Genomics and Your Hospital

A toolkit to support high-quality genomic care

Tool: Resources to support hospitals achieve and monitor safe, effective and high-quality genomic care

*This document is part of the **Genomics and Your Hospital toolkit**, a resource developed to support a 'whole of hospital' approach to genomic care. The complete toolkit is available at **GenomicsToolkit.org.au.***

The genomics toolkit was co-designed with Victoria's leading health services. During the process, it was noted that even in hospitals advanced in their genomics journey, there were opportunities to improve organisation-wide understanding and monitoring of the quality, safety and effectiveness of genomic care, and to link it back to existing clinical governance frameworks.

The Melbourne Genomics *Quality Working Group* was established with the purpose of developing resources to support health services design their approach to measuring the quality of their genomic medicine care. Through a co-design process, possible metrics were drafted and tested with the group.

This document contains two parts:

1. Using clinical governance frameworks to guide decision-making and approach
2. A list of suggested metrics to assess

It's recommended your health service's genomics leadership group or executive sponsor establish clear accountabilities for achieving safe, high quality, value based genomic care and determine optimal monitoring and escalation pathways.

Using your clinical governance framework to guide decision making and approach

Genomic medicine implementation should align with existing clinical governance frameworks and consider key elements particularly relevant to genomic care. This includes the following:

Governance, leadership and culture

1. External/system governance, leadership and culture
   a. There is a significant overhead in safely and effectively implementing genomic medicine practice. Hospitals should consider their role delineation/capability and work collaboratively with partners.

b. As a relatively new specialty, there is significant value in a system-wide approach that includes role delineation, benchmarking and participating in a community of practice.
    i. Active participation in sharing experience and outcomes is critical to achieving high quality genomic medicine care.
    ii. Internal networks should be developed to ensure different specialties work collectively and collaboratively to achieve best practice.
    iii. External networks should be developed and maintained to support data sharing, benchmarking and a community of practice, particularly in the context of limited evidence.

2. Internal governance, leadership and culture
   a. It is recommended that there is executive sponsorship of implementation and clinical governance of genomic care who provides visible, authentic leadership of genomics and ensure priorities are effectively communicated.
   b. It is recommended that a genomics leadership group is established to ensure that genomics is used appropriately, safely and effectively in clinical practice across the organisation and support hospital readiness for genomic care.
   c. While different departments in the hospital may be at different levels of readiness for genomic medicine, it is imperative that a whole-of-organisation view can be seen, reviewed and monitored.
   d. The purpose of the genomics leadership group is to ensure the hospital is ready and able to offer genomic care, and that genomics is used widely, safely and effectively in clinical practice across the organisation. With an organisational wide perspective, the group can provide strategic oversight, governance and advice to both individual departments and to the service as a whole, to support implementation and sustained use of genomic medicine.

Effective systems and processes

1. Consider current systems and processes and determine whether they are optimal for genomics implementation and to ensure its benefits are realised.
2. There should be:
   a. Clear accountabilities and ownership of actions.
   b. Effective planning and resource allocation that directly links to the genomics priorities and program of work.
   c. Consideration should be given to existing policy and procedures and whether new guidance or updates are required to support genomic implementation.
   d. Assessment of the model(s) of care for quality, safety, cost and person-centredness.
   e. Determination of optimal structures to support and check quality of care.

A supported, effective workforce

1. Consider how genomic medicine will impact your workforce's needs, capabilities and scope of practice.
2. As an emerging specialty that crosses multiple specialties and disciplines, hospitals may benefit from assessing their workforce needs against their current and planned genomic activity to ensure they have:
   a. Sufficient staff,
   b. Staff with the right skills,
   c. Staff supported and enabled to achieve priorities,
   d. Staff encouraged to speak up and identify issues and improvements, and
   e. Effective credentialling, performance development and management.

Effective risk management

1. Understand and mitigate risks specific to genomics and put the right controls in place
2. As a relatively new specialty, active risk management is essential to achieving safe, high-quality care.
    a. Hospitals should take a risk-based approach to assessing and monitoring quality/safety and risk of genomic medicine
    b. Hospitals should consider risk when undertaking an assessment of what genomic medicine is appropriate in their service(s).
    c. As some risk controls overlap, and the way these work may be different in different hospitals, hospitals should assess risk controls and mitigations holistically.

Person-centred care

1. Genomics is an emerging specialty which presents complex and difficult choices for entire families. Thus, it is criticality important to have person-centred care as a key outcome of your program and ensure there are systems for:
    a. Ensuring care meets consumer expectations.
    b. Involving consumers in their care with consideration of individual consumers, families and special others.
    c. Involving consumers in program design and review,
    d. Ensuring effective, high-quality communication between staff and consumers,
    e. Ensuring care that is contextualised to a patient's needs, lifestyle and culture,

Continuous measurement, monitoring and improvement

1. Genomic medicine implementation should be based on the approach of continuous improvement measuring and monitoring. This includes:
    a. Development and implementation of a core set of consistent data collection to enable benchmarking and assessment of consistency and quality of care and cost (*see part two below*),
    b. Consideration about requirements for robust data governance,
    c. Demonstrating a commitment to evidence-based approach and continuous improvement, and
    d. Implementing an effective system for monitoring and actioning data.

How does this link to existing clinical governance frameworks?

Genomics care is not standalone. It should be reviewed in the context of your hospital's existing clinical governance framework, capabilities and needs.

Due to the unique and uncommon features of genomics, existing clinical governance frameworks don't necessarily provide hospitals with enough guidance to make good decisions about genomics. That's why the Genomics and Your Hospital toolkit was developed.

The key actions in the toolkit reflect clinical governance domains established by Safer Care Victoria, as summarised in the table below. There may also be value in hospitals undertaking a similar mapping against their local clinical governance frameworks.

Clinical Governance Domain (Safer Care Victoria Framework)	Genomics and Your Hospital key action
Leadership and culture	Form your genomics leadership group
Partnering with consumers	Involve consumers in genomic medicine services
Workforce	Check workforce skills and support
Risk management	Understand and mitigate risks
Clinical practice	Support and monitor quality and value

List of suggested metrics to support safe, high quality genomic care

In considering *how* hospitals might measure the safety, effectiveness and value of genomic medicine care, the Melbourne Genomics *Quality Working Group* determined that metrics should:

- Where possible, build on pre-existing systems or datasets
- Enable consistency and commonality
- Demonstrate the value of genomic testing clinically and financially

And that the **Genomics and Your Hospital** toolkit should reflect existing clinical governance frameworks to support adoption.

In considering *what* to monitor, the Quality Working Group determined the following metrics to be most likely to be both *useful* and *feasible*. This list is not exhaustive and will likely evolve over time as organisational governance of genomic medicine strengthens. Some metrics may not be appropriate for your health service. Please use the list as a prompt to consider what is most relevant and important for your hospital.

Domain for monitoring and review	Element for monitoring and review	Metrics that may be useful for organisational oversight of genomic care	Potential frequency
Overarching considerations	Financial considerations	▪ Actual costs of delivering the genomic medicine **model of care** ▪ Assessment of costs of delivering the genomic medicine care against the benefits achieved*	Annual audit
Overarching considerations	Activity monitoring	▪ Analysis of patient activity relating to genomic medicine (number of tests ordered) ▪ Volume of activity over time (organisational wide and by specialty)	Annual audit
Clinical governance	Leadership and culture	▪ Evidence of effective **genomics leadership group**/organisational oversight ▪ Evidence of escalation and organisational review of issues as appropriate	Annual audit
	Person-centred care	▪ Audit of patient consent quality and analysis of results for learnings and improvements	Annual audit

	▪ Patient satisfaction with the quality of the care and care processes	
	▪ Analysis of patient complaints relating to genomic medicine: – Number and severity of complaints related to genomic medicine – Analysis of complaints for learnings and improvements	Monthly/quarterly depending on local volume, risk and capacity
	▪ Analysis of access to genomic care for relevant priority groups	Monthly/quarterly depending on local volume, risk and capacity
Risk management	▪ Evidence of a **risk assessment** and mitigation plan ▪ Analysis of effectiveness of stewardship arrangements (multi-disciplinary team inputs/outputs/effectiveness) ▪ Evidence of changes in response to risk issues identified	Annual audit
	▪ Adverse events related to genomic medicine: – Number and severity of adverse events related to genomic medicine – Analysis of adverse events for learnings and improvements ▪ Analysis of adverse events related to lack of access to, or delays in accessing genomic care*	Monthly/quarterly depending on local volume, risk and capacity
Continuous improvement, measurement and monitoring	▪ Evidence that: – Data is collected, analysed, reported and responded to – Adverse events and complaints have been analysed for learnings and improvements – Benchmarking is undertaken – Any actions and learnings are documented, monitored and completed	Annual audit
Systems and processes	▪ Evidence that relevant policy and procedure: – Exists – Is useful to the workforce – Is used – Analysis of timeframes for the time from initiation of care to treatment*	Annual audit

	Supported, effective workforce	▪ Evidence of relevant upskilling by staff ▪ Evidence of workforce capability assessment ▪ Evidence of workforce needs analysis ▪ Evidence of role clarity	Annual audit
Clinical practice	Turnaround time	▪ Time from test ordering to returning results to patients: – Turnaround time for completed tests by test type – Time from test ordering to results return by test type	Monthly/quarterly depending on local volume, risk and capacity

**It was noted that these metrics were considered very useful but not currently feasible to collect and it is recommended that further consideration is given to how these may be collected.*

How was this tool developed?

These resources were developed by the *Measuring Quality* working group, set up by the Melbourne Genomics Health Alliance.

The group comprised 14 healthcare leaders, clinical specialists and consumer advocates, bringing together expertise in quality measurement, implementation of new technology and clinical practice, hospital data systems, genomics, health economics, and consumer involvement.

The working group first established a set of principles relevant to genomic care, then drafted and rated a list of metrics to help hospitals measure quality and value.