



The National Clinical Trials Governance Framework case study

Alfred Health

Introduction

In February 2022, all jurisdictions agreed to implement the National Clinical Trials Governance Framework (Governance Framework) in health service organisations under the Australian Health Service Safety and Quality Accreditation Scheme.

For the first three-year accreditation cycle, health service organisations will be assessed against a maturity scale: that is, as either having Established systems, Growing systems, or Initial systems in place to meet the National Safety and Quality Health Service Standards (as provided in the Governance Framework) for clinical trial service provision. Beyond the first three-year accreditation cycle, health service organisations will transition fully to the assessment of their clinical trial services and be assessed as either having met or not-met the actions within the Governance Framework and, receive 60 days to remediate.

Pilot of the Governance Framework

From September 2020 to March 2021, the Australian Commission on Safety and Quality in Health Care (the Commission) conducted a pilot implementation of the Governance Framework in 33 health service organisations nationally.

The aim of the pilot was to familiarise the clinical trial workforce with the accreditation process and to assess the capacity of each health service organisation to meet the actions within the Governance Framework using a maturity scale. That is, whether the health service organisation had:

- **Established systems:** Evidence to demonstrate that all requirements of an action are in place and integrated within the operations of the health service organisation
- **Growing systems:** Evidence to demonstrate that some of the requirements of an action are in place, with plans prepared to implement improvements to address identified gaps
- **Initial systems:** Evidence to demonstrate that the requirements of the action are yet to be commenced or implemented.

Development of case studies

The Commission has developed case studies of participating health service organisations that demonstrated a successful integration of clinical trial services into existing corporate and clinical governance systems. These case studies describe the strategies used by health service organisations to implement the Clinical Governance Standard and Partnering with Consumers Standard, and may serve as a guide for other health service organisations in understanding what successful implementation could look like.

Alfred Health at a glance

State/territory	Victoria
Metropolitan/regional	Metropolitan
Public/private	Public
Single/multi-site	Single
Population covered	> 700,000
No. clinical trials	> 600
Description of the organisation	<ul style="list-style-type: none"> ■ Alfred Health comprises three hospitals: The Alfred, Caulfield Hospital and Sandringham Hospital ■ The Alfred is home to the Alfred Research Alliance comprising Monash University, Baker Heart and Diabetes Institute, Burnet Institute, Deakin University, La Trobe University Nucleus Network and 360biolabs ■ Alfred Health is governed by the Alfred Health Board accountable to the Minister for Health ■ Committees established by the Board include Audit Committee, Community Advisory Committee, Finance Committee, Primary Care and Population Health Advisory Committee, People and Culture Committee, Quality Committee, Remuneration Committee.
Approach to implementation	<ul style="list-style-type: none"> ■ Research Governance Framework Guideline developed and aligned with National Clinical Trials Governance Framework, Quality and Clinical Governance Framework and Alfred Health Strategic Plan ■ Alfred Health Research Leadership and Governance Committee established to monitor implementation and compliance with the Clinical Trials Governance Framework ■ A project officer coordinates the implementation requirements of the Clinical Trials Governance Framework ensuring engagement across the organisation and integration with existing clinical governance processes ■ Close working relationship between risk, safety and quality staff and clinical trials staff fostered ■ Strong executive support established ■ Broad engagement across the organisation during the pilot accreditation assessment ■ Clear understanding of the governance structure, roles and responsibilities across all roles.

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Implementation of the Clinical Trials Governance Framework	Clinical Governance Standard	<ul style="list-style-type: none"> ■ Research incorporated in the strategic plan and organisational structure ■ Processes in place to collect operational metrics through Alfred Health’s Ethics & Research Governance Office database (Access) and reported to the Research and Governance Committee ■ Delegated roles, responsibilities for clinical trials articulated in the Research Governance Framework. Development and Approval of Policies and Guidelines Guideline details the process for the development, approval, implementation and review of all policies and guidelines ■ There is a Risk Management policy, Framework & Guideline. The risk management framework and associated tools align with the Australian Standard for Risk Management (AS/NZS ISO 31000:2018) ■ All stakeholders provided with timely information about safety and quality performance ■ Patient Feedback Guideline outlines how routine and specific feedback from patient, families and carers is collected.
	Partnering with Consumers Standard	<ul style="list-style-type: none"> ■ Strategy is overseen by the Community Advisory Committee and the Patients Come First Committee ■ Consumer register of over 100 consumers ■ Partnering with consumer key performance indicators (KPIs) developed to monitor consumer involvement ■ Guidelines to support effective partnership with consumers established ■ Patient Information Working Group established to improve communication with consumers ■ Collecting Patient Stories is an important component in understanding how patients perceive the health care they receive and how services can improve. A number of online resources are available to support staff to collect and use patient stories.
	Aboriginal and Torres Strait Islander specific actions	<ul style="list-style-type: none"> ■ Aboriginal Health policies and guidelines in place to ensure patients are provided with culturally safe, respectful, and appropriate patient care ■ Innovate Reconciliation Action Plan in place ■ Aboriginal Health Advisory Group supports the planning of initiatives to deliver safe, culturally appropriate and quality care for all Aboriginal and Torres Strait Islander people ■ Patient experience KPIs for Aboriginal and Torres Strait Islander people developed ■ Established Aboriginal Health Outcomes Working Group monitor the KPIs and develop actions to address the healthcare priorities ■ Ngarru Arweet Network enables discussions and collaborative activities to strengthen indigenous research capacity.

Alfred Health comprises three hospitals (The Alfred, Caulfield Hospital and Sandringham Hospital) and covers a population of more than 700,000 people in inner-southern Melbourne. Seven per cent of all patients speak a language other than English with the most common languages being Greek, Russian, Mandarin, Cantonese and Turkish. Alfred Health has identified the homeless as the most significant vulnerable population within the Alfred Health catchment.

The Alfred is a major metropolitan hospital including more than 7,800 staff and is home to the Alfred Research Alliance bringing together eight independent and diverse organisations including Monash University, Baker Heart and Diabetes Institute, Burnet Institute, Deakin University, La Trobe University Nucleus Network and 360biolabs. In 2019–20, Alfred Health had 636 clinical trials open.

Alfred Health is governed by the Alfred Health Board (the Board) which is accountable to the Victorian Minister for Health. The Board comprises nine independent non-executive directors who are appointed for a period of up to three years and can be re-appointed to serve up to nine years. The Board's role is to exercise good governance in achieving the objectives as outlined in Alfred Health's Strategic Plan and the Annual Statement of Priorities.

Governance, leadership and culture

Alfred Health has comprehensive, up to date and appropriate strategies, policies and procedures in place and shows regular engagement with and reporting to the governing body about clinical trial services.

Alfred Health has a mature governance structure in place. The Board understands and promotes safety and quality within the health service organisation and leaders at all levels in the organisation establish and use clinical governance systems to improve the safety and quality of health care for patients. The Board sets the strategic direction and research is incorporated in several goals of the Strategic Plan. Research is included at multiple levels of the organisational structure (see Figure 1 and Figure 2).

The Board has established a number of committees and advisory committees including:

- The Community Advisory Committee – provides advice to the Board on consumer, carer and community participation and other Alfred Health community initiatives
- The Quality Committee – established to ensure that effective and accountable systems are in place to monitor and improve the quality and effectiveness of health services.

The Board monitors variations in health care provision, complaints, compliments and the function of research and clinical trials to monitor progress and report on strategies for safe and high-quality clinical care. Summary reports containing pre-determined KPIs are provided to each meeting of the Board for review.

Alfred Health has processes in place to collect and use metrics to provide quality assurance.

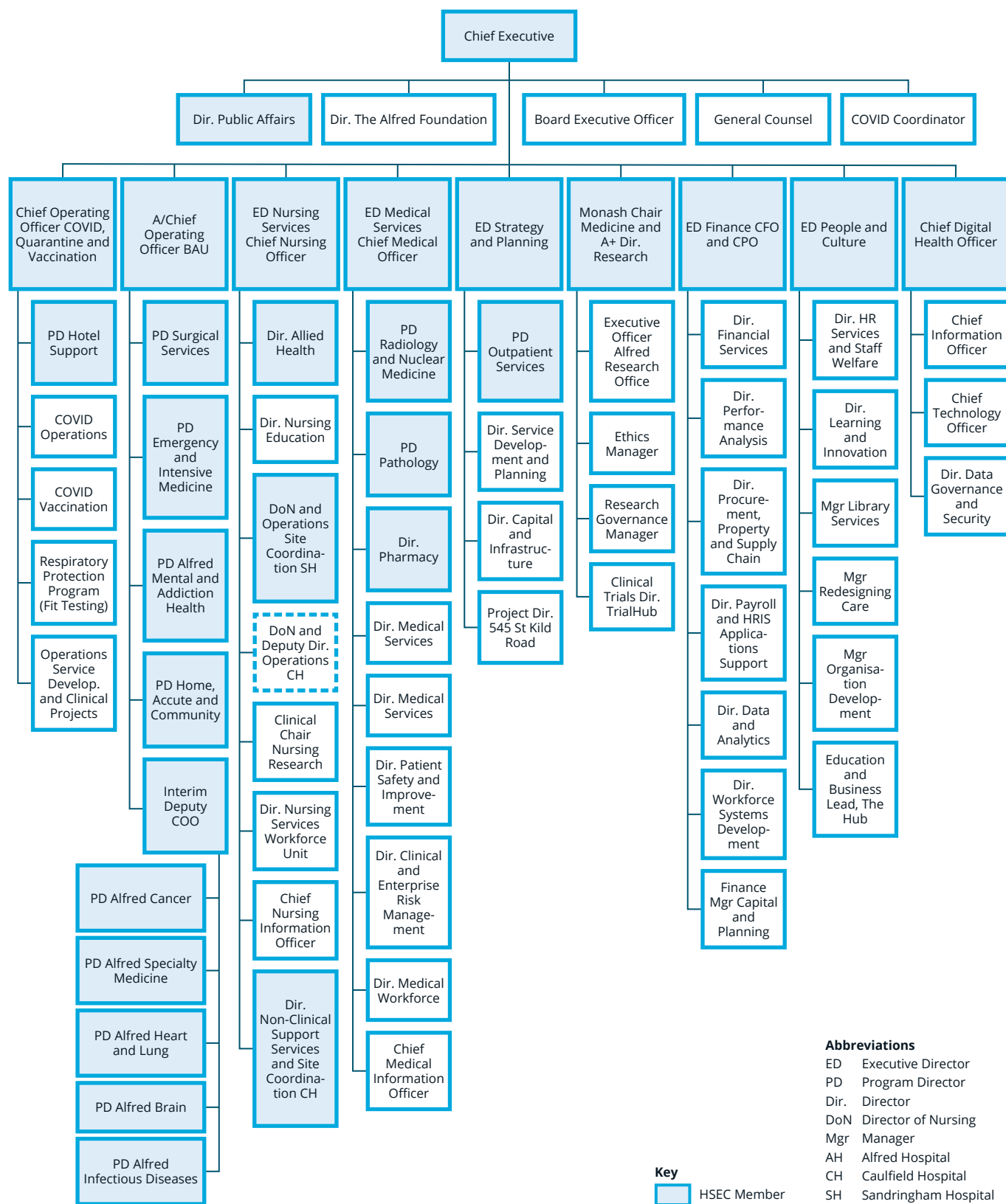
The Alfred Health's Ethics & Research Governance Office collect and report on data covering the timeliness with which human research ethics and site-specific assessment applications are processed as well as:

- Recruitment at a site level
- Number of serious adverse events
- Deviations from protocols
- Amendments of protocols
- Number of audits carried out.

The data is collected through Alfred Health's Ethics & Research Governance Office database (Access) and reported annually to the Executive Committee, quarterly to Director of Research and the Alfred Research Alliance and provides data to the Commonwealth Department of Health via National Aggregate Statistics (NAS).

The roles, responsibilities and accountabilities for safety, quality and clinical governance are clearly articulated in the Alfred Health Quality and Clinical Governance Framework and in workforce position descriptions. The Alfred Health Quality and Clinical Governance Framework aligns with the Alfred Health Strategic Plan. Delegated responsibilities for quality and safety for clinical trials and research are also articulated in the Research Governance Framework, the Code of Conduct of Researchers Policy, and the Principal Investigators Guideline.

Figure 1: Alfred Health organisational structure



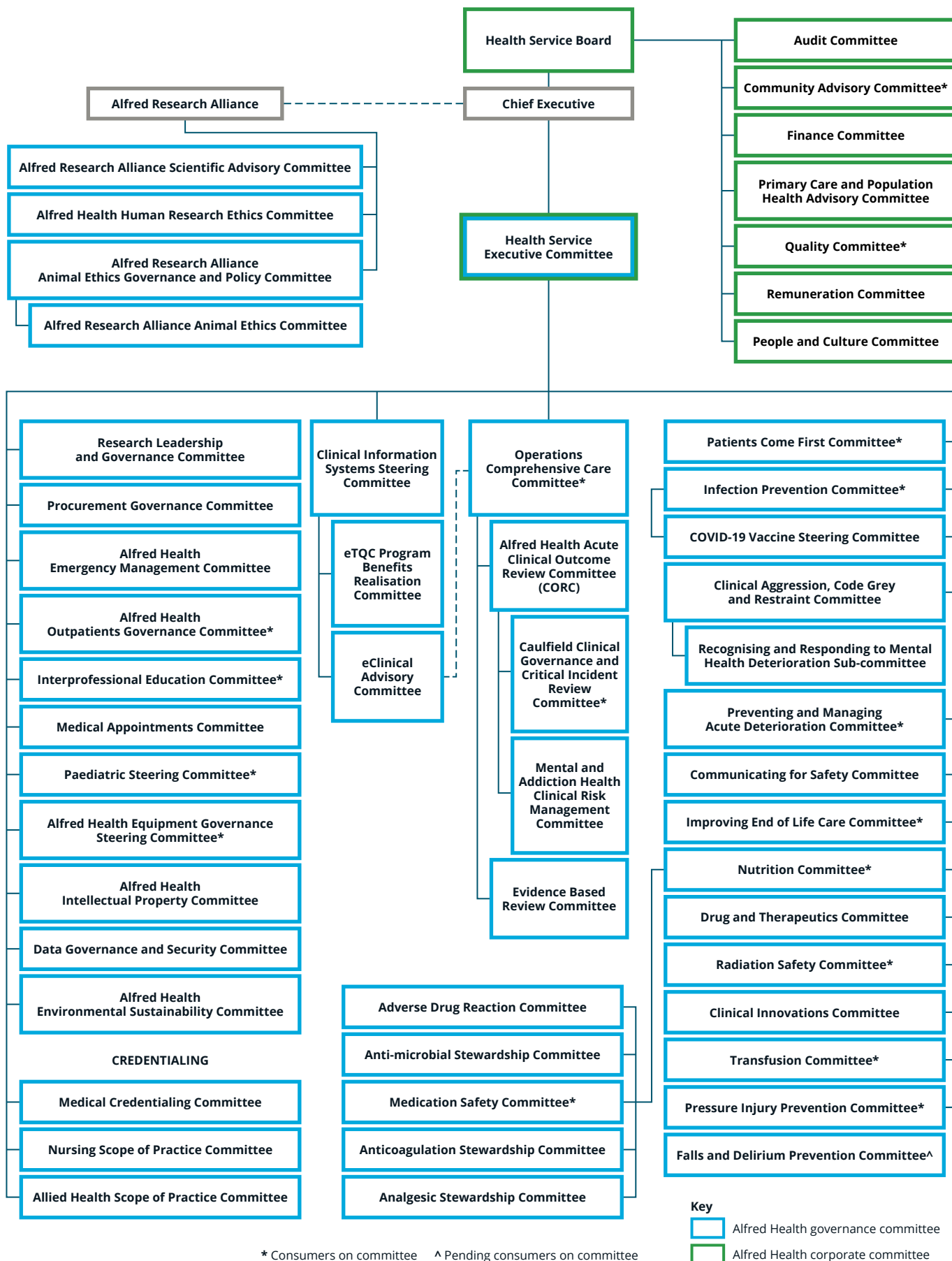
Abbreviations

- ED Executive Director
- PD Program Director
- Dir. Director
- DoN Director of Nursing
- Mgr Manager
- AH Alfred Hospital
- CH Caulfield Hospital
- SH Sandringham Hospital

Key

HSEC Member

Figure 2: Alfred Health committee structure



Patient safety and quality improvement system

Alfred Health has developed guidelines to ensure the contents of policies and guidelines are current and relevant to current practice and core business, evidence-based, underpinned by best practice principles and compliant with all relevant legislation. For example, the Development and Approval of Policies and Guidelines Guideline details the process for the development, approval, implementation and review of all Alfred Health policies and guidelines while the Legislative Compliance Guideline provides guidance to ensure that Alfred Health is compliant with all relevant legislation.

Alfred Health has an integrated clinical and enterprise risk register. High and extreme risks are addressed by specific committees and data is used to support improvement in safety and quality. The responsibilities for risk management are included in The Risk Management Framework and Guideline. All staff are able to report incidents, hazards and near misses through the risk register which incorporates the Victorian Hospital Incident Management System, a data set which is reported monthly to Safer Care Victoria. All clinical incidents are screened and distributed to appropriate line managers for follow up. The incident data are routinely analysed for trends and reported to various committees including the Executive Committee and the Quality Committee. Consumers that have received training are also involved in incident review.

Alfred Health has developed processes to ensure that key stakeholders are provided with accurate and timely information about safety and quality performance in alignment with the Alfred Health Quality and Clinical Governance Framework. Feedback is provided to the workforce on patient safety and quality and any system changes for implementation through various mechanisms:

- Monthly organisational/program/ward scorecards
- Clinical Governance report
- Monthly management pack
- Weekly staff e-Newsletters
- Regular executive roadshows
- Updates through Alfred Health social media platforms.

Feedback to consumers occurs through information boards, publications on Alfred Health website, the annual Alfred Health Quality Account and Alfred Health Annual Report.

Alfred health has a Patient Feedback Guideline in place to provide guidance to the workforce on handling patient complaints and collecting routine and specific feedback from consumers. A Clinical Trials and Research Patient Experience Survey Tool is currently in development to enable the collection of feedback specific to clinical trials participants and their carers.

Partnering with consumers

Alfred Health has developed the Patients Come First Strategy and Plan, a roadmap to supporting the best possible patient experience and engaging consumers in health service planning, design, and improvement.

The Patients Come First Strategy is overseen by the Community Advisory Committee and the Patients Come First Committee. The Community Advisory Committee reports directly to Alfred Health Board. Five working groups report to the Patients Come First Committee:

- Aboriginal Health Advisory Working Group
- Diversity Working Group
- Patient Information and Feedback Governance Group
- Patient Information Consumer Working Group
- Vulnerable Persons Steering Group.

Alfred Health has a consumer register of about 100 consumers who help with service improvement and feedback.

Alfred Health has developed an approach to partnering with consumers including but not limited to:

- Number of trained consumer advisors and volunteers
- Consumer participation in Alfred Health projects
- Consumer involvement in patient information.

Health literacy

Alfred Health identifies the diversity of its consumers through daily reports of inpatients who require language services, inpatients who have identified as Aboriginal or Torres Strait Islander, as well as socioeconomic demographics and health outcome data.

Alfred Health has developed guidelines to support effective partnership with consumers:

- The Health Literacy Guideline provides strategies to reduce the impact of low literacy
- Guideline – Research with Participants Requiring Language Services sets out the Ethics Committee's requirements for the inclusion in research of people who require translated or interpreted information
- Supporting Vulnerable Patients Guideline identifies language requirements as contributing to vulnerability of consumers and provides guidance to staff to recognise patients and carers who may have increased vulnerability when accessing health services.

A Patient Information Working Group has been established to improve communication with consumers so they can access, understand, and use health information provided to them. Ten consumer representatives participate in the working group.

Alfred Health uses a consistent approach to the collection, utilisation, and governance of patient stories outlined in the Patient Stories Guideline. There is a catalogue of patient stories and approval is required to access them. These patient stories aim to bring the human dimension to health care and are considered a powerful patient feedback approach.

Aboriginal and Torres Strait Islander-specific actions

Alfred Health uses formal strategies to improve outcomes for Aboriginal and Torres Strait Islander patients.

Alfred Health has developed:

- The Aboriginal Cultural Heritage Policy which provides an operational framework for the protection of Aboriginal cultural heritage that is practical, legally appropriate, and fosters consistency across the organisation
- The Aboriginal Health Guideline which provides guidance to ensure patients who identify as Aboriginal or Torres Strait Islander are provided with culturally safe, respectful, and appropriate patient care. This guideline defines the roles and responsibilities of the Aboriginal Hospital Liaison Officers and the Aboriginal Access and Support Worker
- An Innovate Reconciliation Action Plan.

Alfred Health has an Aboriginal Health Advisory Group which works in collaboration with Aboriginal and Torres Strait Islander people to support Alfred Health in the planning, implementation and evaluation of initiatives, systems and processes to deliver safe, culturally appropriate and quality care for all Aboriginal and Torres Strait Islander people who access Alfred Health services. The Aboriginal Health Advisory Group has developed a specific set of access, outcome, and patient experience KPI's for Aboriginal and Torres Strait Islander people in collaboration with the local Aboriginal community.

Alfred Health is also part of the Monash Partners, an Advanced Health Research Translation Centre. Monash Partners has established the Ngarru Arweet Network to enable discussions, collaborative activities and relationship building to strengthen indigenous research capacity and progress the priorities of health services.

Approach to implementation

Alfred Health has developed the Research Governance Framework Guideline which aligns to the Alfred Health Quality and Clinical Governance Framework Guideline. The National Clinical Trials Governance Framework and the Strategic Plan. This Framework outlines the safety and quality management systems that Alfred Health has implemented to support the undertaking of safe, high quality and patient-centred research.

The Alfred Health Research Leadership and Governance Committee has been established to monitor implementation and compliance with the National Clinical Trials Governance Framework and will report annually to Alfred Health's Executive Committee.

A project officer coordinates the implementation requirements of the Governance Framework and engagement across the organisation. The project officer has fostered a close working relationship between risk, safety and quality staff and clinical trials staff and has established strong executive support.

Alfred Health ensured broad engagement across the organisation during the pilot accreditation assessment. Board members, executives, managers, clinical trial workforce sponsors and consumers were interviewed and revealed a clear understanding of the governance structure, roles and responsibilities across all roles and highlighted consistency between policies and strategies that are implemented.

Resources

- [*The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials*](#)
- [National Clinical Trials Governance Framework Frequently Asked Questions and fact sheets](#)
- [*The National Clinical Trials Governance Framework Pilot: Executive Summary Report*](#)
- [The Clinical Trials Portal](#)
- [Assessment to the National Safety and Quality Health Service Standards.](#)

Find out more

For more information about The National Clinical Trials Governance Framework visit the [Commission's website](#) or contact the Safety and Quality Advice Centre at AdviceCentre@safetyandquality.gov.au or phone 1800 304 056.

