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HDC's Review of the Code of Health and Disability Consumers' Rights

Submission on the Consultation Document (April 2024)

Advancing technology

Background

These submissions refer only to the section on advancing technology of the Health and Disability Commissioner's (HDC) Consultation Document on the Code of Health and Disability Consumers' Rights (the Code). [1]

NAIAEAG

These submissions are from the perspectives of the National AI & Algorithm Expert Advisory Group (NAIAEAG) which provides expert advice about (amongst other things) the appropriateness, safety, effectiveness, ethics and legality of any artificial intelligence (AI) research, development, projects, partnerships, contracts or implementation within Te Whatu Ora.[2]

NAIAEAG's role is a critical one given the constrained resources the New Zealand health sector is operating under at present. There is a critical need to improve efficiency and quality of the delivery of health services to New Zealanders, which may be achieved through the use of AI and advancing technologies.

HDC Questions

There are two main questions asked about advancing technology in the HDC's Consultation Document:

5.3: What are your main concerns about advancing technology and its impact on the rights of people accessing health and disability services?

5.4: What changes, both legislative and non-legislative, should we consider to respond to advancing technology?

In the time available, these submissions respond only to question 5.3.

For simplicity, we use the term "AI" in these submissions as a shorthand to describe a number of different 'advancing technologies'. NAIAEAG understands that AI encompasses various degrees of complexity in machine learning technologies and recognises several layers of abstraction between AI and the clinician or patient. For the purposes of providing guidance on AI in the context of advancing technologies, we consider the highest risk AI systems most relevant to the rights of people accessing health and disability services to be AI systems that:

- Provide interpretation or summarization of data and/or clinical results
- Provide diagnoses or clinical recommendations of any kind
- Interface directly with clinicians and/or patients
- Assess clinical risk and/or inform treatment planning
- Inform allocation of resources towards patients e.g. triage, bed allocation, prioritisation of planned care

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[1] https://review.hdc.org.nz/consultation-document/ section 5(j)

[2] NAIAEAG's Terms of Reference

Preliminary observations

Code developed before significant technology and data use

We note that the Code came into force on 1 July 1996, nearly 3 decades ago, well before many significant advances had been made in artificial intelligence and the use of health data to train it. The Code was developed after the Cartwright Inquiry in 1987–1988 into the treatment of carcinoma in situ, at which time the use of electronic data in the provision of health care was not a prevalent part of 'services' offered to consumers[3]. The Code has been updated to take into account new circumstances (such as the End of Life Choice Act 2019) but not in relation to data use (as such).

AI challenges existing norms

Across many sectors, not only health, AI tools are challenging existing norms about informed consent and data privacy. Accordingly, it is timely for the HDC to be reviewing the Code and the HDC Act and we thank you for the opportunity to do so.

Innovation Capturing the benefits of AI in healthcare for Aotearoa

The Prime Minister's Chief Science Adviser's (PMCSA) report, *Capturing the benefits of AI in healthcare for Aotearoa New Zealand* (December 2023), refers to existing AI technologies offering the possibility of improving the quality of care people are able to access in New Zealand's health system, while making the system itself more efficient, as well as having the potential to address some long-standing inequities in healthcare that will have positive impacts felt more widely than the healthcare system itself. [4]

The PMCSA's report outlines the key themes for innovations possible through the use of AI — Implementing Te Tiriti o Waitangi and recognising tikanga Māori, Safe and effective AI, AI for equity, Effective control of AI, Evaluated and trusted AI, and Responsible AI.

Scope of advancing technology questions

We note that the advancing technology questions in the Consultation Document form part of Topic 5 "Minor and Technical Improvements". We consider the issues raised by the use of AI in health are significant, complex, rapidly evolving and require multi-disciplinary and diverse input. Furthermore, while some AI can require huge investment at the macro level, it also can be done with minimal investment. The applications are also relatively diverse including across administrative, clinical, back office and infrastructure in healthcare.

Because of these factors, we suggest it may be prudent to revisit the scoping of the current questions in conjunction with multi-disciplinary AI experts. Pending any such reframing, we provide the following feedback.

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[3] The term "Services' is defined in the Code to be mean *health services, or disability services, or both; and includes health care procedures* which are further defined in the HDC Act.

[4] https://dpmc.govt.nz/our-programmes/special-programmes/prime-ministers-chief-science advisor-archives/archive/gerrard-2021-2024

Main concerns about advancing technology and its impact on the rights of people accessing health and disability services (Question 5.3)

Over the past 1 ½ years of its operation, NAIAEAG has observed a number of recurring issues raised by AI which may impact on the rights of people accessing health and disability services as currently described in the Code. They include:

- **Informed consent** in relation to: (a) the use of people's data to develop and train AI models; and (b) the use of already developed AI tools for patient care (relevant to Rights 1, 3, 5, 6, 7, 9). Given that some AI will be black box in nature, the rights of consumers to be fully informed is challenging. It is unclear how much information is required by a reasonable consumer and the amount of information commercial vendors are willing to disclose. Furthermore, because AI tools are continuously being improved, challenges arise for keeping consumers informed of the changes and improvements made to the AI systems that may affect their care.
- **Accountability/liability** has been an ongoing discussion topic within NAIAEAG. Depending on the use case, accountability and liability could lie individually or collectively with individual health professionals, Health NZ, the Ministry and/or developers of the AI tool. We think there is a pressing need for an independent, in-depth multi-disciplinary expert examination in this area (across all sectors) to clarify not only the parties liable but also the extent and implications of such liability.
- **Effective communication:** New Zealand has low rates of health literacy (and likely even lower rates of AI health literacy) which is challenging to effectively communicate with consumers to enable them to understand information about the development and use of AI in health (relevant to Right 5).
- **Services of an appropriate standard:** In some situations, AI tools may be used in New Zealand which have not been trained or validated on New Zealand data, and performance of AI could be suboptimal in some population groups, such as tāngata whaikaha | disabled people (relevant to Right 4). Although the use of AI present risks, within certain areas the healthcare system, provision of care is currently suboptimal and use of AI can help address current limitations. Further, as noted, AI is continuously being improved — the tools are expected to improve with time such that their current performance may not be indicative of their future potential. This is also relevant to Right 4.[5]
- **Māori — right to be treated with respect:** In some situations, AI tools may be used which have not been developed or validated on New Zealand data which may not, therefore, take into account the needs, values, and beliefs of Māori including Māori Data Sovereignty (relevant to Right 1);
- **Cultural, religious, social, and ethnic groups right to be treated with respect:** In some situations AI tools may be used which have not been developed or validated on New Zealand data which may not, therefore, take into account the needs, values, and beliefs of other cultural,

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[5] Including Right 4(4) 4) Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer. **Optimise the quality of life** means to take a holistic view of the needs of the consumer in order to achieve the best possible outcome in the circumstances. Note: Priority 5 of the *Provisional Health of Disabled People Strategy* is to *increase the visibility of disabled people in health data, research and evidence as part of an active learning system.*

religious, social, and ethnic groups and tāngata whaikaha | disabled people and those groups' rights to Data Sovereignty (relevant to Right 1);

- **Bias and discrimination** may arise if the data used to develop the AI reflect existing societal biases or during the development of AI tools if the data upon which they are trained/validated does not include data which represents Māori, people from other ethnic or national origins, and/or tāngata whaikaha | disabled people. Such oversight can perpetuate existing biases and present an obstacle for achieving equitable health outcomes for all (relevant to Right 2).[6]
- **Social and Cultural Licences:** NAIAEAG has also noted issues relevant to social and cultural licences and consultation with stakeholders – for example, whether New Zealanders accept the use of their health data for the development of AI in New Zealand.

Other NZ Regulatory Frameworks

While the Code covers many of the issues described above (apart from social and cultural licences and accountability/liability), many (if not most) of them are also covered by existing New Zealand legislative and regulatory frameworks, described below.

Use of health data for research and use

For example, there are strong frameworks which particularly target the use of health data including:

- The Health Information Privacy Code (HIPC)
- The Privacy Act 2020
- The Health Act 1956
- The Data Protection and Use Policy (DPUP)[7]
- Principles for the safe and effective use of data and analytics[8]
- Professional Standards such as those of the Medial Council of New Zealand[9]
- The National Ethics Advisory Committee's National Ethical Standards for Health and Disability Research and Quality Improvement (the NEAC Standards)
- Te Ara Tika Guidelines for Māori Research Ethics
- Te Mata Ira: Guidelines for Genomic Research with Māori (Te Mata Hautū Taketake | Māori and Indigenous Governance Centre).
- The Guidelines for Researchers on Health Research Involving Māori 2010 (HRC);
- Te Mana Raraunga - Māori Data Sovereignty Network Charter (MDSov Charter) [10]
- The CARE Principles for indigenous data governance.
- Ngā Tikanga Paihere Framework (2020)[11]
- Work from Mana Ōrite Work Programme between Stats NZ and the Data Iwi Leaders Group (DILG) of the National Iwi Chairs Forum (NICF)

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[6] Discrimination means discrimination that is unlawful by virtue of Part II of the Human Rights Act 1993. Section 21 (1) (g) of the HRAct provides that a prohibited ground of discrimination is (f) race: (g) ethnic or national origins, which includes nationality or citizenship: (h) disability.

[7] https://www.digital.govt.nz/standards-and-guidance/privacy-security-and-risk/privacy/data-protection-and-use-policy-dpup/ DPUP was developed to provide both government agencies and non-governmental organisations (NGOs) with clear guidance about what's reasonable, and what's not, when collecting or using people's personal information).

[8] https://www.privacy.org.nz/publications/guidance-resources/principles-for-the-safe-and-effective-use-of-data-and-analytics-guidance/

[9] https://www.mcnz.org.nz/our-standards/current-standards/patient-records/

[10] https://www.temanararaunga.maori.nz/tutohinga

[11] https://data.govt.nz/assets/data-ethics/Nga-Tikanga/2.0-Nga-Tikanga-Paihere-summary.jpg

These frameworks, especially the HIPC and DPUP as well as the Ngā Tikanga Paihere Framework and the MDSov Charter, provide very strong protection for consumers' rights in relation to the use of their data for different purposes.

In the context of health research and quality improvement activities (QI), the NEAC Standards provide strong and robust guidance about the ethical use of data, including in relation to its use for New Technologies (Chapter 13), as do the Te Ara Tika, Te Mata Ira Guidelines and others.

Specific AI Frameworks

A number of frameworks are already in place regarding the use of AI which are protective of consumers' rights, including:

- Health New Zealand's advice on Large Language Models and Generative AI [12]
- Interim Generative AI guidance for the public service [13]
- The Privacy Commission's guidance on AI [14]
- The Algorithm Charter for Aotearoa New Zealand [15]
- The Therapetics Products Act (relating to Software as a medical device) — to be repealed by the Coalition Government.

Data and AI security frameworks

Consumers' rights to the security of their data are also covered by a number of regulatory frameworks including:

- Data.govt.nz's framework for data stewardship (including data governance and data management)[16]
- The National Cyber Security Centre (NCSC) guidelines for secure AI system development[17]
- HISO Security Standards for managing the security of health information[18]

Frameworks protecting consumers from discrimination and requiring engagement

Regulatory frameworks which protect consumers from discrimination and which require engagement with consumers and whānau include:

- United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)
- Pae Ora (Health Futures) Act
- The Code of Expectations for Health Entities Engagement with Consumers and Whānau **[19]**
- The New Zealand Bill of Rights Act 1990 (including, the right to freedom from discrimination on the grounds of discrimination in the Human Rights Act 1993, the right not to be subjected

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[12] Te Whatu Ora – guidelines on the use of GAI

[13] https://www.digital.govt.nz/standards-and-guidance/technology-and-architecture/artificial-intelligence/interim-generative-ai-guidance-for-the-public-service/

[14] https://www.privacy.org.nz/publications/guidance-resources/ai/

[15] https://data.govt.nz/toolkit/data-ethics/government-algorithm-transparency-and-accountability/algorithm-charter/ - signatories include Manatū Hauora — Ministry of Health

[16] https://data.govt.nz/toolkit/

[17] https://www.ncsc.govt.nz/news/secure-ai-system-development?url=news%2Fsecure-ai-system-development%2F

[18] https://www.tewhatuora.govt.nz/health-services-and-programmes/digital-health/data-and-digital-standards/approved-standards/security-standards/

[19] https://www.hqsc.govt.nz/resources/resource-library/code-of-expectations-for-health-entities-engagement-with-consumers-and-whanau/

to medical or scientific experimentation; and the right to refuse to undergo medical treatment)

- The Human Rights Act 1993
- The Fair Trading Act (regarding misleading and deceptive conduct)

HDC examples

Against the background of these frameworks, the potential issues raised by the HDC for the protection and promotion of people's rights under the Code appear to be covered by existing specific frameworks (including, but not limited to those frameworks referred to below):

HDC examples	**Existing Regulatory frameworks**
Risks to the privacy of health information, for example when that information can be picked up by interactions with an AI, rather than being shared willingly	The Code, The Privacy Act, the HIPC and the MDSov Charter [20]
The difficulty of enforcing rights when the provider of a service is not based in this country (e.g., surgery controlled remotely via robots)	This will likely depend upon the terms of the contracts entered into between the NZ based health care providers and the offshore providers of the service
Bias, misleading predictions, adverse events, and even large-scale discrimination by AI models that have been developed through inaccurate or under-representative training data sets	UNDRIP, The Code, the Bill of Rights Act, Human Rights Act, the MDSov Charter Fair Trading Act
Ensuring informed consent for self-improving AI and other technologies that may be learning as they go	The Code, The HIPC, the MDSov Charter
Accountability for upholding consumers' rights if the care is provided by a non-human.	This raises complex legal issues which do not appear to have been resolved, or have a clear answer, at this point in NZ.

Non-Legislative considerations

Understanding how this technology affects the entire care journey from access through to outcome

Within the healthcare system, some uses of AI are being integrated into various stages of patient care. There is a pressing need for improved communications with consumers about how this AI integration might influencing decision-making. Examples include AI used to schedule procedures,

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[20] See also: https://www.tewhatuora.govt.nz/health-services-and-programmes/maori-health/maori-data-sovereignty/

assist with clinical decision making (like diagnostic imaging), and inform long-term treatment planning.

Other challenges raised by AI include:

1) How consent might affect access to care: Some consumers may not want to receive care that involves AI or may want to opt out of certain aspects of AI-enabled care. However, this may limit their options or availability of care, especially if AI becomes more prevalent or essential in the healthcare system. Policy challenges like this will require very careful consideration by all stakeholders.
2) Where AI tools are used for prioritisation of planned procedures or to automatically accept or decline referrals into secondary care, consumers will clearly need to be informed and appropriate risk mitigations taken (for example retaining human oversight). No such tools are currently used within the healthcare system but evidence of similar early tools have emerged (e.g. Equity-based Surgery Waitlist Prioritisation Tool).
3) Impact on secondary opinion: Consumers have the right to seek a secondary opinion from another health practitioner if they are unsure or dissatisfied with the care or advice they receive. However, the advancement of AI may result in a situation where secondary opinion is limited, with no other individual being able to provide knowledge of the AI or the risk associated with its use.

These challenges highlight a need for both consumers and clinicians to know about the use of AI within their care and the potential benefits and risks involved, to ensure their autonomy is respected and honoured. Very important questions arise about the way in which knowledge about AI is communicated and autonomy is respected, especially having regard to the low levels of health and AI literacy, what ‘reasonable’ consumers actually want to know, and social and cultural licences. The spectrum could range from fully informed consent to transparency of use and would likely differ depending upon the context of the use of AI ranging from low risk to higher risk applications. The feasibility of operationalising some of the options across the spectrum will also require careful consideration. A key concept that may ultimately need to be “legislated in” is *transparency.*

These are all high-level issues which are being grappled with on a global basis and across sectors.

Conclusion

A plethora of frameworks currently exist in the health sector, which:

- protect the use of consumers’ health data;
- prohibit discrimination; and
- require engagement with consumers and whānau.

Rather than the concern being that consumers’ rights may not be sufficiently respected and protected in relation to the use of AI (including from the protection given by the Code and its high level principles) the concern might better be focussed on the fact that those protections are anchored in a myriad of Statutes, Codes, Regulations, Standards and Guidelines that are not necessarily easy to navigate. There is also the need to ensure synchronicity and consistency between them and how they are translated into the clinical context.

We support careful consideration of the ways in which AI is being used in health care and its impact on consumers. A review of the existing frameworks and how they interact should also be considered, particularly regarding collective consent, to strengthen the rights of tāngata whaikaha | disabled people and those of Māori, Pacific Peoples and other minority populations, as well as supporting the Privacy Commissioner in relation to increasing penalties for data breach and invasions of privacy.[21]

Issues of accountability and liability for the use of AI raise much wider and complex legal issues which will require independent, careful and in-depth analysis. Changes made by the Coalition Government to the Therapeutics Products Act, especially as it relates to SaMDs, will need to be taken into account in terms of any impact on the protection and promotion of people's rights.

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[21] https://www.rnz.co.nz/news/national/513289/a-lack-of-consequences-for-managing-personal-information-poorly-privacy-commissioner