CLINICAL GOVERNANCE FRAMEWORK FOR DIGITAL HEALTH

Australian Government

Australian Digital Health Agency

Australian Digital Health Agency

ABN 84 425 496 912
Level 25, 175 Liverpool Street, Sydney, NSW 2000
Telephone 1300 901 001 or email help@digitalhealth.gov.au
www.digitalhealth.gov.au

Acknowledgements

The Australian Digital Health Agency is jointly funded by the Australian Government and all state and territory governments.

Disclaimer

The Australian Digital Health Agency ("the Agency") makes the information and other material ("Information") in this document available in good faith but without any representation or warranty as to its accuracy or completeness. The Agency cannot accept any responsibility for the consequences of any use of the Information. As the Information is of a general nature only, it is up to any person using or relying on the Information to ensure that it is accurate, complete and suitable for the circumstances of its use.

Document control

This document is maintained in electronic form and is uncontrolled in printed form. It is the responsibility of the user to verify that this copy is the latest revision.

CONTENTS

Glossary **2**

About this Clinical Governance Framework **5**

The development of our Framework 6

Clinical governance at the Agency **7**

Clinical Governance section 7

Clinical Governance Committee 7

Broader governance. 7

Defining clinical governance 8

Aligning clinical governance with the National Digital Health Strategy 9

Our 5 clinical governance principles **11**

Principle – Leading with our people **13**

Principle – System safety and quality improvement **15**

System safety 15

Quality improvement. 16

Clinical safety risk and incident management 17

Principle – Evidence-based practice **18**

Principle – Person-centredness. **20**

Principle – Partnership **21**

GLOSSARY

Agency refers to the Australian Digital Health Agency.

Consumers collectively refers to the Australian community at large, to which the Agency is accountable under the Public Governance, Performance and Accountability Rule (Establishing the Australian Digital Health Agency) 2016 (PGPA Rule). 'Consumers' also refers to individuals, such as well or unwell members of the Australian community, patients and recipients of aged care, disability or other services. Depending on the context, a consumer may include an informal carer or a family member.

Clinical governance at the Agency is the set of relationships and responsibilities established by the Agency between Australian Government departments, our Executive team, Board, committees, staff, partners, consumers and other stakeholders to deliver and continuously improve safe, high-quality products and services

Clinically safe means that health outcomes are not at risk of being undermined.

Clinical Safety Management System is a methodology that consists of processes, procedures and guidelines that inform clinical safety analysis undertaken by clinical safety experts.

Clinical safety risk and incident management collectively refers to identifying, reporting and managing risks and adverse events, or circumstances which create the potential adverse clinical events, or near misses.

Clinical safety risks are circumstances that may result in a direct or indirect adverse impact on **health outcomes**. Clinical safety risks may be realised through complaints, incidents, events, problems, issues, defects, system failures, non-system failures or other communication pathways into the Agency. They include clinical incidents (such as medication errors) and non-clinical incidents (such as a system outage or cyber attack).

Cultural safety is about shared respect, meaning and knowledge. It is about creating an environment that is safe for Aboriginal and Torres Strait Islander peoples and the diverse Australian community. This includes addressing unconscious bias, racism and discrimination and supporting self-determination. It encompasses the experience of learning together with dignity and truly listening.

Data sovereignty refers to the jurisdictional control or legal authority that can be asserted over data because its physical location is within jurisdictional boundaries.

Evidence-based practice in health technologies involves a structured approach to gathering, interpreting, analysing and evaluating internal and external data, insights and existing research to inform the design, development and delivery of our products and services.

Glossary continued

Health care and care refers to the difference between health care in a clinical setting (generally associated with a healthcare provider or clinician) and care that may be in residential aged or disability care or personal care settings (where a healthcare provider or clinician is not necessarily present). Both are equally important in clinical governance.

Health outcomes refer to observable and measurable improvements in health, function or quality of life (or death) due to clinical or non-clinical care provision. Importantly, health outcomes encompass the consumer's experience, including in their access and use of the Agency's products and services. Health for Aboriginal and Torres Strait Islander peoples does not mean only the physical wellbeing of a person, but also refers to the social, emotional and cultural wellbeing of the whole community. For Aboriginal and Torres Strait Islander peoples, this is seen in terms of the whole-life view.

Health technologies, health technology solutions or **health technology initiatives** refer to things, functions, innovations or industries of a technological, machine or digital nature which aim to improve health outcomes. They encompass the entire network or structure that supports them, including but not limited to functions of the Agency as specified in Part 2, section 9 of the PGPA Rule.

Incident management is the Agency's method of addressing incidents, whether clinical or non-clinical, to reduce their impact or potential impact on health outcomes and to improve clinical safety and quality going forward.

Leadership refers to how individuals behave, communicate, interact with and influence others in the context of their role.

Partners include (but are not limited to) vendors, healthcare and care providers (whether individuals or organisations), state and territory governments, peak bodies, Aboriginal and Torres Strait Islander community-controlled health organisations and other organisations. Partners engage with the Agency in a collaborative environment to accelerate adoption and use of innovative digital health services and technologies.

Person-centredness means always maintaining our focus on consumers and listening to their needs, goals, values, preferences and experiences to ensure the design and delivery of clinically safe, quality products and services.

PGPA Rule means the Public Governance, Performance and Accountability Rule 2016 (Establishing the Australian Digital Health Agency) 2016, made under the Public Governance, Performance and Accountability Act 2013 (Cth). The PGPA Rule establishes the Agency.

Products and services are the Agency's programs and projects. They include the range of health technologies, applications and resources which the Agency designs and/or develops to support or enhance the delivery of clinical and non-clinical care. They also include the organisational, operational and governance structures that support the Agency's programs and projects.

Quality refers to the impact of the Agency's products and services, in supporting and promoting desired health outcomes of consumers. While quality must be consistent with current evidence, it is also subject to consumers' wishes, values and preferences.

Glossary continued

Quality improvement is a system of regularly and continuously reviewing and refining our processes, products and services to constantly improve them.

System safety is an integrated approach to clinical safety in health technologies. It recognises the interaction of different components within the whole and the potential impact of this interaction on consumers.

Workforce refers to all people, whether employed or contracted by the Agency, involved in any decision-making or other task or in the design, development, delivery, evaluation or implementation of our **products and services**. Workforce covers those in non-clinical and clinical roles, and includes leaders at our Board and executive level.

ABOUT THIS CLINICAL GOVERNANCE FRAMEWORK

The Agency is accountable to the Australian community[1] to improve health care and care by providing health technology solutions through our products and services. Clinical governance promotes clinical safety, quality and continuous improvement in the delivery of health care and care, including through health technologies. It comprises a culture of safety and quality that is supported by clinical input and a set of relationships and responsibilities established by our Agency, together with our partners, our workforce and our consumers.

We acknowledge that our products and services form part of broader connected systems and capabilities (both technical and non-technical) that deliver care across the healthcare and care sectors in Australia, through a complex network of participants, perspectives and interdependencies. The clinical safety, quality and continuous improvement of all our products and services matter to us. Consumers' experiences are impacted by our health technology initiatives, and we recognise that their lived experiences are diverse.

Effective clinical governance by our Agency ensures that we operate within a structured, open, transparent and blame-free environment, led by our Board and delivered by our workforce. This visibility builds trust in our Agency and increases confidence in the Australian community that we are supporting connected, person-centred products and services, in a way that is evidence-based and values health outcomes for our diverse range of consumers.

This Clinical Governance Framework provides the structure that supports everyone in the Agency to be accountable for ensuring the clinical safety and quality of our products and services and for continually enhancing them. It is consistent with, and supports, the Agency's functions under the Public Governance, Performance and Accountability Rule 2016 (Establishing the Australian Digital Health Agency) 2016 (PGPA Rule), Part 2, section 9(1)(d).

The Framework advocates for the active management and monitoring of risks, with a strong and effective focus on clinical governance measures. While the Agency has a high appetite for responsible innovation wherever possible, clinical safety, security and privacy will not be compromised to achieve this. Effectively implementing clinical governance helps ensure clinical safety, security and privacy are always managed to a very low risk level.

The Agency acknowledges that trust in health technologies can be lost through inadequate consideration of clinical governance, clinical use cases, workflow and user requirements in the design, development and delivery of our products and services. Accordingly, this Framework drives collaboration and promotes conformance with evidence-based standards to maintain and increase trust in health technologies.

1 See Explanatory Statement to the Public Governance, Performance and Accountability Rule 2016 (Establishing the Australian Digital Health Agency) 2016 Rule: "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 service delivery and health outcomes for the Australian community."

The development of our Framework

The Agency developed its first Clinical Governance Framework in 2017. Since then, it has gone through minor updates and changes as the Agency has matured. After nearly 5 years of implementation, a thorough review of the Framework was initiated at the end of 2021 in partnership with the Australian Commission on Safety and Quality in Health Care. The intention of the review was to enhance principles to better connect across all Agency business areas and be relatable in the context of digital health. The consultation process was led by the Clinical Governance section and included engagement across Agency business areas, internal operational and governance committees and advisory and consumer experts. Formal and informal consultation was also conducted with external clinical governance organisations and independent expert consultants.

CLINICAL GOVERNANCE AT THE AGENCY

Clinical governance underpins the work of our Agency and is one of our key functions under the PGPA Rule (Part 2, section 9(1)(d)), that is 'to develop, implement and operate comprehensive and effective clinical governance, using a whole-of-system approach, to ensure clinical safety in the delivery of the national digital health work program'.

Clinical Governance section

The Agency provides clinical governance assurance to Agency business areas through its Clinical Governance section, which comprises healthcare providers, clinical governance specialists and clinical safety specialists, who assess clinical risks and develop mitigation and management plans. The Clinical Governance section is a single point of entry for the clinical safety service, the Digital Health Adviser service, the partnership with the Australian Commission on Safety and Quality in Health Care and general clinical governance and framework support and inquiries. The Clinical Governance section provides operational oversight and support to the Clinical Governance Committee.

The Clinical Governance section sits within the Clinical Digital Health Governance Standards branch of the Digital Strategy Division, under the executive role of Chief Digital Officer.

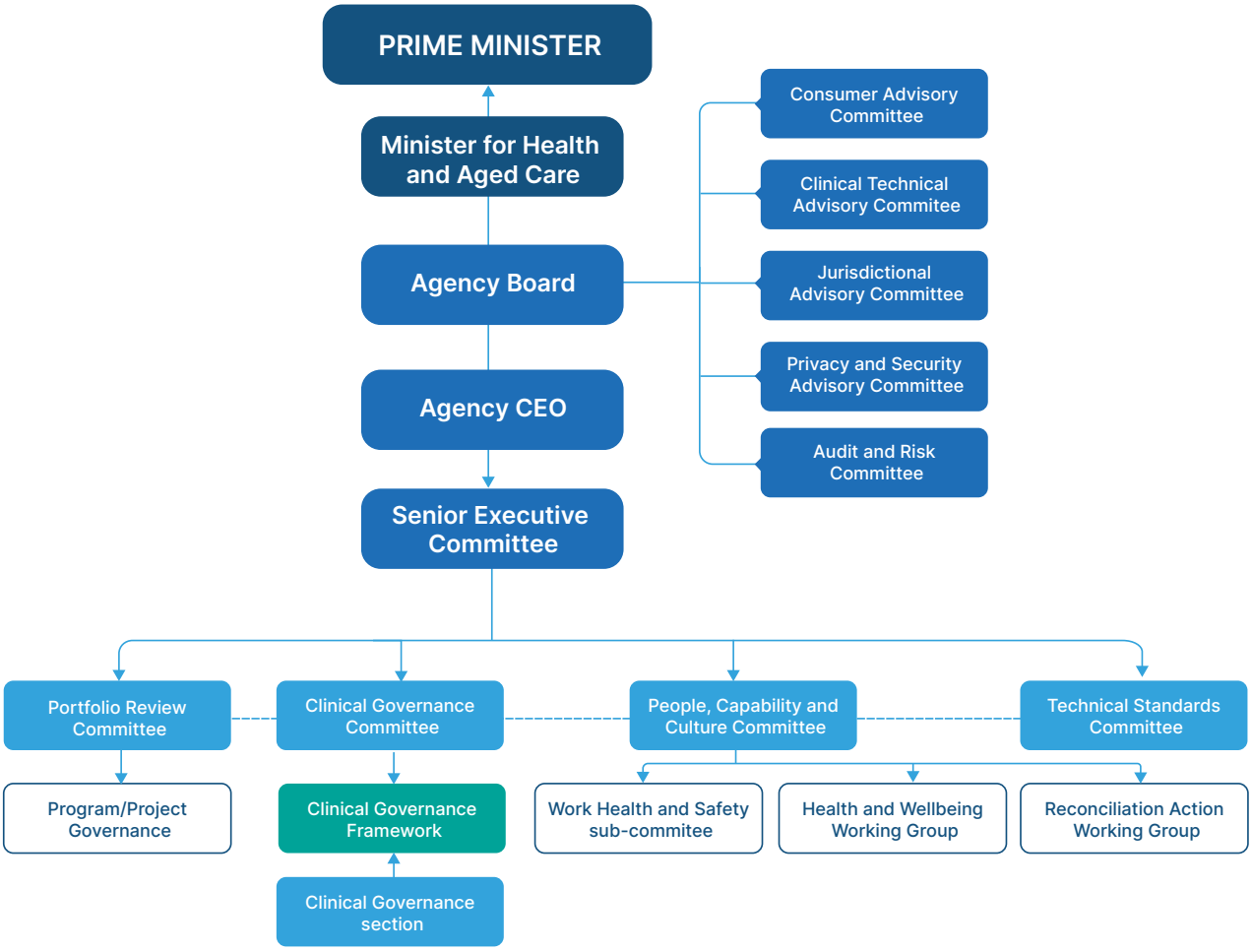
Clinical Governance Committee

The Clinical Governance Committee is an advisory committee that supports the Chief Executive Officer. This committee comprises executive-level staff and senior managers from across the organisation. Membership also includes 2 external clinical experts with diverse clinical backgrounds to provide an informed external perspective. The committee meets monthly and is responsible for ensuring clinical governance is observed in action, is measurable and underpins the Agency's clinical safety, quality and continuous improvement agenda. The Clinical Governance Committee is chaired by the Agency Chief Clinical Adviser.

Broader governance

The PGPA Rule also outlines the required governance structure to support the delivery of clinical governance. Of the 5 committees set out in the PGPA Rule, the Consumer Advisory Committee and the Clinical Technical Advisory Committee have the greater focus on the Agency's clinical governance agenda.

Figure 1: Agency governance and operational structures



Defining clinical governance

Clinical governance at the Agency is the set of relationships and responsibilities established by the Agency between Australian Government departments and our Executive team, Board, committees, staff, partners, consumers and other stakeholders to deliver and continuously improve safe, high-quality products and services. It is the interconnected responsibility of all our workforce and our partners. Our Clinical Governance Framework supports a safety and quality culture that involves a complex collection of leadership behaviours, rules, procedures, monitoring and improvement methods aimed at ensuring better health outcomes.

Clinical governance does not work in isolation but as an integrated component of corporate governance, as shown in **Figure 2**,[2] from the *National Model Clinical Governance Framework*. Clinical governance at the Agency is equally as important as financial, risk and other corporate governance responsibilities. It ensures that our entire workforce – for example, administration support officers, project managers, architects and technical engineers, managers, and members of our executive committees and Board – is accountable to our consumers for ensuring the delivery of products and services that are accessible, clinically safe, person-centred, effective, integrated, of high quality and subject to continuous improvement and support equitable care.

2 Australian Commission on Safety and Quality in Health Care (2017), *National Model Clinical Governance Framework*, accessed 13 January 2023.

Figure 2: Corporate governance responsibilities

Development of our products and services incorporates a comprehensive approach to clinical governance. As the scope of our products and services expands, our evolving, principle-based approach to clinical governance will be vital to the successful implementation, clinical safety and quality of technologically supported healthcare and care services for all Australians. It is critical – not just for our Agency, but for the entire health ecosystem – to continue this evolution as we further embed a strong clinical governance approach within healthcare and care provider organisations.

In the context of our products and services, this Framework ensures the application of clinical governance within our Agency.

Our Framework takes into consideration the *National Model Clinical Governance Framework* and the National Safety and Quality Health Service Standards – in particular the *Clinical Governance, Partnering with Consumers, Comprehensive Care* standards and the *User Guide for Aboriginal and Torres Strait Islander Health*.

Aligning clinical governance with the National Digital Health Strategy

Supporting this Framework is the Agency's vision for a healthier future for Australians through connected health care. We aim to do this by creating a collaborative, person-centred environment to accelerate adoption and use of innovative health technologies.

Our Framework also aligns with the *National Digital Health Strategy*. The strategy has been developed through extensive consultation with consumers, healthcare and care providers, industry partners, organisations and innovators. It is supported by all state and territory governments.

The Framework helps us deliver on our strategic priorities while ensuring clinical safety, quality and continuous improvement of all our products and services.

The Framework complements the Agency's goal to be consistent with:

- the *National Agreement on Closing the Gap*, which aims to address the entrenched inequalities faced by Aboriginal and Torres Strait Islander peoples so that their life outcomes are equitable with all Australians.

- the United Nations Sustainable Development Goal 3, Good Health and Wellbeing ('Ensure healthy lives and promote wellbeing for all at all ages'). In particular, it supports the following targets within this goal:[3]
  - 'Achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all'
  - 'Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks'
- environmental, social and governance considerations, such as human rights (including the rights of Aboriginal and Torres Strait Islander peoples under the United Nations Declaration on the Rights of Indigenous Peoples), clean technology, ethical supply chains, privacy and data security, community engagement, leadership diversity and risk mitigation and management
- the World Health Organization's Global Strategy on Digital Health 2020-2025[4] which shares the global vision 'to improve health for everyone, everywhere by accelerating the development and adoption of appropriate, accessible, affordable, scalable and sustainable person-centric digital health solutions to prevent, detect and respond to epidemics and pandemics, developing infrastructure and applications that enable countries to use health data to promote health and wellbeing, and to achieve the health-related Sustainable Development Goals'.

3 United Nations (n.d.), Sustainable Development Goal 3: targets and indicators, accessed 14 June 2022.
4 World Health Organization (2021), Global Strategy on Digital Health 2020-2025, accessed 13 January 2023.

OUR 5 CLINICAL GOVERNANCE PRINCIPLES

This Clinical Governance Framework applies to our whole workforce. It is underpinned by 5 principles, each of which are equally important to the Agency. These principles enable us to support healthcare and care delivery in Australia through our products and services. They are:

- Leading with our people
- System safety and quality improvement
- Evidence-based practice
- Person-centredness
- Partnership

Figure 3: Clinical governance principles

These principles do not operate in isolation but overlap and together form part of a larger, complex health, technological and social ecosystem within which the Agency operates.

Each team within our Agency will integrate some or all the 5 principles in this Framework through various strategies. The Framework does not prescribe how we will develop, implement or evaluate our clinical governance systems, as this will be dependent on the functions, needs and characteristics of each team. Roles and responsibilities for clinical governance processes and systems shall be clearly documented, managed and accessible for every team throughout the Agency.

Establishing the clinical governance principles is the first part of more detailed ongoing work by the Agency. We are developing intent statements, criteria, actions and examples that will sit under each of the 5 principles. This will ensure the Clinical Governance Framework connects with our Agency workforce and is relevant, actionable and measurable.

PRINCIPLE:
LEADING WITH OUR PEOPLE

Goal: To promote and maintain a workforce and leadership culture that ensures our products and services are clinically safe and of a high quality, in an environment that supports accountability, person-centredness and continuous improvement. We work towards a common goal.

Leading with our people requires effective leadership. Leadership refers to how individuals behave, communicate, interact with and influence others in the context of their role. Leaders may arise from any part of the workforce.

Our Board establishes and exemplifies the culture and language of clinical safety, quality and continuous improvement. This is driven by our Executive team in operations. Our Clinical Governance Committee ensures that the Board's expectations for clinical governance are met in practice, that they are measurable and that they underpin the Agency's approach to clinical governance. We expect our collaborators, partners, stakeholders and other organisations to take a similar approach to clinical governance, which must be person-centred.

Our Agency's Leadership is informed by clinical governance principles and is committed to clinical safety, quality and continuous improvement of our products and services. Leaders are proactive in driving the clinical safety and quality agenda, and this permeates throughout our Agency. Effective leadership is aligned with the Agency's mission, vision and values.

The Agency must ensure that all members of our workforce have the appropriate qualifications, skills, orientation, training, experience, attributes, cultural awareness and competency and oversight to ensure clinical safety and quality in the delivery of our products and services. Specifically, Board members must have relevant skills, experience and knowledge in accordance with Part 4, sections 19(3) and 19(5) of the PGPA Rule.

Our workforce must have an operational understanding of the principles of clinical governance as advocated in this Framework, regardless of whether they have a healthcare or care background, and they should be able to confidently align their skills, training and experience with these principles. The key skills we need for a skilled and effective workforce, now and in the future, are outlined in our Workforce Strategy 2021–2026.

Our workforce uses the principle of evidence-based practice to achieve practical outcomes and to instil confidence and knowledge across the Agency. Clear expectations are set against mutually agreed objectives and timeframes, and projected health outcomes are validated.

Our policies, processes, procedures and systems define the optimal pathway for dealing with clinical safety risks, and the Agency's open culture plays a pivotal role in how we report and manage them.

The Agency also acknowledges that psychological safety is integral to clinical governance. This Framework supports a culture of psychological safety in the Agency, where there is no fear of reprisal or retribution for speaking out, and where errors or near misses can be quickly identified and addressed. The workforce is comfortable sharing their knowledge, ideas, concerns, questions and mistakes in a safe learning environment.

PRINCIPLE: LEADING WITH OUR PEOPLE CONTINUED

Psychological safety also means that we have a transparent, proactive and positive attitude towards reporting. This open culture guides how the people in our workforce think and act in their roles and understand their responsibilities and how the Agency interacts and builds relationships with our partners. A transparent culture is core to our effective and successful operations. This is reflected in the Australian Public Service Values and Code of Conduct in practice.

Further, our Framework is founded on a culture of strong leadership at every level, within clearly defined roles and responsibilities throughout the Agency. Every member of the workforce needs to be heard and encouraged to lead.

Throughout all levels of the Agency's Workforce, our values, attitudes, beliefs and behaviours prioritise clinical safety, quality and continuous improvement. Our Board and Executive team welcome and respect the diversity and uniqueness of individual contributions and ideas of our staff. They acknowledge the impact of individuals' beliefs and behaviours on the design, development and delivery of our products and services, and on the rest of our workforce.

PRINCIPLE:

SYSTEM SAFETY AND QUALITY IMPROVEMENT

Goal: To ensure that clinical safety and quality indicators and clinical and non-clinical incidents are recognised, reported and analysed, and that this information is used to continually improve the products and services provided.

The system safety and quality improvement principle collectively refers to an approach that encompasses clinical safety, continuous improvement and clinical safety risk and incident management.

Implementing this Framework builds confidence that our products and services are safe to use, and that our Agency has a commitment to continuous improvement. An approach of system safety and quality improvement helps us understand and identify how one action, thing or function might impact another and anticipate and prevent unintended consequences, including causing inadvertent harm or other adverse health outcomes through our products and services.

Clinical safety risk and incident management aim to ensure risks are identified and treated and unintended consequences are detected early and immediately addressed and rectified in accordance with the person-centred principle. This approach supports learning and continuous improvement by ensuring review and monitoring of the health, technological and social ecosystem and the effectiveness and impact of individual products and services within that environment.

A whole-of-system approach is consistent with the Agency's function under Part 2, section 9(1)(d) of the PGPA Rule.

System safety

Goal: To understand the potential impact of any action, thing or function on clinical safety, quality and health outcomes outside the boundaries of a focused piece of work within the Agency.

System safety is an integrated approach to clinical safety in health technologies. It recognises the interaction of different components within the whole and the potential impact of this interaction on consumers.

System safety is a method of working that applies integrated systems thinking. It requires us to think about how components of a system interact within, or once they are connected with, healthcare and care systems more broadly – and any potential impact to consumers, as well as our partners.

No matter who we are within the Agency, everything we work on has a broader impact or

PRINCIPLE: SYSTEM SAFETY AND QUALITY IMPROVEMENT CONTINUED

influence across the healthcare and care landscape. Systems that support health technologies are intricate. To provide a seamless and clinically safe experience for consumers, and for healthcare and care providers, we must ensure that systems are interoperable and properly integrated. We develop and evaluate products and services in the context of the entire adaptive, connected health, technological and social ecosystem within which the Agency operates.

We recognise the opportunities for improved clinical safety to be provided by health technologies, but also the potential for unintended clinical safety and non-clinical risks. Some clinical safety risks are clearly understood: for example, risks that exist in paper-based record-keeping may still exist in digital record-keeping. Other risks are unique to health technologies and, at times, are unexpected. Managing identified or emerging risks may require a unique or innovative approach.

When an action, thing or function changes within a system, or within part of a system, we consider and investigate the potential implications for related and connected systems, or other parts of the system. The Agency is proactive in identifying potential and emerging problems. We accomplish this through our principles of person-centredness and collaboration.

Our system safety approach brings a clinical safety focus to all our products and services, and we ensure this by applying a Clinical Safety Management System methodology. As an Agency, and as individuals within the Agency, we promptly identify and manage clinical safety and non-clinical risks and highlight opportunities for continuous improvement across our products and services.

Clinical safety and quality improvement go hand in hand.

Quality improvement

Goal: To improve the quality of health care and care provided to consumers through our products and services on an ongoing and iterative manner.

Quality improvement is a system of regularly and continuously reviewing and refining our processes, products and services to constantly improve them.

A focus on quality and continuous improvement is required to methodically improve our products and services. By standardising processes and structures, quality improvement aims to eliminate unwarranted variation, generate predictable results and optimise health outcomes for consumers, healthcare and care systems and providers.

Quality improvement is continuous and considers the entire life cycle of our products and services. Our Agency goes beyond project management measures to incorporate operational monitoring, maintenance and assurance. We report back to our internal governance committees to demonstrate clinical safety and quality improvement in our products and services to instil confidence in them for all stakeholders.

We measure and evaluate our clinical governance practices so we can be sure that our

PRINCIPLE: SYSTEM SAFETY AND QUALITY IMPROVEMENT CONTINUED

operations enable continuous improvement in the clinical safety and quality of our products and services. To measure improvement, we have Agency-wide systems that:

- identify clinical safety and quality measures and monitor and report performance outcomes
- identify areas for improvement in clinical safety and quality
- implement and monitor clinical safety and quality improvement strategies
- involve consumers, partners and our workforce in reviewing the clinical safety and quality performance of our products and services.

This principle is in line with the Agency's function under Part 2, section 9(1)(d) of the PGPA Rule, which may involve post-implementation review of clinical governance activities and audits of clinical safety[5].

Clinical safety risk and incident management

Goal: To improve the clinical safety and quality of our products and services through systems that detect and prevent scenarios that may result, or have resulted, in an adverse health outcome, as part of systems safety and quality improvement.

Clinical safety risk and incident management collectively refer to identifying, reporting and managing risks and adverse events, or circumstances which create potential adverse clinical events, or near misses.

Clinical safety risks that have been realised are referred to as 'incidents'. Incident management is the Agency's method of addressing incidents, whether clinical or non-clinical, to reduce their impact or potential impact on health outcomes and to improve clinical safety and quality going forward. Incident management is operationalised through the Agency's formal incident management processes and includes systems that identify, report and set out a framework for the prevention and management of incidents.[6]

Incident management is critical for the Agency to manage the clinical safety and quality of our products and services. Our approach is consistent with the *Australian Open Disclosure Framework*, but tailored to the context of health technologies, and we encourage learning from consumer feedback and complaints. Data from incident management enables us to identify opportunities for improvement and potential for innovation in future products and services.

It is critical to be able to monitor, identify, manage and review clinical safety risks and related controls in a systematic manner. This is part of the Agency's safety culture and drives operational improvements.

The Agency operates in a transparent environment. This means that in a supportive and psychologically safe culture, issues and concerns are reported and acknowledged within our Agency without fear of blame. Person-centredness means that healthcare and care providers, consumers and their families and informal carers who express concerns are included in the process of understanding what went wrong and why if there is an incident, and that they are listened to.

5 See Explanatory Statement, PGPA Rule.
6 This is in line with the Agency's functions under Part 2, section 9(1)(d) of the PGPA Rule, as set out in the Explanatory Statement.

PRINCIPLE:
EVIDENCE-BASED PRACTICE

Goal: To ensure our products and services are designed, developed, delivered and continually improved on the basis of effective and appropriate use of data, evidence and existing research to drive clinical safety and quality. In relation to data governance, the best available evidence is used to determine the management of data.

Evidence-based practice in health technologies involves a structured approach to gathering, interpreting, analysing and evaluating internal and external data, insights and existing research to inform the design, development and delivery of our products and services.

The Agency's products and services are informed by evidence-based practice and care models. Evidence-based practice and care models change constantly and rapidly in response to new research, new evidence and data and innovation.

As health technologies evolve, we must keep up through continuous improvement, applying the principles of person-centredness and partnership. We learn from existing and evolving research on emerging technologies, consumer feedback and complaints, and evaluation of incidents (i.e. clinical safety risks that have materialised) to design, develop and deliver products and services that are clinically safe and of high quality. We also actively evaluate our products and services and constantly consider whether improvements can be made. Ongoing evaluation of health outcomes sets benchmarks against which evidence-based practice can be improved.

Health technology advancements and the associated increase in data is enabling the use of machine learning (ML) and artificial intelligence (AI) in healthcare and care. The potential of ML and AI is profound for evidence-based practice. Researchers can use ML and AI to discover more effective ways of delivering healthcare and care services. Healthcare providers can be supported with their clinical decision-making while alleviating time spent finding the relevant information they need. Critical to the success of these emerging health technologies is maintaining trust and ensuring these systems are safe, reliable and understandable in how they work. Clinical governance plays a critical role in building and ensuring trust with the use of emerging health technologies.

When designing, developing and delivering health technologies, we consider consumer journeys and clinical workflows through our principle of partnership. We use contextualised innovation in healthcare or care delivery settings to deliver targeted products and services in accordance with the principle of evidence-based practice to support their ability to optimise health outcomes.

Evidenced-based practice, including the collection of the evidence and any data, must consider Indigenous data sovereignty principles, that is, Aboriginal and Torres Strait Islander peoples' inherent right to govern their communities, resources and Country (including lands, waters and sky). It is the right of Aboriginal and Torres Strait Islander peoples to exercise ownership over Indigenous data. Ownership of data can be expressed through the creation, collection, access, analysis, interpretation, management, dissemination and reuse of Indigenous data.[7]

7 Australian Institute of Aboriginal and Torres Strait Islander Studies (2019), *Delivering Indigenous data sovereignty*, AIATSIS, accessed 12 November 2022.

PRINCIPLE:
PERSON-CENTREDNESS

Goal: To partner with consumers and ensure all our products and services are easy for consumers to access, use and understand, while supporting them in achieving their desired health outcomes. Further, the Agency takes into consideration preferences of consumers and the Australian community as to how their data is managed and used in line with the concept of data sovereignty.

Person-centredness means always maintaining our focus on consumers and listening to their needs, goals, values, preferences and experiences to ensure the design and delivery of clinically safe, quality products and services. We prioritise consumers' needs, goals, values, preferences and experiences in the context of the circumstances (including the task at hand) and place them at the centre of the design development and decision-making process.

Consumers come from a wide range of backgrounds, including Aboriginal and Torres Strait Islander peoples, individuals and families from culturally and linguistically diverse backgrounds, people with a wide variety of lived health and care experiences and people with varying levels of health and digital literacy. Working with consumers must include the practice of cultural safety and consider the social emotional and cultural wellbeing of the whole community.

We work with consumers on health technology initiatives to optimise their health outcomes and realise their goals and preferences. Consumers are involved in our design and development teams so that the Agency can help close that digital health literacy divide to improve usability and achieve desired health outcomes.

We also consider the needs of our partners. In this context, person-centredness means designing, developing, implementing, evaluating and maintaining processes to support the principle of partnership with consumers to inform the decisions of our partners throughout a program or project and the life cycle of our products and services.

Our products and services, and those of our partners, enable various methods of sharing and accessing healthcare and care information, so that consumers can partner with their healthcare and care providers. Every member of our Agency's workforce contributes to the delivery of products and services used and how they are applied throughout a healthcare and care journey. As a result, the Agency and our partners can shape the consumer experience, in partnership with consumers.

PRINCIPLE: PARTNERSHIP

Goal: To ensure our products and services, and the processes associated with them, align with the needs and wants of consumers, supported by the skills and expertise of our partners. Further, input is sought from all areas and skillsets of the Agency when designing and evaluating how data is managed and used and in line with the concept of data sovereignty.

Partnership involves working with consumers and our partners in the design, development and delivery of our products and services.

The Agency puts people at the centre of the design, development and delivery of our products and services. It is how we ensure a focus on the needs and wants of consumers, while harnessing the skills and competencies of our partners – so that our products and services, and the processes associated with them, are fit for purpose. The principle of partnership is also in line with the Agency's obligations under Part 2, section 9(2) of the PGPA Rule and the *Closing the Gap Partnership Agreement*.

Genuine partnership supports shared decision-making with Aboriginal and Torres Strait Islander peoples in the design, implementation, monitoring and evaluation of the Closing the Gap Framework, which is essential to closing the gap in life outcomes between Aboriginal and Torres Strait Islander peoples and other Australians.

Partnership requires collaboration and includes incorporation of lived experience, which influences the design, development and delivery of our products and services. This means that we actively seek to understand how our products and services affect the experience, context, needs, behaviours and workflows of those who use them. This allows us to clearly describe the problem we hope to solve. Without this understanding, our work may result in unusable, potentially unsafe or ineffective products and services that introduce avoidable clinical safety risk or undermine quality.

Partnership provides valuable insights into how our products and services would work for consumers and partners, from all perspectives. It contributes to a positive consumer experience, addresses potential clinical safety and quality issues and ensures consistency with clinical and non-clinical workflows.

Education and training for our products and services must meet the needs of our consumers and partners, assisting them in understanding how to use our products and services to achieve better health outcomes. The Agency appreciates the variety and uniqueness of individual partners and consumers who use our products and services, as well as the insights they bring to our design, development and delivery process.

Understanding our consumers' and partners' digital health literacy levels is critical to meeting their needs. The principles of person-centredness, partnership and evidence-based practice ensure that we deliver products and services that are beneficial to our consumers, and that they can make informed decisions without putting an additional burden on themselves or the healthcare and care system.