in their public health surveillance; (e) awareness campaigns through insight driven targeting; and (f) tracking and prediction for supply chain management.[217] For persons with disabilities, AI can be used to enhance quality of life by providing- (a) technology for access information and communication (ii) technology for mobility (iii) intelligent interface technologies to make persons with disabilities interact socially more easily and effectively; and (iv) technology for the education and training.[218] Committee B's Report suggested 'grand challenges' in sectors like health (e.g., an AI powered public health

[213] MeitY, Office Memorandum, Constitution of four Committees for promoting Artificial Intelligence (AI) initiatives and developing a policy framework (07.02.2018).
[214] MeitY, Artificial Intelligence Committee Reports (2019).
[215] Para 5, MeitY, Report of Committee – A "on platform and data for AI", at p. 14-16.
[216] Para 3, MeitY, Report of Committee - B "on leveraging AI for identifying national missions in key sectors", at p. 5-6.
[217] Para 4.3, MeitY, Report of Committee - B "on leveraging AI for identifying national missions in key sectors", at p. 8.
[218] Para 4.8, MeitY, Report of Committee - B "on leveraging AI for identifying national missions in key sectors", at p. 11.

	centre which supports screening and diagnostics, with doctors handling interventions such as child birth), and called for requests for proposals to solve these challenges.[219] Incubation of companies, technology transfer to established companies, and open software models for public companies to use.[220]
Report of Committee - C "on mapping technological capabilities key policy enablers required across sectors, skilling and re-skilling R&D" (**Committee C's Report**)	Called for creating a national AI strategy that builds four focus areas: (a) creation of a strong R&D foundation (e.g., technologies, Intellectual Property (IP) and algorithms created in India); (b) adoption of an application based mindset (e.g., link the problems and domains such as health with how AI can be harnessed); (c) leveraging startup ecosystem by providing tools and infrastructure; and (d) creating a pool of skilled AI developers and upskilling bureaucrats for making policies.[221] Committee C's Report provides the use of AI to improve nutrition outcomes in public health as an example- (a) Currently, Anganwadi workers (i.e., community health workers) have devices to input and track nutritional data from the World Bank; (b) AI can be used on that inputted data to identify patterns and classify patients based on risks to their health for targeted interventions; and (c) the Anganwadi workers can be trained and upskilled specific to their skill requirements.[222]
Report of Committee – D "on cyber security, safety, legal and ethical issues" (**Committee D's Report**)	Examines various safety and ethical considerations related to AI. On safety, Committee D's Report recommends- (a) Creating safety guidelines with relevant stakeholders in various domains and investing in interdisciplinary research to assess AI impact on society; (b) Creating domain specific safety thresholds; (c) Human involvement where human life is at stake or any other severe implications; (d) Domain specific safety certifications prior to public release of the AI; and (e) Ensuring periodic discussions on the threats of AI.[223] On ethics, Committee D's Report recommends- (a) Creating ethical guidelines with civil society and relevant stakeholders on issues like fairness, transparency, and accountability; (b) Invest in infrastructure (e.g., bias free data sets); (c) Create resources and mechanisms needed to test and certify ethical features; (c) Provide incentives for compliance with guidelines and certifications; (d) Empower the public by raising awareness.[224]

[219] Para 6.1, MeitY, Report of Committee - B "on leveraging AI for identifying national missions in key sectors", at p. 17.
[220] Para 6.2, MeitY, Report of Committee - B "on leveraging AI for identifying national missions in key sectors", at p. 18.
[221] Enablers and Focus Areas, MeitY, Report of Committee - C "on mapping technological capabilities key policy enablers required across sectors, skilling and re-skilling R&D" at p. 13-14.
[222] Annex 4: Use cases for AI in Public Health and Nutrition, MeitY, Report of Committee - C "on mapping technological capabilities key policy enablers required across sectors, skilling and re-skilling R&D" at p. 60-61
[223] Chapter 9, Artificial Intelligence Ethics, MeitY, Report of Committee – D "on cyber security, safety, legal and ethical issues", at p 18 – 19.
[224] Chapter 10, Artificial Intelligence Ethics, MeitY, Report of Committee – D "on cyber security, safety, legal and ethical issues", at p 27 – 28.

4. NITI Aayog's public health surveillance paper (2020)

NITI Aayog released the "Vision 2035: Public Health Surveillance in India: A White Paper" (**White Paper**)[225] in December 2020.[226] The White Paper identifies gaps in India's public health surveillance and suggests four building blocks to bridge the gaps - (a) a federated governance architecture between the union and state governments; (b) unique health ID linked to electronic health records; (c) enhanced use of new data analytics, data science, artificial intelligence, and machine learning; and (d) advanced health informatics.[227]

5. ICMR's Ethical guidelines for application of Artificial Intelligence in Biomedical Research and Healthcare 2023 (Ethical AI Guidelines)

ICMR released the Ethical Guidelines for application of Artificial Intelligence in Biomedical Research and Healthcare 2023 (**Ethical AI Guidelines**). [228] The Ethical AI Guidelines apply to AI tools created for all biomedical and health research and applications involving human participants and/or their biological data.[229]

The key principles outlined in the guidelines include autonomy (i.e., human in the loop);[230] Safety and risk management;[231] trustworthiness;[232] data privacy;[233] accountability and liability;[234] accessibility, equity, and inclusiveness.[235] The Ethical AI Guidelines provide guiding principles in each phase in the lifecycle of AI:

Phase	***Guidance***
Development phase[236]	• Purpose and end goal of data collection by AI developers should be known. • Informed consent needed even if data is not anonymised. • Data collection limited to what is necessary, with defined time limits of data storage. Surplus data should be destroyed and can only be stored with informed consent of patient/participant.

[225] NITI Aayog, Vision 2035: Public Health Surveillance in India: A White Paper (2020).
[226] Press Information Bureau, NITI Aayog releases 'Vision 2035: Public Health Surveillance in India', 14 December 2020.
[227] NITI Aayog, Vision 2035: Public Health Surveillance in India: A White Paper (2020), Executive Summary at p. xiv.
[228] Ethical AI Guidelines.
[229] ICMR, Ethical AI Guidelines, at p. 3.
[230] Para 1.1. ICMR, Ethical AI Guidelines.
[231] Para 1.2. ICMR, Ethical AI Guidelines.
[232] Para 1.3. ICMR, Ethical AI Guidelines.
[233] Para 1.4 (iv). ICMR, Ethical AI Guidelines.
[234] Para 1.5(i), ICMR, Ethical AI Guidelines.
[235] Para 1.7, ICMR, Ethical AI Guidelines.
[236] Para 2.1., ICMR, Ethical AI Guidelines.

	• Have a mechanism to modify or remove data in case patient/participant opts out or asks for change. Users should be able to exercise right to be forgotten. • Highest standards of data security. • Establish a mechanism to ensure feedback from hospitals/doctors reach developers (e.g., for significant findings). • Sourcing of training data and testing data should be documented. They must be reviewed by ethics committees. Document and review any difference between purpose of data collection and the AI tool being developed. • Diverse data necessary, to reduce bias in training data. • More data sets can improve AI tools. Ethics committees must consider this.

Validation phase[237]	• Ensure AI is performing as in intended, when used in the real world.
	• Methods for validation include:
	  ○ Using independent data sets to test the AI (i.e., data not used for training it).
	  ○ Auditing algorithms for deep validation of AI.
	• Clinical validation should include a process for whether the AI solution fits the purpose or not.
	• Multi-sectoral review needed for validation to be robust (i.e., experts from different fields like data science, clinical engineering, public health etc.).
	• SPIRIT-AI and CONSORT-AI frameworks can be considered to design AI assessment trials.
	• Outputs from AI should be explainable. There should be a mechanism for this.

Deployment phase[238]	• Train healthcare providers on the appropriate use of the AI tool. • Healthcare providers involved should be aware of how patient data will be used, whether in a public health decision, patient management or research setting. • In the initial phase of deploying AI, it should be tested in different situations to ensure optimum functioning. • Prior to deployment, healthcare professionals should understand risks, etc. associated with the AI. • Using AI in diagnostic/prognostic settings should be based on risk of the health area (e.g., using AI in oncology may have different risks to say pulmonology).

[237] Para 2.2., ICMR, Ethical AI Guidelines.
[238] Para 2.3., ICMR, Ethical AI Guidelines.

	• Compensation to be given in case of adverse event/injury. The onus to compensate lies on all entities involved in the AI deployment. • There must be a mechanism to switch to other forms of healthcare if the AI tool is malfunctioning. • Users must be aware of biases that can creep in when AI tool is deployed. • Clear disclaimers, terms of use, and information about the AI and using the AI must be provided.

6. First edition of IndiaAI Expert Group Report to MeitY (2023):

In November 2023, MeitY released the *'IndiaAI 2023: First Edition by Expert Group'* (**IndiaAI Report**) that lays the vision, objectives, outcomes and design for each pillar of the National Program on AI or IndiaAI. The IndiaAI Report calls for improving India's AI ecosystem through the establishment of AI Centres of Excellence, implementing a 3-tier infrastructure to improve AI computing, creation of the India Dataset Platform for enabling access to anonymized datasets, skilling India's present and future workforce to adapt to emerging technologies such as AI, and funding mechanisms/scheme for AI focused startups and the manufacture of advanced AI semiconductor chips.

The IndiaAI Report is a product of discussions and recommendations made by seven working groups set up by MeitY in April 2023, as a part of the National AI Program/ IndiaAI program. The working groups examined key gaps in India's AI ecosystem, providing their recommendations on: (a) IndiaAI Centres of Excellence in sectors such as healthcare, (to do foundational research in AI for creating new knowledge); (b) India Datasets Platform (identifying and creating government data sets and data related services); (c) Institutional capacity and design of National Data Management Office (maximising efficiency of data-led governance and public service delivery); (d) IndiaAI Future Design (empowering AI startups with funding and infrastructure); (e) IndiaAI FutureSkills (human resource development with comprehensive AI skills); (f) IndiaAi Future Labs Compute (establish AI compute infrastructure at five locations), and (g) Semicon IndiaAI Chipsets (FutureDesign Design Linked Incentive (DLI) Scheme to providing funding and infrastructure for design, development, and deployment of semiconductors).[239]

The IndiaAI Report sees AI and data as crucial to enhancing healthcare research, delivery, and public health interventions (e.g., tracking epidemics, identifying disease risk factors, and opting for evidence-based policymaking).[240] The IndiaAI Report suggest the creation of a National Data Management Office which will set sector agnostic standards for data storage and retention and guidelines for data security which government bodies like the NHA will have to adhere to.[241]

[239] MeitY, IndiaAI 2023: First Edition by Expert Group.
[240] MeitY, IndiaAI 2023: First Edition by Expert Group at p. 35.
[241] MeitY, IndiaAI 2023: First Edition by Expert Group at p. 59.

VIII. ISSUES FOR CONSIDERATION IN PROJECT BUILD

This section provides a suggested list of issues for discussion by the cohort, based on the landscape captured in this Briefing Paper.

A. Concluding remarks:

The laws and government policies/ papers in this Briefing Paper provide the foundation and principles for ensuring safe, inclusive, and trustworthy AI and healthcare. This includes the Constitution of India guaranteeing the right to health and right to non-discrimination. And specific guideline documents such as ICMR's Ethical AI Guidelines and the various reports and papers from MeitY and the NITI Aayog, which encourage adoption of AI in sectors like healthcare while emphasizing an ethical foundation

There are also government bodies, regulators and ministries who can exercise oversight to ensure inclusive AI and healthcare. The NHA plays a role with the ABDM to encourage the adoption of digital health, while the CDSCO exercises oversight on software medical devices (including AI). Similarly, under the DPDP the Data Protection Board will ensure the DPDP is implemented (e.g., ensuring individuals' data protection rights are protected), which would be key to protecting sensitive health data in various use cases and settings (e.g., research or healthcare delivery). The Indian Government is also actively working to boost AI infrastructure and capabilities, while noting AI's value proposition in specific areas like health.

Despite the existing legal and policy frameworks, significant gaps remain in India's approach to fostering inclusivity in AI-driven healthcare. The current landscape lacks clear, standardized metrics for evaluating the inclusivity of AI systems in healthcare contexts. This absence of concrete benchmarks makes it challenging for researchers, organizations, and government bodies to consistently demonstrate and ensure inclusivity in their AI initiatives.

Moreover, the concept of inclusivity in AI is multifaceted, encompassing issues of data representation, algorithmic fairness, accessibility, and cultural sensitivity. The Indian context adds further complexity due to its vast linguistic, cultural, and socioeconomic diversity. This raises critical questions about where in the AI development and deployment lifecycle inclusivity considerations should be integrated.

For instance, should inclusivity be a primary concern from the initial stages of problem formulation and data collection, or is it sufficient to address it during the testing and implementation phases? Additionally, there's a need for clearer guidelines on how to

balance the rapid adoption of AI technologies in healthcare with thorough inclusivity assessments, especially given resource constraints in many parts of India's healthcare system.

Furthermore, the intersection of AI, healthcare, and inclusivity touches upon multiple regulatory domains, including data protection, medical device regulation, and anti-discrimination laws. This regulatory complexity necessitates a more coordinated, cross-sectoral approach to effectively promote and enforce inclusive AI practices in healthcare.

Addressing these gaps will require collaborative efforts from policymakers, technologists, healthcare professionals, and community representatives to develop comprehensive, context-specific frameworks for inclusive AI in Indian healthcare. This endeavour must also consider how to create accountability mechanisms and incentive structures that encourage stakeholders to prioritize inclusivity throughout the AI lifecycle.

B. <u>Issues for further discussion:</u>

Defining and Operationalizing "Inclusivity" in Healthcare AI:

- What specific criteria should be used to evaluate the inclusivity of an AI healthcare tool?
- How can inclusivity be measured and demonstrated empirically?
- What minimum standards of inclusivity should be required for regulatory approval?
- How might we assess the inclusivity of an AI-driven diagnostic tool for rural populations with limited healthcare access and low digital literacy?

Barriers to Inclusive AI Development and Deployment:

- How can we address data limitations and biases in training datasets?
- What strategies can increase diversity in AI/ML teams and decision-makers?
- How can we improve engagement with marginalized communities in AI development?
- What solutions can overcome economic and infrastructural constraints in accessing AI-enabled healthcare?

Lifecycle Approach to Inclusive AI:

- At what stages of the AI lifecycle should inclusivity be addressed?
- How can we manage potential tensions between rapid AI adoption and thorough inclusivity assessments?
- What ethical considerations arise in data collection and algorithm transparency?

Regulatory and Governance Challenges:

- How can existing regulatory frameworks be adapted for AI-driven healthcare?

- What new governance structures might be needed to oversee inclusive AI in healthcare?
- How can we create accountability mechanisms and incentive structures to prioritize inclusivity?

Capacity Building for Inclusive AI:

- How can we develop inclusivity-focused AI curricula and training programs?
- What strategies can help build multidisciplinary teams with diverse perspectives?
- How can we improve AI/ML literacy among healthcare providers and policymakers?

Implementation and Best Practices:

- How can we develop comprehensive guidelines and assessment frameworks for inclusive AI in healthcare?
- What should standardised inclusivity impact assessment tools for AI healthcare applications look like?
- What should inclusivity-focused procurement policies for public health AI systems entail?
- How can we design targeted funding programs for inclusive AI research and startups addressing health disparities?
- What inclusivity considerations should be mandated in regulatory approval processes for AI-enabled medical devices?
- What are the best practices for community engagement in AI healthcare tool development?
- How can we create public datasets representative of India's diverse population to enable more inclusive AI training?
- How should multistakeholder working groups be structured to address specific inclusivity challenges?
- What should inclusivity modules in medical and public health curricula cover?

SUMMARY OF DISCUSSIONS FROM AUSTRALIA EXCHANGE TOUR

This section summarises the substance of the presentations or remarks and the free-flowing conversations during the meetings as 'key points presented and discussed'. Each meeting was structured to start with introductions, followed by a presentation or remarks by the invited speakers. The Indian Cohort then asked questions based on the remarks or presentations, leading to free flowing conversations. The speakers provided a wide array of insights. However, the points summarised under 'key points presented and discussed' were chosen based on their relevance to the intended outcomes of Project BUILD.

Since the free-flowing conversation section was done under the Chatham House Rule,[59] the summary does not attribute questions or points raised by the Indian Cohort (e.g., insights or case studies from their fields of work) to the specific member of the Indian Cohort. Where necessary, speakers were given access to the summaries featured here, so that the summary could be edited for inaccuracies or be cleared by their legal teams.

DAY 1:

SESSION 1

Dr. Simon Coghlan
Senior Lecturer in Digital Ethics
Computing and Information Systems,
University of Melbourne

Overview:
Provided an overview of the use cases of and challenges with AI in healthcare. Presented his paper on a governance model for AI in healthcare that is based on four principles.[60]

Use cases include:
Medical transcription, therapies for patients, drug discovery, and remote monitoring.

Challenges include:
(a) deploying AI before it is safe to do so; (b) deskilling of medical professionals due to reliance on AI; (c) dealing with biases and discrimination from AI; (d) protecting privacy of sensitive information used by AI through sufficient anonymisation; (e) building trust among doctors and patients alike in using AI in healthcare; (f) difficulties in unpacking the reasoning and learning of AI algorithms in healthcare; and (g) assigning responsibility and liability for AI-based decisions and outputs. Highlighted the need for ongoing monitoring and evaluation of AI tools in healthcare to ensure the AI tool is functioning as intended. And that clinical governance and ethics committees play a role in the audit and accountability of AI tools.

The four elements of the governance model for AI:[61]
(a) *fairness* – fairness means no bias or discrimination emanating from the AI algorithms and should be concerned from the outset of the AI. Consultation with relevant stakeholders is key (e.g., patient groups, lawyers, doctors); (b) *transparency* - explanation of AI models is key to building trust in the AI; (c) *trustworthiness* – AI systems must be validated by the relevant users and intended beneficiaries,

[59] Chatham House Rule - "When a meeting, or part thereof, is held under the Chatham House Rule, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed."
[60] Reddy S, Allan S, Coghlan S, Cooper P. A governance model for the application of AI in health care. J Am Med Inform Assoc. 2020 Mar 1;27(3):491-497. doi: 10.1093/jamia/ocz192. PMID: 31682262; PMCID: PMC7647243.
[61] Reddy S, Allan S, Coghlan S, Cooper P. A governance model for the application of AI in health care. J Am Med Inform Assoc. 2020 Mar 1;27(3):491-497. doi: 10.1093/jamia/ocz192. PMID: 31682262; PMCID: PMC7647243

who must also be educated about to risks and benefits of AI and the level of human oversight; and (d) *accountability* – changes in the laws on responsibility (e.g., consumer laws) and guidelines for medical professionals may be needed to ensure relevant accountability through the lifecycle of the AI.

Prof. Piers Gooding
Associate Professor, La Trobe Law School

And

Prof. Jeannie Paterson
Professor of Consumer Protection and Technology Law, Director of the Centre for AI and Digital Ethics

Overview:
Provided an overview of Australia's legal and governance landscape, including ongoing consultations on AI governance. Covered interesting legal conundrums created because of AI use.

Overview of the Australian legal and governance landscape:
Australia follows a federal structure, with a federal government, state governments and territory governments. Currently, tort law (e.g. on negligence), privacy laws, consumer protection laws (e.g., on the quality of AI tools in healthcare) and medical device related laws (i.e., those overseen by the Therapeutics Goods Administration) apply to AI in healthcare. There are also regulations for healthcare professionals to follow in their profession and internal hospital processes that govern AI in healthcare. AI will challenge Australia's liability laws, intellectual property laws, privacy laws, anti-discrimination laws, and healthcare laws. Additionally, there are different policies and principles, voluntary standards, and on-going consultations to regulate the use of AI more generally, but also in healthcare. For example, the Australian Government Department of Health and Aged Care has a public consultation on "Safe and Responsible Artificial Intelligence in Healthcare legislation and regulation review" which is considering three questions- (a) what AI should the government regulate; (b) who will be affected by AI; and (c) how can the government regulate AI to prevent harms and enable benefits?[62]

Interesting conundrums created by the use of AI:
(a) Consent and its specificity to the purpose for which the consent was given is an issue. The ongoing investigation by the Office of the Australian Information Commissioner (**OAIC**) into Harrison.AI and I-Med's use of patient data to train AI used for radiology, allegedly without patient consent, is an example.[63] Harrison.AI and I-Med partnered to share patient data to train AI for radiology. The OAIC is looking into whether the use of patient data for training the AI can be considered as a secondary purpose that patients can reasonably expect,[64] under the Australian Privacy Principles.[65] (b) Anonymised data is not regulated by the OAIC. However, the sufficiency of data anonymisation for AI is an issue because there is a risk of being re-identified. Additionally, when data is anonymised, it can negatively impact the quality of an AI tool, because often demographic information (e.g., age and gender) can improve the richness of insights drawn about the person and their condition.

[62]Australian Government Department of Health and Aged Care has a public consultation on "Safe and Responsible Artificial Intelligence in Healthcare legislation and regulation review" – Public Consultation (September 2024)
[63]Crikey, Cam, Wilson, Australia's biggest medical imaging lab is training AI on its scan data. Patients have no idea, (19 September 2024); See also Tech Business News, Matthew Giannelis, OAIC Launches Inquiry Into I-Med Radiology's Transfer Of Patient Data To Harrison.ai (25 September 2024),
[64]Tech Business News, Matthew Giannelis, OAIC Launches Inquiry Into I-Med Radiology's Transfer Of Patient Data To Harrison.ai (25 September 2024)
[65]Office of the Australian Information Commissioner, Australian Privacy Principles

(c) AI and especially its more advanced forms like LLMs and LMMs, can learn and change intuitively. So, monitoring and evaluation should be ongoing to ensure that the AI is learning the right things and can be course corrected where necessary. (d) Ascertaining liability and determining where human in the loop is essential for AI used in healthcare is an ongoing discussion globally. For example, Cerebral Inc. a tele-mental health company in the United States of America, was investigated by the Eastern District of New York for its AI pushing drugs for Attention-Deficit/Hyperactivity Disorder to patients even where medication may not have been necessary.[66]

SESSION 2

Anja Nikolic
CEO Australasia Institute of Digital Health

And

Simon Tatz
General Manager, Policy, Advocacy and Workforce Advancement, Australasian Institute of Digital Health

Overview:
Provided insights on the challenges of adopting AI in healthcare in Australia, what 'inclusivity' would mean in the Australian context, and risk-based regulation of AI.

Challenges of adopting AI in healthcare in Australia:
(a) Consumer trust in AI tools and the use of their data is very low because of the fear of discrimination. Consumer advocacy groups need to play a bigger role in improving trust, and Australia needs safe and pragmatic frameworks for the use of data for providing care. Additionally, Australians need to be sensitised on the value of data-drive healthcare to improve their care. They need to be encouraged to donate their health data (e.g., from wearables) and allow reuse of data for healthcare research and innovation.; (b) AI tools in healthcare are technology driven and not driven by clinical needs. Often companies will develop AI that cannot be used as is, in the clinical setting, and therefore better linkages between industry and doctors/ hospitals is essential.; (c) fragmented technology capabilities across healthcare facilities and professionals. Not all healthcare facilities (e.g., general practitioner (**GP**) clinics, or hospitals) have equal technology capabilities. Often, the hospitals or clinics have legacy systems that need massive upgradation before AI can be deployed. Additionally, all hospitals in a country or even in a single state in Australia are connected and inter-operable. Similarly doctors also have varying levels of comfort with AI.

'Inclusivity' in the Australian context:
(a) Representative data sets should be used to train AI because Australia has a diverse population, with people from different parts of the world living in the country. So, if an AI tool is not appropriately trained, it may not work in the country.; (b) Culturally appropriate care is important for first nation and aboriginal peoples where healthcare is a community consideration. People from these communities also grapple with a history of discrimination with respect to healthcare in Australia. AI tools should not exacerbate these inequities and should be designed with the inputs of first nation peoples.; and (c) Ensuring socio-economic and geographic determinants of healthcare access are accounted for while designing AI tools for healthcare. In some parts of Australia, people travel 800 kilometres to access secondary healthcare, because they live in remote areas. Similarly, internet connectivity is an issue because of how spread out the country is.

[66] Eastern District of New York, Press Release, Telehealth Company Cerebral Agrees to Pay Over $3.6 Million in Connection with Business Practices that Encouraged the Unauthorized Distribution of Controlled Substances (4 November 2024).

David Bevan
Principal Evidence and Research Advisor, Victorian Department of Health

Overview:
Reiterated the challenges of adopting AI in healthcare in Australia, raised by the speakers from the Australasian Institute of Digital Health. Provided insights on issues faced by government agencies in encouraging and governing AI in healthcare, and how the Victorian government facilitates AI procurement in the state.

Issues faced by the government in encouraging and governing AI in healthcare:
(a) Scepticism in digital integration from people and doctors alike (e.g., on the use of cloud or interoperability of technology systems) and low patient trust levels in AI; (b) AI manufacturers and vendors are insufficiently grounded in healthcare realities and needs. Additionally, the regulation of AI itself is problematic because ethicists and engineers are not playing a big enough role in the evaluation. In the case of drugs regulation, the pharmaceutical companies have doctors/ pharmacists and people with relevant expertise in the evaluation process. The government needs a dynamic governance framework for AI as opposed to a hard coded law, because AI is innovation is constantly taking place.; (c) Health data use is a challenge because Victorian law does not allow transfer of health data outside the state. Cloud servers are globally located and so it is difficult to keep the data in Victoria.

How the Victorian government facilitates AI procurement in the state:
(a) Emphasis on showing evidence of value or benefit; (b) Funding a concept where AI can be used and creating a free market for hospitals to pick the company. Quantification of a benefit of the AI tool is not always easy or possible. In virtual care for example, it is difficult to show the benefit because there are many components involved and the impact on the patient's care or healthcare outcomes are not immediately seen. In case of remote patient monitoring, there are devices and software that are said to improve efficiency for the clinical care team, but it remains unclear how these tools translate to patient benefit. In the case of productivity tools (e.g., medical scribes), companies argue that such tools reduce times spent on administrative tasks, thus giving doctors more time to spend with patients. But this benefit of additional time needs to be evaluated. (c) Government funding and onboarding of AI can start with the government looking at pilots and research projects before the AI tool is scaled up for larger scale deployment. The state government will not typically buy a single product, but it will invest in concept of an AI product and the hospital or clinic then can access a free market to choose which company to onboard. Prices are fixed by the 'head agreement' set by the Victorian government.

DAY 2:

SESSION 1

Dr Roisin McNaney
Senior Lecturer, Dept. of Human Centred Computing, Monash University

Overview:
Provides an overview of the AI related projects that involve 'co-design' that she is supervising, and steps for embedding inclusion in AI related research. Highlighted that 'inclusion' is a subjective term and that country-specific definitions may be needed to measure 'inclusion'. Additionally, there are limitations to 'inclusion', and sometimes hyper-specificity of the AI tool's market may make the tool unusable.

Projects include:
(a) Creating AI guidelines for identifying and classifying toxic content for eating disorders - to represent men also (they are underrepresented, and efforts are largely on white women white living with anorexia). (b) Identifying the ethical concerns with collecting and information from artificially created triggers. The project employs multi modal biosensing where there are ethical simulations of trauma triggers. (c) Identifying the cultural and racial nuances causing burn out. (d) Designing a participatory data governance framework while working on a wearable for home base sensing of Parkinson's Disease. The project is also looking at ways for people to ethically donate data and onboarding people early on so that their data can be reused. The project found that people are comfortable sharing their data with bigger companies, but that they were uncomfortable with smaller companies because of the volatility of leadership. (e) Co-designing mental health check in services with underrepresented people.

Steps for embedding inclusivity:
(a) Start with a well-defined research question. Co-design the question with the community you intend to serve, to determine what their needs are. Identifying the most suitable way to get rich insights from the community. Researchers can opt for creative methods such organising a session where women in the community paint teacups while sharing their views on an issue.; (b) Equity, diversity and inclusion are key to responsible innovation in AI; (c) Opt for methods like 'Double Diamond" which are frameworks that enable you to think through the problems and solutions in an inclusive way. This framework makes it easier to understand the 'why' of the research and the intended outcomes of the research. It is more inclusive and participatory. (d) The data sets need demographic data to make sure the AI is inclusive (e.g., gender, age, location, or income).

Prof. Wendy Chapman
Associate Dean of Digital Health and Informatics, University of Melbourne

And

Mahima Kalla,
Research Fellow, Centre for the Digital Transformation of Health, Faculty of Medicine, Dentistry and Health Sciences, University of Melbourne

And

Hasan Ferdous
Human-Computer Interaction Research Fellow at the Centre for Digital Transformation of Health, the University of Melbourne

Overview:
Provided the Indian Cohort a tour of the Validitron SimLab, in the University of Melbourne (**the SimLab**), and how the SimLab enables research of AI in healthcare that is inclusive and grounded in realities of providing healthcare.

The SimLab's offerings:
The SimLab has rooms where the use of AI tools can be simulated in different clinical settings (**Simulation Rooms**) – (a) a patient's hospital room, (b) a home setting for remote monitoring and telemedicine, (c) a doctor's consultation room, and (d) a room where the results of the simulation can be monitored. Researchers and organisations can come to test their digital health tools (e.g., AI powered medical note taking or insight gathering from electronic health records) in the digital sandbox and the Simulation Rooms. This simulation and sandbox testing helps spot unintended consequences (e.g., creating harms to the patient or complicating the workflow of the doctor). The multi-speciality team at the SimLab supports the conduct and evaluation of the simulation and its results. The sandbox allows researchers and organisations to upload in both real digital applications and drawings of the actual digital application. This allows for low fidelity prototypes to be created for testing before refining the design and development process, eliminating the need for actual coding at this nascent stage. The SimLab team also supports researchers and organisations in getting insights from specific communities of people (e.g., people with disabilities), having a person whose dedicated role involves outreach and building relationships with "peak organisations" (i.e., organisations that work to represent and advocate for issues affecting a specific community).

Enabling inclusive needs-based research and development of AI in healthcare:
A range of quantitative and qualitative research methods are used to assess effectiveness and inclusiveness of the AI tool. The goal here is to ensure the AI tool does not aggravate health inequities by being barriers to accessing healthcare. There are many determinants of digital health equity and by using frameworks like the Digital Health Equity Framework,[67] researchers and organisations can account for barriers to accessing healthcare (without technology in the equation). This can help ensure that typically excluded populations are accounted for in the research and design of the AI tool. Qualitative research methods also help in enhancing inclusion of the AI tool, including- (a) Progress-Plus is a framework that helps identify characteristics (e.g., location, gender, race, occupation, education, or socio-economic status) that stratify health opportunities and outcomes.[68] (b) Video-reflexive ethnography involves observing a group of individuals discussing an issue and identifying their pain points.[69] (c) Think-out-loud is a method where researchers facilitate stream of conscious type interviews with individuals to get their unfiltered thoughts on an issue (e.g., asking the individual to share their first thoughts about the issue or topic).[70] (d) Poetic transcription is a research method that allows deeper engagement and analysis of the lived experiences of individuals to draw richer insights.[71] These research methods derive insights that an interview or group discussion may not elicit. The results can enrich the development of the AI tool by being a tool to reduce biases and discrimination, or to make the tool more usable in a different cultural context (e.g., with Indigenous people). The SimLab team also highlights the importance of having a project charter that values authenticity in the research and development process from the beginning of the project.

[67]Richardson, S., Lawrence, K., Schoenthaler, A.M. et al. A framework for digital health equity. npj Digit. Med. 5, 119 (2022). https://doi.org/10.1038/s41746-022-00663-0
[68]Cochrane Methods Equity, Progress-Plus (shared via email by Mahima Kalla, Research Fellow, Centre for the Digital Transformation of Health)
[69]Shared via a follow up call with Mahima Kalla, Research Fellow, Centre for the Digital Transformation of Health (call dated 18 November 2024)

SESSION 2

Dr Emerson Keenan
Co-Founder, Kali Health

And

Dean Freestone,
Seer Technologies

And

Dr Keiran McLeod,
Medical Knowledge Lead, Heidi Health

Overview:
This meeting featured a discussion with Heidi Health, Kali Healthcare and Seer — healthtech startups — and their views on the inclusive development of AI tools in the healthcare industry. The focus was around challenges in infrastructure, algorithmic bias, problems with data sharing, regulatory frameworks for approving software as a medical device, and clinical validation for AI-based healthcare tools.

AI Scribes:
Heidi Health uses AI as a medical scribe to generate clinical documentation like notes by capturing conversations between clinicians and patients. The startup supports over 35 languages, and the aim is to reduce cognitive burden on clinicians, particularly those with ADHD, dyslexia, or time-sensitive workflows. The system is designed to be inclusive by incorporating voice interactions for visually impaired users that accommodates those with hearing impairments or physical disabilities. The tool also provides multi-lingual support to bridge the gap with non-English speakers.

Infrastructural and geographical concerns for inclusivity:
One of the issues pointed out by the startups around inclusivity was specific infrastructure and geographical problems. For example, issues like high internet bills and massive data usage stop clinicians or hospitals from incorporating any AI-based services. The lack of infrastructure in rural areas makes it difficult to access AI-based healthcare services.

Using a label system to mark AI tools:
Startups are starting to adopt a food label-type system to describe their data used to develop the tool. This includes demographic factors such as socio-economic factors, age, and other relevant categories. By including this information in the form of a 'label', AI models can provide a clearer picture of who the tool is built for and improve its accuracy and fairness in real-world applications.

Improving adoption and making it easier:
Simple, non-language-dependent instructions, such as icons or arrows, help ensure accessibility for a wide range of users. This helps to build trust and make it easier for the adoption of AI tools in the healthcare space among practitioners and end patients.

Data sharing practices and problems:
(a) One of the issues pointed out was the different standards for collecting data in different hospitals. Furthermore, presently a lot of historical datasets are being used for AI models. These often lack diversity, requiring continuous feedback loops and fine-tuning for inclusivity. Standardized data collection processes and robust feedback mechanisms are necessary to address biases stemming from historical datasets. (b) Hospitals also hesitate to share data due to privacy and liability concerns. The need to clearly communicate how data is de-identified and used was emphasized by the startups, ensuring both clinicians and patients are informed and comfortable.

[70]Shared via a follow up call with Mahima Kalla, Research Fellow, Centre for the Digital Transformation of Health (call dated 18 November 2024)
[71]Simmons M, et al. Stories of chronic illness: exploring qualitative data through poetic transcriptions, Med Humanit 2024;0:1–6. doi:10.1136/medhum-2024-012918; see also – Kalla. M., & Simmons, M. (2020). Women's recovery journeys from Chronic Fatigue Syndrome towards wellbeing: A creative exploration using poetic representation. International Journal of Wellbeing, 10(5), 144-164. https://doi.org/10.5502/ijw.v10i5.1501 (both papers shared via email by Mahima Kalla, Research Fellow, Centre for the Digital Transformation of Health).

SESSION 3

Tessa Matiske,
Program Manager, Australian Genomics

And

Caitlin Howley,
Genomic Research Policy, Australian Genomics

Overview:
Provided an overview of Australian Genomics' mandate and domains of work, and their comments to Australian Government Department of Health and Aged Care's Safe and Responsible Artificial Intelligence in Health Care Legislation and Regulation Review.[72] Summarised the sensitivities of working with first nations peoples' genomics and health data and described the need for greater investments in Indigenous research to understand genetic variations that lie in their genome, and how those variations impact clinical diagnosis. Explored the many relevant use cases of AI in genetics and genomics (e.g., facial recognition for genetic conditions that have recognisable phenotypes or observable characteristics, multimodal linkage of genomic data with electronic medical records, oncology, and forensics). Highlighted the Australian government's recent ban on using genetic testing by life insurance companies.[73]

Australia Genomics overview:
Australian Genomics was formed in 2016 based on a targeted call for research from the Australian Government, which then provided 25 million Australian Dollars, to study and build evidence for the benefit of genomic technologies. And to create policies for harnessing these benefits and build capacity in this area. Australian Genomics was tasked with setting up clinical sites around the country and recruiting patients for reproductive screening for genetic rare diseases. Australian Genomics was refunded for the period of 2021-2025 and is aiming to become an official government agency. Australian Genomics has stopped recruiting patients for their own study and are closely associated with other projects which do. Now the main domains of work are research, health, data, and policy. They aim to work towards a national unified approach to managing genomics data and to ensure co-design with communities like Indigenous people.

Submission to consultation:
Australian Genomics recommended- (a) Ensuring that international precedents are followed and that relations explicitly define situations or applications where AI can be harmful and therefore prohibited. (b) Using a principles approach to define general purpose AI. (c) Ensuring that the "high risk" AI category definition should not be based on technical capability because this will prevent developers from using technical specification standards as a loophole. (d) Ensuring that informed consent is at the key mechanism for processing data. (e) Ensuring that the regulations require the training data sets to be adequately representative.

[72]Australian Government Department of Health and Aged Care has a public consultation on "Safe and Responsible Artificial Intelligence in Healthcare legislation and regulation review" – Public Consultation (September 2024)
[73]The Hon Stephen Jones MP Assistant Treasurer and Minister for Financial Services, Total ban on the use of adverse genetic testing results in life insurance (11 September 2024),

Sensitivities surrounding first nations peoples' data: (a) Data sovereignty is a clear concern for first nations people, as healthcare is also considered a community matter. So, collection of samples and use of datasets in research must respect and adhere to their customs. (b) Historically, genomic differences of first nations peoples were used to discriminate against them. This has made them hesitant to share data for research or receive healthcare. However, it is important to include them at every step in the research process for AI, and while developing regulation, so that biases and discrimination are mitigated. Regulations, should encourage building trust with first nations peoples.

Jane Leong,
Director, Development, Australian Centre for AI in Medical Innovation, La Trobe University

Overview:
Provided an overview of the Centre for AI Medical Innovation's (**CAMI**) mandate and focus areas.

CAMI's mandate:
CAMI is funded for five years by the Victorian Government with the aim of being the state's leading medical innovation centre (9.3million Australian Dollars). CAMI will apply AI to accelerate discovery and development of vaccines, immunotherapies and medical innovation. CAMI will work with anyone including healthcare service provider, medical researchers, public research organisations, universities, and industries. It has existing partnerships with Medibank, Cisco, Olivia Newton John Caner Research Centre (La Trobe School of Cancer Medicine), BioNTech (onsite manufacturing facility). CAMI has purchased the Nvidia DGX H200, a supercomputer with software that makes it possible to do quantum AI and is contemplating options for commercialisation. CAMI will not maintain its own datasets but will be an intermediary helping researchers or organisations work with their datasets. CAMI connects researchers and various organisations to collaborate on research.

CAMI's focus areas:
(a) AI for medical research (e.g., clinical trials) – using AI to accelerate the drug development and vaccine development; (b) courses for training the workforce with AI skills

DAY 3:

SESSION 1

Lisa Kalman
Health Policy Advisory Councillor

Overview:
Provided an overview of options for regulating AI generally and in healthcare, risk-based regulation of AI, and how differences in health systems impact the AI's usability in a country.

Options for regulating AI:
(a) Governments can opt for a whole economy approach (i.e., where AI regulation is principle-based for application across sectors) or a sector-specific approach (i.e., AI in healthcare only),

(b) Governments can also opt to map the risks posed by different AI tools used in healthcare, for the level of risk they pose to human life and health, and then craft regulations appropriate to the different risk classifications of AI tools. For example, human in the loop may not be mandatorily required for all AI used in healthcare. Human in the loop may be required where tools are prescribing drugs or diagnosing and curating treatment plans. (c) Governance frameworks can prescribe risk assessments through the lifecycle, especially for AI that has the power to prescribe medication or make a diagnosis. Transparency requirements can also be prescribed to identify the reasoning used by AI in such complex decisions. Through transparency requirements and risk assessments, government agencies can identify where to require human in the loop, in the processes of the AI. (d) Finally, ascertaining and assigning liability is a concern, because currently doctors are liable to patients when they use of technology, and not necessarily the developer. For example, AI powered medical scribes are growing in use in Australia, but the doctors are liable for the quality of the notes generated by AI. Government policy should focus on assigning responsibility and preventing misuse, including addressing hacking and data manipulation risks.

Impact of differences in health systems on AI usability:

AI must be localised so that it can work for each country's specific healthcare needs and population diversity. For example, a heart risk calculator[74] from New Zealand required customisations before launch in Australia. Additionally, healthcare facilities like hospitals and GP clinics do not collect the same health data points or have the same level of technology readiness. This fragmentation in health data collection and technology readiness impacts AI use in Australia

Vikas David
Digital Mental Health Specialist

Overview:

Provided an overview of tackling data related challenges with AI, how regulations can enable automated and independent AI (e.g., LLMs and LMMS) to truly improve healthcare. Highlighted how it is a challenging proposition to make AI completely inclusive, and that it is better to identify your target market and ensure greater levels of inclusion for that market. Provided the example of his work with UNICEF, where a local administrator was chosen and given various terminologies and phrases, from which the administrator could pick terms based on local norms and culture (e.g., difference in the cultural concepts in a Muslim-majority country and a Christian-majority country).

Tackling data related challenges:

(a) For enabling inclusion, intersecting datasets are necessary (e.g., linking datasets of gender, income level, and urban/rural location). Partnerships and federated learning will help improve inclusivity of the datasets that the AI is trained on (e.g., accessing disease data registries). (b) Synthetic data, augmentation of data, and human in the loop can help increase the amount of data your AI is trained on. (c) Developers should opt for a feedback reasoning loop like "Observe, Orient, Decide, and Act" where they see the data and make decisions based on the data, to keep improving the AI. (d) Developers should also ensure that the AI's outcomes match a human doctor's and ensure healthcare outcomes are matched to the AI's processes.

[74]Heart, Lung and Circulation, Lisa Kalman, Natalie Raffoul, Emily Bradburn, Prof. Garry Jennings, Prof. Mark Nelson, New Australian Guideline and Calculator for Assessing and Managing Cardiovascular Disease Risk, Lisa Kalman, N,(2023) 32, 652 1443-9506/23/$36.00,https://doi.org/10.1016/j.hlc.2023.04.001; Nelson, M.R., Banks, E., Brown, A., Chow, C.K., Peiris, D.P., Stocks, N.P., Davies AO, R., Raffoul, N., Kalman, L., Bradburn, E. and Jennings, G. (2024), 2023 Australian guideline for assessing and managing cardiovascular disease risk. Med J Aust, 220: 482-490. https://doi.org/10.5694/mja2.52280

Regulations for enabling innovation:
AI is already doing a lot automatically. Regulators can encourage such innovation by (a) dictating where meaningful human oversight can come into play; (b) creating a differentiated governance framework where accountability is defined based on their role in the AI lifecycle. So, the regulatory oversight of developers, hospitals, doctors, and the end consumer will depend on how they engage with the AI.

Rohan Sridhar,
Partner, Norton Fulbright Rose

Overview:
Provided an overview of the Australian approach to regulating AI and what AI regulation should account for.

Australia's approach to AI regulation:
The Australian approach opts for risk-based review as the foundation of regulating AI, where every AI tool is not held to the same regulatory standard, because otherwise regulation will stifle innovation. This approach has been effective. Australia also tends to look to adapt to medical device and other relevant regulations from the EU, Canada, and the US, because it increases market access of global products to Australia, and Australian products to these countries.

What AI regulation should account for:
(a) Regulation should clarify whom to hold liable and how to hold them liable for things that go wrong with AI. (b) Ethical considerations around inclusion should be based on a risk-based approach. The question of whose ethics are used in regulation is vital. Understanding AI's capability to account for human behaviour and differences is important, especially in healthcare settings where technology use varies among medical staff. (c) Regulations may be able to regulate AI products that are business-to-business and business-to-consumer differently. Additionally, there are some users of AI, who can be considered smarter than others and thus the AI tool may merit different oversight (e.g., if a doctor is the user of an AI tool, the tool may need less scrutiny than if a patient is the user of the tool).

Nivodita Sharma
Director National Data Projects, ACT Government

Overview:
Reiterated the difference in technology adoption across health systems in Australia. Emphasised the need to avoid re-inventing the wheel on AI regulation, and to adopt what already exists.

Technology differences:
Australia has differentiated maturity on the use of AI and data landscape. For example, not all GPs are tech savvy, and not all state or territory governments collect data from the GPs practicing in their area. However, there is a different system called the Public Health Network which collects data from GPs, some of which is passed on to the Department of Home Affairs (DOHA), which is then processed differently.

DAY 4:

SESSION 1

Jackie Leach Scully
Researcher on Bioethics, Disabilities,
University of South Wales, Sydney

Overview:
Provided an overview of the vocabulary to articulate facets of inclusion required during product development. The product development should be based on a deep understanding of the lived experience of disabilities. Called for "continuous accompaniment of people with disabilities through the lifecycle of AI used in healthcare. Highlighted the need for both laws (because without legal compulsion, changes are less likely to be sustained) and policies (because they act as the bridge to practical application). Flagged the Disability Research on Independent Living and Learning programme (**DRILL**) in the UK as an example of a co-designed programme that serves the need of the disabled community in the UK by making them part of the policymaking process.[75]

Facets of inclusion for product development:

- There are two big problems with inclusivity for disability- (a) Acknowledging that there are differences in the way people experience their disability, and each disability has different needs; and (b) Tackling the tendency to clump 'disability' as though it were a homogenous thing. There are numerous factors involved in terms of impairments such as sensory impairments, visual-hearing mobility impairment, mobility, intellectual, psychosocial.
- There needs to be "continuous accompaniment" model where disability experts are integrated throughout the entire development process, like other essential roles like lawyers or engineers. This approach requires a significant shift in development practices and investment, but it's crucial for creating products that are genuinely useful and inclusive. This approach can ultimately save resources by avoiding the development of ineffective or non-inclusive technologies.
- During product development or even policy designing, it is important to be as imaginative as possible with respect to who's going to be using these product or benefit from the policy. This means really seeing what the diversity of people looks like and feels like for them.
- One way to integrate disabilities lies in adopting a standard approach ('universal design') and then add some variance of it which will be more accessible to people with disability. For example, smartphone with extra-large buttons for people with anxiety. Another example is the close captioning feature in Zoom, which can be handy for those who are unable to hear properly. Developers don't necessarily have to make something specially for people with disabilities. They can make something that everyone can also use with some additional features to accommodate people with disabilities.
- Sometimes usage of technology can determine what aspects of inclusion to measure for because users also adapt the way they use technologies, sometimes beyond what the tool was intended for. For example, deaf people became early adopters of SMS. Or a war photographer integrating a camera holder into his prosthetic arm. This illustrates that metrics for success might need to shift based on these creative uses. This ongoing adaptation by users calls for sustained engagement with technology post-deployment, akin to drug surveillance, to truly understand its impact and utility in everyday life, advocating for a dynamic approach to both evaluation and regulation.

[75] DRILL is is an innovative 5-year UK wide Programme led by disabled people, for disabled people and funded by the National Lottery Community Fund (NLCF) to find solutions about how disabled people can live as full citizens and take part socially, economically and politically. DRILL promotes coproduction and collaboration between disabled people and their organisations, academia, research bodies and policy makers. Disabled people are empowered to have direct influence on decisions that impact on their independent living, particularly in relation to policies, legislation and services. The programme has funded 32 co-produced research and pilot projects in the UK.

Kimberley Robinson,
Head of Life & Health Product, Swiss Re

And

Carly Van Den Akker,
Head of L&H Claims, Swiss Re

Overview:
Provided an overview of the insurance product landscape in Australia and how AI is used to evaluate insurance claims and customers eligibility for policies.

Use of AI in life insurance:
Usage of AI in insurance is limited to superficial ways in preventative health and other things that keep people healthy (excluding any medical treatment). For group insurance, which is available to most working Australians, AI is used to assess risk profiles. (a) Generally, no underwriting is required, and coverage is automatically accepted. (b) Retail insurance involves underwriting, where AI plays a significant role in the initial stages. It analyses risk profiles based on similar cases and claim histories, considers family history, and evaluates potential genetic factors (though there's a moratorium on using genetic testing in Australia). The main purpose of AI in this context is to determine the likelihood of claims and price products accordingly. This process, which involves risk pooling, may result in exclusions based on family history or pre-existing conditions.

In Australia, health insurance accessibility isn't primarily an AI problem. The system is community-rated, meaning people pay similar premiums if they enter at certain ages, with tax incentives and penalties driving participation (around 60% coverage). However, AI could be valuable in optimising trauma insurance products by analysing health insurance data to better understand coverage gaps. For example, different cancers have varying out-of-pocket costs depending on location, treatment types, and available support. AI could aggregate this data to help determine appropriate coverage levels, preventing both under-insurance and excessive coverage.

SESSION 2

Simon Burns,
Partner, GT Law,

And

Jen Bradley,
Special Counsel, GT Law

Overview:
Provided an overview of the Australian government's approach to regulating AI, and some insights from their advisory work with AI medical device companies.

Options for regulation being considered by the Australian government:
The government is considering three regulatory options: (1) Plug gaps in existing laws (on one end of the spectrum) (2) Implement industry-wide regulations similar to the EU AI Act (on the other end of the spectrum), or (3) Create a consistent framework triggered by specific sectors (e.g., health, consumer). The government is also debating who owns this space within the government, whether it is centralised or decentralised. The government is also taking more of an 'interventionist' approach in this space and is applying 'consumer lens' by giving importance to fair business practices, including ethics and AI.

Advisory work with AI medical device companies:

In Australia, the Therapeutics Goods Administration (TGA) has released specific guidelines for AI in medical devices[76] to manufacture specific type medical devices, artificial intelligence, AI, and medical device software. As part of the registration process, manufacturers must provide information and demonstrate conformance to essential principles, which are expressed in an outcomes-based way. The guidelines include requirements for transparency and the relevance of data sets to the Australian population, including Indigenous populations. Data tagging is required to ensure the data source is representative, considering concentration, ethnicities, and diversity in the data sets. The process includes analytic verification, which involves worst-case testing to determine the AI's effectiveness using various data sets. We assist people with the TGA application process and clinical analytics, which is akin to clinical testing but more representative. The TGA is concerned about model drift and has a consultation paper addressing AI-specific issues, including risk ratings and outcome-based essential principles. Currently, prediction tools like AI are classified as low risk by default, which may not be appropriate. The TGA is considering specific requirements to address AI's unique challenges, such as model drift, to ensure device safety and continuity. To address risk management processes in AI regulation, one effective approach is to align with new industry standards, such as the ISO 420 risk management standard. This alignment can be demonstrated in contract terms and during the assessment process. When applying for assessment under the TGA, showing conformity with recognised jurisdiction processes, like the EU medical devices assessment process, is crucial. The EU AI Act now requires that high-risk AI systems incorporate additional conformity elements. Any medical device requiring third-party assessment under EU law must also comply with these elements. The European Standards Board is certifying AI industry standards, and adherence to these standards can demonstrate compliance with the EU AI Act. This includes addressing data bias and ensuring representative data sets as per specific standards.

[76]TGA, Australian Regulatory Guidelines for Medical Devices (ARGMD), (November 2023)

Emily Bogue,
Director, Australian Government Department of Health and Aged Care

And

Leah Martin,
Service Design Lead, Australian Government Department of Health and Aged Care

And

Dr. David Hau,
Senior Medical Advisor, Medical Devices Authorisation Division, Therapeutics Goods Administration

Overview:
Provided a summary of the ongoing AI related consultations (general economy and health sector specific), the TGA's approach to inclusivity questions while evaluating AI medical device applications, and examples of inclusive design in policymaking. Highlighted that inclusion for AI medical device companies can be both in terms of the patients and doctors using their tool, but also in terms of the hardware machines they are plugged into (e.g., an AI tool may work as intended with an x-ray or CT scan machine manufactured by a specific company but not work as well with machines made by other companies).

Ongoing AI consultations:

- Department of Industry Science and Resources – looking to identify high risk AI and establish guardrails. Proposed three regulatory options- (a) each sector would adjust its own legislation as needed; (b) central AI legislation would be created, and sectors would decide to implement it; (c) An economy-wide AI Act would be established, with some sector-specific carve-outs if necessary.
- TGA – consultation on regulating generative AI tools that are not specifically designed for healthcare use (e.g., ChatGPT) but can have implications on health and safety.
- Department of Health and Aged Care - has completed the public consultations regarding the "Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review"[77] (aspects of this public policy consultation are covered in earlier sections of this note). Results on policy actions are likely in early 2025.

TGA's approach to inclusion:

- Inclusivity is integrated into the TGA's assessment of AI-based medical devices and other medical devices. The TGA collaborates with the Advisory Committee for Medical Devices, which includes clinical specialists, technology experts, and consumer advocates. This committee helps determine whether clinical data is generalizable to specific subpopulations or if direct data on those subpopulations is needed, depending on factors such as prevalence, disease mechanisms, and technology functionality in different cohorts. a risk proportionate approach is taken for clinical validation and external validation in different subpopulations, including validation in Australia to ensure generalizability. If a subpopulation has a high prevalence or relevance to the disease or condition, external validation in that cohort is required. The advisory committee, consisting of medical specialists, advises on the generalizability of clinical data and the need for direct data from those subpopulations. Usability studies may also be requested for specific subgroups.
- The TGA also addresses the challenge of limited data for smaller or harder-to-study subgroups, such as young children. They seek input from their advisory committee to determine if clinical data can be generalized or if specific data is required for these groups.

[77]Australian Government, Department of Health and Aged Care, Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review, Public Consultation (September 2024)

- Co-design is aligned with the good machine learning practice guiding principles. One principle is leveraging multidisciplinary expertise throughout the product lifecycle. Manufacturers must address how they satisfy this principle, whether through clinical users like healthcare providers or patient experts. The goal is to integrate into clinical or patient workflows to derive meaningful patient benefits. Manufacturers must address this principle through the dossier they submit to the TGA (e.g., such as design, requirements, and risk management documents). From a clinical assessment perspective, the TGA ensures that the intended patient population is covered in the clinical evidence. If a particular subgroup requires specific consideration, the manufacturer must provide further evidence. This applies not only to major users but also to rare users included in the intended use. Safety and effectiveness for all user types must be demonstrated before approval.
- Risk management requires manufacturers to minimize all risks and ensure residual risk is acceptable for product approval. They must account for risks related to software they didn't develop, like generative AI using the OpenAI platform, by conducting a risk analysis and addressing those risks. The quality management system is also required for medical device approval, capturing adverse events and adjusting risk management to prevent recurrence.

Inclusive policymaking:

- The Department of Health and Aged Care is considering how any policy emergency from "the Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review" will impact diverse population groups. The department focuses on a strong consumer approach, developing networks to hear all relevant voices. Despite efforts, capturing diverse perspectives remains difficult. Health literacy, digital literacy, and AI literacy are interlinked, making it challenging to engage vulnerable populations in Australia. Advisory bodies were set up post-COVID to engage with these populations, but trust issues persist due to limited AI literacy. There is distrust and engaging these groups requires time, specific focus, and engagement, which is difficult within policy design timeframes. Efforts are made to get a good amount of engagement before making policy decisions or regulations, including working with "Peak Organisations" (i.e., those that work closely with the affected communities). Emily and Leah's teams are gathering insights from the public, vendors, and industry to guide the design of meaningful AI policy. The department's approach is informal, learned through past challenges. Unlike the TGA's formal approach, the department starts with targeted consultations to test questions with key stakeholders from academia, industry, and sub-government agencies before going public. This includes webinars for direct feedback and meetings with peak bodies
- The TGA also has a post-market strategy that encourages users of medical devices to report adverse events through a web-based reporting mechanism.

DAY 5:

SESSION 1

Prof. Didar Zowghi,
Team Leader: AI Diversity and Inclusion, CSIRO

And

Prof. Farah Magrabi,
Professor of Biomedical and Health Informatics at the Australian Institute of Health Innovation

Overview:
Categorised and defined the elements of 'inclusive design' in the context of AI. Provided an overview of how using a five-pillar AI ecosystem enables inclusive design of AI including the fact that the pillars are now part of Australian government policy "National framework for the assurance of artificial intelligence in government".[78] Provided an overview of two studies– (a) a literature survey to understand the thinking and work done on diversity and inclusion in AI[79] and (b) a study of AI incident reports on diversity and inclusion.[80]

Elements of inclusive design in AI categorised and defined:
Diversity and Inclusion in Artificial Intelligence refers to the 'inclusion' of humans with 'diverse' attributes and perspectives in the data, process, system, and governance of the AI ecosystem.

- "Diversity means the representation of the differences in human attributes in a group or society.
- Attributes are known facets of diversity, including but not limited to the protected attributes in Article 26 of the International Covenant on Civil and Political Rights: race, colour, sex, language, religion, political or other opinions, national or social origin, birth or other status, age, disability, criminal record, ethnic origin, gender identity, neurodiversity; and intersections of these attributes.
- Inclusion is the process of proactively involving and representing the most relevant humans with diverse attributes who are impacted by and impact the AI ecosystem context."[81]

Five-pillar framework for AI ecosystem
An AI ecosystem has 5 pillars, namely, humans, data, process, system, and governance. Human involvement and governance strategies guide the use of data, the processes, and systems where AI is used, through the lifecycle of the AI. The five pillar framework provides guidance to answer the following questions:[82]

- "Who is Governing? (Stakeholders/Roles) – (a) Governments and Regulatory Bodies: Setting legal and ethical standards; (b) Industry Leaders and Corporations; (c) Establishing internal governance framework; (d) International Organizations: Developing global guidelines and principles; (e) Academia and Research Institutions: (f) Contributing to ethical and technical standards; and (g) Civil Society and Advocacy Groups: Ensuring social justice and public interest

[78]Commonwealth Government of Australia, National framework for the assurance of artificial intelligence in government - A joint approach to safe and responsible AI by the Australian, state and territory governments (June 2024)
[79]Shams, R.A., Zowghi, D. & Bano, M. AI and the quest for diversity and inclusion: a systematic literature review. AI Ethics (2023). https://doi.org/10.1007/s43681-023-00362-w
[80]Rifat Ara Shams, Didar Zowghi and Muneera Bano, CSIRO's Data61, Australia, AI for All: Identifying AI incidents Related to Diversity and Inclusion
[81]From the slides shared by Prof. Didar Zowghi during the meeting. This definition is also covered in her chapter "Guidelines for Diversity and Inclusion in Artificial Intelligence" published in "Responsible AI: Best Practices for Creating Trustworthy AI Systems"
[82] Taken from the slides provided by Professor Didar Zowghi, which she presented at the meeting.

- What is Being Governed? (Data, Process, System) – (a) Data Governance: Ensuring data quality, privacy, and security; (b) Algorithmic Governance: Oversight of AI development and deployment processes; and (c) System Governance: Regulating the integration and impact of AI systems in society.
- When is it Being Governed? (Process, Stages of AI Lifecycle) – (a) Design and Development: Setting ethical and technical standards from the outset; (b) Deployment: Monitoring and evaluating AI systems in real-world applications; and (c) Post-Deployment: Continuous assessment and adaptation to emerging challenges.
- How is it Being Governed? (Methodologies) – (a) Ethical Frameworks: Guiding principles for responsible AI development and use; (b) Regulatory Compliance: Adhering to laws and policies governing AI; (c) Risk Management: Identifying and mitigating potential risks and harms; (d) Transparency and Accountability: Ensuring openness and answerability in AI systems; and (e) Stakeholder Engagement: Involving diverse perspectives in governance processes."

Literature survey on the challenges and solutions for diversity and inclusion of AI:[83]

(a) The study found that "health" is the most topical issue under diversity and inclusion for AI. Other sectors like bias in AI tools used in law are neglected. The study found 55 challenges and 33 solutions for increasing inclusive and diversity of AI. And 24 challenges and 23 solutions for using AI tools to enhance diversity and inclusion. Therefore, there is an imbalance between studies exploring diversity and inclusion within AI and those studies leveraging AI to enhance diversity and inclusion practices. (b) The study also found AI studies were largely related to 'gender' bias, and other factors such as ethnicity and language are frequently overlooked. (c) The study found a significant lack of attention on governance of AI and limited geographic diversity especially from the Global South.

AI incident analysis study:[84]

Prof. Didar's team manually analysed a large set of AI incident reports from online repositories to see their relevance to diversity and inclusion violations. Out of the 16091 AI incidents found across 3 incident repositories,[85] 725 were health related. From the analysis the team developed a decision tree to identify diversity and inclusion related incidents. The decision tree is comprised of four conditions – (a) if any human is directly or indirectly impacted by the AI incident (if not, it is not a diversity and inclusion incident). (b) If the answer to the previous condition is yes, then the second condition is triggered. The second condition assesses whether the AI incident explicitly mentions any diversity attribute (e.g., gender). If the answer is yes, then the incident is clearly a diversity and inclusion incident. (c) if the answer to the second condition is no, then the response is analysed

[83]Shams, R.A., Zowghi, D. & Bano, M. AI and the quest for diversity and inclusion: a systematic literature review. AI Ethics (2023). https://doi.org/10.1007/s43681-023-00362-w

[84]Rifat Ara Shams, Didar Zowghi and Muneera Bano, CSIRO's Data61, Australia, AI for All: Identifying AI incidents Related to Diversity and Inclusion

[85]Repositories used were- AI Incident Database (AIID), AI, Algorithmic, and Automation Incidents and Controversies (AIAAIC), and OECD AI Incident Database. Rifat Ara Shams, Didar Zowghi and Muneera Bano, CSIRO's Data61, Australia, AI for All: Identifying AI incidents Related to Diversity and Inclusion

under the third condition, on whether this AI incident is subject to bias, violates fairness, or results in discrimination. (d) The final condition involves assessing whether the AI incident causes any implicit diversity attributes. Prof. Didar and her team are working on a question bank to enable assessments and scoring for improving diversity and inclusion of AI tools.

Overview:

Provided an overview of how to incorporate inclusivity in practice (while using AI), inclusivity in policymaking for AI, and the patient or consumer perspectives on using AI in healthcare. Described the conduct of two studies – a 'citizen jury' for inclusivity in policymaking (to understand consumer perspectives on AI in healthcare) and a literature review and environmental scan study for inclusivity in practice (to understand AI implementation in hospitals). Noted that a fully representative data set may not be possible and that it is an iterative process to ensure representative datasets, one that includes training humans to use the AI properly as well. Highlighted the Australian Health Practitioner Regulation Agency's AI guidance principles[86] for healthcare professionals using AI (i.e., the doctor is responsible not the AI supplier or manufacturer. Doctors need to have sufficient understanding of the AI to use it in a manner that meets their professional obligations. Doctors need to inform patients about the use of AI and address concerns the patients have about it. Doctors should involve patients in the decision to use AI and get their informed consent. Doctors should ensure privacy and confidentiality and avoid unconsented use of patient data).

Citizen jury:[87]

This is a deliberative democratic method that enables community members to participate in policymaking for laws and policies that affect them. Jurors were asked to discuss the question "under what circumstances, if any, should artificial intelligence be used in Australian health systems to detect or diagnose disease".

- Aim: To understand the concerns Australians had with AI in healthcare, their overall attitude towards AI use in healthcare, and to get their recommendations for safely using AI in healthcare.
- Methodology overview: 6000 Australians were randomly selected and mailed invites by the Sortition Foundation, to participate in the jury, out of which there were 109 unique responses on views AI. From this exercise 31 jurors were selected, after which 2 dropped out. The final juror count was 30, after finding a replacement for 1 juror who dropped out. Jurors closely matched the Australian population based on the following categories - gender, age, ancestry, highest level of education, and location (state/territory, urban/regional/rural). The full jury process took 18 days (16 March – 2 April 2023), with fifteen days online and three days in person in Sydney. There were smaller group discussions, video activities, and during the in person meetings, jurors recorded their deliberation in template documents.

[86] Australian Health Practitioner Regulation Agency, Meeting your professional obligations when using Artificial Intelligence in healthcare (please note this guidance is updated periodically by the AHPRA)

[87] Stacy M Carter, Yves Saint James Aquino, Lucy Carolan, Emma Frost, Chris Degeling, Wendy A Rogers, Ian A Scott, Katy JL Bell, Belinda Fabrianesi and Farah Magrabi, How should artificial intelligence be used in Australian health care? Recommendations from a citizens' jury, Med J Aust 2024; 220 (8): 409-416. || doi: 10.5694/mja2.52283

- **Recurring concerns raised by jury members:** (a) holding decision makers to account; (b) supporting rights, choice and autonomy in healthcare systems; (c) managing conflicts of interest and assuring independent governance; (d) evaluation, transparency, and integrity
- **Overall finding and jurors' recommendations:** The jurors were welcoming of clinical applications of AI as long as there is strong governance, a national approach to AI, and there is training, evaluation, and oversight in clinical practice. There were 15 recommendations across 10 categories of issues. The 10 categories were - overarching charter and framework, balancing benefits and harms, fairness and bias, patients' rights and choice, clinical governance and training, technical governance and standards, data use and governance, open-source software, evaluation and assessment, and education and communication. Recommendations included – (a) application of AI in healthcare is that it must be continually evaluated to ensure the benefits to patients and healthcare professionals outweigh the harms; (b) research forming the basis to use AI in healthcare should be peer-assessed in an unbiased, independent, and robust manner. Australian data, with a sample representative of the population, should be used. International data can be used where justified. (c) Patient rights guideline that is inclusive of and non-discriminatory of individual values/beliefs, choices, accessibility related issues, respecting underrepresented peoples, and being culturally appropriate, is needed. (d) Encourage free and open-source software to ensure transparency, public ownership, financial integrity, collaboration, security, privacy and trust.

Literature survey and environmental scan:

The study was prepared by Farah and others for the Australian Commission on Safety and Quality in Health Care.[88] The study identified the use cases of AI in a clinical setting (e.g., cancer screening, stroke triage), the governance and policy frameworks guiding the use of AI in a clinical setting and identified safety concerns of using AI in a clinical setting. The study found that AI safety is linked to both issues with algorithms but also how humans use the AI. 3% of the errors resulted from contraindicated use by people, 4% of errors resulted from the way people used the AI, and the data input created 82% of the errors. The study also found no evidence of engagement with patients/consumers or AI ethics.

[88]Australian Commission on Safety and Quality in Health Care, Literature Review and Environmental Scan Report, AI Implementation in Hospitals: Legislation, Policy, Guidelines and Principles, and Evidence about Quality and Safety, (Finalised: 29 May 2024)

Dr. Rosemary Kayess,
Disability Discrimination Commissioner of the Australian Human Rights Commission,

And

Lorraine Finlay,
Human Rights Commissioner

And

Kali Goldstone,
Senior Policy Officer – strategic engagement and advocacy, Australian Human Rights Commission

And

Dr. David Silvera,
Principal Research Scientist, CSIRO

Overview:
provided insights on the contours of 'inclusive design', creating enablers of inclusive design, and the CSIRO Australian e-Health Research Centre's (CSIRO Centre) framework to promote innovation and development of safe and effective Artificial Intelligence (AI)-enabled Assistive Technology (CSIRO AI Assistive-Tech Framework).[89] Noted the difference in approach to inclusion of AI for assistive technologies (which inherently are intended to serve people with disabilities) and inclusion of AI more generally. With assistive technologies co-design is essential, while AI used more generally may not incorporate the lived experiences. Companies may find it expensive to go back to the drawing board and redesign for disability, so they try to adapt existing products

Contours of 'inclusive design':
(a) Lived experiences of people with disabilities should be the foundation of AI research, with disabled people defining the problems around which technology is developed. Inclusion should be a priority from the start, not an afterthought. (b) Incorporating lived experiences should be continuous through the lifecycle of the AI, especially with generative AI, which is constantly learning and evolving. (c) Being realistic about AI's capabilities requires a clear understanding of issues the AI is trying to address. (d) For people with disabilities, inclusive research methodology plays a role in the research and development process. This inclusive methodology will help ensure AI systems avoid excluding people with disabilities from healthcare, by relying on able-bodied norms for research and development. (e) Human in the loop is important to catch errors made by AI (e.g., doctors spotting errors in diagnostic reports generated by AI). (f) There is a role for human rights-based impact assessments of AI technologies to assess the full breadth of the impact of AI on various human rights. The Australian Human Rights Commission worked with National Australia Bank to create a human rights impact assessment tool for banks using AI systems in decision-making. The bankers and technology experts were initially unfamiliar with human rights and saw it as an additional layer of regulation. As conversations progressed, the bankers realised it was common sense, and the tool was warmly received because it wasn't an extra layer of regulation. This approach ensures that customers have positive experiences, which is essential for businesses' human rights impact assessments to make economic sense, because it will encourage adoption of the AI tool and while also protecting human rights perspective. (g) Safe testing spaces such as sandboxes will help identify and tackle algorithmic bias by making necessary adjustments early on for ensuring inclusivity from the get-go. After testing a product, it should be taken to the sandbox, tested again, and then released as an updated version. Allowing continuous learning without considering where the data comes from, and potential risks can be problematic. Even with the right data, there are risks in understanding how the algorithm behaves once the data is integrated. The behaviour of the algorithm and the transparency and understanding of the data are critical, especially in deep learning where the amount and type of data make it difficult to understand.

[89]National Disability Insurance Agency and CSIRO's framework to promote innovation and development of safe and effective Artificial Intelligence (AI)-enabled Assistive Technology (AT), (7 November 2022)

Creating enablers of inclusive design:

(a) When building technology, it's crucial to recognise that many AI systems (e.g., voice recognition systems), are built around a very narrow, ableist, normative frameworks. Utilising a broader recognition of the human condition in algorithms, is needed to tackle blind spots. (b) Encouraging inclusive education and research through upskilling will help improve inclusion. For example, the University of New South Wales set up the Disability Innovation Institute to strengthen understanding of the broad spectrum of the human condition and promote a more inclusive research base. (c) People with disabilities (and other vulnerable populations) can be part of the coding and development of AI tools in healthcare. Inclusive education will help to increase the number of such people who enter relevant professions like engineering and then participate in the actual creation of AI tools. (d) Encouraging transparency by providing information about the risks, expectations, and the data used for training AI, and by relying on a robust civil society to tackle data scarcity issues. Even if civil society does not have the exact data researchers or organisations need, they can share what they do know, which can form the basis of how researchers or organisations gather the data they need.

CSIRO AI Assistive-Tech Framework:

CSIRO Centre collaborated with the National Disability Insurance Agency (NDIA) to create the CSIRO AI Assistive-Tech Framework in 2022. The NDIA was interested in standardising and improving the assessment of assistive technologies, especially those marketed as AI or intelligent. The CSIRO AI Assistive-Tech Framework was co-designed with stakeholders relevant to assistive technologies to get the range of information needed to evaluate risks and support informed choices. CSIRO Centre is still developing tools to implement the CSIRO AI Assistive-Tech Framework.

DAY 5:

SESSION 2

Karen Booth,
Chief Clinical Advisor (Nursing) at the Australian Digital Health Agency and the President of the Australian Primary Health Care Nurses Association (APNA)

And

Dr. Amandeep Hansra,
Chief Clinical Adviser, Australian Digital Health Agency

And

Herbert Down,
Branch Manager, Clinical Governance & Assurance Branch, Australian Digital Health Agency

Overview:
Provided an overview of Australian Digital Health Agency's (ADHA) role, ADHA's digital health solutions, and challenges with driving digital health adoption in Australia. Discussed the rise in use of medical scribes and the consequent regulatory challenges.

ADHA's role: The ADHA is predominantly funded by the Commonwealth Government (i.e., federal government of Australia) with approximately 40% of their funding coming from state governments, based on an agreement ratio. The ADHA does not have a regulatory role or enforcement powers. The ADHA can help develop standards for digital health, and can manage projects, deploy technologies in healthcare.

ADHA's digital health solutions: The ADHA manages a portfolio of products and services including My Health Record[90] (and corresponding My Health app),[91] Provider Connect Australia[92], and real time prescription monitoring.[93] ADHA works with Accenture (a national infrastructure provider) to provide My Health Record and does not develop the technology in-house. Accenture handles the backend of My Health Records, which is built on a stack of 89 different systems. Since Accenture handles the backend, they have more access then the ADHA does, which means that the ADHA has to make requests for data from Accenture. However, Accenture is cleared at the highest security level. The ADHA is currently exploring ways to future proof My Health Record, which may change their relationship with Accenture.

Challenges with driving digital healthcare adoption in India:
(a) Consumer trust is a significant issue. Recently My Health Record moved from an opt-in to an opt-out model, which resulted in 3-5% of registered individuals dropping off and having their records deleted. (b) Harnessing the power of health data because of data fragmentation across states and territories but also across health systems. The hope is that the interoperability plans under the National Digital Health Strategy 2023-202[94] will improve the situation. For example, patients will be able to see their medical results as soon as they are uploaded, from all their healthcare providers. (c) For first nations people we have to account for their context and cultural sensitives. For example, if there is only one mobile phone in a first nation family then the apps, we make must account for that. (d) Not all healthcare professionals are on My Health Record. GPs have been incentivised by the ADHA

[90] Australian Digital Health Agency, My Health Record
[91] Australian Digital Health Agency, My Health – a mobile application to access your health records.
[92] Australian Digital Health Agency, Provider Connect Australia
[93] IT News, Eleanor Dickinson, ADHA tables $49m for real-time prescription monitoring system, (8 July 2024)
[94] Australian Digital Health Agency, National Digital Health Strategy 2023-2028

Rise and regulatory challenges of medical scribes: From a clinical perspective, doctors are starting to use AI while the consult with patients one-on-one. AI scribes have become popular in clinical practice in Australia, with around 15 companies emerging in the last year. The Royal Australian College of General Practitioners (**RACGP**) is grappling with the rapid adoption of these tools and the need for proper guardrails.[95] However, doctors are not clear where their notes and data in the scribe goes, or who has access to it. Also, it is possible for AI to misinterpret statements made by patients and record a clinical finding that is inaccurate based on those statements. AI scribes are not regulated as medical devices, but that assessment of what is a medical device and what is not, must evolve with evolution in technologies. For example, AI call agents are now being used instead of medical receptionists. While they claim to be non-clinical and therefore not regulated, they might not catch critical symptoms, such as chest pain. This could introduce harm, as an AI call agent might schedule an appointment for the next day without recognising the urgency of the situation. These AI call agents sit outside the current regulatory framework, so it's crucial to continuously evaluate new tools from a clinical governance and safety perspective. The startup sector needs to be closer to the government to ensure that new ideas, which are great for solving administrative burdens, do not have unintended consequences.

[95]Royal Australian College of General Practitioners, Artificial Intelligence Scribes; see also RACGP's Factsheet on AI Scribes.

ANNEXURE II: SUMMARY OF DISCUSSIONS FROM INDIA EXCHANGE TOUR

BACKGROUND

This document captures the summaries of our discussions in India from 10-14 February 2025 in New Delhi and Bengaluru. In India, we set up meetings with a diverse group of Indian experts across academia, government, think tanks, civil society and industry. We also provided them with key issues for discussion during the exchange tour meetings, from their work experience and projects or research.

The meetings were designed to be interactive, with Indian experts presenting insights based on their work and experiences, followed by open discussions with the Australian Cohort. These conversations provided a deeper understanding of how AI is shaping India's healthcare sector, the policy landscape, and the challenges in building AI solutions that are ethical, effective, and inclusive.

MEETING SUMMARIES

This section provides a summary of the key discussions, presentations, and insights shared during the meetings. Each session was structured to begin with introductions, followed by a presentation or remarks from invited speakers. The session then engaged in discussions, asking questions based on the presentations, which led to dynamic and free-flowing conversation.

Speakers shared a diverse range of perspectives based on their expertise, ongoing projects, and policy engagements. However, the **'Key Points Presented and Discussed'** in this document have been curated based on their relevance to the intended outcomes of Project BUILD, particularly in advancing AI-enabled healthcare governance and inclusivity. Since these discussions were conducted under the Chatham House Rule, this summary does not attribute specific questions, insights, or case studies to individual members of the Indian Cohort or to specific speakers.

DAY 1: AI FOR HEALTHCARE IN INDIA

SESSION 1

Dr. Bharat Agarwal,
Principal Director, Radiology Services, Max Hospital

Dr. Poorvee Mathur,
Head, Grants and Partnerships, Max Healthcare

Adip Puri,
Country Head for India, Asia Pacific Medical Technology Association

Gaurav Mendiratta,
PP and GA Manager, AdvaMed

Shivangi Malhotra,
Senior Associate – Privacy & Policy, Data Security Council of India

Overview:
The discussion focused on challenges and opportunities of AI adoption in healthcare, particularly in the Indian context. Participants shared insights into AI-driven radiology solutions, digital health solutions and the manner of collaborations. A major theme of the discussion was regulatory uncertainty, particularly around data privacy, liability frameworks and data-sharing laws. The lack of standardized de-identification tools and frameworks complicates AI implementation, and the consent-based nature of India's data protection regulations makes it difficult for healthcare providers to use AI effectively. The discussion also examined industry shifts, noting how big tech firms now act as orchestrators rather than acquiring AI startups, and emphasized the need for recognizing AI-based Software as a Medical Device (SaMD) in Indian regulations.

Data Sharing:
A key concern for large hospitals that work with global companies for research, development and deployment of healthcare services is sharing patient data and the compliance associated with it. The lack of clear regulatory frameworks for AI-driven healthcare solutions has resulted in confusion regarding data localization, data sharing and transfer policies of hospitals. Establishing legal agreements between hospitals and AI companies is an arduous process, often taking months due to liability concerns. Moreover, international collaborations are further complicated by cross-border data transfer restrictions, making it difficult for Indian healthcare providers to engage in global research projects. Many legal teams, instead of facilitating AI adoption and data sharing, focus on minimizing institutional risk, leading to lengthy legal negotiations before any collaboration can proceed.

Another issue that was highlighted was how data collection is difficult in India due to its fragmented nature, and that the Ayushman Bharat Mission is aimed at slowly

Consent:
One of the themes of the discussion was around patient consent and the larger problem of consent for healthcare research. The discussion also highlighted that consent processes vary based on the type of healthcare activity. For clinical treatments, informed consent is typically managed by clinicians, who explain procedures directly to patients. However, for research projects, particularly those involving AI and public health initiatives, consent is often less structured and varies based on the ethics committee's approval process.

In the Indian context, the data protection law requires explicit, informed and affirmative consent for the use of data. In the case of healthcare, apart from limited exceptions such as life-saving treatments, public health emergencies or epidemics, there is a rigid framework. This poses challenges for AI-driven healthcare, such as the fact that retrospective data analysis is limited. One of the key concerns highlighted was that while healthcare providers obtain patient consent, there is often a gap in patient understanding about what they are consenting to. Many patients, particularly those with lower literacy levels or from marginalized communities or different socio-economic backgrounds, may not fully grasp the implications of data use in AI models. Even when consent is obtained, patients might not be aware of their right to withdraw it. There was a call for better patient education, ensuring that consent is truly informed and voluntary, rather than just a procedural formality.

In Australia, one of the ways to understand consent for patient data is the degree of social license and acceptance among the community about AI adoption. While patients are generally comfortable with their data being used for improving public healthcare services, concerns arise when the data is leveraged by private firms for monetization. There is a special focus on working with Indigenous communities in Australia, due to historical disparities in health outcomes. Despite this, every ethics committee in Australia is grappling with questions about how to use patient data for research. Some experts suggested alternative approaches for consent, such as the Data Solidarity Principle.[96] This concept moves away from strict individual consent requirements and instead focuses on a broader agreement where patient data can be used for legitimate healthcare and research purposes without explicit consent for every instance.

Patient Cantered Engagement:

A key topic was how patients can be integrated into the research design process. In global grants from organizations like the NIH (U.S.) and NIHR (U.K.), there is often a requirement for community engagement in trial designs. These funding bodies expect researchers to demonstrate how patient perspectives have shaped research objectives, recruitment strategies, and study follow-ups. However, India lacks a formal framework for such community participation, making it difficult to systematically incorporate patient feedback into AI healthcare research. In some larger private hospitals, where patients tend to belong to higher socio-economic backgrounds, patient literacy and willingness to engage in research can be higher. However, this also creates challenges, as more informed patients may be hesitant to participate in research studies due to concerns about data privacy, medical risks, or lack of direct benefits.

[96]Data solidarity – A White Paper. Geneva: Governing Health Futures 2030, Prainsack, B., El-Sayed, S., Forgó, N., Szoszkiewicz, Ł., Baumer, P. (2022, revised January 2025). Available at: https://dthlab.org/wp-content/uploads/2025/02/25_01-DTH-Lab-Data-Solidarity-White-Paper.pdf

AI and Software as a Medical Device:
The Indian MedTech sector is undergoing rapid transformation, with increasing calls for AI-based regulations. Industry representatives emphasized the need for the recognition of Software as a Medical Device (SaMD) under Indian medical device laws. India's recent membership in the International Medical Device Regulatory Forum (IMDRF) is a positive step toward aligning with global regulatory standards. The IMDRF allows India's regulators to learn from international best practices in AI regulation, including frameworks used by the U.S. FDA and European Union. However, participants pointed out that India still faces the challenge of adapting these global frameworks to its unique healthcare ecosystem. The discussion emphasized the need for India to develop localized regulatory frameworks that account for both global alignment and domestic requirements.

SESSION 2

Tavpritesh Sethi,
Associate Professor, Head at Centre of Excellence in Healthcare, IIIT-Delhi

Ranjan Bose,
Director, IIIT-Delhi

Pushpendra Singh,
Professor, IIIT-Delhi

Richa Gupta,
Assistant Professor, IIIT-Delhi

Anubha Gupta,
Professor, IIIT-Delhi

Ganesh Bagler,
Professor, IIIT-Delhi

Overview:
As part of the discussions, a field trip to IIIT-Delhi's campus was facilitated to understand how academic collaborations work in India. The trip also showcased significant research initiatives at IIIT-Delhi including its Medical Cobotics Centre (MCC) and the iHub Anubhuti incubator. The trip consisted of learning more about IIIT-Delhi's trajectory, highlighting its modern campus, diverse student body and interdisciplinary research across six departments, including 11 Centres dedicated to areas such as AI and healthcare. Subsequently, the visit featured presentations on accessibility design for special populations, AI-driven approaches to maternal healthcare, advancements in cancer genomics and VR technology for rehabilitation. It also featured discussions on AI applications in food science and using it to disseminate truthful and relevant healthcare information. Finally, it ended with visiting the MCC and learning more about the different medical innovations taking place in the lab.

IIIT-Delhi:
An overview of the institution was presented, highlighting its status as a state university with administrative autonomy. The university operates with a strong research focus, industry collaborations, and an emphasis on entrepreneurship. It consists of six departments, including Computer Science, Electronics & Communications, Computational Biology, Mathematics, Social Sciences & Humanities, and Human-Centred Design. The university promotes interdisciplinary collaboration and offers specialized programs such as Computer Science with Applied Mathematics, Design, Social Sciences, Biosciences, and AI. IIIT Delhi also has a robust PhD program and several research centres, including the Infosys Centre for AI, Centre for Design and New Media (funded by TCS) and a Centre of Excellence in Healthcare. The university has active international collaborations, including a dual-degree program with State University of New York at Albany and research engagements across 40+ countries, including Australia.

Accessibility and Inclusive Design Lab:
The Accessibility and Inclusive Design Lab at IIIT Delhi is led by a focus on developing AI-driven solutions to enhance accessibility for individuals with disabilities, particularly visually impaired individuals, people with invisible disabilities (such as ADHD and dyslexia) and the elderly. It conducts tactile graphics research to improve how blind individuals interpret raised-line drawings and multimodal learning studies to enhance verbal and textual communication in inclusive education. One of its key innovations is StoryBox, an interactive storytelling system inspired by Rajasthan's Kaavad folk tradition, designed for blind children. The TalkTile project leverages machine learning and augmented reality (AR) to digitally annotate physical books, enabling users to place their fingers on a page and receive real-time audio narration. The lab's research combines AI, human-centred design and inclusive technology to create scalable, real-world accessibility solutions.

Centre of Excellence in Human-Centred Computing:
The Centre leads research on AI-driven interventions in public and mental health, focusing on maternal healthcare, menstrual health, and mental well-being. This includes AI-powered mobile-based training for ASHA workers, addressing gaps in maternal and child healthcare delivery in rural India by providing interactive, speech-enabled learning modules. In the mental health space, their research explores digital interventions for bipolar disorder and schizophrenia, using AI-based mobile applications to improve medication adherence, symptom tracking, and personalized mental health support. The team has also contributed to making government healthcare apps more inclusive, particularly enhancing the accessibility of Poshan Tracker, India's flagship maternal and child nutrition monitoring platform. With a focus on human-centred AI, the centre work integrates machine learning, behavioural research and mobile technology to improve public health accessibility and healthcare training at scale.

Infosys Centre of AI:
The Centre highlighted its research on AI-driven diagnostics and predictive modelling for cancer genomics and cardiovascular diseases focuses on leveraging machine learning and deep learning techniques to enhance precision medicine. In cancer genomics, AI-driven RNA sequencing and whole exome sequencing analysis are applied to study multiple myeloma, using real patient cohort sequencing data from 1360 patients in collaboration with AIIMS Delhi and the Multiple Myeloma Research Foundation (USA). A full pipeline workflow has been developed to identify structural variants and genetic mutations, leading to the creation of a patent-pending AI-powered gene panel for precision oncology and personalized cancer treatment.

AI in Food Science & Nutrition:

A pioneering research initiative at IIIT Delhi, Computational Gastronomy applies AI and data science to food, nutrition, and sustainability. The AI-generated recipe model, Ratatouille, mimics chef expertise by creating new recipes based on ingredient combinations. AI is also used for health and nutrition analysis, evaluating macronutrients, micronutrients, and dietary recommendations for personalized health benefits. Additionally, research on carbon footprint analysis assesses the environmental impact of food production and consumption patterns to promote sustainable eating habits. The insights from this work have led to the creation of Fluoroscope, a startup commercializing AI-driven food science solutions for healthcare and nutrition industries.

Medical Cobotics Centre:

The cohort also visited the MCC which is aimed at being India's first state-of-the-art technology-enabled medical simulation and training facility for doctors, paramedics, technicians, engineers, biomedical researchers, and entrepreneurs. The Centre is also equipped to offer hands-on simulation training to the medical fraternity across the country. It will also act as a test bed for many young start-ups in the medical field that are developing innovations in medical technology, digital medical healthcare, healthcare using AR/VR, AI, robotics, cognitive sciences etc. The cohort visited and saw a human-patient simulator and, how it is being used for training as well as testing innovative treatments and other healthcare tools.

SESSION 3:

Debayan Gupta,
Assistant Professor of Computer Science at Ashoka University

Kshitij Jadhav,
Assistant Professor, Indian Institute of Technology, Bombay

Krithika Rangarajan,
Oncoradiologist, Assistant Professor, All India Institute of Medical Sciences

Overview:

The discussion generally focused on India's AI ecosystem and the developments around AI Centres of Excellence (CoEs) under the IndiaAI Mission. It also focused on funding models, academic research contributions, AI governance frameworks, and challenges in deployment. A key highlight of the discussion was the establishment of three CoEs in Health, Agriculture and Sustainable Cities, backed by a ₹1000 crore (~$120 million) budget. The discussion covered the structure, operational approach, evaluation frameworks, safety and liability concerns, data privacy regulations, and regulatory challenges of the CoE in Healthcare.

Fears of the Indian Community regarding AI and Tech:

People in rural areas have been known to be concerned about data collection, especially around how and why it is being stored. An example was provided on how parents of a young born child in a village were concerned about the usage of their child's photo. This is indicative of how there is a misconception of rural India not understanding the concerns around privacy.

Additionally, there is fear of a kind of digital colonialism. With the Indian governments increased focus on technological sovereignty generally and digital sovereignty particularly, there is growing concern that AI is increasingly controlled by a few in the Global North.

Establishment of AI Centres of Excellence in India:

The CoE focusing on healthcare is set to receive INR 330 crores (~$40 million) over four years. The aim is to bridge the gap between academic research and real-world AI deployment, ensuring that AI-driven solutions address pressing healthcare challenges such as disease screening, chronic disease management, and maternal health.

The selection process for these centres was rigorous, with 55 consortia applying, of which 24 completed the application process. The applications underwent a multi-stage evaluation, where an industry-led Apex Committee (comprising representatives from Google DeepMind, Aadhaar and leading healthcare technology firms) selected four consortia in healthcare to proceed to the next phase. The unique aspect of the selection process was the exclusion of academic representatives from the committee, ensuring that projects were evaluated from an industry perspective rather than an academic research-oriented approach.

Each of the four selected healthcare consortia received INR 2 crores (~$240,000) for a six-month proof-of-concept phase. This funding was not just based on their proposal but also on actual project execution. Unlike previous models where projects were funded based on detailed proposals alone, this initiative required concrete results within six months before scaling up the funding. This "execution-first" approach was a departure from traditional research funding models, ensuring that only practical, scalable, and impactful projects moved forward.

Operational Structure of CoEs: To ensure sustainability and independence, the selected CoEs are mandated to form Section 8 companies, a type of non-profit entity in India that allows for structured governance, stakeholder participation, and legal accountability. The operational framework of these Centres is designed to integrate inputs from government, academia, and industry, ensuring that AI applications are commercially viable, scientifically rigorous and socially beneficial. The Ministry of Education serves as the primary oversight body, coordinating with line ministries such as the Ministry of Health and Family Welfare (for healthcare initiatives) and the Ministry of Housing and Urban Affairs (for sustainable cities initiatives). The CoEs will not be reliant on government funding beyond the initial four-year period, making it essential for them to develop self-sustaining revenue models. This is being achieved by integrating a licensing and commercialization strategy like India's Unified Payments Interface (UPI) model, where open-source components coexist with proprietary commercial applications. To ensure accountability, the CoEs are required to submit quarterly deliverables and undergo independent audits. In a notable departure from past research funding models, in-person site visits were conducted during the selection phase to verify whether the projects were progressing as claimed in their presentations. This real-world validation process helped filter out projects that looked promising on paper but lacked execution feasibility.

CoE in Healthcare:

The healthcare CoE functions as a multi-stakeholder consortium, integrating expertise from IITs, private technology firms, healthcare startups, and medical research institutions. It is not just a research hub but a deployment-oriented initiative, meaning its projects are expected to scale beyond controlled testing environments and integrate into India's national and digital healthcare infrastructure. These include government-backed platforms like E-Sanjeevani and the Ayushman Bharat Digital Mission. The problem identification process is clinician-led, ensuring that AI applications target actual healthcare gaps rather than theoretical research problems. The CoE in healthcare has prioritized five major healthcare domains. These include: (a) cancer screening and early detection; (b) chronic disease management; (c) visual impairment and blindness; (d) infectious diseases and (e) maternal and child health. Typically, AI is developed in silos, which limits its acceptance. Instead of starting with AI, the CoE in Healthcare began by analysing the country's healthcare system, recognising that existing systems are hard to change. For each programme, they identified inefficiencies and determined where AI could make the most impact. The CoE in healthcare focuses on actionable diseases i.e. those which have treatments that exist already:

- Cancer Screening: AI-assisted diagnosis for breast, cervical, and oral cancers using a multi-stage protocol that begins with risk assessment by ASHA workers, followed by ultrasound-based AI triaging and then mammography/pathology confirmation.

- Chronic Disease Management: AI-powered Clinical Decision Support Systems (CDSS) for diabetes, hypertension, asthma and COPD, with a focus on predicting disease exacerbations such as asthma.

- Ocular Disorders: AI models for preventable blindness, particularly for diabetic retinopathy, cataracts, and glaucoma.
- Infectious Disease Detection: AI for tuberculosis, leprosy, and antimicrobial resistance (AMR) tracking.
- Maternal and Child Health: AI-powered tools for early detection of pregnancy risks, malnutrition, and growth delays in infants.

Frontline Healthcare Workers:
A concern highlighted was deploying AI healthcare to work within existing workflows of frontline healthcare workers, because they feel over-burdened with their work. Currently, AI-powered mobile applications are being designed specifically for ASHA and auxiliary nurse midwives (ANMs), ensuring that they can use AI tools with minimal training, and it doesn't add to their burdens.

Independent Validation Compute:
All AI models must undergo third-party validation at IIT Jammu's independent AI evaluation unit before being deployed in healthcare facilities. This process ensures that AI solutions meet regulatory standards and clinical accuracy benchmarks.

The primary success metric for all AI-driven healthcare initiatives is the number of lives impacted, rather than traditional research metrics such as patents or publications. AI models must be tested in real-world conditions, with scalability trials conducted in multiple states and diverse healthcare settings before national rollout.

Data Sharing and Governance Policy:
Data privacy emerged as another key area of discussion, with emphasis on developing secure data-sharing platforms such as MIDAS[97] to ensure patient confidentiality while allowing AI researchers to access necessary datasets. A major challenge identified was balancing data privacy with research requirements—while strict data protection is essential, overly rigid restrictions could stifle innovation.

Inclusivity in CoE of Healthcare:
By nature of the healthcare system in India, since it is a state subject – when you look at deploying you end up looking at the states and their specific people. The consortium of CoE in Healthcare consists of diverse groups and states already ensuring that diversity is there from the beginning. The hiring of the team are aligned with the reservation policies of the government. The guiding principle and metric in deploying solutions is the number of lives touched.

[97]Medical Imaging Datasets for India (MIDAS) is a joint initiative by ICMR, IISc and ARTPARK to create high quality and standardized medical datasets representative of Indian population. Available at: https://midas.iisc.ac.in/landing-page

Inclusive Research Methods:
Another problem highlighted regarding ensuring inclusivity while researching and understanding AI solutions is the power imbalance that exists between frontline healthcare workers. An ASHA worker may often hesitate to critique new digital health tools, fearing that their opinions will not be valued or could lead to negative repercussions. To counteract this, trust and reciprocity were highlighted as key principles that should be embedded into AI-driven healthcare research. An example was a research project from the UK, where a team engaged South Asian women in health-related discussions through an informal tea party rather than structured interviews. This unique approach was intended to eliminate traditional power dynamics in research, allowing participants to express themselves freely in a non-intimidating setting. The CoE of Healthcare is currently looking at involving ASHA workers and other frontline healthcare workers as they deploy solutions and define problems that AI is meant to solve.

Liability:
A minor discussion took place regarding the harms caused due to AI systems deployed in healthcare. Currently, all AI models are assistants and help with clinical decisions, but fundamentally a doctor is responsible for the decisions made and healthcare delivery.

International Collaborations:
The CoE of Healthcare is keen on cross pollination of ideas. They are in the process of exploring international collaborations with centres of excellence in other countries like Singapore and France.

DAY 2

SESSION 1

Amar Jain,
Co-founder, Mission Accessibility

Tavpritesh Sethi,
Associate Professor, IIIT-Delhi

Rajesh Aggarwal,
IAS, Former Secretary, Department of Empowerment of Persons with Disabilities, Ministry of Social Justice and Empowerment, and Chief Commissioner for Persons with Disabilities

Dr Mrs Anita Aggarwal,
Head, Science for Equity, Empowerment & Development Division (SEED)

Overview:
The Workshop on Inclusivity in AI-Enabled Healthcare convened policymakers, researchers, healthcare professionals, and industry leaders from India and Australia to examine how AI-driven healthcare solutions can be designed and deployed in ways that ensure accessibility, ethical governance, and inclusivity. The discussion centred on addressing the barriers that prevent AI technologies from serving all populations equitably, particularly marginalized groups such as persons with disabilities, rural populations, and linguistic minorities.
With AI becoming an increasingly influential force in medical decision-making, from clinical diagnosis to mental health interventions and assistive technologies, the workshop underscored the need for a holistic approach to AI governance that incorporates co-creation, diverse data representation, and systematic oversight. Participants acknowledged that inclusivity in AI is not a one-time effort but an ongoing process requiring continuous refinement.

Smriti Joshi,
Chief Psychologist, Wysa

Noopur Jhunjhunwala,
Co-Founder and Trustee Changeinkk

Bhargavi Kaushik,
Co-Founder, empath.ai

Context and Rationale for the Workshop:

The discussion began with a framing of the importance of inclusivity in AI design. It was noted that while AI offers significant potential for healthcare advancements, these solutions can only be truly effective if they are designed with diverse populations in mind. Key questions raised included how AI can be co-designed with the communities it serves, what methodologies ensure that AI-driven healthcare tools remain representative and unbiased, and what regulatory or policy frameworks are necessary to support ethical AI deployment. The conversation emphasized that inclusivity is a local concern and must be embedded in the foundational stages of AI development rather than being retrofitted later.

Department of Science and Technology's work on building assistive technologies for people with disabilities and the elderly:

The Department of Science and Technology (DST) has played a significant role in advancing assistive technologies and some AI-driven solutions for people with disabilities and the elderly. DST has funded multiple research programs to develop affordable assistive devices for individuals with disabilities and the elderly, emphasizing co-creation with affected communities. DST's interventions include AI-powered assistive technologies, prosthetic advancements, and accessibility solutions such as speech-to-text applications for individuals with hearing impairments.

One of the key challenges identified in DST-led programs is scaling solutions beyond academic prototypes. While over 150 assistive technologies have reached the proof-of-concept stage, many still require industry partnerships for large-scale deployment. The Technology Interventions for Disabled and Elderly (TIDE) Program, conceptualized in 2013, has supported 74 institutions with a budget of ₹39 crore. It has focused on creating inclusive AI solutions, assistive products, and technological interventions that enhance independent living, economic inclusion, and accessibility.

The department is also strategizing for large-scale deployment and commercialization of AI-based assistive technologies by fostering collaboration between startups, academia, and government institutions. The goal is to scale production and distribution to maximize access for Persons with Disabilities (PwDs) and elderly populations.

Inclusivity as an Economic Incentive:

One of the perspectives shared in the discussion was how people with disabilities should not be viewed as only a group of people that needs assistance, but a group Co-Founder, empath.ai with a large economic power to spend. This was done by acknowledging the scale of the disability community worldwide. According to WHO estimates, there are over 1.8 billion people with disabilities globally, making it one of the largest market segments in the world. Participants noted that the purchasing power of persons with disabilities and their families is estimated to be around $13 trillion, which is larger than the Chinese economy. Their disposable income alone is close to $2 trillion, making them a significant consumer group whose needs and preferences should be considered in AI development, rather than merely viewing them through the lens of social responsibility.

Co-Creation with Affected Communities:

It was noted that people with disabilities, the elderly, and marginalized groups must be included as co-creators in AI design rather than as passive subjects of research. The benefits of this approach include more precise problem identification, greater usability and adoption rates, and avoidance of common design pitfalls that overlook user needs. Participants discussed how NGOs and not-for-profit organizations are essential in connecting researchers and developers with affected communities to facilitate a co-design process that ensures real-world applicability.

Case Study of Wysa:

One of the discussions centred on Wysa, a conversational AI chatbot designed for mental health support. Originally developed for English-speaking users, Wysa encountered significant challenges when expanding into non-English-speaking populations. When Wysa was first introduced in India, a direct translation of its English-language AI model into Hindi proved ineffective. The AI-generated responses, while grammatically correct, lacked cultural and emotional sensitivity, making them feel robotic and disconnected. Mental health concerns are often expressed differently across cultural contexts, and a direct linguistic translation failed to capture the nuances of how individuals from different backgrounds discuss their emotions.

To address this issue, Wysa's development team co-designed the chatbot's Hindi-language responses by collaborating with community representatives and psychologists. Instead of relying solely on automated translation, the team worked with rural women in Rajasthan, adolescent girls in tribal communities, and paramilitary personnel to understand the specific mental health vocabulary and expressions used by different demographics.

A significant challenge identified was that mental health stigma in India often prevents individuals from expressing emotions directly. This required AI models to be adapted not just for language but also for cultural interpretations of psychological distress.

The discussion underscored the importance of linguistic and cultural localization in AI-driven healthcare. Without deep cultural adaptation, AI risked alienating the very populations it aimed to serve. Wysa's experience demonstrated that co-designing AI responses with affected communities is essential for ensuring inclusivity in mental health AI tools. Crucially, Wysa's approach to inclusivity was iterative in nature. They kept incorporating feedback, working together with communities on the ground and targeting the relevant users to ensure that the AI-tool can be improved.

Symptom Checker and Clinical Decision Support System in Australia:

The discussion also featured a use-case on Australia's AI-powered clinical decision support system which assists nurses in triaging patients more effectively. This AI system was designed to standardize triage assessments, ensuring that nurses provide consistent and accurate recommendations regardless of their individual experience levels. It was also designed to solve the problem of gap in knowledge between experienced clinicians and nurses, and those who do not have the same levels of experiences.

One of the key challenges faced during implementation was ensuring that the AI aligned with Australia's unique disease prevalence patterns. The AI model was originally based on European medical data, but upon testing, critical differences in epidemiology emerged. Certain diseases that were rare in European populations were far more common in Australia, particularly among Indigenous communities. To address this issue, the model underwent localization through clinical validation with Australian doctors and nurses. The process involved conducting a pilot program in Tasmania, where AI-generated triage recommendations were compared against real-world clinical decisions.

The tool went through strong protocols and standards of safety, accuracy and effectiveness. The system continuously improves by incorporating real-time feedback from healthcare professionals. It was also clear from the beginning that the AI-tool is only to support and aid nurses. The AI model was designed to allow nurses to override its suggestions, ensuring that human expertise remains central to the decision-making process. A year after deployment, follow-up analysis showed a 10% improvement in AI accuracy, largely due to continuous feedback from nurses. This iterative improvement demonstrated that AI systems must be continuously refined based on real-world user input. The human-in-the-loop model, where AI assists but does not replace human decision-making, was identified as a successful practice for ensuring ethical AI deployment in clinical settings

Discussion on Tenets of Inclusivity:

A portion of the workshop was dedicated to outlining and refining the tenets of inclusivity in AI-driven healthcare. These tenets, developed through extensive discussions in India and Australia, aim to provide a structured framework for ensuring that AI-enabled healthcare solutions are designed, implemented, and governed in a way that prioritizes inclusivity. The tenets were initially formulated based on prior conversations in Australia, and this workshop served as an opportunity to stress-test them against real-world use cases and stakeholder perspectives.

There were a few elements discussed during the workshop which include the following:

• ***Problem Definition and Stakeholder Participation:*** One of the key principles in building an AI tool that was discussed was defining the problem statement with active participation from diverse stakeholders. Inclusivity cannot be an afterthought—it must be built into the AI development process from the very beginning. This means ensuring that the voices of patients, caregivers, clinicians, policymakers, and advocacy groups are heard at every stage of development.

• ***Proactive Inclusive Research and Data Diversity:*** For AI in healthcare to be truly inclusive, data diversity is crucial. AI models must be trained on datasets that are representative of the full spectrum of human diversity, including age, gender, disability, ethnicity, language, and socio-economic background. Another issue raised was the difficulty of capturing the lived experiences of marginalized communities in data. Many AI models rely on quantitative parameters, but qualitative aspects of human health and well-being—such as mental health symptomatology across different cultural contexts—are often overlooked. To address this, the workshop explored new research methodologies that integrate community-driven data collection and micro-narratives into AI training processes.

• ***Regular Evaluations and Strong Feedback Loops:*** To measure whether AI solutions are truly inclusive, the participants emphasized the need for regular evaluation frameworks. These frameworks should track disparities in AI-generated healthcare recommendations and monitor how different population groups engage with AI tools. The discussion also highlighted that inclusivity should not be measured solely by whether AI tools are used widely; rather, the focus should be on whether those tools provide equitable benefits to its intended users.

• ***The Future of Inclusivity of AI in Healthcare:*** The workshop concluded with reflections from Mr. Rajesh Agrawal, Secretary of the Department of Empowerment of Persons with Disabilities. He emphasized the inevitability of AI adoption despite the challenges it presents. While acknowledging the risks, he stressed that the potential benefits of AI in healthcare and accessibility far outweigh the drawbacks.

SESSION 2

Siddhartha Bhattacharya,
Secretary General at NATHEALTH

Dr. Rohit Verma,
Assistant Professor, AIIMS

Dr. Shubnum Singh,
Principal Advisor Health Policy Confederation Of Indian Industry (CII)

Munender Soperna,
Group CDIO at Dr Lal PathLabs

Ravi Gaur,
Founder, DRG Path Labs

Overview:
The session focused on how different large healthcare service providers are looking at and utilizing AI in their systems. They examined the evolution of AI adoption, the role of unified health records, and the importance of diverse data. The speakers also provided details on AI's applications in in diagnostics, pathology, and medical imaging, while also highlighting the need for trust, training, and evidence generation for people to be able to rely on AI more easily. There was also comparison between compared the state of AI adoption between India and Australia, noting regulatory challenges and the necessity for standardisation.

AI in Psychiatry:
The discussion opened with a focus on AI's role in psychiatry, particularly in diagnostics, treatment personalization, and neural stimulation. AI-based brain mapping technologies such as functional near-infrared spectroscopy (fNIRs), EEGs, and eye-tracking are increasingly being used to analyse behavioural and cognitive data. However, the absence of structured patient cohorts in India presents a significant hurdle, as Western nations maintain comprehensive health databases that allow for data-driven clinical decision-making. The lack of a nationalized electronic health record (EHR) system further complicates AI's ability to generate meaningful insights.

In efforts to address these gaps, projects are underway to digitize patient data and develop predictive AI models that assist in identifying optimal treatment pathways for conditions like depression and schizophrenia. Despite these advancements, challenges persist in data procurement, integration, and infrastructure, exacerbated by limited technical expertise within clinical teams. Furthermore, existing doctors and psychiatrists and clinicians are already overburdened with existing duties, focusing on developing new tools is difficult. There is an increasing reliance on collaborations with engineering and research institutions to develop AI solutions tailored to India's healthcare environment.

The Evolution of Digital Health in Indian Healthcare: AI adoption in Indian healthcare remains nascent and fragmented due to historical challenges in EHR implementation and interoperability. Early attempts to integrate AI in healthcare, including collaborations with Australian EHR developers, failed due to operational immaturity and cost constraints. Despite government-led initiatives like Ayushman Bharat Digital Mission (ABDM), awareness and penetration of standardized digital health records remain limited. AI-driven decision support tools are primarily used for basic clinical summaries, imaging diagnostics, and operational efficiencies, but widespread adoption is hindered by low digital literacy among healthcare professionals and the absence of interoperable systems.

Indian healthcare institutions are slowly recognizing the importance of structured digital records, yet data silos across hospitals and diagnostic centres prevent seamless building any consistent AI-tool. The speakers also compared India's trajectory with other nations, noting that the complexity of Indian healthcare—spanning vast geographies and varied languages—demands adaptive, localized strategies rather than a single, uniform solution. Widespread EHR adoption is seen as a precursor to more sophisticated AI-enabled clinical decision support systems, promising improved patient outcomes and reduced administrative burdens.

AI in Diagnostics, Pathology and Clinical Decision Support:

The discussion highlighted AI's limited adoption in pathology and diagnostics, largely due to trust issues and regulatory uncertainty. While radiology has seen moderate AI adoption, particularly in stroke detection and lung scan analysis, pathology lags behind. Digital pathology initiatives, such as AI-assisted haematology and sepsis detection, have struggled to gain traction due to concerns over validation, reliability, and regulatory oversight

One of the primary barriers is physician scepticism regarding AI-generated diagnostic reports, as trust in AI models remains low. AI-based pathology tools have been in development for over a decade, yet adoption remains slow due to insufficient validation frameworks. The lack of regulatory clarity on AI-driven diagnostics further exacerbates hesitancy among pathologists and healthcare administrators.

A significant challenge in pathology AI is its high dependency on well-structured, high-quality data, which is currently lacking in most Indian healthcare institutions. Efforts to develop localized AI models trained on Indian patient data are underway, but without a nationalized data-sharing framework, scalability remains limited.

Data Management and AI Implementation:

AI's success in healthcare is dependent on three critical pillars: compute infrastructure, data quality, and model validation. Advances in cloud computing and scalable AI models have made AI implementation more feasible, but poor data quality and inconsistent coding practices remain significant barriers. Indian healthcare institutions generate vast amounts of unstructured data, making AI-driven insights unreliable without structured standardization efforts.

Case Study: Emergency Response System:
An illuminating example of AI in Indian healthcare was brought up with the 108-emergency response system—analogous to a 911 service. Operated in collaboration with government bodies, this service covers over 800 million people, deploying ambulances across urban and rural regions. The system, designed as a public-private partnership, is one of the most technologically advanced emergency networks globally, despite operating in a cost-constrained environment. By layering historical incident data onto Google Maps, operators employ AI-driven analytics to dynamically predict where emergencies are most likely to arise at various times, thereby optimizing ambulance allocation. The results have been substantial, with response times reduced to under 10 minutes in urban areas and 15-20 minutes in rural regions, a major improvement for resource-constrained emergency services.

Need for Digital Literacy and Healthcare Workforce Training:
Speakers emphasized that many clinicians learn technology "on the fly" amid high patient volumes, leaving scant time to pick up new skills or build familiarity with AI. Although medical curricula are starting to evolve, it will be years before these reforms translate into real-world practices across a broad swath of hospitals. In the interim, structured and ongoing training programs are deemed vital for doctors, nurses, and allied professionals to bridge the digital literacy gap and confidently integrate AI tools into routine care. Trust in AI hinges not only on the quality of algorithms but also on clinicians' familiarity with and confidence in them.

5 Ps for AI Implementation: A framework or idea was touted for AI integration in healthcare: Prediction, enabling early disease detection and risk assessment through AI-driven analytics; Personalization, tailoring treatments based on genetic, behavioral, and clinical data for precision medicine; Productivity, improving efficiency by automating workflows, clinical decision support, and hospital resource management; Proactive Care, shifting from reactive treatment to preventive healthcare using wearables, virtual assistants, and AI-driven health monitoring; and Partnership, fostering collaboration between clinicians, AI engineers, and policymakers to ensure ethical, effective, and regulatory-compliant AI adoption.

DAY 4

SESSION 1

Dr. Inv. Shivakiran Makam,
Chief Academics and Innovation Office, HCG

Vikas Dwivedi,
CTO, EnAble India

TK. Srikanth,
Professor, International Institute of Information Technology, Bangalore

Roli Mathur,
Scientist G & Head, ICMR Bioethic Unit

Dhiroj Barad,
Head Legal, Siemens Healthineers

Overview:
The session focused on the critical need for inclusivity in digital health solutions and the challenges faced in designing products that are accessible, inclusive and effective. Discussions covered AI in cancer treatment, highlighting data access barriers, patient consent challenges, and the complexity of developing AI-products without data. The TeleMANAS initiative was explored as a model for scaling mental health services to remote areas, with language barriers, privacy and data governance emerging as key issues. The DPI discussion underscored the difficulty of retrofitting inclusion, with case studies on ride-hailing accessibility for persons with disabilities (PWDs) illustrating the importance of embedding inclusion from the start. A critical theme was trust in AI adoption, with NGOs proving more effective than governments in securing patient data for AI training.

Challenges in Model Development and Data Access:
For cancer hospitals, it was emphasized the complexity of AI-driven cancer treatment, where AI models struggle to keep pace with cancer's evolving nature, requiring multi-specialty decision-making across surgical, immunotherapy, and radiotherapy approaches. Each healthcare specialty favours its own method, making AI training more complicated.

AI's potential in diagnostics and hospital management is significant, but bias in training data remains a major barrier, as hospitals receive diverse patient data from rural, suburban, and urban areas, which
A framework or idea influences model effectiveness. Additionally, data ownership is a key challenge—patients provide consent only for hospital and physician use, preventing AI startups from using it for model training.

One case study was highlighted. It was a saliva-based cancer detection startup that sought validation on 3,000 patients, but patients resisted giving additional consent when approached during treatment due to distress. However, when asked post-treatment during discharge, patients were more receptive due to a sense of gratitude and well-being. This underscores the need for revised patient engagement models that encourage ethical and voluntary data sharing without intruding on vulnerable moments.

TeleMANAS Initiative:

The TeleMANAS initiative, India's national mental health tele-counselling service, has been crucial in providing access to mental health services across the country including remote areas.[98] The service includes regions like Jammu & Kashmir, the Northeast, and Lakshadweep, where geographical isolation limits mental healthcare options. The working tagline that the service had was 'Reaching the Unreached'. The service has handled 100,000+ calls during COVID-19 and continues to receive 3,000 daily calls, showing widespread adoption. However, language barriers remain a significant hurdle, as the system supports 20+ languages but struggles with regional dialects and tribal accents, reducing accessibility for many patients. AI-driven real-time speech translation tools could bridge this gap, but accuracy in mental health contexts remains a concern.

The session also explored how to identify and engage marginalized populations, with no formal framework currently in place to identify such groups. Instead, TeleMANAS relies on government healthcare infrastructure, NGO partnerships, and state-level mental health programs to expand its reach and effectiveness. The initiative also relies on maintaining simplicity in accessing the service, to ensure that anyone can use it as long as there is a single line to call.

Digital Public Infrastructure (DPI) and Accessibility Gaps:

India's Digital Public Infrastructure (**DPI**), including UPI and ONDC, was initially designed without considering marginalized communities, leading to major accessibility challenges. Inclusion efforts only began 3-4 years after DPI's rollout, making retrofitting accessibility difficult. A key example was ride-hailing accessibility, where AI-driven tags were recently introduced to assist visually impaired passengers and wheelchair users, along with real-time driver training videos.[99] The discussion emphasized that inclusion must be built from the start, rather than being added as an afterthought, as retrofitting solutions later is far more complex and expensive.

While building your product, incorporating inclusion at the beginning is a lot simpler. The other improvement in bridging gaps of inclusivity are category managers working under ONDC who are engaging with the community who uses different products and try to incorporate feedback and improve the platform.

"Fully Biased" Models for Disability and Marginalized Groups:

A unique approach was discussed regarding building intentionally biased AI models, designed to exclusively serve marginalized communities, including persons with disabilities (PWDs).[100] An initiative, called DISH, is based on NGO-sourced data, as patients trust NGOs more than government or corporate entities. DISH is unifying platform where people with disabilities and stakeholders can search for assistive solutions. The AI system focuses on assistive technologies, helping PWDs navigate everyday challenges, find relevant products, and access tailored services. In comparison, a normal AI chatbot may give very different answers to DISH since the focus of DISH is only on persons with disabilities.

[98]Press Information Bureau, TeleMANAS revolutionising mental healthcare, (13 October 2024)
[99]The Hindu, Namma Yatri app launches disability friendly services, (5 October 2023)
[100]Enable Solutions

The key insight was that trust is essential for effective data collection, and AI initiatives should prioritize partnerships with community organizations to encourage participation.

Inclusion Problem Determination:

Solutions and problems regarding inclusion are derived from the communities. A large network of NGOs provides inputs on different problems being faced by various communities. NGOs and grassroots organizations are better positioned to identify real-world challenges than government agencies or tech firms. The assumption is that there exists a problem of inclusion but working with NGOs help articulate and define the problem, before moving on to building solutions.

Ethical AI Development and Trust in Data Governance:

A central concern in AI deployment is data governance and patient trust. Many patients hesitate to share data with governments or corporations but are more willing to share data with NGOs, suggesting that community-driven consent models might be more effective than rigid, bureaucratic individual approvals.

AI models must also address bias in training data, as hospitals primarily serving wealthier urban populations risk developing models that fail to generalize to rural or tribal communities. ICMR highlighted the need for more structured AI ethics frameworks, including an ethics committee checklist that ensures AI initiatives address privacy concerns, consent transparency, and data security.

The discussion also stressed data minimization principles—for instance, TeleMANAS deliberately avoids storing voice recordings to prevent privacy breaches, despite potential AI benefits from analysing large voice datasets.

Building Better Data-Sharing Models: Incentivizing Participation:

One of the biggest barriers to AI adoption is the lack of incentives for individuals to share their data. The session explored creative ways to build long-term trust and engagement with communities, emphasizing the importance of reciprocity in data collection. A global case study was presented from the UK, where community outreach programs such as "tea parties" allowed underrepresented groups to share their healthcare concerns in informal settings, leading to better AI training datasets. In India, leveraging existing social structures—such as panchayats, religious institutions, and community elders—could help build trust and encourage voluntary participation. Additionally, it was noted that simply offering future benefits is not enough; immediate value must be provided to participants, such as free AI-powered diagnostics or real-time healthcare advice.

Regulatory Challenges in AI and Healthcare Data Management

A major unresolved issue in India's AI regulatory landscape is data-sharing policies and liability frameworks. Who is responsible when AI-driven medical decisions lead to incorrect diagnoses? Current regulations do not provide clear accountability, creating hesitation among hospitals and healthcare providers in deploying AI at scale. Additionally, cross-hospital collaboration is essential for AI inclusivity, but data-sharing across institutions remains limited due to legal barriers and the lack of interoperability between hospital systems. HCG Hospital's startup incubator (Lumos) is attempting to address this issue by encouraging startups to test their models across multiple hospital networks rather than a single institution, ensuring greater data diversity and reducing bias.

The session concluded with calls for stronger AI validation frameworks, clearer regulatory structures, and cross-sector collaboration to ensure AI augments rather than replaces human decision-making.

DAY 4

SESSION 2

Saji Thoppil,
Founder, DifiNative Technologies

Nivedita Krishna,
Founder, Pacta

Amrita Sengupta,
Research and Program Lead, Centre for Internet and Society

Rohit Satish,
Director, ARTPARK

Shanti Raghavan,
Founder, EnAble India

Sayomdeb Mukherjee,
Senior Manager, EnAble India

Overview:

The session focused on the intersection of digital health and AI in healthcare. Speakers highlighted the significance of inclusive data sources, the challenges in data sourcing, and the problems with relying on datasets from the global north. Challenges such as incorrect data annotations and the need for iterative design were discussed, along with the necessity for audits and independent evaluators for algorithmic oversight. The need for bias mitigation in AI training data, community-led governance models like citizen juries, and embedding accessibility from the start were also some other issues discussed. Ensuring equitable AI deployment across urban and rural environments was emphasized, highlighting the necessity of context-aware AI solutions.

Challenges in AI for Healthcare and Inclusivity:

The discussions highlighted significant challenges in ensuring AI is inclusive, particularly in healthcare. A key concern is the heavy reliance on Global North datasets, which introduce biases when applied in other contexts like India.[101] AI models trained on non-representative data may lead to inaccurate diagnoses, particularly for underrepresented populations. Data annotation is another major challenge, as healthcare practitioners and community health workers play a critical role in ensuring accuracy. Errors in annotations, such as misidentifying the location of tumours, can have severe consequences.

[101]Centre for Internet and Society, AI for Healthcare: Understanding Data Supply Chain and auditability in India, (November 2024)

The burden of AI adoption disproportionately falls on frontline workers like ASHA workers, who are expected to learn and deploy these technologies without adequate support or incentives. The discussions stressed the need for an iterative AI design process, incorporating medical professionals, community health workers, and administrative staff to ensure AI solutions are practical, accessible, and effective.

Regulatory and Evaluation Frameworks for inclusive AI in Healthcare: India's regulatory framework lacks strong enforcement mechanisms for AI and accessibility. Despite having standards such as IS 17802 for accessibility, authorities do not have the ability to impose penalties for non-compliance.

The discussion highlighted how existing healthcare regulations can be applied to AI rather than creating separate frameworks from scratch. Independent evaluators for algorithmic audits were proposed to ensure AI systems comply with ethical and performance standards. However, evaluation remains inconsistent because companies often use proprietary datasets, leading to misleadingly high accuracy claims that may not hold in real-world field settings. Standardizing evaluation metrics, ensuring datasets reflect real-world diversity, and using iterative testing across different settings were identified as essential to ensuring AI solutions perform reliably outside controlled environments. The need for participatory approaches in AI development was strongly emphasized. Benchmark datasets need to reflect real-world diversity, and AI solutions should be evaluated against field data rather than idealized test conditions. The Indian Council of Medical Research (ICMR) and other government bodies were identified as key players in standardizing AI evaluation processes.

Metrics and Challenges in AI for Oral Cancer Screening: One of the points centred on an example regarding evaluation of AI models for oral cancer screening, highlighting the stark difference in performance between hospital settings and real-world deployment. AI models often report 99% accuracy in hospitals, where imaging quality, workflows, and infrastructure are optimized, but accuracy drops significantly in field settings as the context hasn't been considered of a rural region which may only have access to mobile phones and nothing else. This highlighted the need for context-aware AI evaluation metrics, ensuring that solutions are tested in real-world conditions and not just controlled clinical environments. Furthermore, there was an emphasis on geographical variations, particularly in regions like Northeast India, where oral cancer prevalence is high but local datasets are insufficient. It was stressed that AI evaluations should account for regional disease patterns, cost implications of false positives/negatives, and usability for frontline healthcare workers like ASHA workers.

Inclusion Through the Lens of Opportunity: A particularly interesting segment of the discussion reframed the concept of inclusion—not as a compliance burden or a challenge to overcome, but as a massive economic and social opportunity. Historically, healthcare itself was once a loosely structured sector, with pockets of medical innovation scattered across different regions. It was only after the industrialization of healthcare in the 1800s that the field evolved into a structured industry, complete with medical schools, pharmaceutical companies, and regulated hospitals. The same transformation, it was argued, could be applied to inclusion in healthcare and AI—turning it from an edge case consideration into a core economic driver.

The discussion highlighted how accessibility solutions, when designed inclusively, have ripple effects that benefit entire economies. The example of AI-powered mobility services for Persons with Disabilities (PwDs) underscored this point. In one city alone, AI-enabled ride-hailing services generated over €500,000 in revenue while training 214,000 drivers and providing mobility access to 114,000 PwDs. This success demonstrated that inclusive AI models can be commercially viable, proving that businesses do not have to choose between profitability and social impact—they can achieve both.

Beyond patient experiences, the conversation also tackled why businesses and governments should actively invest in inclusive AI. The economic case was clear: an inclusive AI ecosystem doesn't just benefit marginalized communities—it benefits everyone. By addressing disabilities, elderly care, and preventative healthcare, AI could reduce healthcare costs, improve workforce participation, and create new industries. One of the suggestions called for government incentives that reward companies for developing AI solutions that are accessible, inclusive, and aligned with public health priorities.

Community-Led AI and Participatory Design: Ethical concerns surrounding bias in AI models were also raised. Developers often struggle to determine what biases should be corrected and how to standardize debiasing techniques. The discussion emphasized the need for more interdisciplinary teams, bringing together social scientists, healthcare professionals, and technologists to co-develop AI solutions that proactively address bias rather than reacting to it post-deployment.

The need for community-driven AI development was emphasized. AI models should not be developed in isolation by technologists but should involve healthcare practitioners, patients, and frontline workers in their design and evaluation. Citizen juries were discussed as a model for participatory AI governance, where randomly selected citizens were educated about AI and asked to deliberate on ethical and policy concerns. This approach ensures that AI governance reflects public concerns and priorities.

Feedback Loops, Procurement Standards and Governance for Inclusivity: Australia's Healthdirect symptom checker was presented as a case study for responsible AI deployment. The AI-powered system underwent rigorous pre-launch and post-launch evaluations, ensuring it was as safe or safer than the previous non-decision-making tree algorithms. A key takeaway was the importance of feedback loops, where healthcare professionals perform real-time adjustments to AI recommendations, and the feedback leading to improving accuracy over time. However, usability concerns were raised by nurses who were using the tool. They also provided feedback on the user experience, which was subsequently augmented by Healthdirect.

The discussion also explored the differences between B2B and B2C AI applications and how procurement standards vary between these categories. In B2B settings, such as hospitals procuring AI systems, the tendering process is often stringent (example of Australia's Healthdirect symptom checker was given), with clear requirements defined. Companies bidding for contracts must demonstrate compliance with these requirements, making procurement an effective tool for ensuring equitable AI development. However, B2C AI applications, such as consumer-facing healthcare apps, often bypass these procurement safeguards. Unlike hospitals, startups and tech companies can launch AI-powered healthcare apps directly on platforms like the Play Store or Apple's App Store without being subject to procurement-based compliance checks. This gap creates a regulatory blind spot, where consumer-facing AI solutions may lack inclusivity features and fail to meet accessibility standards.

An idea from the discussion was that large procurers—whether governments, hospitals, or healthcare providers—can mandate inclusivity and accessibility in their procurement processes, even if no regulatory obligation currently exists.

Funding for AI-enabled healthcare solutions: A significant challenge in AI implementation is the economic trade-offs between public health investment and AI-driven innovation. India's healthcare spending is just 1.1% of GDP, raising questions about whether AI funding should come from healthcare budgets or broader AI initiatives. Participants emphasized that AI must be optimized for public health outcomes, ensuring it does not divert resources from essential healthcare services. The binary framing of regulation versus innovation was challenged, with speakers noting that strong guardrails and checks are necessary to prevent harm while still fostering innovation. Equitable AI could be integrated through existing clinical governance frameworks rather than creating separate AI-specific guidelines.

DAY 5

SESSION 1

Arvind Badrinarayanan,
CEO, MUSEinc India

Dr. Uma Nambiar,
Executive Director, IISc Medical School Foundation

Sunil Kumar Bhattacharjee,
Associate Director - Digital Initiatives, Manipal Hospitals

Prateek Madhav,
Co-Founder, AssisTech Foundation

Overview:
The session examined AI's role in assistive technologies, public health, hospital workflows, and regulatory challenges in India. Key barriers to AI adoption were identified, including policy fragmentation, funding inefficiencies, clinician resistance, and regulatory hurdles under India's Data Protection Law (DPDP). Odisha's successful AI-enabled telehealth program was contrasted with failed pilots elsewhere due to bureaucratic inertia. The debate on big tech vs. startups highlighted the financial and regulatory struggles of smaller players. A notable insight on gender inclusivity in AI development emerged, with a female-led engineering team designing a superior digital stethoscope by accounting for physiological differences. The discussion underscored the need for cross-sector collaboration, regulatory sandboxes, and inclusive innovation policies to drive AI adoption in India's healthcare system.

AI in Assistive Technologies: The discussion started with a focus on AI-driven assistive technologies, particularly in India's healthcare ecosystem. The potential for AI to enhance accessibility was emphasized, particularly for individuals with disabilities. The conversation underscored that AI applications extend beyond traditionally recognized disabilities, encompassing acquired and temporary impairments as well as elderly care. The expanding role of AI in assistive technology was framed in the context of India's rapid technological transformation, which has seen the emergence of over 450 startups in this space.

The discussion highlighted AI's role in areas such as independent mobility for visually impaired individuals, early detection of autism, and AI-assisted communication tools. The conversation further examined the role of industry associations, particularly NASSCOM, in fostering innovation and advocating for policies that support the growth of AI-enabled assistive technologies. It was acknowledged the necessity of government intervention to create a strategic framework that promotes such innovations at scale

Public-Private Collaboration in Healthcare Infrastructure: The discussion shifted towards the role of institutions in advancing med-tech innovation. A large-scale hospital project, under development at the Indian Institute of Science (IISc), was presented as a case study. The hospital, designed to accommodate 830 to 1000 beds, is not merely a medical facility but a dedicated centre for med-tech research, intended to foster interdisciplinary collaboration between engineers, doctors, and data scientists. The integration of AI into this hospital's digital ecosystem is expected to enhance research on medical imaging, pathology, and decision-support mechanisms tailored to Indian populations.

However, challenges in government funding for research were highlighted. While institutions like IISc receive priority funding for healthcare research, the process remains inefficient and is marked with delays. The discussion emphasized the need for better financial structuring and collaboration with private sector entities to ensure sustained innovation in AI-driven healthcare solutions.

Challenges in Scaling AI Pilots in Public Health Systems: The conversation turned to the challenges faced by startups and institutions in executing AI pilot programs within government healthcare systems. Participants emphasized that while AI has demonstrated significant promise in diagnostics and treatment planning, fragmented regulatory policies and bureaucratic inertia have stifled its large-scale deployment. A key insight was that healthcare remains a state-controlled subject in India, with differing policies across states. As a result, funding and decision-making are often decentralized, making it difficult for AI solutions to gain traction.

The discussion presented a successful case study from the Indian state of Odisha, where AI-enabled telehealth programs had been effectively implemented. Odisha's government actively facilitated technology adoption, allowing district medical officers to utilize AI-generated data insights for targeted interventions. Despite these setbacks, it was noted that AI-led pilot projects in states like Odisha have demonstrated the ability to screen and process large volumes of patient data, leading to significant public health insights. However, a recurring challenge is the absence of clear regulatory pathways for scaling these innovations across states and ensuring their long-term sustainability within government programs.

AI Adoption in Hospital Workflows: AI integration into hospital workflows was a major focus, particularly in the context of clinical efficiency and decision-support systems. Hospitals are increasingly deploying generative AI to optimize administrative functions. One prominent use case involved AI-generated summaries for nurse shift handovers, which helped summarise the standard 60-page documentation faster. This innovation has significantly improved workflow efficiency, reducing the time required for handovers from 90 minutes to approximately 20 minutes. Another innovation was using a tool for doctor's prescriptions. The tool would allow clinicians to instantly digitise case sheets using a smartpen and encoded paper – ensuring that the data captured is now in the hospital's archives.

However, resistance to AI adoption persists among healthcare professionals, particularly among doctors who prefer traditional documentation methods. AI-enabled tools must seamlessly integrate into existing workflows without requiring major behavioural changes from clinicians. A discussion emerged around data-sharing in healthcare. Hospitals possess extensive datasets that could fuel AI research, yet concerns over regulatory compliance, particularly under India's data protection law, have led to hesitancy in sharing data. The absence of incentives for hospitals to contribute their datasets for AI research was identified as an impediment to develop tech.

A key regulatory challenge discussed was India's strict laws on ultrasound imaging, which prohibit remote diagnosis due to concerns over gender determination. While these laws were originally designed to combat female feticide, they now hinder the deployment of AI-powered ultrasound screening in rural areas.

Regulatory Sandboxes in AI-Enabled Healthcare: The conversation also addressed regulatory sandboxes designed to test AI-driven medical technologies before full-scale deployment. While such frameworks exist, they often suffer from bureaucratic inefficiencies. An example was cited where an AI-driven telemedicine sandbox was nearing deployment when a change in government leadership halted its progress indefinitely. Such disruptions highlight the unpredictability of government-led AI initiatives in India.

Gender Inclusivity in AI Development: The discussion concluded with a reflection on gender inclusivity in AI healthcare product design. A case was presented where a digital stethoscope, developed by a predominantly female engineering team, performed better in real-world conditions due to design choices that accounted for physiological differences between male and female patients. This was not intentional. The insight emphasized the broader importance of inclusivity in AI development, ensuring that diverse perspectives contribute to better, more effective solutions.

DAY 5

SESSION 2

Dr. Sree Niranjanaa Bose,
PhD , Technical Lead - Healthcare, BGSW

Krity Kansara,
Product Manager, Responsible AI, BGSW

Rizma Banu,
Co-Founder, Atom360

Trisha Chatterjee,
Co-Founder & CTO at ImmunitoAI

Chandrashekhar K,
Founder & CEO at Forus Health Pvt. Ltd.

Dr Ravikiran Manapuram,
Founder & MD, Medevplus

Ankit Bajaj,
Director, PrivaSapien

Muralidhar Somisetty,
Founder & CEO, Yogifi by Wellnesys

Overview: The session focused on the various AI healthcare tools that startups are working on. There was a comprehensive overview of the Australian healthcare market, addressing current challenges and the potential of technology to enhance access to care. Discussions also touched on the need for diverse datasets to mitigate biases, the regulatory frameworks governing AI in healthcare, and the crucial requirement for transparency in AI systems.

Australia's Tech and MedTech Landscape: Australia's technology sector is the third-largest contributor to the country's GDP and employment, following mining and banking. While Melbourne and Sydney serve as major hubs, emerging clusters in South Australia (defence technology) and New South Wales (commercial enterprises) are diversifying the ecosystem. MedTech in Australia is still in a nascent stage, with innovations largely stemming from hospital systems and clinical practices rather than startups.

AI-enabled healthcare tools in Australia: AI adoption in Australian healthcare has primarily been in an assistive role, with human oversight ensuring clinical accuracy. Examples include AI-powered scribes used by general practitioners to document consultations, and AI-based clinical decision support (CDS) systems at HealthDirect, Australia's government-funded virtual health provider. HealthDirect receives over 1.3 million calls annually, where AI helps nurses standardize responses, reducing variability due to differences in individual clinical experience.

The CDS system enables consistency while allowing nurses to override AI recommendations based on clinical judgment. Transparency around AI use remains a complex issue—while HealthDirect acknowledges AI-powered tools in its symptom checker, it does not explicitly disclose AI involvement during patient interactions. Ongoing regulatory efforts aim to balance transparency with practical considerations, ensuring AI governance adheres to ethical and safety standards.

Australia's Therapeutic Goods Administration (TGA): Australia's TGA has been proactive in setting AI standards for medical applications, distinguishing between AI-assisted tools and autonomous decision-making systems. Software classified as a medical device requires rigorous validation before regulatory approval. Many AI applications in healthcare—such as radiology image analysis and clinical triaging—are considered low-risk when operating under human oversight. However, if AI autonomously diagnoses conditions (e.g., diabetic retinopathy), it falls under stringent regulatory scrutiny.

International harmonization efforts align TGA standards with those of the US FDA and UK MHRA. The intended use of AI solutions plays a crucial role in determining classification—screening tools that refer patients to specialists are regulated differently from diagnostic tools that provide definitive medical assessments. Regulatory carve-outs exist for certain health applications, but companies aiming for the Australian market must engage with local healthcare providers and adhere to evolving compliance frameworks.

Diagnostic Testing Differences in India and Australia: A major point of contrast between Indian and Australian healthcare systems is accessibility. In Australia, government-funded Medicare mandates that diagnostic tests require a general practitioner's referral, preventing direct-to-consumer testing. Test results are typically held for seven days before patients can access them online, ensuring physicians interpret and communicate findings. This regulatory structure ensures controlled medical decision-making but may slow down patient access to routine diagnostics.

In contrast, India's predominantly out-of-pocket healthcare model allows individuals to directly access lab tests without physician intervention. While this offers greater flexibility, concerns exist about over-testing, misinterpretation of results, and lack of regulatory oversight. The discussion also highlighted Australia's national screening programs, which proactively encourage preventive healthcare, whereas India's healthcare system faces logistical challenges in implementing widespread preventive screening.

AI in Retinal Imaging: AI-driven retinal imaging solutions have emerged as a powerful tool in detecting ocular diseases such as diabetic retinopathy, glaucoma, and cataracts. Forus Health, a leader in AI-powered eye care solutions, has conducted over a million screenings across diverse setups, including varying lighting conditions and different levels of staff training – this helped in improving the accuracy of the product regardless of setting on the ground.

A key challenge in retinal imaging AI has been adapting to the differences in how light reflects on eyes of different ethnic backgrounds, requiring sophisticated calibration to ensure accuracy. Image quality varies based on eye type and light reflection, differing among Caucasian, African, and other populations. Furthermore, retinal scanning products need to be able to screen a wide age range, from neonates to elderly patients with cataracts.

Deployment strategies for these AI solutions are tailored to different levels of healthcare providers, starting with specialists, then general practitioners (GPs), and finally primary care centres. The goal is to get endorsement from the practitioners and only after validation deploy it at scale. Despite these kinds of checks, in some eye scan products AI systems failed to accommodate conditions like colour blindness. It was noted that this limitation was only discovered post-deployment, underscoring the need for pre-emptive inclusivity planning. Furthermore, it is also a process to improve inclusivity.

Synthetic Data: One of the primary discussions around synthetic data is its role in increasing the diversity of training datasets. In many healthcare AI applications, models trained on limited or non-representative datasets struggle with bias and inaccurate predictions for underrepresented populations. In applications where real patient data is scarce, synthetic data can help bridge gaps, but it must be carefully validated against real-world clinical outcomes. Data transformation techniques can help compensate for limited datasets, but synthetic data augmentation is not always reliable, especially for complex biological models.

Explainability as a parameter for Inclusivity: One of the key challenges in AI is bias—particularly when models are trained on non-representative datasets. For instance, AI-based dermatology tools have historically struggled with accurately diagnosing conditions on darker skin tones due to a lack of diverse training data. If an AI system cannot explain why it reached a certain conclusion, it becomes difficult to identify and correct these biases. Explainable AI allows researchers and clinicians to trace the decision-making process, uncover where biases might exist, and take corrective measures to ensure equitable performance across all demographics.

A recurring theme in the discussion is the need to shift from "fixing" inclusivity issues after deployment to integrating fairness principles from the start. It was noted that most AI companies still take a reactive approach, identifying biases only after their systems fail to perform fairly. Instead, fairness should be built into AI development from the concept phase, particularly in areas such as dataset collection, algorithm design, and validation testing.

DEFINITIONS OF INCLUSIVE DESIGN

INTRODUCTION

This section provides a sampling of definitions or articulations for "inclusive design", and "inclusion in AI" and suggests reasons for adopting a working definition of inclusion in the context of AI. The definitions have been curated from:

- British Standards Institute (**BSI**) - a standards setting and accreditation body,
- AccessiBe - an accessibility consulting organisation,
- Interactive Design Foundation - a global virtual design skilling platform,
- Infosys Knowledge Institute (**Infosys**) and Microsoft - information technology (IT) companies, and
- Inclusive Design Research Centre (**IDRC**) - a centre in the Ontario College of Art & Design University, comprised of open-source developers, designers, researchers, educators and co-designers proactively working to make emerging technologies and processes inclusive.[102]
- Data61 team of the Commonwealth Scientific and Industrial Research Organisation (**CSIRO**)[103] - the Australian government's National Science Agency which focuses on scientific and industrial research.[104]

SAMPLING OF DEFINITIONS SUGGESTED BY OTHER ORGANISATIONS:

BRITISH STANDARDS INSTITUTE ON INCLUSIVE DESIGN:

Defines inclusive design as - "*The design of mainstream products and/or services that are accessible to, and usable by, as many people as reasonably possible … without the need for special adaptation or specialised design.*"[105] Cambridge University in its Inclusive Design Toolkit[106] relies on BSI's definition to clarify that inclusive design does not suggest one product should cater to the entire population. And that inclusive design should guide design strategies to cater to a diverse population by: "*(a) developing a family of products and derivatives to provide the best possible coverage of the population; (b) ensuring that each individual product has clear and distinct target users; (c) reducing the level of ability required to use each product, to improve the user experience for a broad range of consumers, in a variety of situations.*"

AccessiBe ON INCLUSIVE DESIGN:

Suggests that "*Inclusive design is an approach that aims to create products, services, and environments that accommodate the broadest possible audience. Unlike traditional design methods, it values and prioritizes human diversity, ensuring that every individual, regardless of their abilities or circumstances, can benefit from the designed solution.*"[107]

INTERACTIVE DESIGN FOUNDATION (IDF) ON INCLUSIVE DESIGN:

Describes inclusive design as "*an approach to create accessible products and experiences that are usable and understandable by as many people as possible. It goes beyond accessibility to consider users' diverse needs, backgrounds and experiences.*"[108]

[102]The IDRC was up in 1993 by Dr. Jutta Treviranus and is run by her team. Read more about the centre and the Dr. Treviranus' scholarship on the three dimensions of inclusive design here and here, respectively.
[103]CSIRO is Australia's national science agency and innovation catalyst, which works towards solving the greatest challenges through innovative science and technology.
[104]The Data61 team is led by Project BUILD's Australian cohort member, Professor Didar Zowghi.
[105]Cambridge University, Inclusive Design Toolkit,
[106]Cambridge University, Inclusive Design Toolkit,
[107]AccessiBe,
[108]Interactive Design Foundation

INFOSYS ON INCLUSIVE DESIGN:

"Inclusive design — the newest and the most advanced approach — actively looks for disenfranchised and underrepresented people and seeks to create solutions for them first. It focuses on a more holistic group of solutions and processes, which considers identities, cultures, and diverse perspectives with research and collaborative design. Sometimes these solutions serve a niche market but generally benefit all people — an approach described as "*solve for one, extend to many.*"[109]

MICROSOFT ON INCLUSIVE DESIGN:

"*Inclusive Design is a methodology, born out of digital environments, that enables and draws on the full range of human diversity. Most importantly, this means including and learning from people with a range of perspectives.*"[110] The definition is based on principles that call for- (a) exclusion be identified; (b) people and diverse perspectives at the centre of the design process; and (c) designing for people having benefits for the general population.[111]

IDRC ON INCLUSIVE DESIGN:

Considers "inclusive design" to have the following three dimensions - (a) Recognize diversity and uniqueness where the importance of self-knowledge and self-determination are key considerations that can be promoted by enabling customisations and allowing interoperability; (b) Inclusive process and tools where co-design occurs meaningfully and not as a token exercise, including with the help of diverse design and research teams; and (c) Broader beneficial impact where there is recognition that design does not occur in a vacuum, but in a system of systems, thereby necessitating the consideration of longer term and broader impacts of the design.[112]

CSIRO ON DIVERSITY AND INCLUSION IN ARTIFICIAL INTELLIGENCE:

"Diversity and Inclusion in Artificial Intelligence (AI) refers to the 'inclusion' of humans with 'diverse' attributes and perspectives in the Diversity and Inclusion in Artificial Intelligence (AI) refers to the 'inclusion' of humans with 'diverse' attributes and perspectives in the data, process, system, and governance of the AI ecosystem.

- *Diversity refers to the representation of the differences in attributes of humans in a group or society.*
- *Attributes are known facets of diversity including the protected attributes in Article 26 of the International Covenant on Civil and Political Rights (ICCPR): race, colour, sex, language, religion, political or other opinions, national or social origin, property, birth or other status; and (given the non-exhaustive nature of Article 26, attributes explicitly protected under Australian discrimination federal law, including but not limited to) age, disability, criminal record, ethnic origin, gender identity, immigrant status, intersex status, neurodiversity, sexual orientation; and intersections of these attributes.*
- *Inclusion is the process of proactively involving and representing the most relevant humans with diverse attributes who are impacted by, and have an impact on, the AI ecosystem context.*
- *AI ecosystem refers to the collection of 5 pillars (humans, data, process, system, and governance), plus the environment (application or business domain) within which the AI system will be deployed and used." (CSIRO Definition).*[113]

[109]Infosys Knowledge Institute, Kurt Schafer, Madeleine Roberts, Jeff Mosier, Inclusive Design: Diverse Voices Lead to Products That Work for Everyone, (27 September 2022),
[110]Microsoft Inclusive Design,
[111]Microsoft Inclusive Design,
[112]IDRC, What is inclusive design?,
[113]Didar Zowghi and Francesca da Rimini, "Guidelines for Diversity and Inclusion in Artificial Intelligence" published in "Responsible AI: Best Practices for Creating Trustworthy AI Systems"; and CSIRO's Diversity and Inclusion in AI Guidelines.

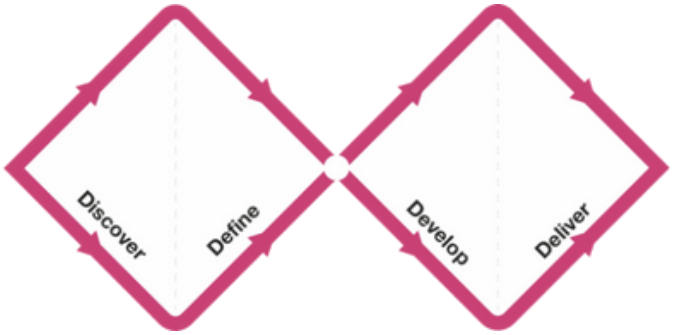
SUGGESTED RESEARCH METHODOLOGIES TO IDENTIFY, EVALUATE OR MEASURE INCLUSIVE AI IN HEALTHCARE

INTRODUCTION

This Annexure contains an indicative list of various co-design methodologies to ensure inclusivity of AI in healthcare. Co-design in healthcare originated from human-centred design (HCD) and participatory design, evolving as a response to the need for more inclusive, patient-centred, and effective healthcare solutions. For inclusive AI in healthcare, co-design will enable the intended beneficiaries (e.g., those typically underrepresented/ excluded) "continuously accompany" the research and deployment of AI in healthcare. Their lived experiences can inform identification of the use cases of AI in healthcare and the actual product design, deployment, and improvements. Co-design was a key learning from the two Exchange Trips in Australia and India. This indicative list has been compiled with guidance from cohort members and invitees of both learning trips.

II. SUGGESTED RESEARCH METHODS

DOUBLE DIAMOND



Design thinking approach that enables human centred design:

1. Discover rather than assume the problems by learning from the affected people.

2.Define the challenge based on affected people's insights.

3.Develop solutions by co-designing them with a range of different people.

4.Deliver by small scale testing and improving what works, while rejecting what does not work.

Eg: Using the Double Diamond Design Process, a co-designed AI mental health assistant can improve accessibility in remote areas. In Discover, insights from individuals, caregivers, and professionals can identify barriers like stigma and limited support. Define focuses on developing an AI chatbot that provides culturally sensitive self-care and crisis support. During Develop, the chatbot can be prototyped with diverse user input, integrating CBT techniques, mindfulness, and distress signal recognition. Finally, in Deliver, it can be deployed via low-bandwidth apps or SMS, continuously refined through real-world feedback to enhance inclusivity and effectiveness. This method was used during COVID to create mobile health apps. By using this codesign approach, developers identified critical physical and psychological requirements for the design of the mHealth apps that support self-management for patients.

THINK-OUT-LOUD

The Think Aloud Method[114] is a simple way to improve healthcare apps by understanding how people use them and listening to their thoughts. Users talk out loud about what they find easy or confusing while using the app. This helps designers understand what works well and what needs fixing, making the app easier to use and more helpful for everyone. This can be done through stages, interviews, and surveys to understand challenges.

Eg: A research team used the Think Out Loud (TOL) approach to evaluate the usability of a smartphone app designed for individuals at risk of Type 2 diabetes. Participants were asked to verbalize their thoughts while navigating the app, providing real-time feedback on its functionality and ease of use. The findings revealed that while users found the app generally intuitive, they also identified minor usability issues that required improvement. This feedback helped the developers refine the app's design, making it more user-friendly before further evaluation in a randomized controlled trial. By leveraging the TOL method, the study ensured that user-driven insights directly influenced the app's final version, enhancing its effectiveness and accessibility.

PROTOTYPING ACTIVITY/ NARRATIVE PROTOTYPING

Narrative prototyping in healthcare uses stories and role-playing to test new tools. Patients, doctors, and caregivers simulate real-life scenarios, helping designers identify issues and refine solutions early. This ensures healthcare innovations are practical, user-friendly, and effective.

Eg: A team designing an AI-powered mental health chatbot could use narrative prototyping by scripting a conversation between a user experiencing anxiety and the chatbot. Role-playing this interaction with real patients and therapists helps determine if the chatbot's responses feel empathetic, clear, and helpful, or if they need adjustments to avoid misinterpretation or frustration. By integrating narrative prototyping, healthcare solutions become more relatable, intuitive, and effective, ensuring they truly meet the needs of patients and providers.

VIDEO REFLEXIVE ETHNOGRAPHY

Video-Reflexive Ethnography (VRE) is a research method used in healthcare to improve practices by recording real-world interactions and then reviewing them with the people involved. It helps healthcare teams reflect on their own actions, uncover challenges, and identify opportunities for improvement in patient care.

Eg: Video Reflective Ethnography (VRE) was used to enhance the safe administration of Variable Rate Intravenous Insulin Infusions (VRIII) in hospitals. Healthcare professionals were video recorded during routine VRIII procedures, and the footage was later reviewed collaboratively to reflect on challenges and improve practices. This process helped identify safety risks, refine protocols, and enhance clinician awareness of potential errors. As a result, workflow adjustments and a culture of continuous learning were fostered, leading to improved patient safety.

COMMUNITY ARTS/ PEER RESEARCH

Community arts and peer research make AI-driven healthcare more inclusive by capturing real-world experiences. Storytelling, theatre, and digital media help marginalized groups express healthcare concerns, while peer researchers - patients or caregivers - collect insights to ensure AI solutions meet actual needs.

Eg: Community artists could collaborate with public health researchers to create murals depicting local perspectives on AI-driven disease prediction models. These murals can visually communicate fears about AI decision-making in healthcare access and concerns over marginalized communities being misrepresented in data. In Brazil, community arts have already been explored to understand challenges in health care.

[114] Jaspers MW, Steen T, van den Bos C, Geenen M. The think aloud method: a guide to user interface design. Int J Med Inform. 2004 Nov;73(11-12):781-95. doi: 10.1016/j.ijmedinf.2004.08.003. PMID: 15491929.

BLUE-SKY SPECULATION

Blue-sky speculation is about imagining bold, futuristic ideas that go beyond what technology and science can currently achieve. It encourages creative thinking about how AI could completely transform healthcare in ways that might seem impossible now but could become real in the future.

Eg: AI-integrated brain-computer interfaces (BCIs) could enable direct communication between patients and therapists without speaking, helping those with severe anxiety, trauma, or conditions like locked-in syndrome express their emotions effortlessly. Blue-sky speculation in healthcare is being used widely to ensure that AI is not just leveraged for diagnosis but also for treatment of diseases.

PROGRESS PLUS

The PROGRESS Plus framework is used to analyse health equity by identifying social factors that influence healthcare access and outcomes. It stands for Place of residence, Race/ethnicity, Occupation, Gender, Religion, Education, Socioeconomic status, and Social capital, with "Plus" covering additional factors like disability or age. Applying this method to AI in healthcare ensures that AI-driven tools and policies are designed to be inclusive and address health disparities.

Eg: An international team of experts has applied the PROGRESS-Driven Approach to address equity, diversity, and inclusion in cognitive outcomes following traumatic brain injury (TBI). The approach integrates knowledge translation, sex- and gender-based analysis, intersectionality, and brain health equity to ensure more inclusive healthcare solutions. By applying the PROGRESS-Plus framework, researchers identified disparities in TBI recovery based on socioeconomic status, gender, and access to rehabilitation services. Using this equity-focused approach, the team has developed tailored interventions that address gaps in care, ensuring better access to treatment for marginalized populations.

POETIC TRANSCRIPTION

Poetic transcription is a qualitative method that transforms interviews and observations into poetry, capturing emotions and lived experiences. In AI and healthcare, it highlights patient concerns, ethical dilemmas, and the human side of AI-driven care, making insights more impactful and relatable.

Eg: Imagine interviews with individuals using an AI mental health chatbot. Instead of reporting findings through standard summaries, a researcher might reshape their words into poetry to highlight the emotional weight of the experience. Use of poetry has proven to help in medical teaching, helping medical trainees understand patient care better

INCIDENT REPORT SEARCH ON PUBLIC DATA BASES

Accessing public incident report databases helps identify biases, failures, and safety concerns in AI-driven healthcare tools. By analysing real-world data on medical errors, device failures, and patient safety issues, developers can design AI systems that are more

Eg: Several research groups have analysed 16,091 AI incidents from three databases, identifying 725 healthcare-related cases linked to diversity and inclusion. They developed a decision tree with four conditions: (a) human impact, (b) explicit diversity attributes, (c) bias or fairness violations, and (d) implicit diversity concerns. In 2022, the European Parliamentary Research Service released

SIMULATION RESEARCH

Simulation research in healthcare and AI uses virtual models, synthetic data, and computer-generated environments to enhance medical systems, treatments, and AI solutions. It enables researchers to test algorithms, predict outcomes, and evaluate risks in a controlled setting without real-world consequences.

Eg: AI-driven 3D modelling of patient-specific lumbar spine anatomy enhances patient understanding during consent and aids surgical trainees in visualizing anatomy before surgery, improving precision and outcomes.

FRAMEWORK FOR DIGITAL HEALTH EQUITY

The digital health equity framework ensures accessible, inclusive healthcare by addressing Digital Determinants of Health (**DDoH**). It considers individual factors (digital literacy, access), interpersonal influences (family, peers), community resources (infrastructure, culture), and societal factors (policies, economy). This approach promotes equitable, impactful digital health solutions.

Eg: An AI-powered diabetes app can ensure inclusivity through the DDoH framework. It offers voice commands and multilingual support (individual level), caregiver alerts (interpersonal), integration into community programs (community), and subsidized access via government partnerships (societal), promoting equitable healthcare. Research indicates the need for measurement-based approaches to assess digital health equity.

COMMUNITY-BASED PARTICIPATORY APPROACH

A community-based participatory approach (**CBPA**) in AI and healthcare ensures that patients, caregivers, and local stakeholders actively shape AI solutions. This method fosters collaborative decision-making, incorporating lived experiences and cultural insights to design more equitable and effective AI-driven healthcare tools.

Eg: For genomic healthcare, Centre for Population Genomics collaborates with multicultural communities to create representative genomic resources, promoting equitable access to genomic medicine in Australia. Using a community-based participatory approach, they engage underrepresented groups, co-design culturally respectful recruitment strategies, and collect and responsibly share genetic data to enhance diversity in genomics research.[115]

[115] Centre for Population Genomics, Partnering with Multicultural Communities to Increase Representation in Genetic Research: A Case Study of the OurDNA Pilot with the Sydney Filipino Community, March – May 2023 (full study report here).