

CLINICAL GOVERNANCE PERFORMANCE REPORT



Australian Government
Australian Digital Health Agency



Australian Digital Health Agency

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MESSAGE FROM THE CHAIR

Dear Ms Cattermole PSM,

On behalf of the Clinical Governance Committee, I am pleased to submit our Clinical Governance Performance Report for the 2021–22 period.

This report was endorsed by the Agency Board on 8 December 2022 and approved for presentation to you.

I commend this report to you as a record of our achievements.



A handwritten signature in black ink that reads "Steve Hambleton". The signature is written in a cursive, flowing style.

Dr Steven Hambleton AM
Chair
Clinical Governance Committee
14 December 2022

MESSAGE FROM THE CHIEF EXECUTIVE



On behalf of the executive team, I am pleased to introduce the Australian Digital Health Agency's *Clinical Governance Performance Report 2021–22*.

This report represents my commitment to our values of transparency and accountability for clinical governance in action across the Agency.

As we celebrate the Agency's successful track record in building national digital health capabilities, we also acknowledge the important contribution our healthcare experts make to the safety, usability and value of My Health Record and our other products and services for Australian health care, digital partners and the community.

I thank our Clinical Governance section and Clinical Governance Committee for their work in developing this report. It is a testament to the importance of clinical governance in digital health, showing how the My Health Record system and other products and services we deliver to the community continue to improve health outcomes and experiences.

A handwritten signature in black ink, appearing to read 'Amanda Cattermole', with a stylized flourish at the end.

Amanda Cattermole PSM
Chief Executive Officer
Australian Digital Health Agency
23 December 2022

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SUMMARY AND HIGHLIGHTS

Clinical leadership is essential in any health-focused organisation and is critical when delivering digital health technologies used at the point of care. The Australian Digital Health Agency is tasked with developing, implementing and operating comprehensive and effective clinical governance, using a whole-of-systems approach to ensure clinical safety in the delivery of the national digital health work program.

This is an overview report on clinical governance performance within the Agency. Its purpose is to demonstrate how the Agency has met its obligations under the Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016 (Cth) Part 2, 9(d).

In 2021–22, the Agency continued to embed clinical governance across its activities and products. Challenges in the healthcare sector brought about by the COVID-19 pandemic have accelerated many changes in digital health delivery and emphasised the importance of clinical governance.

Highlights for 2021–22	
Planned activities	Achievements
 <p>The Agency implemented a new committee structure and decision-making process to strengthen clinical governance. These changes included establishing the Clinical Governance Committee (CGC) as one of our initial 3 principal committees and the embedding of clinical governance into the Enterprise Portfolio Management Office (EPMO) processes to effectively hardwire clinical governance and assurance into program and project delivery.</p>	<ul style="list-style-type: none"> • The CGC met 11 times in the period. • Membership was expanded to include external clinical expertise. • Various teams across the Agency presented to the committee presenting 19 different pieces of work. • EPMO processes now specifically identify engagement with clinical governance personnel at Gate 1.
 <p>Clinical governance is well established as a critical factor in Agency activities.</p>	<p>Clinical governance has underpinned key pieces of Agency work designed to improve the sharing of information throughout the healthcare sector. This included work in the aged care sector and NSW local health districts and the development of the <i>National Healthcare Interoperability Plan</i>, which will be released early in 2023.</p>

Highlights for 2021–22 continued

Planned activities	Achievements
 <p>The COVID-19 pandemic increased both consumer need for health information and the sector’s need to collect health data, while simultaneously reducing face-to-face contact. Together, these factors have driven an increase in digital health initiatives, including tracking vaccination efforts and electronic prescribing.</p>	<p>Clinical governance has been an integral part of development in these areas, ensuring that clinical safety and assurance are considered and included in all changes. The Agency has also supported health literacy training programs, which have been delivered through community groups and libraries, to support the broadening use of digital health initiatives.</p>
 <p>The My Health Record system is a central pillar of the Agency’s work and delivery of digital health in Australia. Clinical governance has contributed to ongoing My Health Record system updates and initiatives, including improvements to the mobile interface for healthcare providers and consumers.</p>	<ul style="list-style-type: none"> • Completion of 9 major My Health Record system releases and completion of clinical safety go-live reports. • Participation by the Clinical Safety Service team and digital health advisers (DHAs) in multiple project co-design teams, steering committees and programs of work.
 <p>The Agency conducted a continuous improvement activity focused on how we apply clinical governance to our work. This includes a focus on the Clinical Governance Framework to:</p> <ul style="list-style-type: none"> • fit better within the context of digital health and be more relatable to our staff • bring greater visibility to clinical safety methodology • promote safety-first thinking across the organisation • provide greater engagement with the Agency DHAs with a focus on quality, efficiency and effectiveness of service delivery. 	<p>The Clinical Governance section initiated a significant program of work to integrate clinical governance and systems-safety thinking across the Agency. This has included:</p> <ul style="list-style-type: none"> • review and refresh of the Clinical Governance Framework • review of the methodology that underpins clinical safety analysis and an approach that will be more contemporary • rebrand of clinical reference leads to DHAs and review to ensure we have the right expertise engaged in the right piece of work at the right time • establishment of a memorandum of understanding to renew the partnership with the Australian Commission on Safety and Quality in Health Care.

1 CLINICAL GOVERNANCE IN THE AUSTRALIAN DIGITAL HEALTH AGENCY

The Australian Commission on Safety and Quality in Health Care describes clinical governance as the set of relationships and responsibilities established by a health service organisation to deliver safe and high-quality health and care. It relates to clinical safety, quality and continuous improvement.¹

Digital health services and technologies are changing how health and care are provided and experienced globally. Digital health offers opportunities to increase the depth and breadth of information availability at the clinical interface, create efficiencies and reduce errors, all of which will improve clinical safety and quality in health and care. These opportunities come with challenges that require careful consideration and navigation to ensure they meet the intended outcomes for consumers and their healthcare providers. To maintain trust in digital health, it is critical that digital health implementations avoid or mitigate potential clinical safety hazards and risks that may arise in a consumer's healthcare journey.

Constant vigilance of our broader digital health system, supported through governance structures and a culture of safety, is required to build, deliver and maintain oversight and management of the unique challenges in clinical safety and quality that digital health presents. These challenges extend beyond technology to the whole-of-system implications of digital enablement.

1.1 Our purpose

While the Agency is not a provider of direct clinical care to the Australian community nor a regulator of digital health, it has a responsibility to ensure clinical safety and quality improvement throughout the development of the products, services and infrastructure it manages.

Part 2 (9d) of the Agency's establishing legislation states that a core function of the Agency 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.

The Clinical Governance section of the Agency sits within the Clinical and Digital Health Standards Governance branch under the direction of the Agency's Chief Digital Officer. The section also works in close collaboration with the Agency's Chief Clinical Adviser.

¹ Australian Commission on Safety and Quality in Health Care (2021) [Clinical Governance Standard](#), accessed 12 January 2023.

The section's responsibilities include:

- planning and delivering clinical governance, articulated in the Clinical Governance Framework and supported by the Clinical Governance Committee (CGC)
- delivering clinical governance leadership, education and advice on digital health initiatives to ensure systems and products are fit for purpose in health and care
- providing clinical safety analysis, advice and assurance in the design, build and implementation of systems and products to support the delivery of clinically safe products and services for consumers and healthcare providers
- oversight of the partnership agreement between the Agency and the Australian Commission on Safety and Quality in Health Care
- service provision of real-world healthcare providers with digital health expertise into the design and development life cycles of our Agency products and services.

Clinical governance is engaged in the Agency's life cycle activities of digital health – at the core of everything we do – from product development to operations and incident management.

The design and delivery of the My Health Record COVID-19 dashboard provides a good example of how the section operates in practice. The dashboard development involved both Clinical Safety Service team representatives and 4 digital health advisers (DHAs), formerly known as clinical reference leads (CRLs), as active participants in the project's core design team. Advice from DHAs informed the consumer vaccination journey and what health information was important to vaccination providers.

The Clinical Safety Service team identified hazards that could affect consumer health outcomes and whether clinical safety objectives were met. This input was considered by the Agency Experience and Service Design team working collaboratively with other experts. User testing with consumers from different backgrounds and experiences refined the dashboard so it was easy to navigate and understand.

The outcome of this collaboration was that the COVID-19 dashboard aligned with up-to-date health advice and met the needs of consumers in their vaccination journey. The CGC reported these insights and outcomes to broader Agency representatives, promoting the clinical governance principles applied.

1.2 Consumer and stakeholder engagement

The Clinical Governance section works closely with consumers and stakeholders to ensure their input is used to benefit Agency products and services and to strengthen the clinical governance advice provided across the Agency.

The Partnerships, Education and Clinical Use branch is responsible for managing partnerships with key stakeholders and for providing education on digital health technologies for healthcare providers and consumers. The branch ensures that all relevant stakeholder groups are consulted on key work items. It also provides access to consumer advisers who give feedback

and input into projects being delivered across the Agency. This ensures, for example, that digital health literacy programs for consumers align with healthcare provider programs and that terms are commonly understood. The key focus is to support positive clinical outcomes and help consumers take an active role in managing their own health and care.

The Clinical and Digital Health Standards Governance branch is a key stakeholder of the Partnerships, Education and Clinical Use branch. It provides additional subject-matter expertise and assurances that programs and projects are meeting a variety of needs. This includes a service that enables access to health sector experience through the DHAs. The DHA service has been in place for over 10 years, being first established under the National E-Health Transition Authority (NEHTA). The DHAs are experienced in digital health. They bring their everyday health industry experience to support the Agency in design, development and implementation of clinically safe, high-quality, useful and usable products and services. In addition, as advocates for the Agency and the products and services it delivers, DHAs also provide a positive representation of engagement between the Agency and the healthcare provider community.

Teams across the Agency can obtain direct clinical feedback and input into the work they do through the DHA service. State and territory health departments have been offered access to our DHAs for contracted projects, such as the inclusion of a DHA on a Victorian Department of Health Clinical Advisory Group.

The Partnerships, Education and Clinical Use branch works with the Clinical Governance section to ensure that clinical governance advice and perspectives are captured in Agency communications, and that consumer input is also used to improve clinical governance efforts.

Consumer engagement is essential to contribute to the effectiveness of many core clinical governance activities related to, for example:

- community awareness of COVID-19 pathology results in My Health Record
- use of My Health Record in aged care (see section 3.1.2)
- use of electronic prescriptions in vulnerable communities
- communications and marketing campaigns for the Australian community.

The community engagement team liaises with various consumer groups, such as:

- Consumers Health Forum of Australia
- Mental Health Australia
- National Aboriginal Community Controlled Health Organisation
- Federation of Ethnic Communities' Councils of Australia
- Council on the Ageing Australia
- Carers Australia
- Advance Care Planning Australia
- LGBTIQ+ Health Australia
- National Rural Health Alliance.

The Agency engaged with multiple external stakeholders in addition to those listed above to ensure we had the right expertise collaborating on the design and development of our products and services. These included the state and territory health departments, software vendors, healthcare providers and organisations, peak bodies, the national infrastructure operator and other government agencies such as the Australian Commission on Safety and Quality in Health Care.

1.3 External assurance

Since 2012, the Australian Commission on Safety and Quality in Health Care partnered with the Agency, providing valuable contributions that helped to shape the My Health Record system and other major products and services developed by the Agency to date.

In November 2021, the Agency renewed its longstanding partnership with the Australian Commission on Safety and Quality in Health Care through a memorandum of understanding (MoU). The MoU articulates the importance of the organisations' roles in promoting safety and quality in digital health and, ultimately, in facilitating better health outcomes and experiences for Australians. The arrangement provides for ongoing collaboration, including meetings between the chief executive officers twice each year. This collaborative approach aims to support the 2 agencies' shared vision of effective clinical governance and clinical safety and quality of the national digital health work program.

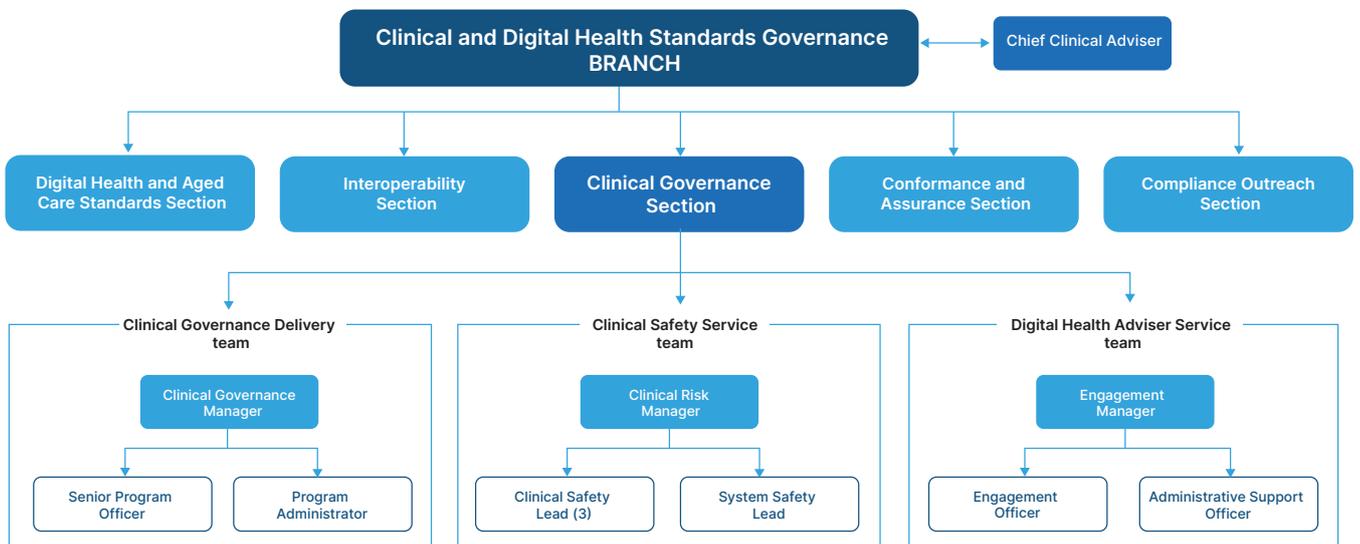
2 CLINICAL GOVERNANCE SECTION 2021-22

The Agency's clinical governance program is delivered at all levels of the Agency's operations. The Chief Clinical Adviser supports the executive and the clinical governance section and chairs the CGC (see section 2.2.1).

The key elements of the Agency's clinical governance function are delivered by the Clinical Governance section in 3 teams (Figure 1):

- The Clinical Governance Support team leads work on the broader clinical governance approach. The team stewards the Clinical Governance Framework, supports the operations of the CGC and coordinates external assurance activities.
- The Clinical Safety Service team provides clinical safety assurance and analysis across Agency products and services through applying the Clinical Safety Management System (CSMS).
- The Digital Health Adviser Service team manages the engagements, relationships and associated processes that integrate real-world healthcare provider expertise into the Agency's work.

Figure 1: Structure of the Clinical Governance section



2.1 Updates to our structures and processes

In 2021, the Agency implemented a new committee structure and decision-making process following a comprehensive review of the Agency's organisational and governance structures.

Changes to structures included:

- establishing the CGC with focused terms of reference (TOR) to ensure clinical governance is embedded across the Agency. The committee membership includes 2 independent clinical advisers to provide an external assurance perspective on matters brought to the committee.
- establishing the Enterprise Portfolio Management Office (EPMO), designed to lead and embed an enterprise-level, integrated delivery focus and controls – such as defining clinical governance engagement touchpoints for project managers – so that clinical governance has effective and timely influence in the delivery of programs and projects.

Changes to processes included:

- reporting by the Clinical Governance section to the EPMO to enable it to assess engagement with clinical governance against Agency programs and projects. This reporting provides a measure of the projects and programs assessed as requiring services from the Clinical Governance section. This includes those where clinical governance is actively engaged or where a resource could be allocated.
- a review of the CSMS to ensure it is contemporary and fit for purpose to support a scalable service. The review enabled better support for stakeholders in the Agency to monitor for clinical safety issues, which can be referred to the team of specialists when necessary.
- a review of the DHA service to ensure a highly engaged and informed DHA group that contributes to implementing the Agency's annual work plan and Australia's National Digital Health Strategy – Safe Seamless and Secure.

These structural changes to the integration of clinical governance throughout the Agency are intended to embed the Agency's Clinical Governance Framework more deeply.

2.2 Clinical Governance Support team

The Clinical Governance Support team provides education, advice and support regarding clinical governance to Agency staff. This team also supports the Agency's CGC (see section 2.2.1) and the Agency's Chief Clinical Adviser, Dr Steve Hambleton AM. Dr Hambleton is a Brisbane-based general practitioner and was the final Chair of NEHTA. He has extensive involvement with digital health at a national level.

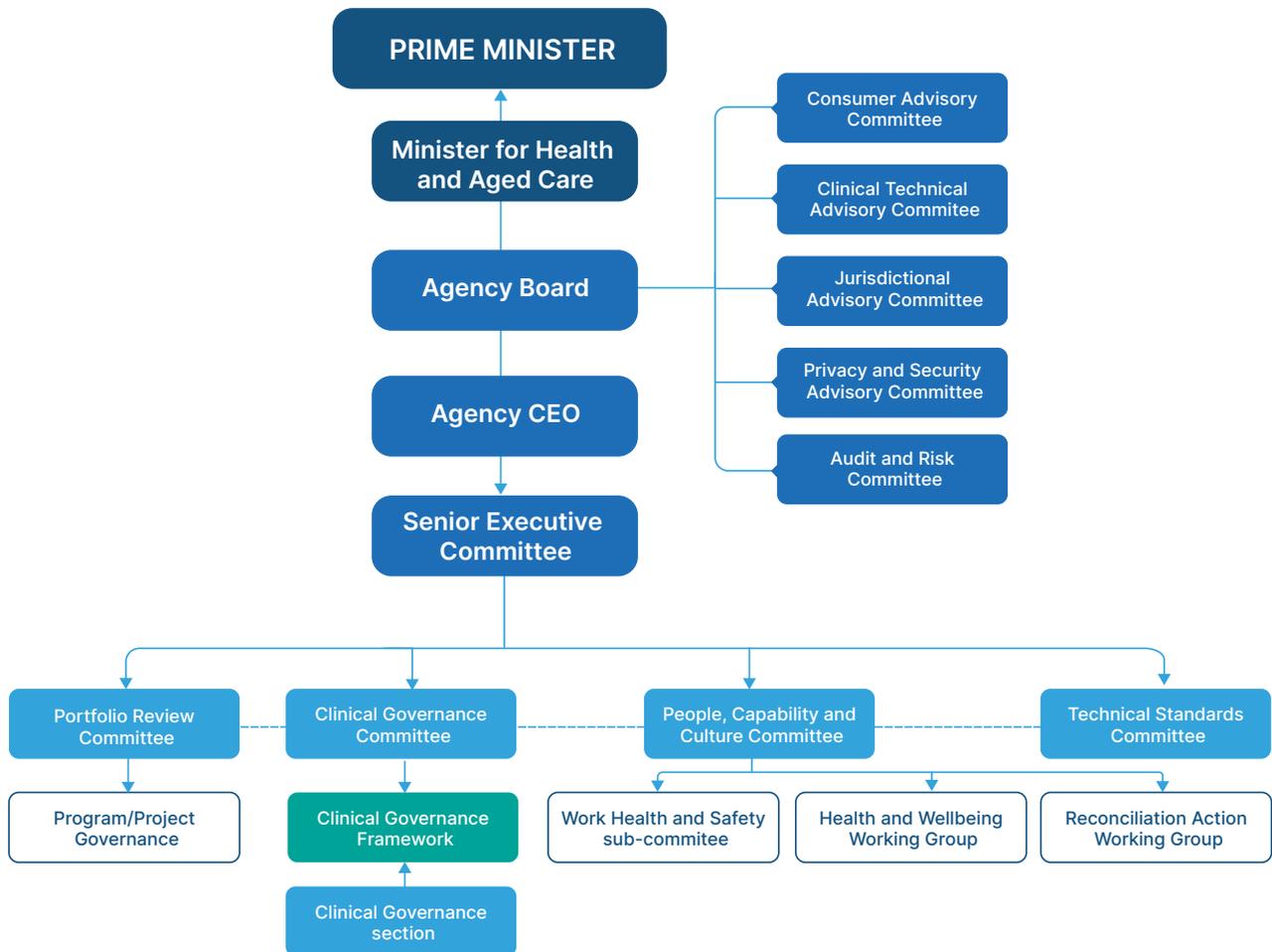
2.2.1 Clinical Governance Committee

The CGC is responsible for ensuring clinical governance is observed in action, is measurable and underpins the Agency's safety, quality and performance agenda. The CGC also provides advice to decision-makers on clinical governance across the Agency.

The CGC began operation in May 2021 and is chaired by the Agency Chief Clinical Adviser. Membership is drawn from senior executives and leaders and external clinical experts. In September 2021, the CGC welcomed 2 new independent clinical members, Associate Professor Amanda Walker (palliative care physician, Clinical Director Australian Commission on Safety and Quality in Health Care) and Dr Helen Almond (lecturer in clinical governance with extensive experience in nursing).

At every meeting, the committee receives reports from the Incident Management team, the Clinical Safety Service team and the EPMO, so the members have oversight of current risks and issues related to clinical safety and quality. The CGC may call on subject matter experts (internal or external) and guests to attend meetings to contribute and progress matters. Figure 2 demonstrates the positioning of the CGC within the broader Agency governance structure.

Figure 2: Agency governance structure



2.2.2 Performance and outcomes

The CGC provided oversight on activities related to clinical governance across the organisation, including the reviews initiated within the Clinical Governance section.

Examples include:

- review of the Clinical Governance Framework by the Australian Commission on Safety and Quality in Health Care
- review of the DHA service
- review of the CSMS
- clinical safety insight report into My Health Record releases
- clinical safety reviews, consolidated action plan and integration into the Agency operational teams.

In November 2021, the committee completed a 6-month review of its operation, as part of the Agency's broader committee governance structure review. Changes to the membership and operations provided a broad range of skills and perspectives to ensure the committee remains contemporary and delivers against its TOR. The new TOR for the committee were adopted in March 2022 after approval by the Agency Chief Executive Officer.

2.3 Clinical Safety Service team

The Clinical Safety Service team consists of 5 specialised roles filled by staff with healthcare provider backgrounds and expertise in health technologies. This team actively contributes to developing Agency products through managing and resolving clinical safety and quality risks and issues. The team provides clinical safety advice in consultation with DHAs and Agency stakeholders as well as through collaborative engagement in meetings of project working groups.

The Clinical Safety Service team provides advice and assurance for new and existing products and services by applying methodology under the CSMS. This system is made up of procedures, processes, templates and guidelines and guides the identification of clinical safety hazards common in digital health such as:

- incorrect information, where health information in the digital record does not match the healthcare recipient's medical history; this is a potential consequence of misidentification, human error or a system defect
- misleading or ambiguous information, where health information in the digital record may be misleading or ambiguous; this is a potential consequence of human error, a system defect or errors in implementation
- loss of information, where health information intended for sharing may not be shared because of failures in meeting agreed standards or interoperability requirements, implementation issues, expired authentication or system outages or degradation
- context of health information is misunderstood, not understood, not easily understood, not maintained, is hidden or is unable to be determined.

The CSMS supports aspects of the overarching Clinical Governance Framework by guiding the identification, assessment and management of clinical safety hazards and risks in digital health.

2.3.1 Performance and outcomes

The Clinical Safety Service team reports monthly to the CGC to outline clinical safety activities undertaken to assure the safety of the Agency's portfolio of products and services.

During 2021–22, the key clinical safety activities included:

- My Health Record releases and changes, including the COVID-19 dashboard and changes to align immunisation information to current health advice
- classification of clinical documents in My Health Record to improve discoverability of health information
- clinical safety assurance of the 'my health' app through design, development and testing
- embedded support and clinical safety advice on programs focused on aged care, diagnostic imaging and medicines safety
- clinical safety assurance of the National Infrastructure Modernisation (NIM) program activities, including rehosting the My Health Record database, renewing the information exchange gateway and upgrades to support FHIR® capability.

The CGC was provided with monthly tracking of outcomes and the risks of these activities, along with clinical safety assurance reports. These give an overview of the identified clinical hazards and how they are managed to ensure that the Agency releases products that are safe for consumers in health and care.

2.4 Digital Health Adviser Service team

The Agency has maintained a group of 49 DHAs, engaged through an AusTender procurement process in 2019. DHAs are expert advisers who are healthcare professionals from across the sector with contemporary experience in clinical practice and expertise in digital health subject matter.

The DHA service is central to the work of the Agency, particularly clinical governance. DHAs are respected contributors to the clinical safety and quality of Agency products and services. Our DHAs provide valuable contributions and real-world experience to the Agency product and project teams. The DHAs also play an important role in promoting the My Health Record system and digital health more broadly to their colleagues and the wider community.

2.4.1 Performance and outcomes

DHAs undertook several important activities to support implementation of the Agency's work program and the National Digital Health Strategy. For example, DHAs represent their clinical and healthcare specialty as part of the core design team for specific product development, such as improvements to the My Health Record system. They actively contribute their clinical knowledge and suggestions for product design that align with clinical workflows.

DHAs also actively support the adoption and integration of digital health tools into clinical use, including My Health Record and electronic prescriptions. DHAs contribute to developing education and training materials, co-present at peer-to-peer educational events and speak at national conferences and events that target healthcare providers and consumers.

The DHAs were involved in multiple areas of work, including:

- the Aged Care Program (see section 3.1.2)
- the National Goals of Care Collaborative (which developed the National Guidelines²)
- research and insight projects focused on primary care, aged care and My Health Record
- incident management
- committee representation
- several marketing and media campaigns.

An example of this DHA engagement in practice is the fast-tracking of the electronic prescribing project during the COVID-19 pandemic (see section 3.2.2). This project demonstrated how Agency work areas, the Clinical Safety Service team and DHAs come together to integrate clinical governance. Several general practitioner and pharmacist DHAs were significant contributors to the rollout of this important and time-critical work.

² Australian Digital Health Agency (2021) [National Guidelines: Using My Health Record to store and access advance care planning and goals of care documents](#), National Goals of Care Collaborative, accessed 12 January 2023. Membership detailed in Appendix I – accurate at the time of writing.

3 ACTIVITIES SUMMARY 2021–22

The ability of digital health technology to record and share accurate and potentially life-saving information is key to making healthcare delivery in Australia safer and more efficient. The Agency's whole-of-system approach sees clinical governance embedded through the life cycle of product and service delivery.

In 2021–22, clinical governance at the Agency continued to evolve in line with Agency priorities in the context of the overall health landscape. The Clinical Governance section continued to work across the Agency and contribute to ongoing activities and programs, while working to accommodate new opportunities and partnerships with the Australian Government Department of Health and Aged Care, state and territory health departments and industry.

3.1 Supporting information sharing

Accurate, up-to-date information supports the delivery of high-quality health and care. A goal for the Agency is ensuring that information can be shared easily between healthcare providers and with consumers across platforms while aligning with clinical governance principles.

3.1.1 The Connecting Australian Health Care – National Healthcare Interoperability Plan

Interoperability is a strategic priority in Australia's National Digital Health Strategy. The objective is connected care in Australia where systems enable the sharing and access of health information when and where it is needed.

Australia has systems in place to enable interoperability, such as national healthcare identifiers. We continue to make progress as shown by the rapid national uptake of electronic prescribing.

However, easily sharing meaningful information between clinical systems is yet to be fully realised in Australia. Healthcare providers see this as the major barrier to using digital health to improve health and care.

Following national consultations in 2019 to inform interoperability principles and priorities, the Agency worked with state and territory health departments to develop a draft Connecting Australian Health Care – National Healthcare Interoperability Plan, which was released for consultation at the end of 2021. The final plan will be released in 2023. Five priority areas have been identified through the stakeholder consultations: identity, standards, information sharing, innovation, and benefits.

Clinical governance played an integral role in the development of the plan, to ensure alignment with the Clinical Governance Framework. This included routine feedback through workshops, webinars and other forums and reviewing drafts of the plan as it was developed. The DHAs played a key role in prioritising digital health initiatives that would best progress interoperability in the Australian healthcare system; this shaped the roadmap for interoperability.

The Interoperability team will continue to engage with and draw on the expertise of the Agency's panel of DHAs.

3.1.2 Aged care transfer summary

The Agency is supporting the Australian Government Department of Health and Aged Care in implementing the government's response to the Royal Commission into Aged Care Quality and Safety, specifically, recommendations 66 (b) and 68. These recommendations intend to improve the transition of care for residents between health facilities and support the universal adoption of digital technology and My Health Record in the aged care sector. The Agency has established a dedicated Aged Care Program to coordinate implementation of the recommendations.

The first key element of the Aged Care Program supported by stakeholders and our DHAs is to deliver an aged care transfer summary (ACTS) and to include it in My Health Record. This is the primary mechanism to digitally capture and share relevant health information (e.g. allergies, current medications, clinical profile/status) when a resident of an aged care facility is transferring to another health facility such as a hospital.

With relevant and accurate information being available through the ACTS, healthcare providers will be able to make informed decisions about the continuity of care for that resident.

The ACTS project harnessed clinical input and leadership through:

- consultations and engagement of DHAs with related industry expertise and experience at each stage of this project
- regular engagement with and feedback from aged care peak bodies and industry
- meetings of the Aged Care Digital Advisory Group³ to provide advice on project updates and outcomes.

The ACTS project is also considering and managing clinical safety through:

- embedding a clinical safety expert in the project working groups
- exploring clinical safety considerations with DHAs, such as incorporating information on advance care planning and medication administration
- engaging DHAs with experience and service design teams to validate clinical use cases and criticality of clinical information requirements
- engaging with state and territory health departments and industry to confirm and validate clinical information requirements.

3.2 Increasing digital health use

In 2021, the development and introduction of digital health innovations delivered to Australians accelerated markedly. This occurred when it was needed most – triggered by the COVID-19 pandemic.

³ The Agency established the Aged Care Digital Advisory Group as a representative panel of stakeholders from Australia's aged care industry to provide independent advice to the Agency's Aged Care Program. Co-chairs include a consumer, clinician and industry representative. Membership consists of software, medical, nursing, consumer and industry peak representatives including state and territory health departments and the Department of Health and Aged Care. There are 27 members who meet every 2 months.

3.2.1 Pandemic response

As a result of the impact of the COVID-19 pandemic, Australians are now experiencing what it means to have a better connected healthcare system. By 30 June 2022, more than 100 million telehealth consultations and 65 million electronic prescriptions had been provided.

Clinical governance support was provided to Agency teams that partner with state and territory health bodies and educate consumers, vendors and healthcare providers and that partner with state and territory health bodies to deliver clinically safe digital health systems across Australia.

Clinical governance was provided through:

- clinical safety and clinical governance reviews of digital health literacy programs for consumers and healthcare providers before 'go live', with a focus on supporting positive clinical outcomes and experiences
- DHAs testing or providing input into pilot programs or projects
- the Aged Care Digital Advisory Group capturing and discussing key clinical and consumer insights into the development and ongoing management of the program.

3.2.2 Fast-track of electronic prescribing during the COVID-19 pandemic

Electronic prescribing gives prescribers and their patients flexibility when issuing and filling prescriptions. Patients can still choose which pharmacy they attend to fill their prescription and can use either electronic prescriptions or traditional paper prescriptions.

The Agency delivered the technical framework to help clinical software systems create, collect and store electronic prescriptions. Agency DHAs played a key role in developing this technical framework.

The Agency convened the Electronic Prescribing National Change and Adoption Working Group, which includes DHA clinical representation, to coordinate messaging to fast-track the implementation of electronic prescribing. The Electronic Prescribing National Change and Adoption Working Group had representation from across the primary care sector, including medical software vendors, pharmacists and general practitioners. The meetings provided a direct pathway from health practitioners and software support teams back to the Agency and the Australian Government Department of Health and Aged Care on key risks and issues, as well as input and advice on the implementation plan and staged rollout.

The Agency also delivers the conformance profile for electronic prescribing, which manages key risks related to the transition from paper to electronic prescriptions. Software developers who wish to build products that support electronic prescribing are required to have their software assessed against the conformance profile. As of 30 June 2022, 82 versions of software products were conformant to the electronic prescribing technical requirements. These software products enable prescribers, dispensers and consumers in Australia to have the option of safe and secure electronic prescriptions. At least 98% of community pharmacies had dispensed an electronic prescription.

Clinical governance was integrated into electronic prescribing through:

- clinical considerations and clinical safety advice provided in developing the technical framework and fast-track rollout
- engagement of internal and external stakeholders in a review and update of conformance test specifications
- robust processes for managing clinical risks, incidents and enquiries by the Medicines Safety program, Clinical Safety Service team, Conformance and Assurance team and DHAs
- engagement with consumers to monitor user satisfaction with electronic prescribing.

In addition to providing support for the adoption and integration of My Health Record into clinical use, DHAs contributed to education and training and technical materials to support uptake of electronic prescribing. Crucially, DHAs connected the Agency with other practitioners and consumers who provided case studies and examples of the impact of electronic prescribing to successfully promote adoption across the sector.

3.2.3 Digital health literacy for consumers

Low health literacy is associated with less use of preventive health and care services, increased hospitalisations and use of emergency departments and a higher economic burden for treatment.⁴ Finding ways to empower consumers to use digital technologies to support their healthcare needs is an important aspect of the Agency's work.

The Agency partnered with the Good Things Foundation to help deliver our Consumer Digital Health Literacy Program.⁵ The program is designed to improve people's uptake of and confidence in using My Health Record, supporting them to gain the essential digital skills and confidence to manage their health and wellbeing.

3.3 Improving digital health infrastructure

Developing technology to support health and care must look beyond technical requirements to embed clinical governance and meet user needs. Clinical governance is an integral part of improving applications and infrastructure.

3.3.1 Next-generation mobile applications for consumers

Engaging with Australians via mobile applications and providing vital health information has become increasingly important in response to the COVID-19 pandemic.

My Health Record is a secure digital place to store health information, including vaccinations, prescriptions and emergency contacts. It enables Australians to easily share health information across providers. My Health Record was launched in July 2012 (then called Personally Controlled Electronic Health Record) and has evolved rapidly in response to user needs, technological capacity and specific events.

⁴ Australian Commission on Safety and Quality in Health Care (2014) [Health Literacy: Taking action to improve safety and quality](#), accessed 12 January 2023.

⁵ Australian Digital Health Agency (n.d.) [Digital Health Learning: for everyone](#) [Course], accessed 12 January 2023.

Since 2016, third parties have been able to build products that integrate with My Health Record. This is supported through the Agency's Developer Centre, which provides our software community with the technical specifications required to integrate with Agency products.

The Agency has been working on supporting new functionality for mobile devices connected to My Health Record. This includes exploring enhancements to the mobile gateway that connects mobile applications, enhancing the [Developer Centre](#) that supports onboarding mobile developers and progressing a national assessment framework for mobile health (mHealth) applications.

The mHealth applications environment is complex, with an estimated 350,000 health-related apps available through app stores. Given the pace at which the mHealth landscape is evolving, many jurisdictions worldwide are grappling to establish an effective balance between fostering innovation in mHealth while ensuring that mHealth apps are safe, usable, high quality, cost-effective and trustworthy. Research and consultations have shown that both consumers and healthcare providers are unclear on how to determine if an mHealth app has these attributes. The Agency, in partnership with Queensland Health, is leading work to consider a national assessment framework for mHealth apps.

Clinical governance was integrated into mobile health activities through:

- engagement of DHAs according to their clinical discipline, expertise and experience in the mobile space
- assembly of a core design team at the initiation stage of a project to steer, endorse and approve products and documentation; this team included a clinical safety representative, DHA representative and a clinical usability analyst
- consideration of all third-party applications and organisations submitted via the Developer Centre before connection to software testing environments
- review and endorsement of vendor requests by clinical safety experts before products are released into production environments.

3.3.2 Mobile access to My Health Record for the sector

Many healthcare providers currently use the Healthcare Information Provider Service (HIPS) to access My Health Record through their healthcare organisation. HIPS is a middleware and interface service designed for health systems, particularly within large hospitals, to connect hospital patient administration systems and electronic medical record systems to the healthcare identifiers service and the My Health Record system. Different healthcare systems can be connected to share health data using HIPS to upload and view My Health Record patient information. HIPS is also used by several private hospital groups, pathology laboratories and providers of diagnostic imaging services.

HIPS is a key element of the Agency's strategy to support uptake and meaningful use of My Health Record. HIPS enables the seamless integration of health systems (such as patient administration, pathology and diagnostic imaging systems) with My Health Record and the Healthcare Identifiers Service. Of Australian hospitals connected to My Health Record, around half of public hospitals and 20% of private hospitals use HIPS to connect and upload.

By using HIPS Mobile, developed in 2021, clinicians can view patient records when attending the ward or delivering outpatient care. This provides a seamless patient view on a tablet or phone, for example, that is consistent with the desktop view to better integrate the clinical workflow at the bedside.

To improve the user experience for healthcare providers, these clinical governance initiatives were implemented:

- A DHA was engaged in the design discovery process for the user experience and in the design workshops for the user interface.
- A show-and-tell session was run with the Clinical Safety Service team to identify clinical hazards and obtain feedback on screen mock-ups and wireframes.
- User testing was conducted by DHAs and Clinical Safety Service team members in a demonstration environment to provide real-time feedback on screen designs.
- Monthly showcases and show-and-tell sessions were held with the Agency assurance team (including clinical governance, privacy, policy, legal, cyber and conformance) to solicit input and feedback.

3.3.3 National Infrastructure Modernisation Program

As the System Operator of the My Health Record system, the Agency contracts Accenture Australia Holdings Pty Ltd to operate and manage the My Health Record system as the National Infrastructure Operator (NIO).

The NIM Program is an initiative funded by the Australian Government to modernise the national infrastructure and replace the current NIO services with more flexible and contemporary arrangements. The NIM Program consists of a series of technology projects that will deliver refreshed and contemporary digital products and services. The first 2 projects focus on the delivery of a new Health API Gateway, which is an enabler for mobile technology and secure messaging, and the rehosting of the My Health Record system onto modern, scalable and secure infrastructure (data centre rehosting).

The aim of clinical governance in the NIM Program is to ensure the clinical safety of our products such as My Health Record as they undergo technology changes. A key clinical safety objective is that My Health Record continues to function and perform as expected for healthcare providers and consumers.

The NIM Program team engaged the Clinical Governance section in a number of ways. Examples include:

- workshops and engagement with branch managers and senior executive across the Agency DHA engagement
- review and input from Clinical Governance section members on project artefacts
- clinical safety assurance of the development of the new Health API Gateway.

For each project under the NIM Program, the Clinical Governance section was invited to nominate a representative to participate in the core design team and assurance process. The same approach was applied for changes and improvements to the current national infrastructure for My Health Record. The program will continue to engage the Clinical Governance section, including DHAs and clinical safety experts.

4 FUTURE PLANS

From the early days of the Personally Controlled Electronic Health Record to now, the Agency's programs have incorporated clinical safety by design, with input from experienced staff and healthcare providers. Over time, the approach has matured from one focused solely on clinical safety to become a comprehensive clinical governance, assurance and leadership program.

As the use of digital health services increases, this evolving multi-pronged approach to clinical governance will be increasingly central to the success and safety of technologically supported health services for all Australians. It is critical, not only for the Agency but also for the industry, to continue this evolution as we develop the new National Digital Health Strategy and further embed digital technologies within health service organisations.

Our philosophy is one of clinical safety, quality and continuous improvement, with ever-growing integration and use of real-world expertise, so that all facets of the Agency's work embed person centred mindsets and a clinical governance focus.

4.1 Embedding clinical governance across the Agency

As the EPMO matures, we expect to continue to embed clinical governance across all business functions in the Agency's operations. This will further deepen the Agency's implementation of clinical governance activities.

4.2 Optimising the Clinical Governance Framework and clinical safety service delivery model

In 2021, the Australian Commission on Safety and Quality in Health Care reviewed the Agency's Clinical Governance Framework and made recommendations to ensure the framework remains contemporary and fit for purpose in a digital health context. Key recommendations were to simplify and strengthen the clinical governance principles that are core to framework. The updated framework principles will be published early in 2023. Further work will be carried out to identify clear actions and examples under each principle that Agency staff can relate to and measure against.

In 2022, the Agency engaged AMOG Consulting to review the CSMS to contemporise the evidence-based methodology and ensure its sustainability and scalability to support management of clinical safety across the Agency. The review includes recommendations to update the existing CSMS to align with best practice and the requirement to integrate clinical safety systems and thinking across the Agency.

The reviews of the Clinical Governance Framework and the CSMS are intended to increase the organisation's awareness of and focus on clinical safety, quality and continuous improvement in all products and services. These reviews will be followed by education and communication about the findings and implementation of the recommendations across 2023.

4.3 Providing national and international leadership

Clinical governance in digital health is an emerging area internationally. The Agency and the Australian Commission on Safety and Quality in Health Care will together deliver a summit on Clinical Governance in Digital Health in February 2023. The Agency is a leader in Australian digital health, and the Australian Commission on Safety and Quality in Health Care has established its place in clinical governance through the National Safety and Quality Health Service Standards.⁶

The summit will bring together leaders in the health technology and direct care delivery environments with a focus on clinical governance. Policymakers and influential senior leaders will share their experiences and insights on digital health implementations and their thoughts for the future, drawn from their years of experience procuring, implementing, developing and using digital health solutions and services.

Clinical governance is central to the provision of health and care services that are safe, are of high quality and are continually improving. Clinical governance in our digital health solutions should be implemented not because we must, but because we care about the health outcomes and experiences of our communities.

Digital health solutions are changing how health and care are provided and experienced worldwide. Implementing clinical governance in the Agency demonstrates a connection between the work we do and the broader health sector. It provides evidence the Agency cares about clinical safety, quality and continuous improvement, and it builds confidence and trust that Agency products and services are creating the right solutions for the Australian community.

⁶ Australian Commission on Safety and Quality in Health Care (2019) [National Safety and Quality Health Service Standards](#), accessed 12 January 2023.