EXPLORING A DIGITAL HEALTH GOVERNANCE FRAMEWORK FOR NEW ZEALAND: A MIXED METHODS STUDY

BY

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Abstract

Digital technologies are no longer simply considered an enabler but are now fundamental to how organisations do business, operate, and are transforming products, services, and organisational models. Digital health has been acknowledged as transformative for health systems and is considered essential to driving greater efficiency, accountability, and transparency, helping address the social determinants of health, and in achieving improved health outcomes across different populations. Between 2020 and 2022 the COVID-19 pandemic has catapulted digital health solutions and enabled rapid technology development across health systems. However, many countries still struggle with executing their national digital health strategies, with disparate, siloed, aging technology key barriers to success. Considered fundamental to implementing successful national digital health solutions is the governance framework driving nationally led programmes of work.

This research aimed to inform a comprehensive national digital health governance framework for New Zealand through a sequential mixed methods study to generate case studies of New Zealand, and two international jurisdictions, Australia, and the United States of America. The case studies were developed from publicly available grey, white, and internet literature. Semi-structured interviews with 1-3 key stakeholders from each country took place to add the perspective of people involved in developing digital health governance frameworks and systems at a national level.

Findings show that governance structures, policy, social, and technical factors can heavily influence the success or failure of implementing national health information technology strategies. Well-coordinated and open approaches are more likely to achieve success than those where accountability and transparency are not apparent. Key to success is constructing enabling legislation and establishing an overarching governance structure that can reach across the whole of a health system. The findings will be useful for countries such as New Zealand as they demonstrate what is involved in developing an effective and sustainable governance approach to national digital health, thus ensuring it is positioned as fundamental for improving health outcomes and aiding continuity of care.

Key terms

eHealth, governance, national health information platform, information and communications technology (ICT), information technology (IT), health information exchange (HIE)

Acknowledgements

"If I have seen further, it is by standing on the shoulders of giants" Isaac Newton

This dissertation has only been made possible by the people who surround me. With wisdom and compassion, I have been guided and supported throughout this process by my wider family, friends, and colleagues. When the mountain felt unclimbable, I lent on those that could help me reach the top. It is indeed because I have stood on the shoulders of giants that this work has been able to be completed. It is with heartfelt gratitude to them that I dedicate this dissertation to.

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To achieve all that is possible, we must first attempt the impossible. If my dissertation inspires just one person to partake in higher education, or if indeed if my research comes to fruition, then I will have achieved what I set out to do. I am forever grateful for the journey.

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List of abbreviations

ADHA – Australian Digital Health Agency

AI – Artificial Intelligence

API – Application Program Interface

CHIP – Children's Health Insurance Program

COAG – Council of Australian Governments

CPI – Consumer Price Index

DHA – Digital Health Association

DHB – District Health Board

eHealth – Electronic health

EHI – Electronic Health Information

EHR – Electronic Health Record

GDP – Gross Domestic Product

GFC – Global Financial Crisis

GPs – General Practitioners

HL7 FHIR – Health Level Seven – Fast Healthcare Interoperability Resources

Health NZ – Health New Zealand

HHS – Health and Human Services

HIE – Health Information Exchange

Hira – National health information platform of New Zealand

HIS – Health Information Strategy

HITECH Act – Health Information Technology for Clinical and Economics Act

HIPAA Act – Health Insurance Portability and Accountability Act

HSQC – Health and Safety Quality Commission

ICT – Information and Communications Technology

IoT – Internet of Things

Iwi – A Māori community or people

mHealth – Mobile health

MHR – My Health Record

MP – Member of Parliament

MMP – Mixed Member Proportional electoral system

NEHTA – National E-Health Transition Authority

NHI – National Health Index

NZBOS – New Zealand Blood and Organ Service

NZDHA – New Zealand Digital Health Agency

NZePS – New Zealand electronic Prescription Service

ONC – Office of the National Coordinator for Health Information Technology

PCEHR – Personally Controlled Electronic Health Record

PHARMAC – The Pharmaceutical Agency

PHO – Primary Healthcare Organisation

Rangatiratanga – The right of the Māori people to rule themselves; self-determination

Te Aka Whai Ora – The Māori Health Authority

Te Tiriti o Waitangi – The Treaty of Waitangi, a founding document of New Zealand signed in 1840 between the British Crown and Māori Chiefs. It is widely accepted as a constitutional document that establishes and guides the relationship between the Crown and Māori, New Zealand's indigenous peoples.

WAVE – Working to Add-Value to E-Information

Chapter 1: Introduction

1.1 Background

New Zealand is at a juxtaposition in digital health. While information and communications technology (ICT) is extensive across hospitals and the health ecosystem in general, systems remain largely siloed and fragmented, not fully interoperable, and many systems are outdated. Paper trails and inefficient ways of working still exist (Ministry of Health, 2021; Simpson et al., 2020). New Zealand's 2022 health sector reforms, however, have identified that data and digital are one of five key shifts required to enable consumers access to safe, high quality, and convenient services to facilitate consumer driven health (Little, 2021). Additionally, the COVID-19 pandemic disrupted the status quo and advanced the digital health agenda considerably where technology solutions became fundamental in aiding the response to the pandemic. As a result, investment in digital health has been made at a scale not seen before and national programmes of work have begun (Little, 2022). However, imperative to the successful delivery of data and digital across New Zealand's restructured health system will be an effective governance structure for digital health. This dissertation details research that sought to understand, describe, and learn from national digital health strategies and governance structures in Australia and the United States of America (USA) that could be used to help inform a more effective and overarching governance framework to ensure the successful delivery of national and integrated digital health solutions across New Zealand.

Health systems are diverse, multi-level, and complex and are often governed by the state. Adding to this complexity health systems are affected by many social, political, and economic factors. To function successfully they rely on several stakeholders working together (Carnicero & Serra, 2020; Marcelo, 2021). High standards of communication, accountability, and transparency must underpin any governing structure in the public sector (State Services Commission, 2014). In New Zealand there are several types of state-governed entities including public service departments, State-Owned Enterprises, Crown-owned companies, and Crown Entities (The Institute of Directors, 2019). Of relevance to this dissertation is the Crown Entity due to its potential to be an appropriate governance structure for digital health. The Institute of Directors (2019) describes Crown Entities as being "legally separate from the Crown but government has a controlling interest in them" (The Institute of Directors, 2019, p.40). The Pharmaceutical Agency (PHARMAC), New Zealand Blood and

Organ Service (NZBOS), and the Health Quality and Safety Commission (HSQC) are examples of Crown Entities in New Zealand's health system (Ministry of Health, 2021). For New Zealand health Crown Entities to avoid criticisms, funding must be sufficient and legislation enabling, incorporating the principles of Te Tiriti o Waitangi (The Treaty of Waitangi), a founding document of New Zealand that underpins the relationship between Crown and Māori and where the Treaty "places obligations on the Crown regarding the health of Māori communities" (Health and Disability System Review, 2019, p.11).

Digital technologies have profoundly changed the global political, social, and economic practices of the world (Steindl, 2021; WHO, 2021b). According to the King IV (2016) report on corporate governance, "technology is no longer simply an enabler" (p.6) but is crucial to how organisations conduct business and operate, as well as in the transformation of products, services, and organisational models (Institute of Directors in Southern Africa, 2016). Many different factors influence digital technology implementation across nations, including the maturity levels of governments. When looking at these maturity levels, varying degrees of success are indicated (Dener et al., 2021). In healthcare systems, the promise of delivering on digital solutions to improve health outcomes that are tangible, consistent, and measurable remains a challenge and maturity levels are behind other sectors (Dener et al., 2021; Snowdon, 2020). The Organisation for Economic Cooperation and Development (OECD) states that:

> Becoming a digitally mature government requires establishing sound governance principles, arrangements, and mechanisms to shape and monitor actions upstream, while being transparent and responsible in the provision of public services and outcomes downstream. Such governance is particularly critical to ensure that the decisions taken by the government are coherent, consistent, and co-ordinated across policy areas and levels of government. (OECD, 2021a, p.8)

Digital health is the term used to describe ICT services across healthcare systems. A broad term, digital health encompasses eHealth, mobile health (mHealth), virtual health, telehealth as well as the use of advanced computing sciences in the Internet of Things (IoT), big data, genomics, robotics, machine learning, virtual reality, and artificial intelligence (AI) (Cory & Stevens, 2020; Lotman & Viigimaa, 2019; Snowdon, 2020; WHO, 2021b). The World Health Organisation (WHO) states that digital health plays a vital role in strengthening health

systems and public health, increasing equity in access to health services, and in achieving universal health coverage (WHO, 2021b). The OECD (2021b) recognises that "providing safe, effective, responsive and patient-centred care, that is also cost-effective and accessible, requires that those making decisions – from patients to health care providers, managers and scientists – have timely and accurate health data and information" (p.136). Today, consumers have access to a wide range of health information via health apps and the internet; therefore, citizens must be at the heart of all digital transformation in healthcare, positioning them to become partners in and the drivers of their own healthcare decision making (Snowdon, 2020).

Digital health is also transforming healthcare systems; reducing costs and errors, allowing for greater efficiency, accountability, equity, transparency, continuity of care, and improving health outcomes (Carnicero & Serra, 2020; Makeham, 2020). However, the OECD (2019) reported that the digital transformation of health is further behind than other industries such as finance and aviation. National digital health programmes are complex, multifaceted, and rely on many different stakeholders including the public and private sectors, clinicians, industry, academia, and consumers to collaborate to achieve successful outcomes (Asian Development Bank, 2021). Morrison et al. (2011) explain that the reason for difficulties is most often from "a complex interplay between organisational, social and technical factors" (p.26). When large-scale programmes have failed or taken longer than expected to deliver, questions around the effectiveness of their governance frameworks have been raised (Ekeland & Linstad, 2020).

Engagement in digital health communications at a population and community level can foster societal development, increase equitable access to healthcare, serve to aid behaviour change, and help connect rural and remote areas (Grady et al., 2018; Marcelo et al., 2018). Crucial to New Zealand's overall digital health governance strategy will be obtaining equitable health outcomes across socioeconomic groups and incorporating, recognising, and respecting the principles of Te Tiriti o Waitangi (Ministry of Health, 2021). Digital health governance, strategies, and actions must therefore incorporate collaboration, co-design, partnership, and fairness between providers, health services, and Māori. Digital health is thought to help address the social determinants of health[1] and provide a means of empowering people and

[1] The social determinants of health (SDH) are the non-medical factors that influence health outcomes. They are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces and systems include economic policies and systems, development agendas, social norms, social policies and political systems. (WHO, 2022)

whanau (family/community) to manage their own health and wellbeing (Blake & Shepherd-Wiipiti, 2022).

Between 2020 and 2022 the COVID-19 pandemic tested the resilience of health systems and caused unprecedented disruption; life expectancies fell, and healthcare inequities increased creating long-lasting health impacts across the world (OECD, 2022b). COVID-19's presence highlights that protecting the health of nations is crucial for economic security and that there is great need for strong leadership, agility, responsiveness, and mobility in health information technology (IT) systems implementation (WHO, 2021a). Digital health has been at the centre of solutions for the pandemic advancing the digital health agenda considerably and enabling rapid technology development across health systems (ITU, 2021; Marcelo, 2021; OECD, 2021). In a recent OECD digital health survey, it was reported that prior to the pandemic, telehealth consultations accounted for fewer than 10% of all healthcare consultations, however, by mid-2020 "almost one in three adults had used a remote consultation" (OECD, 2021c, p.136) increasing to almost one in two by early 2021 (OECD, 2021c). Digital health can no longer be an afterthought but must be embedded in health systems operations to ensure resiliency, adaptability, capability, continuity, and in being able to respond rapidly to large disruption such as pandemics, climate change, or economic recessions (OECD, 2022b; WHO, 2021a).

Good digital health governance has been identified as the foundation for stakeholder coordination, uniting efforts, and avoiding sector fragmentation. It also improves the functioning of health information systems to support broader health goals and can transform the way healthcare is delivered. Ultimately, good digital health governance enables a move from being care-focused to being actively health-focused (Marcelo et al., 2018). The Asian Development Bank explains that "in the absence of clear governance structures, policies, processes, roles and responsibilities are blurred, resulting in fragmentation, wastage of resources, duplication of efforts, nonstrategic investment decisions, and a lack of common standards" (Marcelo et al., 2018, p. 3). According to the WHO's *Digital Health Strategy 2020-2025*, "historical review shows that ill-coordinated or disjointed digital health initiatives lead to vertical or stand-alone information and communications technology solutions, that although well-intended, often result in information fragmentation and, consequently, poor delivery of services" (WHO, 2021b, p. 15). The OECD recommends that the right governance structures be established in order to capitalise on the benefits of decades of government investment in digital technologies. Robust, transparent, and accountable

governance is believed to help advance the digital transformation of public sectors, such as health (OECD, 2021b).

Established in 2018, the Data and Digital Directorate inside New Zealand's Ministry of Health solely focuses on the delivery and execution of digital health and has several hundred personnel working on national health IT projects (Ministry of Health, 2021a). To address the siloed health IT approach in New Zealand, a programme of work to create a national health information exchange (HIE) has recently begun – *Hira* – a Māori term meaning "to have significant bearing on future events" (Ministry of Health, 2021b, para. 3). *Hira* will enable a national "virtual electronic health record by drawing together a person's latest health data from trusted sources" (Ministry of Health, 2021b, para. 6). As well as this, in 2021 the New Zealand government announced a comprehensive health system reform consolidating the current system of 20 autonomous District Health Boards (DHBs) to two overarching delivery bodies; Health New Zealand and Te Aka Whai Ora (Māori Health Authority) (Department of the Prime Minister and Cabinet, 2021a).

As the health reforms become a reality from July 1, 2022, if governance structures for digital health bringing key stakeholders into decision making are not prioritised and developed, health ICT projects could risk being delayed or worse, grind to a halt. Any delay could jeopardise New Zealand's ability to respond to future public health events, result in worsening health outcomes, increased strain on the health workforce, and further lagging behind international standards in integrated health IT systems.

1.2 Research objectives and question

This research used a sequential mixed methods approach to investigate two national digital health systems and governance structures: Australia and the United States of America (USA), in order to inform a comprehensive governance framework for New Zealand digital health. The objectives were to identify the:

1. Similarities and differences between digital health governance frameworks of Australia and the USA with New Zealand;
2. Usefulness and applicability of the Australian and USA digital health and digital health governance frameworks in a New Zealand setting; and
3. Ways a digital health governance framework based on successful international models can address Treaty of Waitangi issues and Vision Matauranga of Aotearoa New

Zealand's health system and potentially improve long-term health outcomes, equity, and accessibility of healthcare services for Māori.

The research question is: What strategies and components are used in successfully implemented independent international digital health governance frameworks that can be applied to the New Zealand health system context?

1.3 Introduction to the researcher

I am a Master of Health student at Victoria University of Wellington concentrating on policy, planning, and health systems. For a decade up to the early 2000's I worked in the IT sector in disaster recovery and service delivery management. I have a dual interest in this research as I am also the Chief Executive Officer (CEO) of the Digital Health Association (DHA). At the DHA I work with industry, key sector leaders, and stakeholders in government including the Ministry of Health, Health New Zealand, and Te Aka Whai Ora to advance and advocate for digital health across New Zealand.

1.4 Dissertation overview

While New Zealand is not alone in its underdevelopment of a national integrated digital health system, some Asian, American, Australian, and European jurisdictions are further ahead (Cory & Stevens, 2020; Mechael & Ke Edelman, 2019; OECD, 2021). This dissertation sought to understand through a case study method how autonomous and independent national digital health governance frameworks in Australia and the USA have affected the roll out of a national digital health strategy. Chapter 1 introduced the topic of digital health and the need for a governance framework and structure, research question, and key terms. Chapter 2 gives an overview of the literature relating to the topic. In Chapter 3 the research methodology and design including considerations for rigour and ethics are presented. Chapter 4 presents country-based case studies describing digital health and their development. The findings related to what would work as a digital health governance framework and what are the key considerations for setting this up are outlined in Chapter 5 and the final chapter is a brief conclusion.

Chapter 2: Literature Review

2.1 Introduction

This chapter provides a review of the literature relating to best practice governance structures especially within a digital health environment. The literature review found that there are several international frameworks developed to assist governments in their decision and policy making around the formation of governance structures for national digital health IT systems delivery. A second search included a review of best practice governance principles that could be incorporated in digital health governance.

2.2 Search strategy

An initial literature review using Google Scholar, the internet, and the Victoria University online library, Te Waharoa, was conducted using key words and phrases focusing on factors associated with digital health and digital health governance. Search term combinations included digital health/digital health strategy/eHealth/information and communications technology/health information and communications technology/health IT/health information exchange/COVID-19 digital health; and governance/digital governance/eGovernment/eGovernance/digital health governance/eHealth governance/health IT governance. Although the history of digital health dates back to the 1960s no date limitations were placed on the search criteria as there were few articles in the early time period. Literature was reviewed for common themes and implications pertaining to digital health governance.

The second search on principles of governance was conducted in the same databases using search term combinations of corporate governance/governance principles/best practice governance; principles of accountability/responsibility/fairness/transparency; and independent governance/accountable governance.

For each country case study, a third search took place using the same databases. Search terms including the country name, were: population/history/geography/political system/economics/GDP; and health system/digital health/eHealth/health information technology/digital health governance. For New Zealand I also searched for the term Data and Digital Directorate, for Australia the Australian Digital Health Agency, and for the USA the Office of the National Coordinator for Health Information Technology.

Findings from the literature are presented in two parts. Part 1 provides a brief overview of the literature, which includes the names of some countries that have successfully introduced digital health governance. It is from these countries that Australia and the USA were chosen. It also presents findings relating to models of governance developed by international organisations such as the WHO, the Asian Development Bank, and the European Union. This section concludes with a summary of the key features of the governance structures. Part 2 outlines what is known about the principles of good governance. Once the countries of interest were determined, additional targeted literature was undertaken to complete the case studies.

2.3 International ICT governance models

The literature review revealed several themes and that there are well developed international ICT governance models that promote the implementation of an independent and autonomous framework collectively bringing together key stakeholders, policies, and strategies to capitalise on technology investment. Several models focus on digital health governance while others have a wider view looking at overall digital interoperability across governments and public services. The search identified that countries including Australia, Denmark, Estonia, the United Kingdom (UK), and the USA have established digital health governance frameworks that are autonomous and independent (Essén et al., 2022; OECD, 2021b).

According to a recent qualitative systematic review, public governance is discussed extensively in social and political sciences and can be defined as "an interactive process through which society and economy are steered toward collectively negotiated objectives" (Ansell & Torfing, 2016, p.4). Digital health governance must incorporate a multifaceted and complex environment and should take into account "the health system's challenges and strategies, its leadership, the interests and rights of all stakeholders, the laws needed, and the difficulty of implementing ICT into the health system" (Carnicero & Serra, 2020, p.8).

The European Union, states that successful digital health starts with political will and good governance (European Commission, 2017). The *Refined eHealth European Interoperability Framework* is based off *The New European Union Interoperability Framework* which promotes four levels of governance: legal, organisational, semantic, and technical (Figure 1). The purpose of the model is to demonstrate that the implementation of successful interoperable digital health solutions needs "cooperation and effort on different organisational levels and requires different levels of expertise" (eHealth Network, 2015, p.11). It also

illustrates that any digital health activity must first start with the description of the desired outcomes and the definition of the problem statement (eHealth Network, 2015).

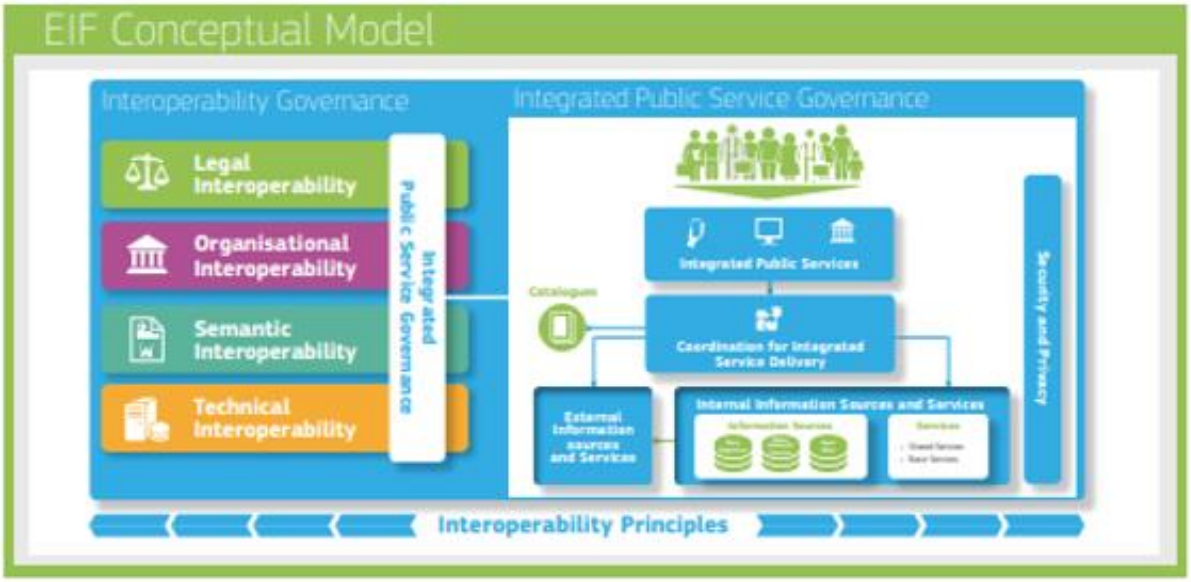

***Figure 1*: European Interoperability Framework (EIF)**
Source: *The new European interoperability framework: Promoting seamless services and data flows for European public administrations.* European Union. https://data.europa.eu/doi/10.2799/78681 ©2017 Publications Office of the European Union

In 2012 the WHO and International Telecommunication Union (ITU) developed a comprehensive three-part *National eHealth Strategy Toolkit* which recognises that countries seeking to develop and implement their national digital health strategies will face many well recognised challenges such as fragmentation of systems, rapidly changing environments, and scarcity of resources. The toolkit promotes an inclusive approach, a commitment to open communication, and a willingness to engage with key stakeholders. Developing a national vision and implementing overarching governance mechanisms are considered fundamental to successful completion of national digital health strategies. Further, the ongoing evaluation and monitoring of any digital health strategy will aid in securing the long-term investment and support from key stakeholders (WHO & ITU, 2012b; WHO, 2016). Figure 2 depicts the different components of developing a national digital health strategy.

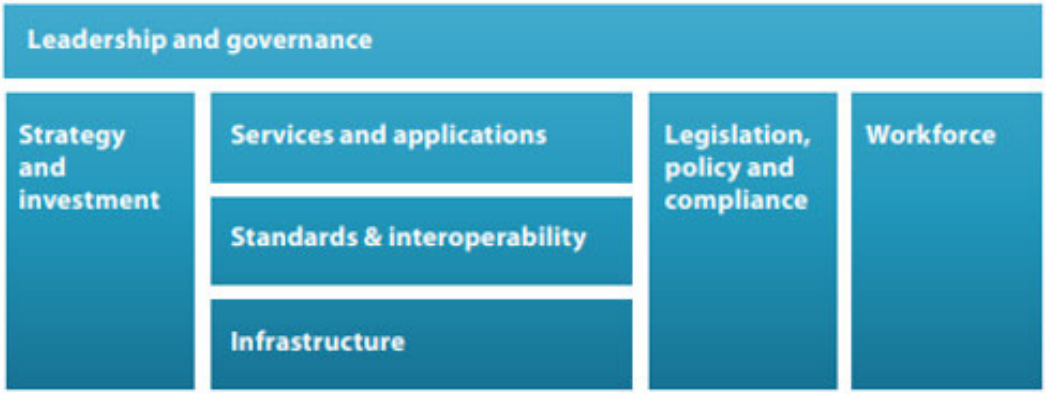

***Figure 2*: eHealth components**
Source: *National eHealth strategy toolkit* World Health Organisation and International Telecommunication Union. https://www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf. ©2012 World Health Organisation and the International Telecommunication Union

The Asian Development Bank states that "poor governance has thwarted the opportunity for smart and strategic investment decisions to be effectively and efficiently implemented" across digital health programmes (Marcelo et al., 2018, p.3). It promotes eight principles of good digital health governance including: accountability, equity and inclusion, transparency, participation of appropriate stakeholders, confidentiality, effective and efficient use of resources, responsiveness, and alignment with the rule of law. By following these principles "the foundation for stakeholder coordination and policies that enable solutions and investments, avoid duplication and fragmentation, and harmonise efforts" can occur (Marcelo et al., 2018, p.4). Figure 3 outlines key enabling factors to achieve holistic governance in digital health.

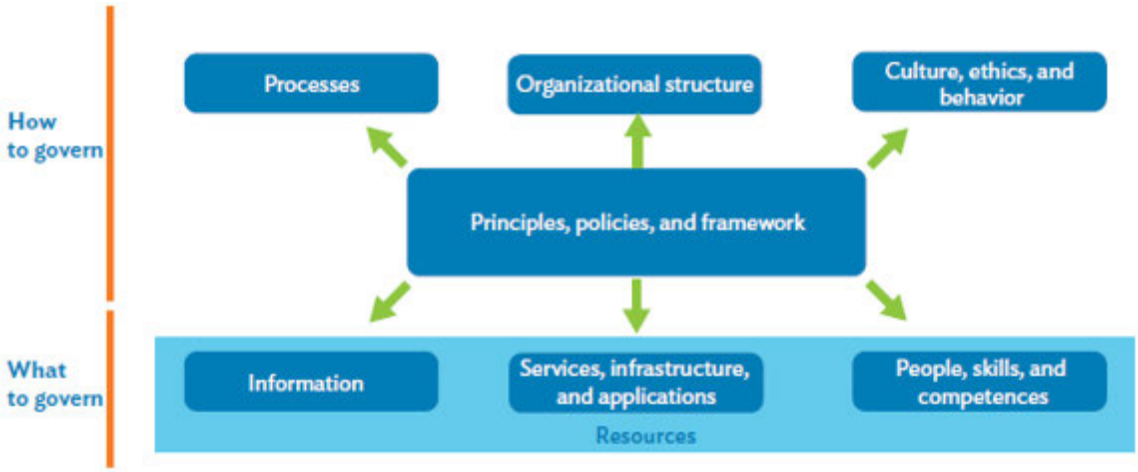

***Figure 3*: Enablers of digital health**
Source: *Transforming health systems through good digital health governance* (Issue 51). Asian Development Bank. https://www.adb.org/publications/transforming-health-systems-good-digital-health-governance. ©2018 Asian Development Bank

As well as defined governance models, New Zealand can look to successful implementations of interoperable digital health solutions in other countries. Literature shows that countries such as Australia, Canada, Denmark, Estonia, Finland, Israel, Malaysia, Singapore, Sweden, the Netherlands, the UK, and the USA are further ahead in the implementation of their national digital health strategies than other jurisdictions (OECD, 2021; Thiel et al., 2019).

2.4 Principles of governance

A review of what is purported to be good governance principles across both the public and private sectors was undertaken to add to the overall discussion on how governance for digital health in New Zealand could be framed. According to Graham et al (2003) organisational governance is "the agreements, procedures, conventions or policies that define who gets power, how decisions are taken and how accountability is rendered" (p.1). A further definition of organisational governance by Juiz et al. (2014) is "something that provides structure for determining organisational objectives and monitoring performance to ensure that objectives are determined" (p.10). Overall, governance is seen as those activities, policies, rules, and structures that are established to manage the performance, relationships, and outcomes of an organisation or entity. How governance is executed can be the difference between an organisation thriving or failing to deliver on key goals, strategies, and targets. In the public sector Juiz et al. (2014) states that "good governance leads to good management, good performance, good investment of public money, good public behaviour and good outcomes" (p.11).

Identified in the literature are several key principles pertaining to good governance including but not limited to responsibility, accountability, fairness, transparency, legitimacy, responsiveness, rule of law, inclusiveness, effectiveness, and participation (United Cities and Local Governments Asia Pacific, 2021). Good governance can improve performance, increase stability and productivity, reduce and mitigate risks, enable faster and safer growth while fostering trust and improving reputation (Ministry of Business, Innovation & Employment, 2022). While all these principles are important, for this review the principles of responsibility, accountability, fairness, and transparency are most applicable to public sector governance.

Responsibility

The principle of responsibility focuses on the roles, duties, and functions in place to govern an organisation. Typically, governance involves a Board of Directors who are responsible to an organisation's shareholders, stakeholders, and investors (Karabulut et al., 2020). In the public sector a shareholder could be a government minister (Department of the Prime Minister and Cabinet, 2022). Responsibility refers to Board members acting on a "fully informed basis, in good faith, with due diligence and care, and in the best interest of the company and the shareholders" (OECD, 2015, p.45). Responsibility also includes applying those laws and ethical values that ensure the validity of an organisation (Witherell, 2002). The Controller and Auditor General, New Zealand explains that "clear roles and responsibilities make the differing interests transparent and foster effective decision-making" (Controller and Auditor-General, 2021b, para. 3).

Accountability

Being held accountable is the ability to explain, justify and take responsibility for organisational performance, actions, and decisions (Graham et al., 2003). Under the accountability principle, there are usually consequences for poor performance (Ali, 2015). This principle refers to the mechanisms put in place to hold those to account for the operational performance, outcomes, and actions of an organisation (Bovens, 2007). The principle of accountability is results driven as opposed to responsibility which is task oriented (McGrath & Whitty, 2018). The Controller and Auditor-General in New Zealand refers to public sector accountability as the "legal and reporting framework, organisational structure, strategy, procedures, and actions" (Controller and Auditor-General, 2016, p.9) to ensure the use of public money and those that make decisions affecting citizens can be held responsible for their actions.

Fairness

The principle of fairness relates to the equal treatment of all invested shareholders and stakeholders and treating people with equality (Karabulut et al., 2020). Fairness can identify both equity and the rule of law and should recognise the interest of stakeholders and how their contribution can help determine the long-term success of an organisation (OECD, 2017; van Doeveren, 2011). Opportunities for all shareholders and stakeholders to vocalise their grievances, including having rights to information is considered crucial to the principle of fairness (OECD, 2015).

Transparency

Transparency means openness and disclosing all matters publicly pertaining to an organisation's performance, processes, and structures (Fox, 2007; Karabulut et al., 2020). These can include the "financial situation, performance, ownership, and governance" of an organisation (OECD, 2015, p.37). Transparency is considered crucial for influencing the behaviour of organisations and those governing them as well as allocating resources effectively. Without transparency, weak disclosure can contribute to poor performance, unethical behaviour, and a loss of integrity and trust with stakeholders. Transparency takes into account that shareholders, stakeholders, and potential investors need to access regular, reliable, understandable, and comparable information in order to assess the performance, stewardship, and management of an organisation (OECD, 2015; van Doeveren, 2011).

2.5 Chapter summary

The literature review demonstrates that a coordinated, independent, and autonomous approach that supports inclusion, disclosure of information, engagement with stakeholders, and a commitment to open communication aids successful implementation of national digital health strategies. It also shows that there are well-developed digital health governance and strategic frameworks that less digitally mature countries could utilise to advance their digital health agenda.

The review on governance found that responsibility, accountability, fairness, and transparency are key principles of good governance and should be considered when establishing governance structures for any organisation. Evaluation of proven digital interoperability frameworks and governance models implemented in other jurisdictions or developed by international bodies, could inform a new sustainable approach to digital health governance in New Zealand.

Chapter 3: Methodology and Research Design

3.1 Introduction

This research used a sequential mixed methods methodology combining both quantitative and qualitative data to create case studies of New Zealand, Australia, and the USA (Harrison et al., 2020; Shorten & Smith, 2017).

3.2 Research design and setting

Creating country-based case studies was chosen as the approach to provide comparisons between countries and inform the research objectives. Firstly, a case study method was conducted to analyse and identify key concepts, potential gaps, and issues in New Zealand, Australia, and the USA. The case study analysis provided an in-depth and multi-faceted understanding of the complex issue of digital health and digital health governance, allowing a "critical, reflective perspective which seeks to take into account the wider social and political environment that has shaped the case" (Crowe et al., 2011, para. 9). A critical appraisal of the literature helped "identify the strengths and weaknesses of studies, determine how much confidence to have in the findings, and to ensure recommendations and conclusions properly reflect the quality of evidence reviewed" (Hong & Pluye, 2019, p.449). Secondly, in-depth semi-structured interviews via virtual methods of up to three key stakeholders in the chosen jurisdictions were conducted. The interviews included closed and open-ended questions to elicit data about digital health and digital health governance frameworks to inform the case studies (Adams, 2015).

3.3 Samples

Sampling used purposeful and convenience approaches to identify the key stakeholders (Palinkas et al., 2015; Suen et al., 2014). Stakeholders were selected based on the role they have played in the application of their digital health ecosystem and on availability for interviews. All stakeholders approached consented to be interviewed.

3.4 The countries and participants

New Zealand

1. Dr Lloyd McCann – Chief Executive Officer, Mercy Radiology and Clinics
2. Dr Robyn Whittaker – Public health physician and mHealth researcher, Waitemata District Health Board
3. Mr Shayne Hunter – Deputy Director General, Data and Digital, Ministry of Health

Australia

1. Ms Amanda Cattermole – Chief Executive Officer, Australian Digital Health Agency
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USA

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3.5 Methods and data collection

Data sources for each case study included literature (grey, white, and the internet), national key documents, and key stakeholders' interviews. The literature review used key terms and phrases, data were screened for eligibility criteria where the article focus was digital health and digital health governance, and critically appraised (Xiao & Watson, 2019). The review had three purposes: to provide country contextual details; to assess the ongoing debates in digital health and digital health governance; and to identify features related to digital health governance that have been reported as successful.

The semi-structured interviews were chosen as interviews can "add greater depth of interpretation that infuse the previous analysis with rich context" (Harrison et al., 2020, p.487). Participants were able to set the time and place of the interviews and initial introductions sharing personal background, work settings, and outlining the relevance of the topic took place to ensure a rapport was established. Targeted questions arose from the findings of the literature review. Interview topics focussed on the development of digital health systems and included: role and length of time in role; type of system; strengths and weaknesses; use of governance frameworks; stakeholder involvement; indigenous peoples involvement; lessons learned.

The interviews were recorded via Microsoft Teams, transcribed, and then analysed to create a summary of the key points regarding digital health and digital health governance.

Procedures

1. Case study framework developed;
2. Database and internet searches for literature;
3. Interview template developed;
4. Ethics approval obtained;
5. Interview/s of key stakeholders recorded via the internet and transcribed;
6. Interviews coded and analysed;
7. Country case studies developed; and
8. Lessons and implications for a New Zealand framework generated.

3.6 Analysis

Using content and thematic techniques the analysis involved two stages. Stage 1 involved the creation of the case studies where firstly descriptions of the country details such as the political systems, health systems, digital health governance models, and their digital health systems were collated. The interview data were integrated with the literature findings to provide a comprehensive overview of each case study.

Stage 2 involved identifying lessons from the case studies, the literature, and targeted analysis of interview data for potential development and application for the New Zealand setting (Nowell et al., 2017). This included identifying structural as well as operational and governance considerations important for the development of a digital health governance framework in New Zealand.

3.7 Rigour

Rigour is defined as "the quality or state of being very exact, careful, or with strict precision, or the quality of being thorough and accurate" (Cypress, 2017, p.254). Key ways of addressing rigour concern managing trustworthiness, credibility, dependability, confirmability, and transferability (Nowell et al., 2017). The analysis aimed to be balanced, referencing back to systematically collected literature and the interview quotes were used to

support the findings. The research implications target New Zealand but may be useful in international contexts.

To establish trustworthiness, readers need to be assured findings are worth paying attention to, are accurate, and that conclusions have integrity (Long & Johnson, 2000). Peer debriefing was sought by supervisors to check for author bias and prejudice and to ensure the data was accurate.

Credibility of data is used to establish confidence that results are true, valid, and believable (Forero et al., 2018). To obtain credibility, literature was collected systematically, and time was initially spent with the participants to gain trust and an understanding of the context of their experiences. The interview process allowed for both focus and flexibility, expansion of answers, and the opportunity for participants to request further information (Forero et al., 2018). Quotes from the literature and interviews have been used to demonstrate themes. To maintain credibility participants were offered the opportunity to check their transcripts for accuracy and a copy of the final report (Creswell & Miller, 2000). Four of the six participants checked their quotation transcripts and made minor changes.

Dependability refers to the stability of findings over time and that similar findings would be found if the research was repeated in a comparable time or context (Forero et al., 2018). To ensure dependability the data extraction method involved recording data systematically and managing researcher bias through peer review ensuring one jurisdiction was not privileged over another.

To achieve confirmability, interpretation of literature and interviews have not been based on my particular preferences but grounded in the literature and data retrieved (Korstjens & Moser, 2017). Reflections on decisions made, values, pre-conceived ideas, potential bias, and the emergence of findings were conducted with my supervisors on a regular basis (Korstjens & Moser, 2017). Supervisors conducted verification coding regarding the literature criteria and interview questions and ensured the data answered the research question.

Transferability is the “degree to which the results can be generalised or transferred to other contexts or settings” (Forero et al., 2018, p.3). To achieve transferability rich and thick descriptions have been provided and special care given to the sources of data as well as presenting the material with sufficient simplicity that others can examine the findings (Cypress, 2017).

3.8 Ethics

Ethics approval was granted from the Victoria University of Wellington Human Ethics Committee (No. 30041) (Appendix 1). It was recognised that although the topic and focus of the research did not seek to obtain personal information, the participants may share critical perspectives of their experiences. Ethically managing the content of the interviews was therefore important. Key ethical issues addressed were: informed confidentiality, privacy, non-maleficence, respect, conflict of interest, and consent (Allmark et al., 2009; Ministry of Health, & National Ethics Advisory Committee, 2020). An information sheet (Appendix 2) and consent form (Appendix 3) were disseminated to the participants to convey how these ethical matters would be addressed. Participants signed and returned consent forms prior to their interviews.

No pressure was exerted on stakeholders to participate in the interviews. All participants agreed to being named in the final report. Interviews were conducted in a virtual setting that addressed participants need for privacy. Participants were assured that there should be minimal risk and harm associated with participating and that interview recordings would be securely held in a password protected server. Participants had the right to withdraw from the research, and to decline to answer any question. Respect was always given for participants time and the information gathered from them.

Participants were advised that the information is for the purposes of the research as a student, but that the final report is likely to be shared with the Minister of Health, the Ministry of Health, Health New Zealand, Te Aka Whai Ora, and other key stakeholders in New Zealand's health sector. They were also assured that the raw data will be securely kept on an appropriately firewalled and protected server for a minimum of 6 years to ensure security and validity.

3.9 Limitations

The research has been limited by the scale and scope of a dissertation and by the short timeframe which limited the number of available participants to interview in each country. This research could be expanded in future to include other countries and more participants.

Chapter 4: Case Studies

4.1 Introduction

A case study approach is used to show a direct comparison between New Zealand's current digital health system and governance structure to those of the countries chosen, Australia and the USA. Australia and the USA were chosen for the type of digital health governance structures they have as well as access to key stakeholders for the interviews. Careful consideration was given to the type of country, its political system, and the effects a national digital health governance structure has had on the roll out of national health IT strategies. By systematically reporting on the three countries, the case studies show the differences and similarities of the structures and therefore contribute to the discussion on what could inform an alternative governance approach to digital health in New Zealand.

Using four phases, the case studies include a description of each country's:

1. Geography, population, economic status, and political system to capture their history, development, and their unique characteristics;
2. Health system;
3. Current digital health governance model; and
4. Digital health journey and timeline.

Throughout the case studies, quotes from the interviews are used to give context and to add the stakeholder perspective to the literature.

4.2 New Zealand

Country overview

New Zealand is an island country that lies remotely in the South Pacific Ocean and has an estimated population of 5.1 million (Statistics NZ, 2022a). Its landmass is approximately 268,000 km^2 with a population saturation of 19 people per km^2 (The World Bank, 2022). Approximately 14% of New Zealand's population live rurally with the rest living in urban areas and over one-third are located in the greater area of its largest city Auckland in the North Island (Health and Disability System Review, 2019). New Zealand is ethnically diverse with 179 nationalities being represented in its population (Statistics NZ, 2020).

A developed nation, New Zealand enjoys a high standard of living; the GDP in 2021 was US$247.685 billion with annual growth of 5.6% (International Monetary Fund, 2022; Statistics NZ, 2022). Life expectancy is higher than the OECD average of 81 years, at 82 years combined (OECD, 2021c). Its population is mostly New Zealand European/Pakeha at 70% however there is also a significant proportion of Māori (indigenous peoples) comprising 17.1% of the population (Statistics NZ, 2021a). On average, Māori have 7.5 years lower life expectancy and poorer health outcomes than the rest of the population (Statistics NZ, 2021b). The *Health and Disability System Review Interim Report* (2019) states that "Māori and Pacific peoples are significantly more likely to live in areas of high socioeconomic deprivation than other populations" (p.17). The inclusion of Te Tiriti o Waitangi principles and honouring government obligations to Māori communities is essential when developing health policy in New Zealand (Department of the Prime Minister and Cabinet, 2021a).

New Zealand is a sovereign nation and a member of the Commonwealth, "an organisation of 54 countries – most with a shared history as part of the former British Empire" (New Zealand Foreign Affairs & Trade, 2022, para. 1). Its Head of State is Queen Elizabeth II, represented by a Governor General. New Zealand's Parliament is unicameral meaning it has one chamber, the House of Representatives. The Prime Minister heads the government along with 119 other Members of Parliament (MPs) who are elected every 3 years by a Mixed Member Proportional (MMP) voting system (Office of the Clerk/Parliamentary Service, 2016). New Zealand's system is based "on the principle that power is distributed across three branches of government – Parliament, the Executive, and the Judiciary" (New Zealand Parliament, 2016, para. 2). Parliament makes the law, the executive carries out the law, and the judiciary interprets the law (New Zealand Parliament, 2016).

New Zealand's health system

New Zealanders have universal access to healthcare and its health system is largely funded by the taxpayer at 70% (OECD, 2021c). New Zealand's government sets an annual budget to fund healthcare services and drives health policy agendas and service requirements (The Commonwealth Fund, 2020c). This includes "inpatient, outpatient, mental health, and long-term care, as well as prescription drugs" (The Commonwealth Fund, 2020c, para. 1). In 2019 New Zealand spent US$4,212 per capita on its health system and 9.74% as a percentage of its GDP (OECD, 2021c; The World Bank, 2022).

New Zealand's health and disability system structure was a complex maze of governance and providers where the overall responsibility for planning, purchasing, and providing health services, including hospitals, primary care, and community services, lay with 20 geographically defined District Health Boards (DHBs) (Ministry of Health, 2021a). DHBs were Crown Entities, legislated for under the Crown Entities Act 2004, and reported to the Minister of Health (Ministry of Health, 2021a; The Institute of Directors, 2019). Each DHB had their own Board and Charter whose main function was to "improve, promote, and protect the health of people and communities" (State Services Commission & Ministry of Health, 2010, p.9). The Ministry of Health acted as the principal advisor and funded a range of national services as well as providing regulatory functions. DHBs made decisions about how they allocate their budgets, including how much to spend on both the development and management of IT systems (Ministry of Health, 2021a). Figure 4 outlines New Zealand's previous health and disability system structure. However, this changed on July 1, 2022, where New Zealand's largest health sector reform in two decades came into place (Department of the Prime Minister and Cabinet, 2021a).

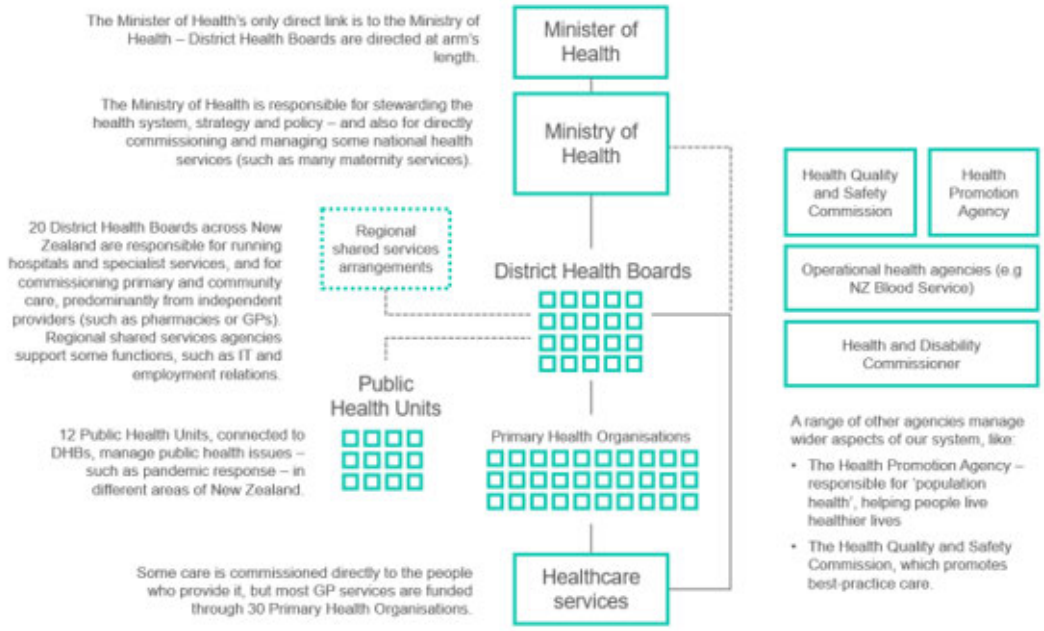

***Figure 4*: New Zealand health and disability system 2002 - 2022**

Source: Our health and disability system: Building a stronger health and disability system that delivers for all New Zealanders https://dpmc.govt.nz/sites/default/files/2021-04/heallth-reform-white-paper-summary-apr21.pdf ©2019 Department of Prime Minister and Cabinet

Dr Lloyd McCann argues that:

> *New Zealand has this inherent nature where, as a society we prefer devolved solutions, devolved approaches to governance, and devolved approaches to leadership. One of the challenges and complex problems health needs to solve is striking that balance between do we need an element of uniformity, consistency, and centralisation in governance that still permits that flexibility and that autonomy at a local level.*

New Zealand's health sector reforms have been driven by "significant and persistent issues in delivering equity and consistency for all" (Department of the Prime Minister and Cabinet, 2021a, p.1). A term coined 'postcode lottery' is widely used to describe New Zealand's levels of care across the country, meaning "the care you receive depends on where you live, and which DHB and Primary Health Organisation covers you" (Department of the Prime Minister and Cabinet, 2021a, p.6). The new delivery health agency, Health New Zealand, will be governed by an independent Board who will advise the Minister on the transition to the new structure and on its ongoing performance (Department of the Prime Minister and Cabinet, 2021b). Figure 5 shows the new health system structure.

Mr Shayne Hunter explains that *"Health New Zealand is a public health service providing hospital and specialist services, but it commissions services for primary and community settings."*

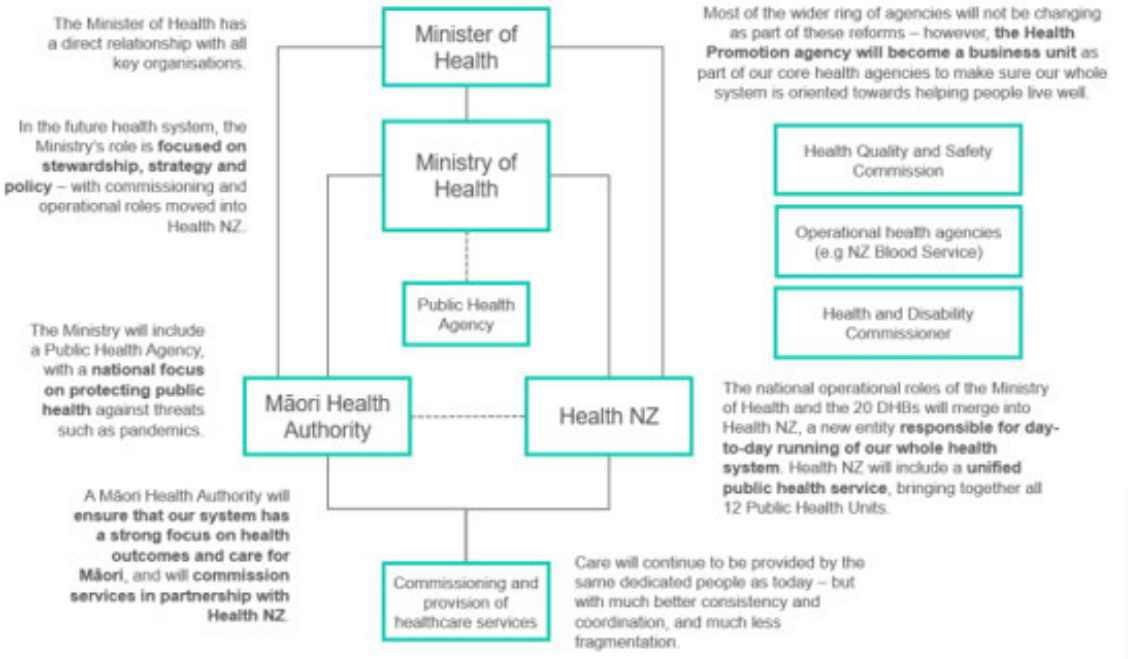

***Figure 5*: New Zealand health system reform structure July 1, 2022**

Source: Our health and disability system: Building a stronger health and disability system that delivers for all New Zealanders https://dpmc.govt.nz/sites/default/files/2021-04/heallth-reform-white-paper-summary-apr21.pdf ©2019 Department of Prime Minister and Cabinet

Considered central to the reforms is a changed view on how Māori health is both managed, executed, and influenced. Acknowledging that the disparities are wide between Māori and non-Māori, and that the principles of Te Tiriti o Waitangi must be observed, alongside Health New Zealand will be a new statutory entity, Te Aka Whai Ora, the Māori Health Authority. This entity will have its own governing Board to oversee its foundations and direction (Department of the Prime Minister and Cabinet, 2021b). The new health structure aims "to strengthen rangatiratanga[2] Māori over hauora Māori, empower Māori to shape care provision, and give real effect to Te Tiriti o Waitangi" (Department of the Prime Minister and Cabinet, 2021a, p.7). The reforms also have a central aim of improving equity of access and health outcomes for all people across New Zealand (Department of the Prime Minister and Cabinet, 2022).

[2] Rangatiratanga was used in Article 2 of the Māori language version of Te Tiriti o Waitangi to convey the idea of unqualified exercise of Māori chieftainship over their lands, villages and all their treasures. Rangatiratanga is often associated with sovereignty, leadership, autonomy to make decisions, and self-determination. This includes leadership within the whānau and community, as well as leadership within business and politics. (Independent Māori Statutory Board, 2022)

According to Dr Robyn Whittaker:

> *With the Māori Health Authority and co-governance from the very beginning we are probably going to be global leaders in the area of equity and Māori data sovereignty if we take time to figure this all out and take it seriously.*

New Zealand digital health governance

National digital health initiatives are governed by a top-down[3] approach, meaning they are overseen and managed by a senior leader within a data and digital directorate inside a health delivery agency (Ministry of Health, 2018). Top-down approaches require a strong leader and good culture to achieve success and are often influenced by the management style of the person leading (Malsam, 2019). In the past 3-years, to assist with strategic and investment goals in digital health, Mr Hunter explains that there were some advisory bodies established:

> *When I became Deputy Director-General, I set up a Digital Investment Board to provide advice on strategy and investment. While they were not governing strategy or investment delivery, they did form an important part of a governance ecosystem to ensure we were making progress on the right things. We also have a National Digital Leaders Group which includes DHB digital leaders and the Ministry of Health to discuss and align DHB and national digital health strategies. Again, this was an advisory body but did form an important part of a governance ecosystem.*

The health sector reforms have continued with a similar structure by placing this directorate in an 'enabling' management tier within Health New Zealand and appointing a Chief of Data and Digital as chief steward. This role will link closely with the policy arm of the Ministry of Health (Health New Zealand & Māori Health Authority, 2022). In addition, the Boards of Health New Zealand and Te Aka Whai Ora have established a joint working group to guide and drive the data, digital, and innovation agenda (Health New Zealand & Māori Health Authority, 2022). According to Mr Hunter:

> *The reforms will enable a different governance structure to what we've had in the past. In terms of data and digital, that means governance can provide*

[3] The top-down approach to governance is based on the principle that senior managers make wide decisions that trickle down to lower departments. The decisions are first weighed on variables like frequency and severity, and then made based on the higher or lower levels of such variables. Upper management gathers and acts upon the knowledge, which employees carry out. (Eby, 2018)

> *stronger direction across the system. There will be layers of governance and starting at the top, the Boards of Health New Zealand and the Māori Health Authority have established a joint Data, Digital, and Innovation Working Group co-convened by a member from each of the Boards. In time this is likely to become a formal Board sub-committee. The Chief Executives of the Ministry of Health, Health New Zealand, and the Māori Health Authority have also established a Joint Oversight Group, to guide and support national approaches at an operational level. This is initially focused on data collection, access, and governance.*

Since the 2019 health system review and the COVID-19 pandemic the government has indicated that data and digital services will act as a key driver to unify health services and shift the health outcomes of New Zealanders. This recognition has for the first time resulted in significant funding and the establishment of national programmes of work, including *Hira*, to facilitate full digital ecosystem connectivity and digital capability uplift across the health system (Gunasegaran, 2021). The data and digital directorate shared the *Data and Information Strategy for Health and Disability*, accompanied by a 3-year roadmap which acknowledges that "if we want a connected, equitable and sustainable health system that actively supports good health outcomes for all New Zealanders, we need to improve the way we collect, manage, use and share data and information" (Ministry of Health, 2021, p.6). Mr Hunter explains that:

> *One of the five key shifts in the health sector reforms is digital which is huge in terms of acknowledgement. This sends a very strong signal that digital is important, and we've not had that before. We have programmes that are addressing technical debt as well as supporting modernisation and transformation which are significant.*

While it is intended that this new digital health governance structure will help drive national health IT programmes in a more coherent way, it still follows a top-down approach to governance where leadership and culture could influence success significantly, it is not legally recognised as independent from Health New Zealand and has little autonomy to drive digital health across the whole of the health system. Health New Zealand is mandated to report publicly through the *Health Systems Indicators Framework*, however, there is no indication that the data and digital directorate will be required to publicly report on outcomes,

regulations, data, policies, financial information, and deliverables (Controller and Auditor-General, 2021a; Ministry of Health, 2021b). Dr McCann argues that:

> *The ONC in the U.S. and the Australian Digital Health Agency have specific mandates to roll things out, but another thing those organisations do very well is engage their stakeholders and the different components of those communities. It is about systematising and creating those forums for engagement where there is robust debate and discussion and then having the ability to move forward in a specific direction after you've had the opportunity to debate and engage*. He goes onto say that *the principle of partnership is key but then the principle of handing power over to some key stakeholders, like consumers in particular, but also having the vendor community at the table, having academia at the table, as well as providers and funders is critical.*

New Zealand digital health

New Zealand has faced many well recognised challenges with its attempts to co-ordinate health IT systems nationally. While there is considerable innovation across the country, systems are largely dispersed disparately within the 20 DHBs and legacy systems often operate individually with little inter-agency and public-private collaboration, the result being duplication of policies, efforts, and technology (Deloitte, 2015; Ministry of Health, 2021; Simpson et al., 2020). Consequently, the current health IT ecosystem has limited ability to share and scale from local to national levels (Ministry of Health, 2021). The 2021 *Data and Information Strategy for Health and Disability* states that "the sector as a whole is grappling with aging infrastructure, limited mechanisms for accessing data and information, workforce shortages, and data literacy challenges" (Ministry of Health, 2021, p.12).

While the amount of digital capability in New Zealand's healthcare system is significant, Mr Hunter explains that:

> *New Zealand has some really good digital capability in the system, but I would argue that some of it is getting a bit old and clunky now in terms of architecture and technology, nonetheless we're more connected than some other countries. I don't think there is any country in the world that has it 100% right.*

At secondary and tertiary levels some progress has been made with a handful of regional DHBs working together to attempt to provide an integrated approach. These regional systems are not a nationwide solution however, they have limited inoperability between healthcare providers, nor do the public have access to their medical data from a secondary system level (Health and Disability System Review, 2019). While many of the issues relate to a national strategy for digital health, other issues have also been apparent regionally. Dr Whittaker shared some of the challenges that have faced Auckland, New Zealand's largest city:

> *As well as having the three DHBs across Auckland, we've had quite different leadership and policies within services that exist within one city. They have been divided into three groups with different thoughts, perspectives, and priorities. In one way that is good to get local priorities, but in another it can hamper things for example when you are trying to get standardisation of certain systems across one city. It is about finding the right balance which is the difficult thing and even with the new structure we are still going to be trying to find that balance of getting the priorities and needs of a local population met.*

Primary care systems have moved further forward than secondary and tertiary hospital systems with the introduction of patient portals. Most patients can book appointments online, view their health data related to primary care, and communicate with their GPs either via email or video consultation. GP practices can also electronically refer patients to specialists, receive electronic hospital discharge summaries, send prescriptions via an ePrescription service, NZePS, and transfer patient records between practices electronically (The Commonwealth Fund, 2020a).

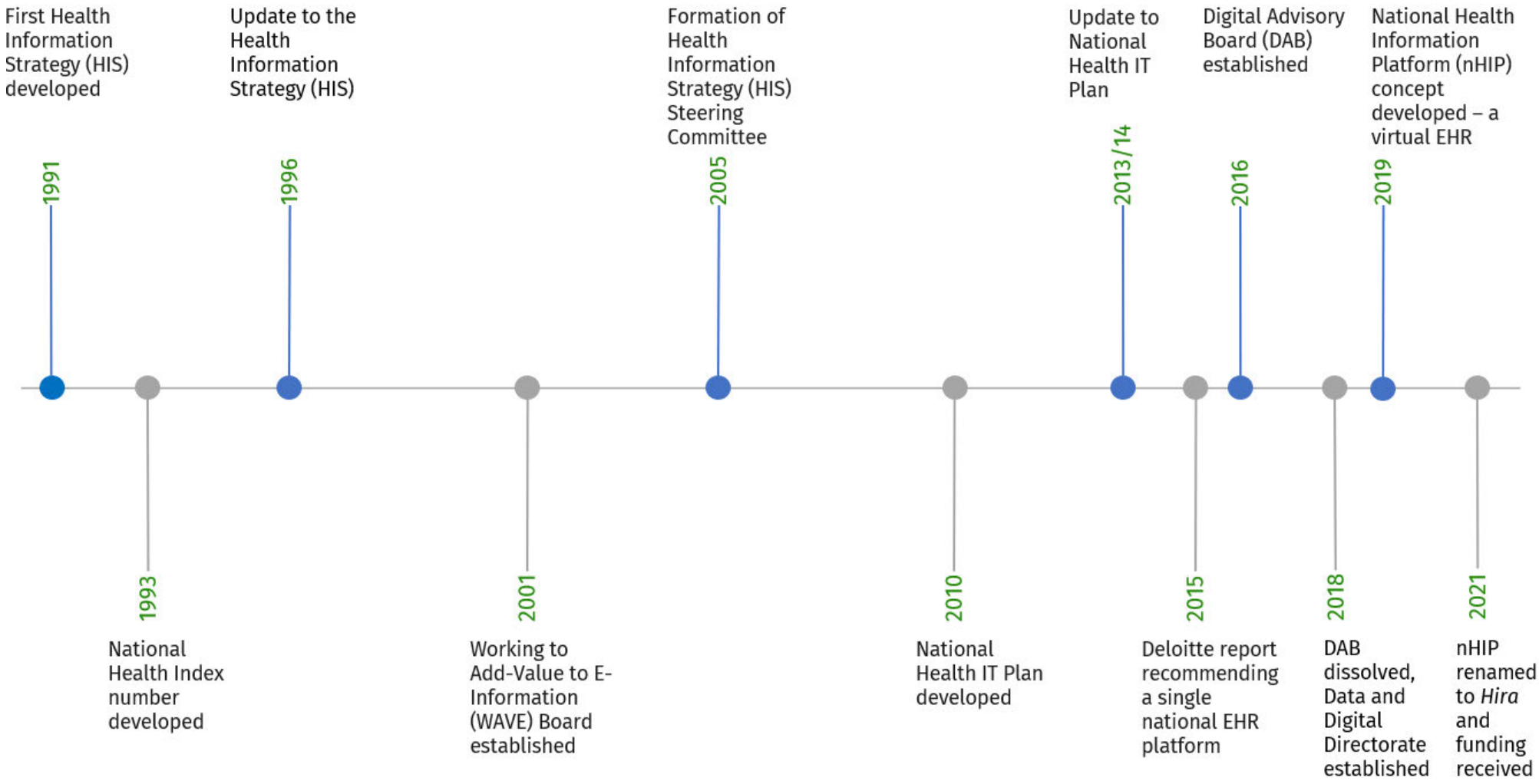

***Figure 6*: New Zealand digital health timeline**

Dr McCann shared his thoughts on New Zealand's current digital health infrastructure:

> *I think there are pockets of excellence, there are pockets of good, but let's acknowledge that there is a lot that is poor as well. There are a number of reasons that have led us to this, but one of the critical things here is that it actually relates back to overall New Zealand culture. We've ended up with a system, that is in fact 20 systems that have been in operation for two decades now. I don't think you can argue with the principles around the establishment of those district health boards, because they are systems that are responsive to the needs of the community they serve. So even though there are similarities between Auckland and Invercargill there are differences between Auckland and Invercargill, there are differences between Auckland and Kaitaia, Wellington and Kaitaia, etc. What we failed to appreciate at the time, is that despite requiring that local flexibility, that local autonomy, there are things that do need to be consistent and should be consistent, nationally, in order to enable good outcomes for people.*

New Zealand's chequered history of digital health strategies and governing bodies has contributed to the siloed and fragmented health IT ecosystem today. Dating back to 1991, the then Department of Health released its first *Health Information Strategy* (HIS) (Ministry of Health, 2001). Soon after the National Health Index (NHI) a "unique seven alphanumeric identifier for each patient which plays an important role in the access and exchange of patient health information" (Ragaban, 2016, p.21) was developed. Today, the NHI forms the cornerstone of digital identity in the health system, catapulted by the COVID-19 pandemic and the technologies that were rapidly built to respond to the global health crisis (McBeth, 2020; New Zealand Government, 2022).

The HIS was updated in 1996, with the goal that timely, accurate, and robust IT information would be available to consumers by the year 2000 and all those "individuals and agencies involved in the provision of health and disability support services" (Shipley, 1996, p.6). After slow progress, in 2001 the then Labour-led Government established the first information technology health-related advisory board – Working to Add-Value to E-Information (WAVE) – to provide impetus and guidance in the implementation of a health IT strategy (WAVE Advisory Board, 2001).

In 2005, further changes saw the formation of the HIS Steering Committee, the functions of which sought to expand on the WAVE report. The goal was to improve the quality, availability, and sharing of information across health IT systems (Ministry of Health, 2005). Progress was made but systems had still not actualised the national interoperability objectives thus in 2010 a National-led Government formed the National Health IT Board. Developing the *National Health IT Plan,* this Board's aim was to create a "more cohesive program (sic) of implementation to enable an integrated healthcare model" (Ragaban, 2016, p.24). Subsequently, the plan was updated in 2013/14 with a 'lessons learned' approach outlining achievements to date and signalling the direction of interoperability from 2015 to 2019 (Ragaban, 2016). However, reportedly, due to under-funding and mixed messaging, in 2016 the Health IT Board was replaced with the Digital Advisory Board (DAB), containing just three members (Corner, 2016; Ministry of Health, 2017; Pullar-Strecker, 2016).

The DAB's aim was to "to help the Ministry understand the potential benefits of existing, in-progress and future digital and information-related technologies and to support the development of the strategies needed for their systematic uptake" (Ministry of Health, 2017, para. 1). The DAB was dissolved in October 2018 when a restructure of the Ministry of Health led to the establishment of a data and digital directorate headed by a Deputy Director-General as chief steward. The directorate became a part of corporate services and has since been responsible for the development of national health IT programmes of work (Ministry of Health, 2018).

New Zealand had to quickly respond to the 2020 COVID-19 pandemic, by increasing its capabilities in several digital areas across health after finding itself in a situation where the siloed aging systems hampered national coordination efforts for the pandemic (Clarkson, 2021). As the pandemic shifted in pace, New Zealand continued to respond with technology to meet the demand of new variants of the virus. The arrival of the pandemic shifted the conversation around the importance of digital technologies as fundamental to improved and more equitable health outcomes across the health system (Baker et al., 2020; Ministry of Health, 2022). Dr Whittaker sums up the benefits and limitations of New Zealand's initial digital health response to COVID-19:

> *We are lightyears ahead of where we were three years ago because of COVID. But interestingly data and digital were not part of the initial response, it was only about the logistics. Data and digital went and did its*

> *own thing as they saw there were great things that could be done to really help the response, but they were not at the top table. There was a point when there was a realisation that they* [the Government] *needed the data, analytics, and software developers as part of the actual solution. We would want to avoid the same thing happening moving forward.*

The lack of integrated health IT and data sharing in the past two decades has contributed to a lack of continuity of care for health consumers. It has prevented seamless communication and added to the 'postcode lottery' system (Goodyear-Smith & Ashton, 2019; Ministry of Health, 2021; Walters, 2019). New Zealand's provider-focussed health system means consumers have little control over their health data or their patient experiences, and often find themselves repeatedly re-telling their health stories resulting in duplication, medical errors, and poor patient experiences (Simpson et al., 2020).

An example of the systems not placing the consumer at the heart of information sharing is outlined by Dr Whittaker:

> *The boundaries of the DHBs in Auckland meant we couldn't share information about one person who lives essentially in the same city getting care from several different people perhaps across different DHBs. Things like this make no sense from a consumer's perspective. If we had had them* [the consumer] *at the table, we would have at least had that common-sense check about our approaches which might have helped us move a bit quicker.*

At a technical level, standards, for example HL7 FHIR[4], which set the rules for how health IT providers capture and communicate data, remain inconsistent. This inconsistency can hinder the sharing of health information (Ministry of Health, 2021). Additionally, change management is not often prioritised or funded, which can result in the reluctance of the health workforce embracing new technologies (Ministry of Health, 2021; Simpson et al., 2020). According to Mr Hunter *"we've had a long-standing commitment to some of these things* [standards, privacy, security] *but I don't think we've had as much traction as we would like because I don't think we've ever had the money to invest."*

[4] The HL7® FHIR® (Fast Healthcare Interoperability Resources) is a standard for exchanging healthcare information electronically to help advance interoperability. EHRs and digital health systems present patient data in different ways e.g., medications, encounters) and FHIR® provides a means for representing and sharing information among clinicians and organisations in a standard way regardless of the ways local systems represent or store the data. (eCQI Resource Centre, 2022)

Similarly, Dr McCann raises issues with the standards for digital health:

> *I don't believe our thinking has yet evolved to the point where we have agreed to endorse, invest, and mandate standards, recognising that standards will build the spine for the digital health infrastructure for the country that will allow us to get on and do what we need to do. If we are able to connect in with standards, that will allow us to innovate, adopt new solutions, and utilise different technologies and approaches.*

The future state for digital health in New Zealand is to uplift digital capability in the current aging infrastructure and to enable a much more cohesive and connected system through *Hira*. It is envisaged that in 3-years' time consumers will have access to their health data via patient portals, connecting both primary and secondary data through a virtual EHR and enabling consumers to have more control of their health and wellbeing (Ministry of Health, 2021a). However, if New Zealand continues to apply a top-down approach to the governance of digital health where structures are not inclusive, transparent, or held accountable, continued delays and failures could result.

The New Zealand case study shows that establishment of multiple strategies and governance frameworks for digital health by successive governments over several decades has meant the realisation of national integrated digital health solutions have not yet been realised (Ragaban, 2016). While there has been significant government investment in digital health in the last three years, as well as strong leadership and coordination from the data and digital directorate, in the past, digital health governance structures have lacked adequate investment and resources, political bi-partisan support has not been apparent, and regulations to support national health IT strategies such as standards adoption have not been forthcoming (Deloitte, 2015; Ministry of Health, 2020; Pullar-Strecker, 2016). Gaps remain in stakeholder engagement, transparency, and accountability, however, there is also a great opportunity to secure a sustainable overarching digital health governance framework that will ensure the ongoing success of national digital health solutions through New Zealand's health sector reform. Mr Hunter argues that:

> *Over a period of time, we need to establish all the right settings and those settings need to take a longer-term view on things. There is quite a bit of work to be done in this area…we could find a million and one reasons to wait but you learn by doing, by getting on with it, and rolling your sleeves up.*

4.3 Australia

Country overview

Australia is the sixth largest country in landmass at 7,692 million km^2 and considered to be one of the oldest land surfaces in the world (Australian Government, 2022b). It is situated in the southern hemisphere and is known for its rich resources and the mining of minerals (Minerals Council of Australia, 2016).

Due to the vastness of its land, population density in Australia is only three people per km^2, however, 86.2% of Australia's 25.9 million people live in urban areas, mostly situated along the coastlines (The World Bank, 2020). Some 270 ethnic groups are represented in Australia although approximately 58% are classified as Anglo-Celtic with only 3.3% estimated to be Aboriginal or Torres Strait Islander (indigenous peoples) (Australian Human Rights Commission, 2018). Life expectancy in Australia is the sixth highest in the world at 83.44 years combined (Australian Bureau of Statistics, 2021), however, similar to New Zealand, indigenous Australians have approximately 8.2 years lower life expectancy and poorer health outcomes than non-indigenous Australians (Australian Institute of Health and Welfare, 2020). The Australian Government has made a commitment to 'close the gap' between non-indigenous and indigenous Australians by 2031 in areas around life expectancy, health outcomes, child mortality, education, and employment. A new way of working has been agreed where the Australian Government "acknowledges that to close the gap, Aboriginal and Torres Strait Islander people must determine, drive and own the desired outcomes, alongside all governments" (Australian Government, 2022a, para. 4).

Australia is a developed country that enjoys a high standard of living. Its GDP in 2021 was US$1.48 trillion that despite COVID-19 and lockdowns had a growth rate of 4.2%. Australia's economy is the 14th largest in the world (Australian Bureau of Statistics, 2022; International Monetary Fund, 2022).

Similar to New Zealand, Australia is a sovereign nation and part of the Commonwealth. The Head of State is Queen Elizabeth II who is represented by a Governor General; however, this is more of a formal, symbolic, and ceremonial position (Parliament of Australia, 2022). Australia differs from New Zealand in the way its government is run. Similar to the USA, Australia is a federation comprising of six States and two self-governing Territories which each have their own constitutions, governments, and laws (Parliament of Australia, 2022). The federal government makes laws for the whole of Australia including the likes of foreign

policy, defence, trade, welfare payments, taxation, and immigration (Parliamentary Education Office, 2022). Like New Zealand, there are three levels of government including the legislature, executive, and judiciary where the legislature makes the laws, the executive carries out the laws, and the judiciary interprets the laws (Parliament of Australia, 2022). Australia's Parliament is based on the Westminster-style government following the UK model. It is bicameral with two houses – the House of Representatives containing 151 members and the Senate containing 76 members. Executive power is granted to the Prime Minister and Cabinet, a policy-making body made up of Ministers selected by the Prime Minister, who ensure laws are providing Australians with the services they need (Parliamentary Education Office, 2022).

Australia's health system

All Australian residents are entitled to healthcare through Medicare, a universal health insurance scheme, where "Medicare covers all of the cost of public hospital services" and "also covers some or all of the costs of other health services" including physician services and Pharmaceuticals (Australian Government, 2018, para. 7). Working Australians pay a levy via income tax to fund Medicare (Australian Government, 2022). The Government also provides assistance for those with disabilities via the National Disability Insurance Scheme (Olney & Dickinson, 2019). The States and Territories of Australia are responsible for the delivery of health services including "public hospitals, ambulances, public dental care, community health (primary and preventative care), and mental health care" (The Commonwealth Fund, 2020b, para. 7). In addition to the funding provided by the Federal Government, States and Territories contribute their own funding to healthcare services through taxes and levies. Figure 7 outlines the Australian health system structure.

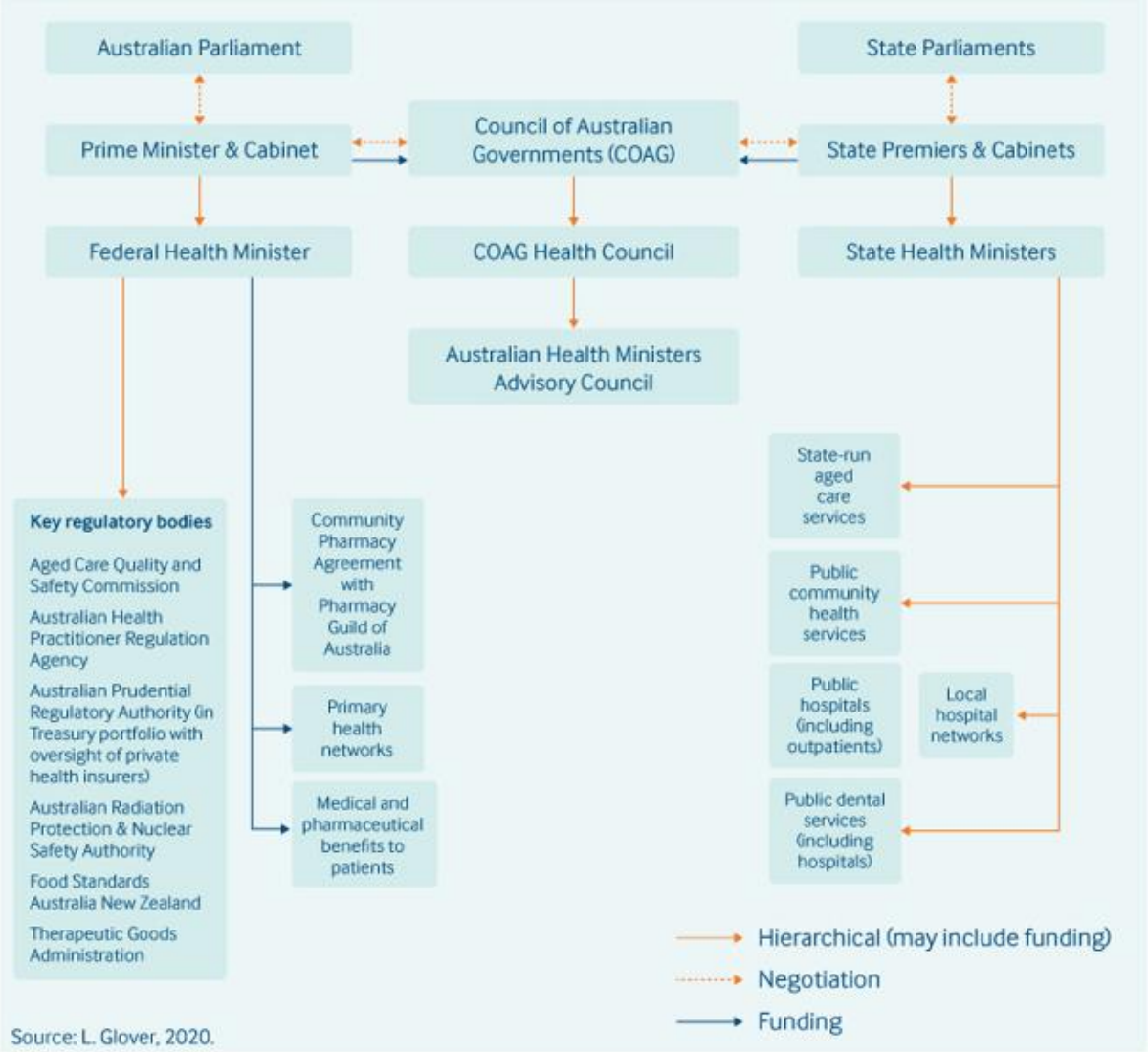

***Figure 7*: Organisation of the health system in Australia**

Source: The Commonwealth Fund International Health Care System Profiles: Australia https://www.commonwealthfund.org/international-health-policy-center/countries/australia ©The Commonwealth Fund

Latest figures show Australia spent AUD$202.5 billion on health goods and services or US$4,919 per capita (OECD, 2021c). This equates to approximately 10% of Australia's GDP. The Australian Federal and State Governments funded approximately 65% of health spending in 2019-2020 where the remainder was funded via private health insurance or out-of-pocket spending (Dixit & Sambasivan, 2018; OECD, 2021c).

Australian digital health governance

Established in 2016, national Australian digital health efforts and coordination is governed by a Corporate Commonwealth Entity – the Australian Digital Health Agency (ADHA). Its purpose is to provide "better health for Australians enabled by seamless, safe, secure digital health services and technologies that provide a range of innovative, easy-to-use tools for both patients and providers" (Australian Government, 2021, p.7). Ms Amanda Cattermole stated that the agency was a joint initiative of all the States, Territories, and the Commonwealth:

> *The idea was that the Agency would be a connector between primary care, which the Commonwealth is responsible for, and the hospital systems which the States have primary responsibility for which meant that it couldn't sit in either camp, it had to sit as an apex of both and the only way that could happen was to stand up a construct that had its own Act.*

As a Corporate Commonwealth Entity, while still part of the Australian Federal Government, it has a separate legal identity where it can enter into its own contracts and has enabling legislation that "establishes the scope of their activities and a multi-member accountable authority (such as a board of directors)" (Department of Finance, 2021, para. 26). Reasons for creating a Corporate Commonwealth Entity may include: a board of directors can be established to provide independent governance; and the body requires independence from central government policies and direction (Department of Finance, 2021). The Agency works alongside Australian States and Territories in order to implement a national digital health strategy and infrastructure and is funded jointly by the Federal, State, and Territory governments (Australian Government, 2022c).

The ADHA is legislatively accounted for under the Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016 as part of the Public Governance, Performance and Accountability Act 2013 (Australian Government, 2017). It has a 10-member skills-based Board which sets the objectives, strategies, and polices of the Agency and is held accountable for its deliverables (Australian Government, 2021). The Agency's Charter is based on the principle that "good corporate governance can add to the performance of the Agency" (Australian Government, 2022c, p.6). Board members are appointed by the Minister of Health and must have the skills, knowledge, and experience within the field of health and digital health that allows them to perform the duties outlined in the Charter (Australian Government, 2022c). Explaining the Board's makeup Ms Cattermole

says *"the Agency's Board is skills-based and drawn from all parts of the system, so they have great reach. They can be great ambassadors across the system when setting direction."*

The Agency has two reporting lines: the Commonwealth Minister for Health and the State and Territory Ministers through the Health Council (Australian Government, 2021). Alongside the 10-member Board, are 5 advisory committees who are directly accountable to the Board and provide regular advice, recommendations, and insights to the Agency. Each committee operates "within the broader framework of Part 6 of the Agency Rule" (Australian Digital Health Agency, 2022e, p.6) and is Chaired by a current Board member. The advisory committees are governed by a common charter setting out their purpose and functions (Australian Digital Health Agency, 2022e).

These 5 advisory committees are the Jurisdictional Advisory Committee; Clinical and Technical Advisory Committee; Consumer Advisory Committee; Privacy and Security Advisory Committee; and the Audit and Risk Committee (Australian Digital Health Agency, 2022b). Ms Cattermole shared her thoughts about the governance structure when she became CEO of the Agency in 2020:

> *When I first came in, I was a bit shocked by the level of governance. We have a Board, which is made up of 10 experts and is very carefully articulated by the ADHA's governing legislation. We also have 5 advisory committees. That is a lot of governance for an agency of 400 to 500 people which is fully legislated for. But 18 months down the track, while it seems like a lot of oversight, in many ways it works. With the notion that we have a deep group of consumers, a deep group of clinicians and industry experts, it can take the heat out of the obvious twitches.*

The Agency is held accountable for its deliverables and must publicly release performance reports such as its financial statements, budgets, policies, annual work plans, strategies, health IT data for example usage rates of My Health Record (MHR), privacy and security breaches, complaints etc., as well as rules, and charters (Australian Government, 2021). Dr Malcolm Thatcher argues that accountability and transparency has made a difference to the performance of the Agency:

> *Because it is a government agency, we must be held accountable for how we spend our money and on what value we create. We are accountable for the performance and utility of the MHR and the value it provides. I believe the*

> *performance of the Agency, as a consequence of the accountability framework, is much stronger under the new arrangement of the Agency.*

Additionally, there are benefits of being a standalone agency affecting policy and project direction positively:

> *With the Agency having its own Board and its own statutory underpinnings, we've got ourselves the opportunity to play in an ecosystem that mainstream government departments don't, and that has been really quite important. The fact we reach into industry and consumer groups in a way that most other mainstream Commonwealth departments can't means we have a chance to strategically frame up policy settings in digital health*. Cattermole

Australian digital health

Australian digital health has had a notably controversial and turbulent path to reach where it is today (Andargoli, 2021). 23 million Australians now have access to the national electronic health record infrastructure – My Health Record – but the path to achieve widespread adoption was dominated by many social, technical, and policy issues including public resistance due to privacy and safety concerns, siloed and disparate systems across Australian States and Territories, lack of transparency and consultation by government bodies, and considerable changes in policy direction from the Federal Government (Andargoli, 2021; Hambleton & Aloizos, 2019; Jolly, 2011; Rowlands, 2020).

As early as 1993 the Australian Federal Government recognised the need for health IT to play a part in the delivery of health services. Computerised prescriptions were the first technology innovation to help aid the reduction in prescribing, dispensing, and administration errors (Hambleton & Aloizos, 2019). A strategy to computerise general practices emerged in 1998 resulting in approximately 90% of GPs using computers, while concurrently, each State and Territory were rolling out their own health IT systems (Andargoli, 2021; Rowlands, 2005).

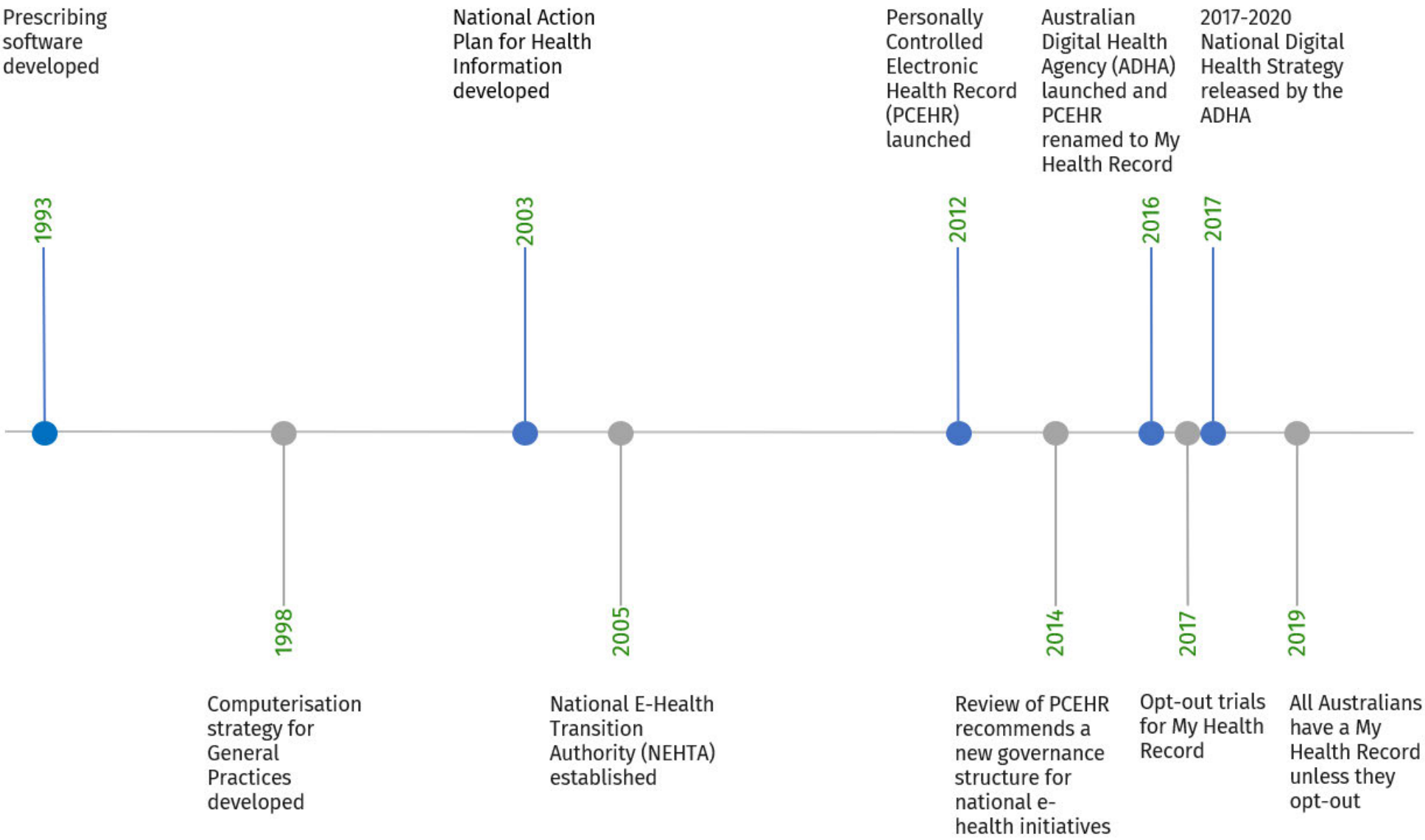

***Figure 8*: Australian digital health timeline**

Continuing with recognising electronic health as an important initiative to advance healthcare in Australia, in 1999 the Federal Government's first attempt at national coordination was through establishing the National Health Information Management Advisory Council (NHIMAC) (Pearce & Haikerwal, 2010). Its major initiative was the launch of Health*Connect*, a project proposed to "generate longitudinal, summarised, electronic health records (EHRs) to complement the records held by individual healthcare providers" (Rowlands, 2005, p.245). Trials began in the States and Territories however, barriers to adoption including a lack of connectivity infrastructure, policy issues, and privacy concerns began to emerge slowing initiatives down (Andargoli, 2021).

The biggest change in direction for digital health in Australia came in 2004 when a report commissioned by the Federal Government from a Boston consulting company recommended that due to dispersed health IT initiatives across the States and Territories that together under the Council of Australian Governments (COAG) a national body be established to provide the direction, strategy, and foundations for national electronic health (Hambleton & Aloizos, 2019; Jolly, 2011). The National E-Health Transition Authority (NEHTA) came into existence in July 2005 to "advance the e health (sic) agenda through development of e health standards, clinical terminologies and patient and provider identifiers" (Jolly, 2011, p.24).

Initially the early assessment of NEHTA was positive, where the Authority had established a focus for a national programme of work and had built a substantially skilled workforce to advance health IT nationally. As well as this they "created unique health care identification numbers for all individuals, providers and organisations" (Hambleton & Aloizos, 2019, p.2). However, criticisms emerged that the Authority was not transparent, did not engage with key stakeholders appropriately, and that conversations were mostly one-way (Jolly, 2011). With a change of Government in 2007, the Labour Coalition commissioned its own report on electronic health progress from Deloitte, who in turn outlined a series of 22 recommendations including that an 'independent' body be established to "undertake the oversight of strategy, management, execution of work programmes and standards development and compliance functions" (Jolly, 2011, p.28). The new Government adopted almost all the recommendations except for establishing the national independent body to deliver electronic health initiatives (Andargoli, 2021; Jolly, 2011).

Challenges continued for Australian national health IT around funding streams, systems remaining siloed and fragmented across the States and Territories, and privacy and safety

concerns regarding the use of technology from health providers, consumer groups, and legal bodies who took a conservative view of EHR adoption (Jolly, 2011; Showell, 2011; Woodley, 2019). Despite this, an ambitious target of launching a national electronic health record was set and on July 1, 2012, the Personally Controlled Electronic Health Record (PCEHR) was launched with an 'opt-in' basis, meaning Australians could choose to sign-up for an electronic health record (Hambleton & Aloizos, 2019; Pearce & Haikerwal, 2010). Uptake was slow with utilisation of the record continuing to be struck by many difficulties and was considered to be a 'wicked problem'. Key infrastructure had failed to be put in place and stakeholders were left out of the conversation (Andargoli, 2021; Showell, 2011). Hambleton & Aloizos (2019) explain that "a distrust of computer systems in general, lack of complete integration into clinical information systems, a lack of useful clinical content, concerns about privacy and security, the impact of patient controls, and poor uptake in the population" contributed to the issues of adoption and trust (p.2).

Issues with the PCEHR's rapid development began to emerge after poor health informatics standards development and lack of consultation resulted in a stalemate between NEHTA and the health informatics standards development community. Cost of adjustments to the PCEHR and a disintegration of good relationships contributed to the failings of NEHTA and a solution was needed (Rowlands, 2020). A report into the PCEHR was commissioned in 2013 which found that NEHTA did not "have the confidence of the industry or audience that it is attempting to represent" and that a "reset of this function is critical to ensure the Australian health industry can continue to evolve with a strong set of foundational capability that will enable operating efficiencies for all providers, whilst driving improved patient care benefits" (Royle et al., 2013, p.20). The review identified several governance issues including a lack of representation and engagement, being overly bureaucratic, an inability to balance the need of government and the private sector, and a lack of transparency (Australian Government, 2016). The explanatory statement for the creation of the ADHA stated that "although the PCEHR system directly affects healthcare providers (private and public), the medical software industry and individuals, the current governance predominantly comprises public sector organisations. A prime example of this problem is the NEHTA board which is made up of the heads of the Commonwealth, State and Territory health departments" (Australian Government, 2016, para. 12).

In 2016 the Australian Digital Health Agency as an independent Corporate Commonwealth Entity was established, the PCEHR was renamed to the My Health Record (MHR), and an

opt-out[5] system for the MHR was recommended, signalling a significant change in direction, governance, and oversight of national digital health initiatives in Australia (Hambleton & Aloizos, 2019). The government recognised that:

> Once established, the Agency will become the single accountable organisation for digital health in Australia. It will be the national body responsible for the evolution of the digital health capability, through the leadership, coordination and delivery of a collaborative and innovative approach to utilising technology to support and enhance a clinically safe and connected national health system to improve health service delivery and health outcomes for the Australian community. (Australian Government, 2016, para. 15)

When the Agency was created "*The Minister wanted to establish an independent Board to have governance oversight where ultimately the Minister, through the Department of Health, makes the policy decisions on the Agency's work programme."* Thatcher

Employing a middle-out[6] approach to governance where all stakeholders are consulted and included, social influence is taken into account, and value networks are created, the Agency is now held accountable for its actions and deliverables and has the autonomy and authority to act on behalf of the Commonwealth (Australian Government, 2016). Taking a 'lessons learned' approach, it has persevered with mending the past and building trust, however, it has taken time and commitment to do so. With a focus on updating current aging infrastructure of the MHR and a commitment to standards and interoperability, the Agency is edging forward with its national plans through the National Modernisation Infrastructure programme (Australian Digital Health Agency, 2020).

Thanks in-part to the COVID-19 pandemic public privacy concerns have largely dissipated, with a recent 2021 consumer survey finding that 70% of Australians are willing to use virtual or telehealth options and 80% are comfortable with sharing their health data digitally (Brown, 2021). Dr Thatcher argues the pendulum has swung and that:

[5] The Australian 'opt-out' scheme means that consent for 'secondary use of information' is implied if people do not opt-out of the MHR. Members of the general public have to take action if they do not want their health data to be used for purposes other than clinical care. (Medical Director, 2018)

[6] The middle-out approach takes into account social influence and maximises the efforts of all stakeholders who are working towards the same goal. It recognises the importance of having a network of collaborators who provide feedback, create feedback loops, and efficient governance strategies. (London Datastore, 2022)

> *The public generally believe now that the value utility for My Health Record outweighs the risk.* [He stated] *three to five years ago we didn't have the social license for MHR. I think the whole opt-out pivot needed to happen and now after COVID-19 I believe we have the social license to accelerate digital health.*

The ADHA is now preparing to:

> *Implement standards by the coalition of the willing and by the belief that the industry and the public want us to get on with it* [interoperability]. *We believe there is a place for regulation, but in the absence of it we will be the steward for standards settings so that interoperability can be enabled.* Thatcher

Today the Agency has recognised the importance of open consultation with all stakeholders and is building out its next generation of the Australian Digital Health Strategy, due to be released in July 2022 (Australian Digital Health Agency, 2022d). Consultation for this exercise has been key. According to Ms Cattermole, building the next strategy:

> *Has been a massive consultation exercise. We have run forums in every jurisdiction, in large parts of regional Australia, and with community groups. We've also sub-contracted parts to key lead organisations like the Consumer Health Forum or the Federation of Ethnic Community Councils. We've also stood up a very complex human centred design capability and a cutting-edge mixed methods research methodology that we are applying because of the amount of literature that exists today. We're mixing the insights with the academic literature and then we're retesting this with the forums. We're hoping that this time when people hear it* [the Strategy] *back, they will hear the things that matter to them most.*

The Australian case study shows that the path to achieve sustainable national digital health solutions can be fraught with many social, political, and technical issues. However, by learning from past mistakes and recognising that digital health would be unable to advance without establishing an independent and accountable governance structure as a Corporate Commonwealth Entity has enabled Australia to strengthen their approach to national digital health and regain some trust with stakeholders. Enabling legislation and employing a consultative, inclusive approach has now started to change the conversation around national health IT implementation in Australia.

4.4 USA

Country overview

Located in the Northern hemisphere, the USA is the world's third largest country in landmass at 9.834 million km^2. It is host to a population of 334.5 million people who are highly diverse in both race and ethnicity largely due to sustained global immigration over the past 250 years (United States Census Bureau, 2022). The largest proportion of the population identify as non-Hispanic white at 60.1%. The two other major ethnic groups are Black or African American at 13.4%, and Hispanic or Latino at 18.5% (United States Census Bureau, 2022). The USA has a population saturation of 37 people km^2 and 82% live in its urban areas which comprise just 2% of its landmass overall (United States Census Bureau, 2022; World Economic Forum, 2022).

The USA is the world's greatest economic power with a GDP of US$23 trillion with annual growth of 5.7% in 2021 and contributing 24% to the world's economy (USA Bureau of Economic Analysis, 2022). Its wealth comprises of four main activities – a highly developed, technologically advanced services sector (particularly in the areas of healthcare, financial services, technology, and retail), manufacturing, agriculture, and the harvesting of its natural resources (Focus Economics, 2022). While the USA has great economic wealth, 11.4% of its people live in poverty and the COVID-19 pandemic has had a significant impact on life expectancy dropping it to an average of 77.3 years in 2020 from 78.9 years in 2019 (United States Census Bureau, 2022). This is well below the OECD average of 81 years (OECD, 2020).

As a federal republic of 50 states, the USA is considered a representative democracy whereby elected persons from all the states represent their constituents in government (Haxhiu & Alidemaj, 2021). Like New Zealand and Australia, the governmental system has three branches including the legislative, executive, and judiciary, "whose powers are vested by the U.S. constitution in the Congress, the President, and the Federal Courts, respectively" (The White House, 2022b, para. 1). The United States Congress is a bicameral system containing two chambers – the Senate and the House of Representatives. These two chambers have the sole authority to enact legislation and declare war, as well as to accept or reject Presidential appointments, and hold considerable investigative powers (The White House, 2022e). The President of the USA is the head of state, the head of government as well as the Commander-in-Chief of the armed forces. They are responsible for the "execution and enforcement of the

laws created by Congress" (The White House, 2022d, para. 5). The electoral system is complex with federal elections being held once every second even year (the mid-terms) on the first Tuesday after the first Monday in November, however, the President sits for a term of four years, with a maximum of two terms (The White House, 2022a). The President is not directly voted in by popular vote, instead, an Electoral College process is used by which pre-selected individuals enter a process of voting for a candidate determined by the results of the popular vote. This process is a long-standing institution and was meant as a "compromise between the election of the President by a vote in Congress and election of the President by a popular vote of qualified citizens" (National Archives, 2019, para. 1).

The 50 States represent the people of the USA and have extensive authority. Each State, which is headed by an elected governor, has its own written constitution, governments, and laws and are modelled after the Federal Government whereby they each have an executive, legislative, and judicial branch (The White House, 2022c). A State also has two Senators, regardless of population size, who sit in the Senate of the United States Congress and, depending on population size, elected officials represent their people in Congress through the House of Representatives. The States are responsible for all laws that the Federal Government is not for example, public health, hospital systems, welfare, conservation, policing, and schools (Smith et al., 2005).

USA health system

American citizens do not have universal access to healthcare but rather receive their healthcare via a complex mixed system where part is publicly financed through Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and Veterans or Military Health Services. However, the majority (57%) of the population rely on group health insurance covered by their employers or private insurance through marketplaces. Only 26% of all healthcare spending in the USA is covered by government schemes (OECD, 2021c). Nine percent of Americans are uninsured or do not qualify for publicly funded assistance (International Society for Pharmaeconomics and Outcomes Research, 2022). Figure 9 shows the structure of the USA health system.

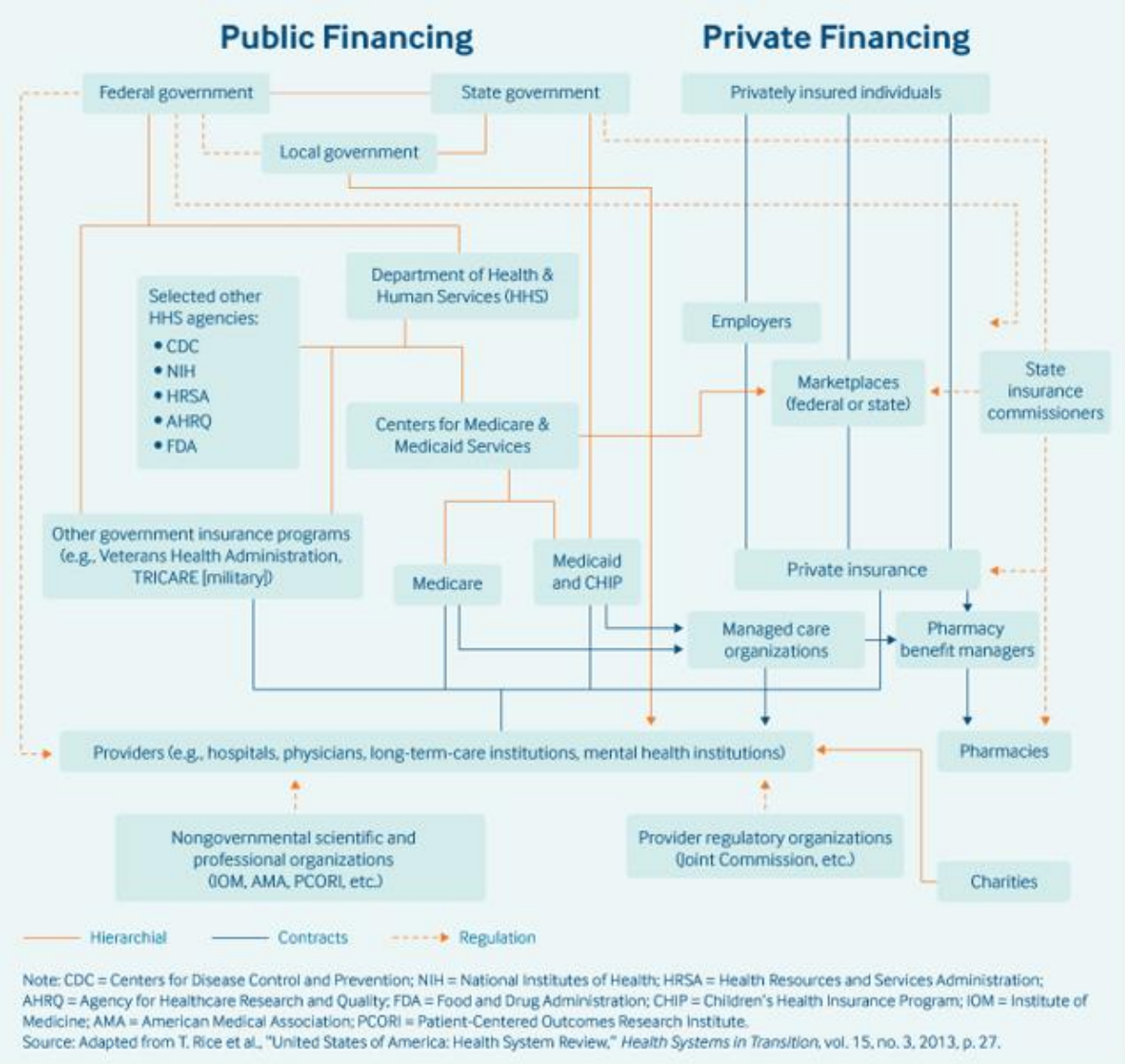

Figure 9: **Organisation of the health system in the United States**

Source: The Commonwealth Fund International Health Care System Profiles: United States https://www.commonwealthfund.org/international-health-policy-center/countries/united-states ©The Commonwealth Fund

The USA spends the largest amount on healthcare per capita in the OECD at US$10,948.5 in 2019 (OECD, 2022a) climbing to US$12,530 in 2020 largely due to the COVID-19 pandemic (Centers for Medicare & Medicaid Services, 2021). This amount represents 19.7% of the USA's GDP with the estimated total spend being US$4.1 trillion in 2020 (Centers for Medicare & Medicaid Services, 2021; Scott et al., 2022). The considerably higher healthcare spend over every other country can be attributed to "the greater use of medical technology and higher prices" (Tikkanen & Abrams, 2020, para. 1). This higher spend does not necessarily translate into better health outcomes however, with the chronic disease burden

and obesity rate two times higher than the OECD average, and with a lower life expectancy and a higher suicide rate than other developed nations (Tikkanen & Abrams, 2020).

USA digital health governance

In the USA national health IT efforts are governed and coordinated by The Office of the National Coordinator for Health Information Technology (ONC). The ONC is a principal federal entity and is organisationally situated within the Office of the Secretary within the U.S. Department of Health and Human Services (HHS) (The Office of the National Coordinator for Health Information Technology, 2022a). Similar to New Zealand's Minister of Health, the Office of the Secretary for HHS reports directly to the President with the ONC directly reporting to the Secretary. Mr Steven Posnack explains the reporting structures:

> *We're part of what is called the Department of Health and Human Services which is a cabinet agency that directly reports to the President. The Secretary is the equivalent to a Minister of Health in other countries. We ultimately report to the Secretary who would be your Minister of Health. We are an executive branch under the President's umbrella.*

The ONC is charged with "formulating the Federal Government's health IT strategy and leading and promoting effective policies, programmes, and administrative efforts to advance progress on national goals for better, safer, and more equitable healthcare through a nationwide interoperable health IT infrastructure" (The Office of the National Coordinator for Health Information Technology, 2022a, p.7). Through enabling legislation and regulation setting, the ONC has a holistic and middle-out approach to health IT governance believing that its activities are central to creating a patient-centred health system, helping address the social determinants of health and equitable healthcare, while simultaneously improving the "quality, safety, efficiency, and affordability of healthcare" (The Office of the National Coordinator for Health Information Technology, 2022a, p.11). According to Mr Posnack:

> *The work that the ONC undertakes has a 360-degree view of things – we speak to patient advocacy groups, industry, researchers, and healthcare providers. Part of our mission is enabling access to medical information that allows healthcare providers to give the care that improves lives. In terms of our authority, if the Secretary of the Department for Health and Human Services wishes to do something in digital health, then it is our job to help execute that.*

The ONC is legislatively mandated for in the 2009 Health Information Technology for Economics and Clinical Health Act (HITECH Act), the Medicare Access and CHIP Reauthorisation Act 2015, and the 21st Century Cures Act 2016 (The Office of the National Coordinator for Health Information Technology, 2022a). The ONC operates under the principles of open government to "improve transparency, competition, and innovation in the healthcare industry" (The Office of the National Coordinator for Health Information Technology, 2022, para. 1). Its performance and management requirements are mandated in law, meaning it must publicly publish and submit financial statements, report on health IT adoption rates and health IT data, strategic plans, provide congressional reports, and publish laws, regulations, and policies (The Office of the National Coordinator for Health Information Technology, 2022). Mr Posnack argues that:

> *Having enabling legislation is key. Legislation is often not detailed but it sets out the large policy objectives and is designed to give the executive branch* [the ONC] *authority to design and implement regulations that enact the law.*
>
> He shared that a law could be as simple as *The Department of Health and Human Services are to create a health informatics training programme for health professionals with funding of US$100m.* And, importantly, once the law is created the ONC could *"then unpack this and build out the regulations that enable the requirements to be met to be able to deliver the programme.*

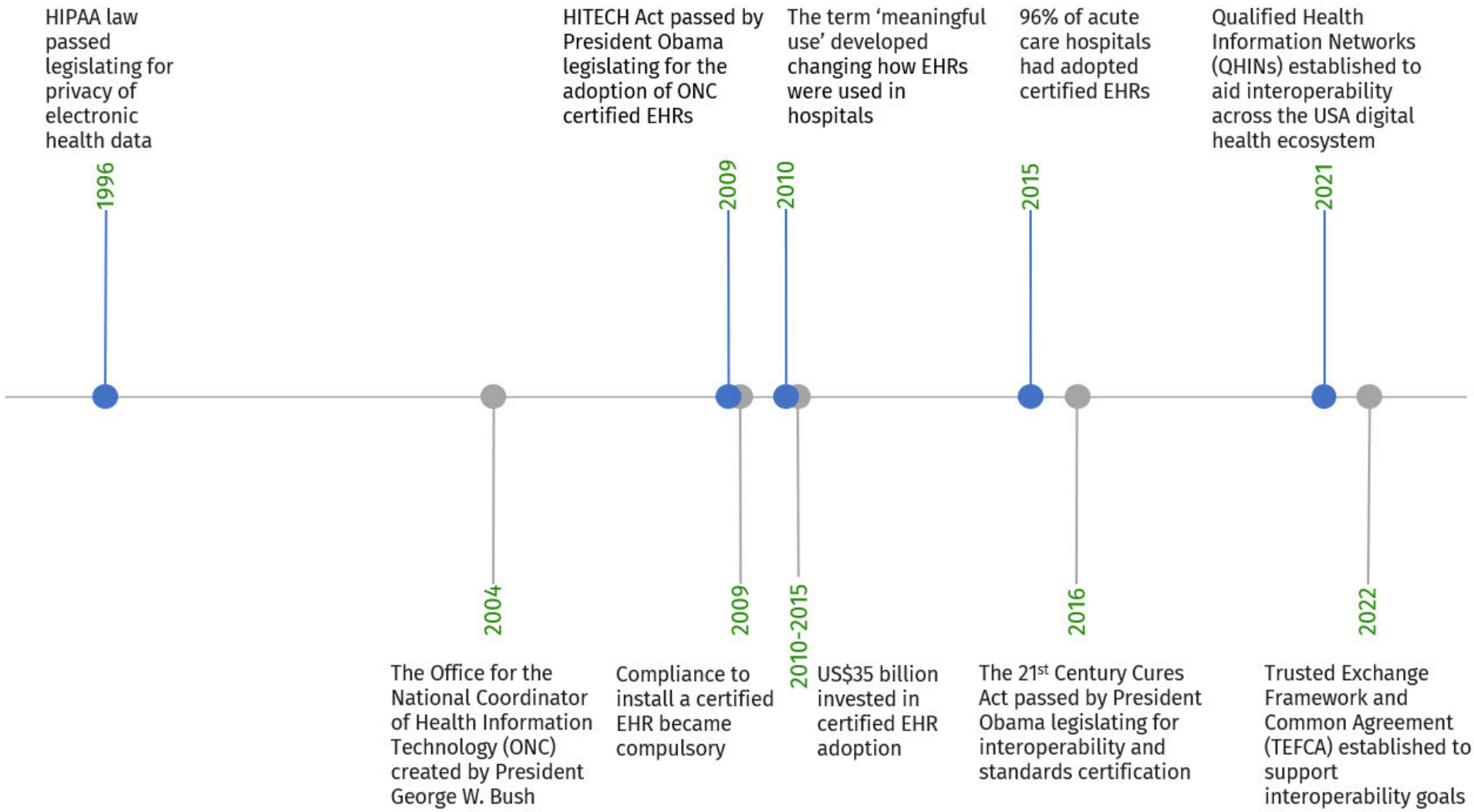

***Figure 10*: USA digital health timeline**

USA digital health

Like many countries, the USA has a chequered history with the adoption of ICT within their health system but is now considered an exemplar in "standardisation for health system interoperability at large scale" (Rowlands, 2020, p.54). In the USA the use of computers in healthcare dates back to the 1960s, however, recognition from government was not realised until the passing of the 1996 Health Insurance Portability and Accountability Act (HIPAA Act), created to protect the privacy and security of health information of consumers whether it was stored on paper or electronically (Edemekong et al., 2008; The Office of the National Coordinator for Health Information Technology, 2018). By 2004, the health system remained largely paper-based across clinical settings and health information exchanges were considered virtually non-existent (The White House, 2004). Recognition that a national body to coordinate ICT advancement in healthcare was needed, President George W. Bush created the position of the National Coordinator of Health Information Technology in April 2004, through executive order 1335, leading to the establishment of the ONC (Bush, 2004; Lukaszewski, 2017). The ONC's purpose is to "provide leadership for the development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of healthcare" (Bush, 2004, para. 1). Mr Posnack describes the early journey of digital health in the USA:

> *Electronic health records, digital health investments, and activities were experimented on as early as computers started being used. There were academic medical centres, and people like our prior National Coordinator for the ONC, Don Rucker, who started their medical work in the 1980s…He started to look at how digitisation of data and analytics in health could be used.*
>
> *When the internet started taking shape in the 1990s and 2000s, we started to see these other industries pull forward in terms of their use of tech. People then looked at healthcare and realised everything was still on paper and a lot of money was being spent on administration. In 1996 the HIPAA law was passed essentially as an administrative business-to-business simplification law and so the payment side of healthcare went electronic first. Early-stage interoperability was important to the business-to-business operations and the HIPAA law established administrative transaction standards. This kicked off*

> *a rapid cycle of development and work in the backend of healthcare, but the frontend was all paper still.*
>
> *From there, there was an expectation that healthcare needed to move into the digital environment which would advance safety and care coordination as well as help realise untapped savings.*

In 2009, early in the Obama Administration, there was a realisation that healthcare was still largely managed by paper-based siloed systems where only 12% of hospitals had implemented EHRs, causing significant inefficiencies and errors (Conn, 2016). Costs and maintenance of implementing EHRs as well as concerns about the return on investment were seen as key barriers to adoption. Following the Global Financial Crisis, health IT was seen as an essential foundation to restructuring the American health system, as a way to reduce costs, and in being able to provide efficiency, quality, safety, and patient-centred care (Buntin et al., 2010). To promote and advance the adoption of health IT and aid in the development of a nationwide health information exchange, the HITECH Act was passed as a part of the American Recovery and Reinvestment Act (ARRA) 2009 (United States Government Accountability Office, 2015). Up to US$35 billion was invested and provided as incentives to aid this implementation and the ONC was given a "set of authorities and responsibilities to carry out its mission" (DeSalvo et al., 2015, p.507).

> *Right at the beginning of the Obama Administration the Congress passed the ARRA Act. Just like any legislative process, the train is moving, and so there was a question on what else could we hook up to the train. They were putting out hundreds of billions of dollars following the Global Financial Crisis as part of the stimulus bill. Now was the chance to add in stimulus for electronic health record adoption which provided incentives across the U.S. at scale. There was a low adoption rate of electronic records in hospitals, ambulatory, and outpatient providers. As a result of the stimulus, did we accomplish an adoption goal? The answer is unequivocally, yes.* Posnack

Compliance with the HITECH Act became compulsory on November 30, 2009, and the term 'meaningful use' came into existence. Providers had to prove that the systems they implemented could be used in a meaningful way (United States Government Accountability Office, 2015).

Meaningful use is defined in the Act as to:

1. Demonstrate use of certified EHR technology in a meaningful manner, such as e-prescribing;
2. Demonstrate that certified EHR technology is connected in a manner that provides for the electronic exchange of health information and improves the quality of healthcare; and
3. Submit information in a form and manner specified by HHS. (Chin & Sakuda, 2012, p.51) (United States Government Accountability Office, 2015, p.5)

Through the adoption of certified EHRs, the 5 broad goals of meaningful use are:

1. To improve quality, safety, efficiency and reduce health disparities;
2. Improve care coordination;
3. Improve population and public health;
4. Engage patients and their families in their own healthcare; and
5. Promote privacy and security of EHRs. (Chin & Sakuda, 2012; Thomas, 2011)

Mr Posnack outlines the evolution of legislation between 2004 and 2009:

> *The goal that was set in 2004 from the Bush Administration was reinforced and reinvigorated in statute and law in 2009. We tried some things from an executive branch and administrative perspective but there wasn't a big change, it was more organic. We then looked at what we could do to convince healthcare providers to stop doing what they were used to doing as routine on paper and show them that there was a better way. The incentive money certainly helped, and the HITECH Act set a path.*

Despite incentives, barriers continued to slow down the adoption of certified EHRs such as increased costs, workforce training time, workflow redesign, and the need to hire and train health informaticians (Chin & Sakuda, 2012). Penalties for noncompliance were introduced to ensure adoption took place. By the end of 2015, in its May 2016 data brief, the ONC reported that 96% of acute care hospitals had adopted certified EHR systems (Henry et al., 2016). Despite this success there were barriers to be overcome:

> *We found that between 2009 and 2016 there was a period of adjustment, and that the biggest barrier of adoption was training people in highly technical computer systems and workflows that they weren't used to. I think a lot of people just expected intelligent healthcare providers to be super users of technology and we underestimated the amount of training and interpersonal dynamics with human/computer interaction. In order for people to adopt the systems they had to have incentives to do so and for them to believe it was the future.* Posnack

While adoption rates of EHRs had significantly improved by the end of 2015, interoperability between these systems was not largely apparent nor did patients have easy access to their electronic health information (Lengyel-Gomez et al., 2017). To support nationwide digital health integration, in December 2016 at the end of his administration, President Obama passed the 21st Century Cures Act. The Act's basic core principles regarding health IT were to "advance interoperability; support the access, exchange, and the use of electronic health information; and address occurrences of information blocking[7]" (The Office of the National Coordinator for Health Information Technology, 2020, p.25644). Through the regulation and development of standardised application program interfaces (APIs[8]) the ONC final rule supported easier and more convenient access to electronic health information, for example through smartphone applications, by the adoption and certification of standards such as HL7 FHIR. The rule within the Act is designed to give Americans improved access to quality health information to inform their health choices (The Office of the National Coordinator for Health Information Technology, 2020). Mr Posnack explains that:

> *Some of the coordination work the ONC does is around the standards setting perspective. Standards setting gives them* [the industry] *more predictability, stability, and consistency in terms of how to engage in the market. Tensions can arise when we require for example FHIR APIs to be part of their systems because we want it to be easier for clinical users and other users in the healthcare sector to pick applications that work with the data they produce*

[7] "Information blocking is a practice whereby digital health providers or healthcare providers "interfere with the access, exchange, or use of electronic information" (The Office of the National Coordinator for Health Information Technology, 2021, para. 1).

[8] An API is the acronym for Application Programming Interface, which is a software intermediary that allows two applications to talk to each other. Each time you use an app like Facebook, send an instant message, or check the weather on your phone, you are using an API. (Mulesoft, 2022)

> *but we feel it will always create more opportunities for innovation and competition if we do it this way.*

While there is an acknowledgement that there is still work to do, to date progress has been made through a unified approach under the strong leadership and governance of the ONC. Mandating standards and endorsing a modern API approach have been critical to advancing a national interoperable health IT infrastructure (Johnson et al., 2021). Future efforts are concentrating on national coordination via Qualified Health Information Networks which will "connect to one another and enable their participants to engage in health information exchange across the country" (HHS Press Office, 2022, para. 1). The newly formed *Trusted Exchange Framework* outlines a set of principles to guide foundations for health information exchange and is supported by a contract advancing those principles called the Common Agreement (HHS Press Office, 2022).

> *We're now working on network-to-network connectivity. The U.S. is a big country with lots of different networks, some of them are State and some of them are regional. We now have national umbrella networks that are starting to talk to each other. Government comes in to collaborate on what we call a Trusted Exchange Framework Common Agreement across these networks. This can help to sort out some of the policy disagreements and the government can step in to provide bridging. We see this as a coordination opportunity and role.* Posnack

The USA case study is a lesson in how to achieve sustained approaches to national digital health implementation through a coordinated governance framework. Recognising early the importance of digital health by creating the ONC in 2004, the USA government realised there was potential to improve health outcomes by building a more equitable, sustainable, efficient, and patient-centred health system through digital health. While the USA's journey has not been without its challenges, their ability to reflect and make change is admirable. By creating enabling legislation to achieve widespread certified EHR and standards adoption, and having a coordinated, unified approach, the USA are advancing with their plans to achieve interoperability amongst all 50 states' health systems.

4.5 Case study comparisons

The three case studies show the importance of having a unified, coordinated, transparent, and accountable governance framework to realise national digital health goals. Both Australia and the USA differ in their country makeup to New Zealand where they have a two-tier government system involving States and Territories each with their own government and much larger populations. While it would be easy to say their situation is not applicable to the New Zealand context, if we look at it another way, essentially New Zealand created 20 different health governments with the establishment of the 20 DHBs (Little, 2022). The same issues that have plagued Australia and the USA in digital health are the issues that face New Zealand; siloed disparate health IT systems that are fragmented and aging.

Taking a lessons learned approach from Australia and the USA, barriers to adoption of national digital health systems include: poor governance structures and policy, lack of coordination, transparency, and communication, poor workforce uptake, increasing costs, and technical issues. Dr Thatcher comments that: *"if you put effort into those enablers upfront - for example around policy and technology that enables interoperability, then I think you will be in a good place."*

Dr McCann argues that*:*

> *It is about drawing down those key principles that a number of the international frameworks identify, applying them to our context, and learning the lessons around what's actually worked and hasn't worked. You could make an argument that our current approach to date has been very expensive and hasn't really worked. So, let's take what has actually worked in the U.S. and Australian models, look at the principles they've applied to the processes and structures that actually drive change, and changes in behaviour. There are a number of common principles and common themes that can be applied from those frameworks but then there is also the opportunity to drill down a level deeper in areas where we are still having a lot of difficulty shifting the dial that will actually help us to make progress.*

Through the establishment of the ONC and by receiving bi-partisan support at a Congressional level, the USA has advanced its national digital health goals and has become an exemplar in the adoption of certified EHRs and standards. They continue to make steady progress through a tightly managed and coordinated approach and by providing incentives

and disincentives to aid uptake. Today their goals include a move towards a fully interoperable and country-wide solution by establishing the necessary frameworks to support consultation, innovation, and adoption of modern technologies to achieve interoperability (The Office of the National Coordinator for Health Information Technology, 2022b). Mr Posnack explains how having enabling legislation has contributed to the advancement of the digital health agenda in the USA:

> *To have a law that is digital health focused is amazing because it gives us a direction and enables us to implement that law, and we can say here is what is required to do that. Sometimes that includes incentives and sometimes penalties.*

While Australia has moved considerably further forward with the establishment of the ADHA, some barriers and issues from the National E-Health Transition Authority (NEHTA) period still affect them including mistrust from industry and a lack of consistent data standards (Knibbs, 2022). However, a strengthened, coordinated, and consultative approach with greater transparency and accountability under the ADHA has gone a considerable way to advancing the digital health agenda. Uptake of the My Health Record, through the opt-out approach and following COVID-19, is now significant reaching almost all of Australia's population. A focus on standards adoption and modern technology approaches to achieve interoperability are being rolled out. Despite the progress made, Ms Cattermole states that:

> *Our biggest challenge remains interoperability. We have pieces of it, and it is growing, but it is still very complicated. We created the API gateway to enable greater interoperability but what we don't have yet is an agreed set of standards. What we have had for a decade is industry regulating itself. So, one thing you could do better than us is to mandate standards which would make a huge difference to the future of your interoperability. At the moment we are trying to do that retrospectively, so if I had the chance up front, I would set some of this in stone.*

From the case studies, it is clear that government decisions and governance frameworks can aid or abet digital health adoption and that policy, social, and technical factors can feature heavily in success and failure of implementing national digital health solutions. Establishing autonomous accountable government entities and applying a middle-out approach to governance, where stakeholders are consulted and included, social influence is considered,

and value networks are created, appears to be more successful, compared with New Zealand who employ a traditional top-down approach where leadership and culture can influence heavily on success or failure. To mitigate future failures, advance digital health, and recognise that it as a fundamental tenant for improving health outcomes New Zealand can jump the evolutionary queue by learning from Australia and the USA's failures and triumphs in digital health governance.

Chapter 5: Considerations for a New Zealand digital health governance framework

5.1 Introduction

The findings presented in this chapter recognise that national digital health initiatives and governance frameworks need to move beyond only considering the technology solution and incorporate the broader determinants of effective and accountable governance to be successful (Peterson et al., 2016; Post et al., 2010). A balance between centralisation and decentralisation must be struck when considering governance frameworks, policies, and strategies, if the objectives of a connected national digital health system are to be achieved (Kierkegaard, 2015). The frameworks must also consider "normalising a more cohesive and collaborative approach among agencies to cross-cutting issues and supporting the Crown to fulfil its responsibilities under Te Tiriti o Waitangi" (Gregory & Maynard, 2019, p.37).

"Governance at the centre needs to be more about enabling. It should be about the settings and empowering the system to be able to leverage those settings." Hunter

The health system is highly complex. Digital health governance must take into account the difficulty of implementing ICT across a challenging environment, the rights and interests of all stakeholders including consumers, the laws implemented and needed, and the health system's leadership (Carnicero & Serra, 2020). Acknowledging this complexity, Dr McCann argues that:

> *This very much fits the complex domain. If we were talking about, how do I treat a pneumonia, it's a simple problem – diagnose it, give antibiotics, monitor, it generally resolves – we're not talking about problems like that here, we are talking about complex problems. We need the voices, the lead indicators, the lag indicators, those connections, and that network in a structure like a Digital Health Agency that is overarching. All those feeder groups need to come into it that allow us to develop more robust solutions and more robust governance frameworks to solve the complex problems. As soon as we try to apply a simple solution to a complex problem, we're just creating a lot of other complex problems.*

The Pae Ora (Healthy Futures) Bill 2022 legislates that digital health functions be developed and managed by a Chief of Data and Digital under the new umbrella organisation responsible

for health service delivery; Health New Zealand (Health New Zealand & Māori Health Authority, 2022; Parliamentary Counsel Office, 2022). But due to its overarching and fundamental function across the health system and the complex, technical, and multifaceted nature of digital health, coordinated accountable governance utilising an inclusive and broad structure is essential. International evidence and the case studies in this dissertation demonstrate that development of an independent digital health governance framework is beneficial; one that will provide the coordination, accountability, and transparency required to acknowledge that digital health is foundational infrastructure for improving health outcomes, creating efficiency in daily workflows for the health workforce, and in providing rigour around healthcare outputs and deliverables (Gauld, 2007; Hamilton, 2013; Kierkegaard, 2015).

> *We need to get over the mindset of we're trying to create too many committees etc. Governance needs to be manageable, but we also need to acknowledge that if we don't get the right voices in, or there is a voice that is missing, generally we're not accounting for all the potential, inputs, outputs, and complexities and therefore you create more problems downstream.* McCann

Following are considerations and a potential framework for establishing a New Zealand Digital Health Agency (NZDHA) as a Crown Entity to manage and govern digital health in New Zealand.

5.2 Application of a Crown Entity for New Zealand digital health governance

Given the options for New Zealand public governance, the best approach for a NZDHA is likely a Crown Entity. These findings are now targeted using this lens. It could be argued that Crown Entities in New Zealand establish a layer of bureaucracy not necessary and one which is cumbersome and problematic. Commentary purports this to be true of the 20 DHBs established in 2002 under the Crown Entities Act 2004 where system fragmentation and siloed ways of working became apparent (Department of the Prime Minister and Cabinet, 2021a). However, looking at this differently, Crown Entities also remove a layer of bureaucracy by having a direct reporting line to their government minister and must be publicly held accountable for their actions, outputs, and deliverables providing a necessary level of scrutiny in how taxpayers dollars are spent (Public Service Commission, 2014). They're also able to reach across all agencies within a health system, as opposed to operating under a top-down single entity such as Health New Zealand. The international case studies of

Australia and the USA provide a window into how independent and autonomous government entities which are held publicly accountable can help drive and secure the national digital health agenda thus yielding a more coordinated, succinct, and successful approach to country-wide integrated health IT systems.

New Zealand has set itself key goals in the delivery of a national digital health infrastructure that will connect current disparate legacy systems and achieve connected healthcare services for consumers. Significant funding has recently been received. To accomplish this, and to ensure the funding is appropriately spent, the governance structure of digital health must recognise the importance and complexity of this task and help deliver on these goals. Set out in this dissertation are 7 considerations to establish a sustainable and independent digital health governance framework for New Zealand in the form of a Crown Entity.

Establishing a NZDHA as a Crown Entity similar to countries such as Denmark, Estonia, Australia, and the USA would ensure that national digital health strategies can transcend across multiple governments and health system agencies for example Health New Zealand, Te Aka Whai Ora, the Ministry of Health, and primary and community care settings (TEHIK, 2022; The Danish Health Data Authority, 2022). This agency would have its own line appropriation and funding stream like other Crown Entities in New Zealand (Controller and Auditor-General, 2022). It would also have the authority to engage stakeholders such as other government departments, the public health sector, the private health sector, health insurance providers, industry, academia, Iwi, the health consumer, and the community to achieve digital health interoperability goals. Unlike in the past, this agency would have the mandate, authority, resources, and continued funding to ensure compliance and completion of national digital health systems including full system integration.

> *One of the critical roles for governance in my view, and this is why I do think we need an empowered entity, is to be able to sell that governance vision around consistent, uniform, and common approaches that allow autonomy, flexibility, and localisation for the platforms that are in place*. McCann

The intent of a NZDHA would to be to promote sector collaboration, encourage innovation, honour New Zealand's commitment to Te Tiriti o Waitangi, acknowledge and include small to medium businesses building digital health solutions, and to foster an environment of transparency, accountability, and communication, while delivering on the expectations of all stakeholders including the Government.

It must be inherent that as part of the legislation guiding a NZDHA, that accountability, equity frameworks, and transparency are embedded. In setting up a Crown Entity it will be important for the government to be able to reflect on the experiences of other Crown Entities, addressing what has been successful and acknowledging critiques for example there are reported issues with PHARMAC's funding, equity framework, and transparency (New Zealand Institute of Economic Research, 2020). The lessons for a potential NZDHA Crown Entity must be that legislation is enabling, it considers access and equity, and allows for flexibility, transparency, and the scrutiny of spending taxpayers' dollars. In addition, a NZDHA must be appropriately funded year on year to keep up with the rapid pace and scale at which digital technologies evolve.

> *Legislation needs to be focused on what are the key outcomes and what the future would look like, what would be different for health consumers. The law needs to be able to adapt and be nimble in order to be effective*. Posnack

A NZDHA would be charged with designing, coordinating, funding, and implementing a national digital health strategy for New Zealand. It would also provide transparency, resource allocation, risk management, monitoring, and evaluation of the strategy through regular publicly available reports, financial information, data, and regulations. The *Health and Disability System Review* (2020) acknowledges that "accelerating digital transformation would require strong clinical, technical, project and change management leadership" (p.223). Therefore, lines of hierarchy and accountability would need to be clearly defined, with Health New Zealand, Te Aka Whai Ora, the Ministry of Health, and the Government adding value as key stakeholders in providing policy, regulations, standards, and legal and national health frameworks.

Agile development

An iterative agile development[9] approach would enable a NZDHA to respond rapidly to the emerging needs, priorities, and goals of a national digital health programme, managing the risk of the complicated and multifarious task of implementing a national interoperable health IT system. In a recent report on digital governance, the OECD explains that the design and execution of government information technology projects should be:

[9] Agile project management values and techniques allow project teams to work on smaller increments, review their work often, and include feedback right away to avoid costly failures. Agile government is inspired by agile software development. Agile government procedures reframe traditional decision-making by involving internal and external users as part of processes from day one and elicit continual feedback loops. (Mergel et al., 2020)

> Efficient and effective in the sense that there must be strategic foresight: opportunities are quickly seized, risks are quickly mitigated, and changes are quickly made based on a continuous cycle of diagnosis, feedback and iteration. Experimentation, learning and feedback feature as key elements in the agile approach. This is in contrast to a "waterfall" approach where tasks are undertaken in a linear, systematic and rather rigid fashion. (OECD, 2021a, p.84)

Crown Entities have the authority to enter into their own contracts, allowing them to establish and utilise an agile procurement approach (Public Service Commission, 2022). This would ensure efficient use of available resources, deliver value early, and provide fiscal savings as a result (Marcelo et al., 2018; Mergel et al., 2020). Mr Hunter argues that procurement settings in New Zealand:

> *Don't support the way we do digital. It is often difficult to get business cases through and to get funding. Our business cases and gateway assurance frameworks are tied to the old waterfall project way of doing things. If you can't procure in a way that is aligned to the modern agile way of doing digital, then innovation gets stifled. This is a policy setting problem.*

And according to Dr Whittaker procurement rules have stifled innovation:

> *The government rules of procurement have been where the pendulum has swung quite far with an overly cautious approach. A lot of innovation that we really wanted to encourage in terms of digital health were quite impacted by the government rules of procurement. While the rules are there for good reason, to safeguard against improper use of public money, they are applied so rigidly that it really has impacted how we have been able to move on a lot of things.*

Principles of good governance

To mitigate associated risks of poor governance, a NZDHA should adopt principles of good governance including:

- Responsibility – clearly defined roles and implementing effective and efficient strategies that make the best use of available resources;
- Accountability – data processes are managed and those making decisions are held to account for the performance and delivery of outcomes;
- Fairness – ensuring equity and inclusivity of all shareholders, stakeholders, and investors, and responding to the needs of stakeholders;
- Transparency – undertake the public reporting of key data sets including annual plans, data, financial statements, governance structures, strategies, and outcomes.

The end goal is to implement a properly governed, funded, and resourced integrated national digital health solution in which owners and designers of digital health systems and public health services are held accountable and execute "interoperability requirements, public administrations collaborate with each other and with businesses and citizens, and information flows seamlessly to support a single digital [health] market" (European Commission., 2017 p.7). Mr Hunter argues that:

> *There could be benefit to a Crown Entity for digital health because it is one step removed from the Minister. But you've got to create an environment where people are not concerned about making certain decisions and are enabled to make things happen. You can constrain through governance, but you can enable through governance as well, so it is about balance.*

Leadership from Government

In addition to creating a NZDHA, strong political will is required to ensure digital health is an enduring priority in the health sector (Peterson et al., 2016; Post et al., 2010). The establishment of good governance mechanisms to determine the overall shared objectives and drive national digital health goals is vital, however this cannot happen without the necessary leadership and impetus from Government and Cabinet. Traditionally with a change of government comes a change in direction (Simpson et al., 2020). To avoid this, it is recommended that the Government of New Zealand establish a Crown Entity, which would provide a long-term framework and would be less vulnerable to devolution due to changes in

government. The *National eHealth Strategy Toolkit* recognises that "national planning processes, particularly significant reform or transformation initiatives, require sustained leadership and commitment from senior government officials and health sector leaders" (WHO & ITU, 2012a, p.16).

> *One thing that has been remarkable for us is the bipartisan support at a Congressional and political level. Party's see success in their health policy interests being driven by digital health and that digital health is a big part of the solution.* Posnack

Treaty of Waitangi considerations and obligations

Te Tiriti o Waitangi strives for elimination of inequities for Māori, improving health outcomes, and to embed any improvements across New Zealand. Māori are consistently and disproportionately represented negatively in health and well-being outcomes in New Zealand (Health Research Council, 2010). The health system in New Zealand is committed to mana tangata: "achieving equity in health and disability outcomes for Māori across the life course and contributing to Māori wellness" (Ministry of Health, 2020, para. 8). A NZDHA would be required to honour this commitment through its governance framework by including Māori through co-design, partnership, and co-creation and by gathering and analysing data to reflect on any findings to address Māori rights, Māori data sovereignty, worldviews, knowledge, and Māori processes and protocols (tikanga Māori) (Health Research Council, 2010). A NZDHA would also have to address the principle of rite tahi (equality) through creating a positive and inclusive digital health governance framework that works for Māori, by Māori, capturing the principles of mahi tahi (partnership) and whai wahi (participation) between the Crown and Māori (Victoria University of Wellington, 2021). A NZDHA should partner with Te Aka Whai Ora, and through legislation factor Te Tiriti o Waitangi into its strategies, programmes, and deliverables. Improving the delivery and reach of digital health across New Zealand and into Māori communities through good kawanatanga (governance) is essential and will provide opportunities for Māori to achieve more equitable health outcomes.

The potential benefits to Māori are wide including better access to care when and where it is needed, culturally appropriate and protected digital health systems being implemented, improved health outcomes, and increasing equity and equality through access to data and digital health tools and programmes.

Funding of a NZDHA

Funding of a NZDHA needs to be carefully considered. Lessons from the ONC and the ADHA can be addressed in New Zealand. Mr Posnack argues that:

> *Our budget has not been CPI adjusted and it's been largely the same since we were created. However, during that time we have had new statutory requirements and we've been asked to roll out new regulations which requires us to do a lot of work and public education, and this is taken out of the normal operating budget. This can be restrictive, and it would be good to have more funding to go along with the new requirements.*

Similarly in Australia *"funding for our Agency is an issue because traditionally we haven't been in forward appropriations, so funding happens from year to year. This can mean we don't have enough funding and can also create uncertainty."* Thatcher

In order for a NZDHA to be appropriately and credibly funded a cost-benefit analysis must be undertaken. Past recommendations have been that to reach global health IT funding standards DHBs should spend 5% to 6% of their budgets on digital health, however the reality is that DHBs have only spent a maximum of 2.3% often resulting in poor uptake and delivery of health IT systems, limited access, poor interoperability, and disparate siloed and aging systems (Ministry of Health, 2020). Therefore, it is recommended that a NZDHA is funded with 6% of Vote Health year on year, and that this is adjusted for the Consumer Price Index (CPI) as well as takes into account rapid global advancements in technology. This will provide adequate and necessary funding to ensure the long-term success and viability of a NZDHA and national digital health initiatives, as well as recognise how crucial it is to the efficient running of the health system and in improving health outcomes.

Participants had strong opinions on what is important in a governance framework for digital health that New Zealand can heed:

Dr Thatcher stated:

> *Before you launch into technology solutions, I would strongly recommend that your government develops their policy position around funding. The funding needs to be tied to healthcare delivery and certain outcomes in terms of the use of the technology.*

Dr McCann states that:

> *When we've got the principles around true partnership constructed, it's then about making a decision on the form that digital health governance is going to take for this country and leaving it there for a period of time. If a government ideologically disagrees with the structure and changes it at the end of a 3-year political cycle, there is not going to be enough time for it to embed and make a difference.*

Mr Posnack has similar thoughts about change:

> *Change takes time and it's okay to be impatiently patient. Incremental progress wins at the end of the day. One thing I have learned from a government perspective is that if we try to go too far, too hard, and too steep, then we end up having to cycle back…Creating a digital health agency that through an overarching governance structure, is empowered to improve the outcomes of health consumers and can have the authority to engage key stakeholders through partnership to accomplish national digital health goals is something I think people could get behind.*

Learning from the Australian journey, Cattermole argues that:

> *Digital health is a future tenet of health; it is absolutely fundamental. It is now understood that it is a key platform to improve health systems and health outcomes. The only way for the Agency to contribute to this is to become a trusted partner with good ideas, to deliver on promises. We constantly find ourselves at the apex of policy and delivery, making sure that we do enough to persuade people about the benefits of digital health.*

The New Zealand participants views included:

> *I believe we do need a national governance structure that provides an overarching direction and national principles that are consistent but then this needs to trickle down into everything we do in health service delivery and still enable innovation to happen at the coalface.* Whittaker

Mr Hunter has the final word *"we just have to learn, mature, and better understand how to get things done. We've got to be prepared to invest."*

Key considerations for a NZDHA structure

1. The government should restructure the governance approach to digital health and establish a NZDHA as a Crown Entity reporting directly to the Minister of Health. This will require legislation.
2. As part of a NZDHA the government should establish a skills-based Board including: an independent Chair; and representatives from the Ministry of Health; Health New Zealand; Te Aka Whai Ora; consumer and equity; industry and standards; privacy and security; clinical; research and innovation; and audit and risk.
3. Establish 6 advisory sub-committees with focused roles as part of the governance framework:
    a. Clinical;
    b. Consumer, equity, and hauora Māori;
    c. Audit and risk;
    d. Privacy and security;
    e. Technical and standards; and
    f. Industry and innovation.
4. Establish a taskforce to manage the transition from the current governance structure to the framework recommended in this dissertation.
5. Fund a NZDHA with the appropriate level of funding at 6% of Vote Health and adjusted for CPI year on year.
6. Apply the governance principles of transparency, accountability, responsibility, and fairness to build confidence in the new governance structure.
7. Adopt an iterative agile approach to procurement, project delivery, and governance.

5.2.1 A framework for effective digital health governance in New Zealand

Digital health affects the whole of a health system, not just one part, and requires national direction and leadership to ensure cohesiveness and coordination in systems development (Deloitte Centre for Health Solutions, 2021). As well as this the consumer today has at their fingertips access to a wide range of health information through the internet and health apps.

Consumers expect more connection and seamless communication when they are receiving healthcare services (Snowdon, 2020). Therefore, it must be considered that governance of digital health cannot be placed in only one part of New Zealand's reformed health system through a top-down management approach but should have tentacles across every agency and region within the new structure. Figure 11 depicts how the proposed NZDHA, as a Crown Entity, would be able to connect with all other entities that govern and deliver health in New Zealand.

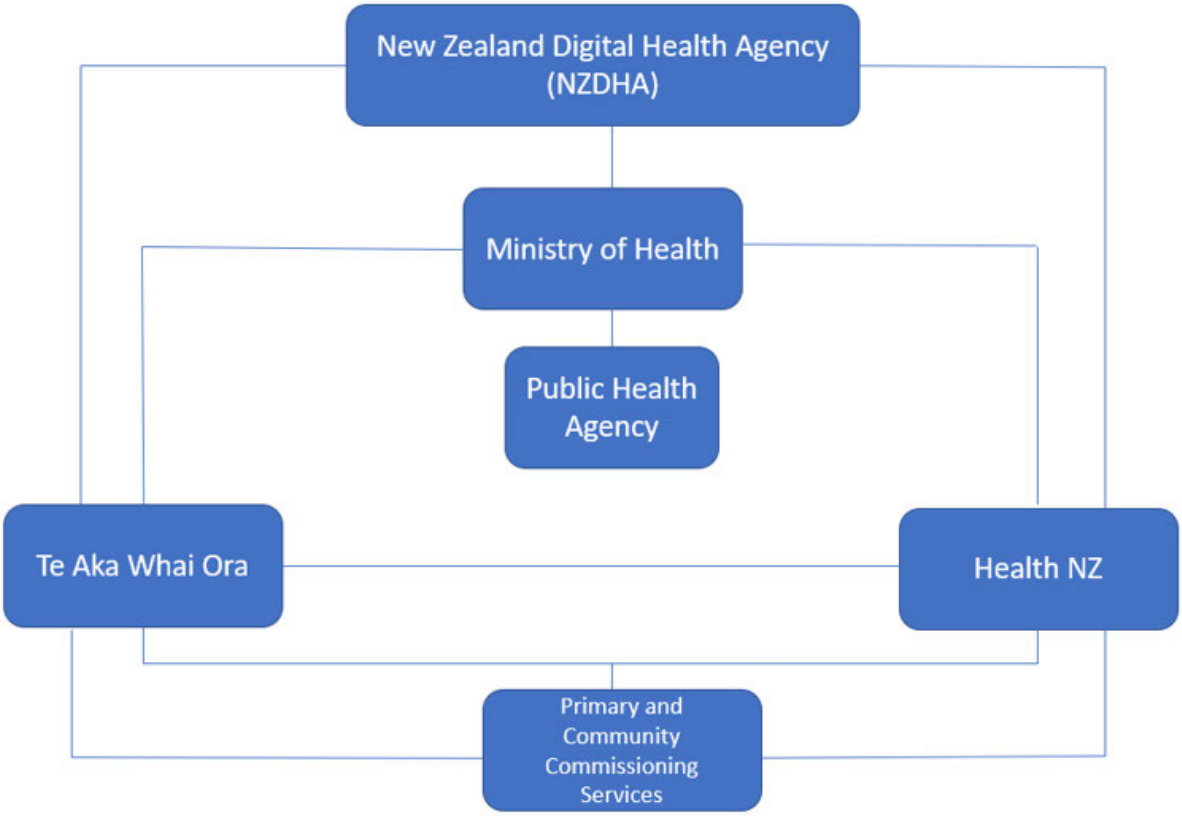

***Figure 11*: NZDHA potential reach as a Crown Entity**

A NZDHA would act as a Crown Entity along with other health system Crown Entities such as PHARMAC, the HSQC, and the NZBOS. Figure 12 depicts the health system structure after the reforms, with a NZDHA as a Crown Entity.

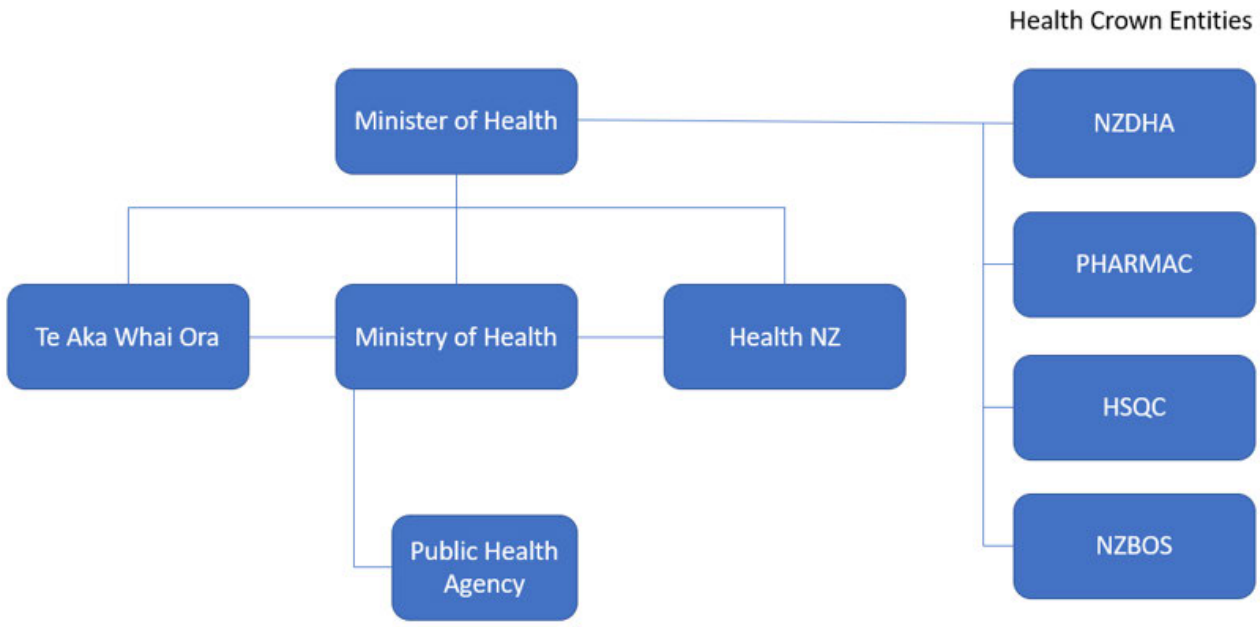

***Figure 12*: New Zealand health system structure with a NZDHA Crown Entity**

NZDHA Board

A NZDHA Board would act as chief stewards of the Agency and its responsibilities would include setting strategy, reviewing performance, and maintaining overall responsibility and accountability for the entity. The Minister of Health would set a letter of expectation and the Board would report directly to the Minister. Figure 13 shows the recommended governance structure of a NZDHA Board and sub-committees. Mr Hunter argues that currently:

> *We don't necessarily take a skills-based approach to governance. We tend to think that* [a person] *has to know health and know what is required in health to be able to govern. I think from a governance point of view we need to be thoughtful about what is the best way to govern.*

Ms Cattermole expresses what is vital is *"standing up a Board of experts that can have tentacles across the whole of the health system and which would be informed by a range of advisory bodies."*

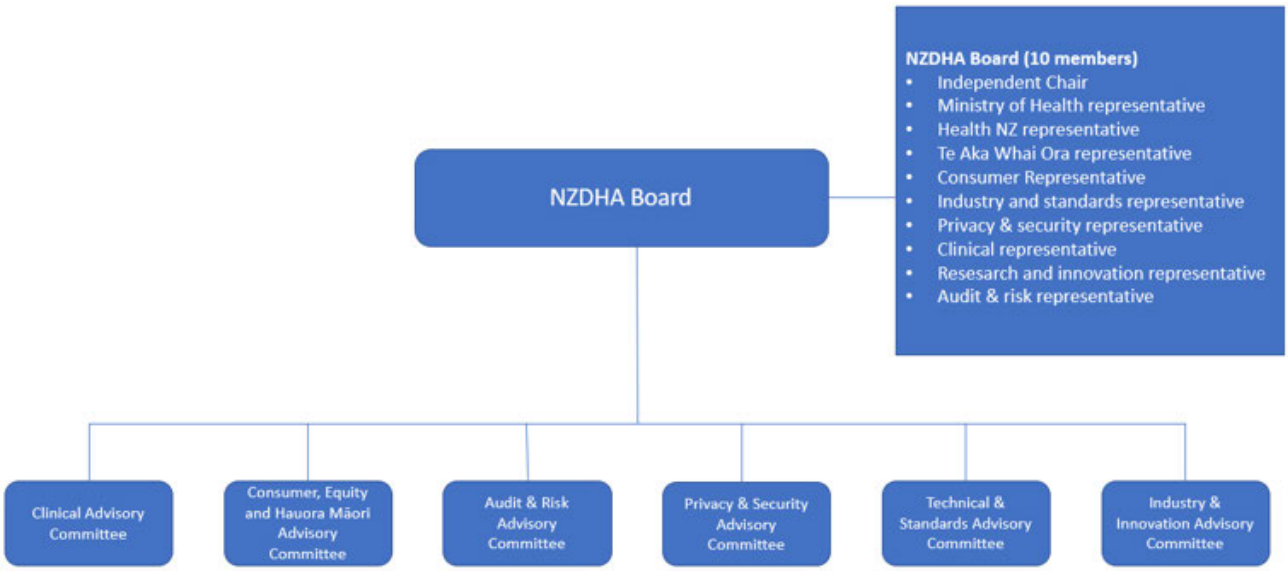

***Figure 13*: NZDHA Board and governance structure**

NZDHA Sub-committees

NZDHA sub-committees would provide specialist focus in critical areas to the Board and management tier of the Agency. They would meet regularly and include skills-based representatives. From time-to-time sub-committees may co-convene to combine skills and advise the Board on wider or more specific issues. The Board would have the right to convene other sub-committees in specialist topics if deemed necessary. A brief description of 6 key sub-committees is provided.

Clinical advisory committee: As shown in the USA, roll out of digital health solutions cannot be successful without the necessary input from clinicians and the health workforce. Understanding the needs of the health workforce is critical to achieving consensus and buy-in of digital health systems. The clinical advisory committee would advise on workforce adoption and integration of digital health solutions and on the usability, usefulness, and efficient and effective delivery of digital health in a clinical setting.

Consumer, equity, and hauora Māori advisory committee: The consumer, equity, and hauora Māori advisory committee would ensure key messages about digital health are communicated appropriately to consumer stakeholders and consider the interests of all minority groups including the disabled, Māori, Pasifika, and different socioeconomic and ethnic groups within New Zealand. Critical for this group is to consider and advise on Te Tiriti o Waitangi obligations, commitments, and responsibilities to enable equity in health

outcomes for Māori through digital health. Co-design, co-creation, and partnership across digital health solutions are crucial principles to be considered by this committee.

Audit and risk advisory committee: Audit and risk functions are fundamental for any organisation and committee members would provide independent advice to the Board specifically in meeting the requirements and obligations under the Pae Ora (Healthy Futures) Bill 2022 and the Crown Entities Act 2004. This sub-committee would provide assurance processes regarding the Agency's financial statements and record keeping, internal audit processes, risk management and oversight, and provide accountability measures for spending taxpayer dollars.

Privacy and security advisory committee: Privacy and security were key social and policy issues faced by the Australians on their digital health journey. A privacy and security advisory committee would advise on legal issues relating to copyright, data, privacy, confidentiality, legal liability, and data sovereignty. They would also advise on security risks within the development and roll out of digital health solutions at a national level.

Technical and standards advisory committee: Key to success for the USA has been their focus on and the mandating of standards and certification in the adoption of EHRs. The technical and standards advisory committee would advise on architecture and systems integration in national digital health, the technical landscape across the health system, on the use and adoption of standards, the implementation specifications for standards, and any certification criteria.

Industry and innovation advisory committee: A key lesson from the Australian digital health journey is to ensure that industry is seen as key stakeholders and partners in digital health implementation. Continuous, open, and transparent communication with industry is seen to aid any national programme of work. The industry and innovation advisory committee would advise as partners on key industry initiatives, incentives and disincentives, industry mood and appetite, contribute to standards adoption buy-in and roll out, connect in with appropriate industry bodies, and provide advice on how to capitalise on innovation in digital health. This committee would also advise on and/or develop an innovation framework specific to digital health where a national innovation hub could be established to acknowledge and commit to New Zealand developed innovative solutions in digital health.

Legislation

In order to ensure the longevity and success of a NZDHA, legislation must be enabling and agile enough to be able to keep up with the rapid pace of development in technology and provide an enduring framework that reaches across successive governments. For suggested amendments to the Pae Ora (Health Futures) Bill 2022 see Appendix 5.

Mr Hunter argues that:

> *We need to be thoughtful about legislation because when we legislate, we are making something law. We have to design legislation in a way where it can adapt and be used over time. It is not easy to get legislation changed so we can find ourselves locked into a way of doing things because we have legislated for it.*

Learning from the USA, Mr Posnack's perspective on how enabling legislation has advanced the digital health agenda is useful:

> *Legislation needs to be focused on what are the key outcomes and what the future would look like, what would be different for health consumers. The law needs to be able to adapt and be nimble in order to be effective.*

Chapter 6: Conclusion

This research used a case study approach to investigate the New Zealand, Australian, and USA digital health strategies and governance frameworks. The case studies provide lessons in how to progress a country's national digital health agenda through establishing an autonomous governance structure enabled by legislation. While the journeys have been different and not without challenges, both Australia and the USA have demonstrated that a coordinated, consultative, and regulated approach through an independent government entity has been crucial to the advancement of national digital health strategies. To achieve set goals and provide overarching reach into every aspect of their health systems, the countries use a middle-out governance structure maximising the efforts of stakeholders and which considers social influence and creates a value network of collaborators and expertise.

There is no one part of the health system that is not touched by digital health, however, it also remains that in New Zealand there is no one part of the health system that is fully connected by digital health. By drawing lessons from our own history and those of the international jurisdictions, as well as how health IT played a critical role in the response to COVID-19, we can recognise that digital health aids health system resilience, more equitable health outcomes, and economic security. By heeding these lessons, New Zealand has the opportunity to develop a gold standard national digital health system.

Creating an independent and accountable NZDHA as a Crown Entity which can govern and steer national digital health programmes to successful completion would allow for the full democratisation of healthcare enabled by data and digital where consumers can participate in their own health. It would also recognise that data and digital are foundational and essential to the improvement of health outcomes of New Zealanders and acknowledge that digital health is no longer just an enabler but fundamental to operations, how our health system is run, and is an overarching function of all the different agencies governing the new health system: Health New Zealand, Te Aka Whai Ora, and the Ministry of Health.

In New Zealand, Māori health equity is seen as vital to the improved health and well-being of all New Zealanders. In order to achieve greater equitable health outcomes for Māori, and to honour the fundamental principles of Te Tiriti o Waitangi, the successful implementation of national digital health solutions with Māori co-governance, co-creation, and partnership is crucial. Improving the delivery and reach of digital health into Māori communities through

the kawanatanga (governance) of a NZDHA framework outlined in this dissertation will provide an opportunity for New Zealand to bridge the divide by understanding the gaps through data and in providing increased access to core health services.

Data and digital today are fundamental tenants of health and have become as important as the health workforce in providing essential care to health consumers. By utilising digital health as a central function to create and connect a patient-centred health system, New Zealand can help address the social determinants of health and advance toward improving the efficiency, safety, quality, and affordability of healthcare. However, a strong enduring government commitment, ongoing sustained funding and support, and effective, accountable, and transparent national governance structures are essential for success.

While this research identifies and challenges previous and current approaches to digital health governance, it also provides a foundation for New Zealand to be progressive and forward-thinking from the start of the 2022 health sector reforms. By leveraging off international case studies, and striking the right balance between centralisation and decentralisation, the New Zealand Government has an exciting opportunity to establish an independent New Zealand Digital Health Agency as a Crown Entity with its own line appropriation and legislation, and with the authority, resources, and continued investment to act, providing the catalyst to finally achieve the long-term objective of a connected consumer-driven health system through digital health.

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Appendices

Appendix 1: Ethics approval letter

VICTORIA UNIVERSITY OF WELLINGTON
TE HERENGA WAKA

[redacted]

TO	Ryl Jensen
FROM	Professor Stephen Marshall, Acting Convenor, Human Ethics Committee
DATE	16 December 2021
PAGES	1
SUBJECT	**Ethics Approval** **Number: 30041** **Title: Exploring a digital health governance framework for New Zealand: A mixed methods study**

Thank you for your application for ethical approval, which has now been considered by the Human Ethics Committee.

Your application has been approved from the above date and this approval is valid for three years. If your data collection is not completed by this date you should apply to the Human Ethics Committee for an extension to this approval.

Best wishes with the research.

Kind regards,

[redacted]

Prof Stephen Marshall

Acting Convenor, Te Herenga Waka—Victoria University of WellingtonHuman Ethics Committee

Appendix 2: Participants information sheet

VICTORIA UNIVERSITY OF WELLINGTON
TE HERENGA WAKA

Exploring a digital health governance framework for New Zealand: A mixed methods study

INFORMATION SHEET FOR PARTICIPANTS

You are invited to take part in this research. Please read this information before deciding whether or not to take part. If you decide to participate, thank you. If you decide not to participate, thank you for considering this request.

Who am I?

My name is Ryl Jensen, and I am a Masters of Health student in the School of Health at Victoria University of Wellington. This research project is work towards my dissertation.

What is the aim of the project?

This project aims to explore the implementation of national digital health solutions and potential digital health governance frameworks in international jurisdictions to inform a comprehensive digital health governance framework for New Zealand.

What is my research about?

Digital health refers to the information and communication technology (ICT) services across healthcare systems. A broad term, digital health encompasses eHealth, mobile health (mHealth), virtual health, telehealth as well as the use of advanced computing sciences in the Internet of Things (IoT), big data, genomics, robotics, machine learning, virtual reality, and artificial intelligence (AI) (World Health Organization 2021).

Considered fundamental to implementing successful national digital health solutions is good governance (Marcelo et al., 2018). Without good governance, it is thought that digital health projects can be subject to delays and even failure. It is widely considered that good digital health governance requires sustained levels of effort and coordination from different organisational levels, open communication, and the uniting of key stakeholders across sectors.

This research aims to explore national digital health solutions in international jurisdictions through a sequential mixed-methods study to inform a comprehensive governance framework for New Zealand. Case studies and semi-structured interviews will help inform whether there are any current governance gaps in New Zealand's digital health management. The outcome of this research could lead to a well-informed sustainable governance framework for national digital health solutions in New Zealand.

Your participation will support this research by generating and adding the unique human experience of the implementation of digital health systems in your country. Your accounts will help provide a greater depth of interpretation and a rich context to the research findings. This research has been approved by the Victoria University of Wellington Human Ethics Committee application number 30041.

How can you help?

You have been invited to participate because of your involvement in the development of your national digital health system in your country. If you agree to take part, I will interview you via Microsoft Teams or Zoom. I will ask you questions about digital health and digital health governance in your jurisdiction. The interview will take about 1 hour. I will video/audio record the interview with your permission and write it up later. You can choose to not answer any question or stop the interview at any time, without giving a reason. You can withdraw from the study by contacting me at any time before 28 February 2022. If you withdraw, the information you provided will be destroyed or returned to you.

What will happen to the information you give?

You can choose whether the information you give during the interviews is to be confidential or attributed to you.

A. If you choose, your contribution to the research and the organisation you work for will remain confidential. This means that the researcher named below will be aware of your identity and that of your workplace, but the research data you provide will be combined and your identity will not be revealed in any reports, presentations, or public documentation. Pseudonyms may be used for quotes. However, you should be aware that in small projects your identity might be obvious to others in your community. In this case, only my supervisors, the transcriber (who will be required to sign a confidentiality agreement) and I, will read the notes or transcript of the interview. The interview transcripts, summaries, and any recordings will be kept securely and destroyed on 31 May 2023.

OR

B. You can be named in the final report, and with organisational approval, your organisation can also be named. In this case, you will be given a full copy of the transcript from your interview for review and confirmation. The final report may include direct quotes from your interview. At the point of review, you may choose for the information you give to become confidential. Your identity will then be protected and will not be revealed. The interview transcripts, summaries, and any recordings will be kept securely and destroyed on 31 May 2023.

What will the project produce?

The information from my research will be used in my Masters dissertation, a report to Health New Zealand and the Ministry of Health New Zealand, and/or academic publications and conferences.

If you accept this invitation, what are your rights as a research participant?

You do not have to accept this invitation if you don't want to. If you do decide to participate, you have the right to:

- choose not to answer any question;
- ask for the recorder to be turned off at any time during the interview;
- withdraw from the study before 28 February 2022;
- ask any questions about the study at any time;
- receive a copy of your interview recording;
- receive a copy of your interview transcript;

- read over and comment on a written summary of your interview;
- be able to read any reports of this research by emailing the researcher to request a copy.

If you have any questions or problems, who can you contact?

If you have any questions, either now or in the future, please feel free to contact Natalie Lindsay or me:

Student:

Name: Ryl Jensen

[redacted]

Supervisor:

Name: Natalie Lindsay

Role: Lecturer

School: Nursing and Midwifery

[redacted]

Human Ethics Committee information

If you have any concerns about the ethical conduct of the research you may contact the Te Herenga Waka—Victoria University of Wellington HEC Convenor by emailing hec@vuw.ac.nz.

References

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Appendix 3: Participants consent form

Exploring a digital health governance framework for New Zealand: A mixed methods study

CONSENT TO INTERVIEW

This consent form will be held for a minimum of five years.

Researcher: Ryl Jensen, School of Health, Victoria University of Wellington.

- I have read the Information Sheet and the project has been explained to me. My questions have been answered to my satisfaction. I understand that I can ask further questions at any time.
- I agree to take part in a video/audio recorded interview.

I understand that:

- I may withdraw from this study at any point before 28 February 2022, and any information that I have provided will be returned to me or destroyed.
- The identifiable information I have provided will be destroyed on 28 February 2027.
- Any information I provide will be kept confidential to the researcher and the supervisor and the transcriber.
- I understand that the findings may be used for a Masters dissertation a report to Health NZ and the Ministry of Health, New Zealand and/or academic publications and/or presented to conferences.
- I understand that the observation notes/recording will be kept confidential to the researcher and the supervisor and the transcriber.
- I understand that organisational consent has been provided and the organisation will/will not be named in any of the reports.
- My name will not be used in reports and utmost care will be taken not to disclose any information that would identify me.

OR

- I consent to information or opinions which I have given being attributed to me in any reports on this research: Yes ☐ No ☐

- I would like a copy of the recording of my interview: Yes ☐ No ☐
- I would like a copy of the transcript of my interview: Yes ☐ No ☐
- I would like a summary of my interview: Yes ☐ No ☐
- I would like to receive a copy of the final report and have added my email address below. Yes ☐ No ☐

Signature of participant: _____

Name of participant: _____

Date: _____

Contact details: _____

Appendix 4: Countries and participants biographies

New Zealand

1. Dr Lloyd McCann – Chief Executive Officer Mercy Radiology and Clinics & Head of Digital Health for Healthcare Holdings Ltd

Dr Lloyd McCann is a graduate of Auckland University Medical School, New Zealand and is currently the chief executive officer for Mercy Radiology and Clinics as well as the head of digital health for Healthcare Holdings Limited.

Lloyd is a fellow of the Royal Australasian College of Medical Administrators and worked as a beachheads advisor for New Zealand Trade and Enterprise (NZTE). Whilst based in the UK, Lloyd worked as the medical director for Harris Corporation, Healthcare Solutions and was an elected member on the TechUK Health and Social Care Board as well as a technical advisory group member for the Global eHealth Ambassadors Programme. He completed a mixed clinical and managerial fellowship at the Oxford University Hospital NHS Trust in emergency medicine and performance improvement.

Lloyd is often called upon to advise government and was a member of the expert panel for the recent New Zealand Health and Disability System Review. He currently serves as a health services strategy advisory board member for the Accident Compensation Corporation (ACC) in New Zealand and is an Independent Director for Formus Labs.

He is an equity advocate and an advocate for digitally enabled value-based healthcare. (Mercy Radiology, 2022)

2. Dr Robyn Whittaker – Public health physician and mHealth researcher, Waitemata District Health Board

Dr Robyn Whittaker is a Public Health physician currently leading the innovation stream within the Institute for Innovation and Improvement at Waitemata District Health Board. She leads the Leapfrog Programme of enterprise-wide strategic projects, partnerships with industry and academic institutions (such as the Precision Driven Health research partnership), and a Centre for Health IT & Creative Design that works with DHB staff to develop and trial new things.

Robyn is also an Associate Professor at the National Institute for Health Innovation, University of Auckland, where she co-leads the Health Informatics and Technology research

team. Her research interests are in mHealth (mobile health) – particularly designing and trialling interventions to be delivered to people via their mobile phones.

Robyn contributes to several national and international groups including the World Health Organisation/ International Telecommunications Union's Informal Expert Groups for the 'Be Healthy Be Mobile' global initiative, the NZ Telehealth Forum Leadership Group, the Board of the NZ Health Innovation Hub, the management team of the MedTech Centre of Research Excellence, the editorial board for JMIR mHealth & eHealth, and is a consultant on several international research projects. She was a NZ Harkness Fellow in 2010/11 during which time she was an invited expert on the Secretary of Health & Human Services' Text4Health Advisory Committee. (Health Informatics New Zealand, 2022a)

3. Mr Shayne Hunter – Deputy Director General Data and Digital, Ministry of Health New Zealand

Shayne Hunter was the Deputy Director-General, Data and Digital at the Ministry of Health from 2018 to 2022.

Shayne has spent the last 21 years in the health and disability sector where he developed a strong a passion for information and technology enabled improvements for the system and for the health outcomes for individuals and our population.

His previous role was as the Chief Information Officer (CIO) for Capital & Coast, Hutt Valley and Wairarapa DHBs where he was a member of the ELT for each DHB. He was also previously the chair of the Central Region DHB's CIO group and the Chair of the Health Sector National IS Leaders Forum. Prior to his role as CIO, he was based at the Ministry and led a number of national initiatives in the area of medicines management.

Shayne started his career with IBM and went on to establish a number of start-up businesses based on emerging technologies. From there he has held delivery and leadership roles in government and the private sector. (Health Informatics New Zealand, 2022b)

Australia

4. Ms Amanda Cattermole – Chief Executive Officer, Australian Digital Health Agency

Amanda Cattermole is the Chief Executive Officer of the Australian Digital Health Agency, a role she commenced in September 2020.

Prior to this Amanda was the Chief Operating Officer at Services Australia (formerly the Department of Human Services). Amanda served as interim Chief Executive Officer during the 2019/20 bushfires season in Australia.

Amanda held several other senior roles at Services Australia, including an extended period as Deputy Secretary, Health and Aged Care, responsible for the delivery of more than $60 billion in annual payments and services to Australians under Medicare, the PBS and in the aged care sector.

Amanda has also held senior roles in the Commonwealth Departments of Treasury, Prime Minister and Cabinet and Families, Housing, Community Services and Indigenous Affairs, and the Victorian Department of Health and Human Services and the Western Australian Department of Indigenous Affairs.

In her earlier career Amanda worked as a lawyer in Victoria, the Northern Territory and Western Australia.

Amanda holds a Bachelor of Laws, a Bachelor of Commerce, a Master of Laws, and a Master of Business Administration.

Amanda received the Public Service Medal for outstanding public service leading reform in providing housing for Indigenous people in remote communities and the National Gambling Reform laws. (Australian Digital Health Agency, 2022a)

5. Dr Malcolm Thatcher – Chief Technology Officer, Australian Digital Health Agency

Dr Malcolm Thatcher is the Chief Technology Officer at the Australian Digital Health Agency, a role he commenced in February 2021.

Dr Thatcher leads the Technology Services Division, responsible for the operation of high quality, trusted, reliable and secure national digital health infrastructure and health support systems. The Division also provides internal IT services and support to Agency staff.

Dr Thatcher completed his doctoral degree (PhD) at the Queensland University of Technology (QUT) with a focus on digital risk and governance in healthcare. He also holds an Honours Degree in Computer Science from the University of Queensland, a Masters' Degree in Applied Computer Science from QUT and has completed a certificate course in Leadership Strategies in Information Technology with Harvard University. In 2018, Dr Thatcher published a book on Digital Risk and Governance for use by CEOs and governing boards.

Dr Thatcher is a Fellow of the Australasian Institute of Digital Health, a Fellow of the Australian Computer Society, and a Graduate of the Australian Institute of Company Directors. (Australian Digital Health Agency, 2022c)

United States

6. Mr Steven Posnack – Deputy National Coordinator for the Office of the National Coordinator for Health Information Technology

Steven Posnack serves as the Deputy National Coordinator for Health Information Technology.

Prior to this role he served as executive director of the Office of Technology. In this role, Mr. Posnack advises the national coordinator, leads the ONC Health IT Certification Programme, and directs ONC's standards and technology investments through the ONC Tech Lab, which organizes its work into four focus areas: pilots, standards coordination, testing and utilities, and innovation. He led the creation of the Interoperability Standards Advisory, the redesign of ONC's Certified Health IT Product List (CHPL), created the Interoperability Proving Ground, and developed the C-CDA Scorecard.

Prior to serving as the director of the Office of Standards and Technology, Mr. Posnack led ONC's federal policy division within the Office of Policy and Planning from 2010 to 2014. In this capacity, he led ONC's regulatory affairs, legislative analysis, and several federal policy development and coordination activities. From 2005 to 2010, he served as a senior policy analyst within ONC's Office of Policy and Research. In that position, he co-authored the Nationwide Privacy and Security Framework for Electronic Exchange of Individually

Identifiable Health Information. He also led a cross-HHS policy team that worked with the Drug Enforcement Agency (DEA) as it developed its regulation for the electronic prescribing of controlled substances (EPCS).

Mr. Posnack earned a Bachelor's degree in computer science from Worcester Polytechnic Institute, a Master's degree in security informatics from Johns Hopkins University Information Security Institute, and a Master's degree in health policy from Johns Hopkins University Bloomberg School of Public Health. He also maintains a Certified Information Systems Security Professional (CISSP) certificate. (The Office of the National Coordinator for Health Information Technology, 2022b)

Appendix 5: Recommended edits to the Pae Ora (Healthy Futures) Bill 2022

New Zealand Digital Health Agency

(1) There is the establishment of a New Zealand Digital Health Agency (NZDHA).

(2) The New Zealand Digital Health Agency is a Crown Entity for the purposes of section 7 of the Crown Entities Act 2004.

(3) The Crown Entities Act 2004 applies to the New Zealand Digital Health Agency except to the extent that this Act expressly provides otherwise.

Objectives of the New Zealand Digital Health Agency:

(1) The objectives of the New Zealand Digital Health Agency are—

(a) to improve health outcomes for New Zealanders through the delivery of national digital health services and systems; and

(b) to improve health outcomes for all New Zealanders enabled by seamless, safe, secure digital health services and technologies that provide a range of innovative, easy-to use tools for both patients and providers;

(c) to improve health outcomes for Māori through the delivery of national digital health services and systems; and

(d) to improve health outcomes for Māori enabled by seamless, safe, secure digital health services and technologies that provide a range of innovative, easy-to use tools for both patients and providers;

(e) any other objectives it is given by or under any enactment or authorised to perform by the Minister by written notice to the board of the Digital Health Agency after consultation with it.

(2) In this section, **eligible people** means people belonging to a class specified in regulations made under **section 97** as being eligible to receive services funded under this Act.

Functions of the New Zealand Digital Health Agency

(1) The functions of the New Zealand Digital Health Agency are—

(a) to maintain and manage a national digital health strategy that applies consistently throughout New Zealand; and

(b) provide intuitive, seamless, secure, and accessible national digital health services that add value and benefit; and

(c) to engage as it sees fit, but within its operational budget, in research to meet the objectives set out in **section 76(1)(a)**; and

(d) to empower people to be active participants in a digital health environment; and **(e)** to advance governance, drive collaboration and promote conformance with standards to increase trust in digital health services; and

(f) to build capability, engagement, and innovation in the health system through digital health services; and

(g) to perform any other functions, it is for the time being given under any enactment or authorised to perform by the Minister by written notice to the board of the New Zealand Digital Health Agency after consultation with it.

(2) The New Zealand Digital Health Agency must perform its functions within the amount of funding provided to it and in accordance with its statement of intent (including the statement of forecast service performance) and (subject to **section 59**) any directions given under the Crown Entities Act 2004.

The New Zealand Digital Health Agency to consult in implementing objectives and performing functions.

In performing its functions, the New Zealand Digital Health Agency must, when it considers it appropriate to do so, —

(a) consult on matters that relate to the management of digital health expenditure with any sections of the public, groups, or individuals that, in the view of the New Zealand Digital Health Agency, may be affected by decisions on those matters; and

(b) take measures to inform the public, groups, and individuals of the New Zealand Digital Health Agency's decisions concerning the national digital health strategy.

Board of the New Zealand Digital Health Agency to ensure advisory committees:

(1) The board of the New Zealand Digital Health Agency must ensure that there are advisory committees under clause 14(1)(a) of Schedule 5 of the Crown Entities Act 2004:

(a) digital health advisory committees are to provide objective advice to the New Zealand Digital Health Agency on digital health solutions and their benefits in their area of expertise including but not limited to:

i Clinical advisory committee

ii Audit and risk advisory committee

iii Privacy and security advisory committee

iv Technical and standards advisory committee

v Industry and innovation advisory committee

(b) a consumer, equity, and hauora Māori advisory committee to provide input from a consumer and/or patient point of view and advise on hauora Māori and Te Tiriti o Waitangi obligations.

(2) Despite clause 14(1)(a) of Schedule 5 of the Crown Entities Act 2004, the members of the digital health advisory committees are appointed by the Minister of Health in consultation with the board of the New Zealand Digital Health Agency.

Publication of notices:

The Minister must, as soon as practicable after giving a notice under **section 76(1)(b) or 77(1)(e)**, publish in the *Gazette*, and present to the House of Representatives, a copy of the notice.

Membership of board of the New Zealand Digital Health Agency:

The board of the New Zealand Digital Health Agency consists of up to 10 skills-based members appointed under section 28 of the Crown Entities Act 2004.