

KEY ACTIONS
for health service
organisations

Fact sheet 3: National Clinical Trials Governance Framework – Partnering with Consumers Standard overview

Background

The Australian Commission on Safety and Quality in Health Care (the Commission) has developed the National Clinical Trials Governance Framework (Governance Framework) as a first step towards implementing the National Safety and Quality Health Service (NSQHS) Standards and achieving accreditation of health services for the conduct of clinical trials.

The Governance Framework aims to ensure that clinical trials are conducted in a safe environment and in a high-quality manner for improved health outcomes for patients and the community. The Governance Framework is based on the NSQHS Standard 1: Clinical Governance Standard and Standard 2: Partnering with Consumers.

Since 2013, it is mandatory for all public and private hospitals and day procedure services to be assessed through an independent accreditation process to determine whether they have implemented the NSQHS Standards.

Following the pilot, it is anticipated that clinical trial services will be assessed using a maturity scale for each action within the Governance Framework to provide a description of success. That is, the Commission recognises that health services will be at different stages of maturity in their ability to implement the actions provided in the Governance Framework. It is expected that improvements should be achievable over a planning cycle of three years, although this will depend on the health service organisation.

The maturity scale is a guide for progressive improvements in each of the criteria within the Governance Framework including: demonstration that initial systems are in place; the health service

organisation is growing systems and the health service organisation has established systems.

Services not required to be assessed to the NSQHS Standards can voluntarily opt to apply the Governance Framework, for best practice and quality improvement purposes.

What is the Partnering with Consumers Standard?

- The Partnering with Consumers Standard requires health service organisations to establish partnerships with patients, carers, families and consumers in the design, and evaluation of all clinical services including clinical trial services
- Partnerships are necessary at all levels of the organisation to ensure that a health service organisation achieves the best possible outcomes for all parties¹. Delivering clinical trials that are based on partnerships provides many benefits for patients, consumers, clinicians, health service organisations and the health system. There is evidence of links between the existence of effective partnerships, with positive experience for patients, high-quality health care and improved safety².



The Partnering with Consumers Standard has four criteria:

- Clinical governance and quality improvement systems to support partnering with consumers
- Partnering with patients in their own care
- Health literacy
- Partnering with consumers in organisational design and governance.

Implementing this Standard

Implementing the Governance Framework in a health service organisation or trial site involves governing bodies, clinicians, clinical and non-clinical managers, patients, consumers, researchers, clinical trial coordinators and sponsors as well as, well-designed systems to deliver, monitor and account for the quality of clinical trial service provision.

This Standard requires health service organisations to:

- Establish mechanisms to form partnerships with patients, in their own care, including when participating in clinical trials
- Support patients, consumers and carers to actively participate in the organisational design and governance of clinical trial services
- Health service organisations ensure that patients, trial participants and consumers are provided with information about their healthcare rights
- Ensure information on clinical trials is provided to trial participants, patients, carers and their families, and consumers.

Next Steps

1. In early 2020, the Commission will pilot the Governance Framework in hospitals and day procedure units. Insights gained from the pilot will inform the approach to implementing the Governance Framework and the refinement of supporting resources.
2. Following the pilot, it is anticipated that when your organisation accreditation next occurs, your clinical trials service will also be assessed using a maturity scale for each action.

Find out more

Information on the Governance Framework is available on the Commission website at safetyandquality.gov.au/clinical-trials

Relevant information and documents:

[National Clinical Trials Governance Framework and User Guide for Health Service Organisations Conducting Clinical Trials](#)

[National Clinical Trials Governance Framework introductory video](#)

[National Clinical Trials Governance Framework fact sheets](#)

[NSQHS Standards \(second edition\)](#)

[National Model Clinical Governance Framework](#)

[NSQHS Standards User Guide for Governing Bodies](#)

You can also email the clinical trials project team at: CTgovernance@safetyandquality.gov.au or call 02 9123 3600.

References

1. Australian Commission on Safety and Quality in Health Care. Patient-centred care: improving quality and safety through partnerships with patients and consumers. Sydney: ACSQHC; 2011.
2. Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open* 2013;3:e001570.

