Tool: Guide to embedding genomics into your health service's risk management system

Genomics and Your Hospital

A toolkit to support 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, embedding genomics into your health service's risk management system was identified as a key action for hospitals seeking to implement genomic care.

Introduction

Assessing, understanding, and where necessary, mitigating risk associated with emerging clinical practice is an essential component of effective clinical governance. Effective risk management requires a structured approach that includes both proactive and reactive components and ensures the systems, processes and culture support staff to identify and escalate risks and concerns.

This guide has been developed as a 'model' risk register specifically for genomic medicine. Genomics has a number of **unique and uncommon features** that need to be considered, including:

- its diffusion across multiple clinical specialties and disciplines,
- the need for workforce development,
- the need to ensure sustainable resourcing and funding of the whole model of care,
- the current lack of information on effective models of care, and
- the lack of information on metrics to monitor value and effectiveness of care.

As a result, this document has been developed to support organisations to consider risks specific to genomic care and appropriate local mitigations. An Excel version of the risk register is **available on the website** for you to download and adapt for your health service.

There are three sections to this document:

1. Risk management systems
2. Overarching organisational risks specific to genomic care
3. Risks at each step of the genomic care patient journey

Please note these lists are not exhaustive and may not be appropriate for your particular context. They are included for the purpose of allowing a structured consideration within your **genomics leadership group** (or equivalent) to enable identification of potential local genomic risks and appropriate mitigation strategies.

Genomic risks in real-life

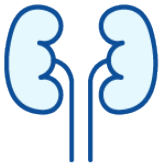
Understanding and mitigating risks in a new practice is vital to ensuring safe, effective and high-quality care. The following real-life anonymised case studies have been included to illustrate why incorporating genomics into your hospital's risk management system is important.

Complex results are misinterpreted

A gene panel test ordered for a child with seizures identified a variant of uncertain significance in a gene associated with cardiac failures. Because of the inherent uncertainty of these variants' clinical significance, current guidelines recommend that family members should **not** be tested to predict their future risk. The treating clinician referred the entire family for both cardiology and genetic tests based on the gene variant, even though there was no evidence this particular variant could cause heart failure. The family experienced months of anxiety and expensive, unnecessary tests because the treating clinician misinterpreted the appropriate clinical action for this complex result.

Systemic roadblocks compromise care

Patients referred to genetics services can languish on waiting lists, due to a high demand for clinical geneticists. In one case, a patient with recurring 'stroke-like episodes' waited a full year for her genomic test result, first due to a backlog and then a lack of follow-up. While waiting, they had a stroke, requiring lasting rehabilitative support. When the test result was tracked down, it identified a readily treatable genetic condition. The stroke could have been avoided with timely access to genomic information.



Patients who need genomic testing can't access it

A confident and informed patient scheduled to receive a kidney transplant demanded a genomic test to help identify why her kidney was failing. The test identified a genetic abnormality in her liver, which would have caused the transplanted kidney to fail as well. Armed with this information, a dual liver/kidney transplant was performed, and the patient is now doing well. This test is still not standard practice.

Risk management systems

This section details the key elements of a clinical risk management system. Considerations specific to genomic care are mapped to each of the key elements, which your genomics leadership group may find helpful to review.

Key elements of a risk management system[1,2,3]	Key considerations of these in the context of genomic care
Identify and prioritise organisational risks (i.e., development and maintenance of a risk register)	▪ Understand risks specific to genomic care and develop relevant control and monitoring systems ▪ Consider the interface between known areas of organisational risk and implementation of genomic care ▪ Ensure coordinated oversight of genomic care risks (e.g., through a **genomics leadership group**)
Ensure systems for identifying and responding to, and learning from: - Complaints - Incidents - Adverse events and near misses	▪ Ensure incidents, complaints, adverse events and near misses in genomic care are documented and managed as per your organisational incident management/complaints system ▪ Ensure learnings from these are feedback to relevant staff and consumers
Ensure effective policy and procedure systems	▪ Consider whether current policies and procedures are appropriate for genomic care: - Do they need updating? - Are new policies/procedures required?
Ensure good healthcare records	▪ Consider where and how different components of the patient's genomic care journey will be documented in the medical record? Is there a risk of fragmentation? How will this be managed?
Ensure action is taken to reduce risks	▪ Ensure that risks identified in the genomic care risk register have clear actions and accountabilities against them to mitigate the risk ▪ Ensure actions are monitored for completion and effectiveness
Routinely collect and monitor meaningful data to measure outcomes and performance	▪ Ensure good systems for **collecting, reviewing, monitoring and acting on data relevant to genomic care**
Implement processes for service review and evaluation	▪ Consider mechanisms for regular **review of genomic care** to determine broader learnings and potential improvements
Communication, education and training: - Report on risks to the workforce and consumers - Consider training requirements for risk management	▪ Consider what training your genomic workforce may require in risk management for their roles ▪ Consider where **reporting on the data, learnings and improvements in genomic care will occur and how frequently**

[1] https://www.safercare.vic.gov.au/sites/default/files/2024-08/Victorian%20Clinical%20Governance%20Framework.pdf

[2] Action 1.10 | Australian Commission on Safety and Quality in Health Care

[3] https://www.safercare.vic.gov.au/sites/default/files/2024-08/Victorian%20Clinical%20Governance%20Framework.pdf

Overarching organisational risks specific to genomic care

This section details the potential risks, consequences and controls specific to genomics on an organisational level. It also has prompts to help your organisation assess these risks in your local context.

Review these risks in the context of your hospital and consider:

1. Is this risk relevant in your setting?
2. How would you risk rate it?
3. Do you have any controls/treatment in place? If so, what are these?
4. Are any additional controls/treatments required? If so, what are these?
5. Are there any additional overarching risks that have not been considered here? And if so, review the risk rating, and consider controls and treatments.

Risk	Potential consequence(s)	Potential controls/treatments
Lack of role clarity including lack of single point accountability	▪ Failure in process potentially resulting in harm e.g. due to incomplete/delays to patient treatment	▪ Documented roles and responsibilities at each step of care pathway ▪ Documented roles and responsibilities for escalation of issues /concerns ▪ Implementation of **quality metrics and systems** ▪ Formation of **genomics leadership group** ▪ Review of **new tests/models of care** by genomics leadership group ▪ Benchmarking and horizon scanning for best practice ▪ Completion of **model of care assessment** to ensure costs, equipment, and workforce needs known and completed ▪ Completion of **new genomic practice screening tool**
Failure of integration across clinicians/steps		
Failure to ensure coordinated introduction and quality review	▪ Ad hoc, non-standardised development of genomic care with the quality-of-care unknown ▪ Waste of resources	
Inability to appropriately resource effective end-to-end processes	▪ Bottlenecks/gaps in care processes. ▪ Staff burnout/fatigue	
Risks associated with not undertaking testing	▪ Patients experience harm related to delayed or incomplete treatment as a result of not getting the optimal genomic tests ▪ Potential unnecessary utilisation of other treatments	
Lack of clarity about financial costs of tests and whole care pathway	▪ Program cessation due to lack of funds	
Lack of appropriately skilled, sufficient workforce	▪ Program reduction/cessation due to insufficient workforce	
Insufficient/inappropriate governance of non-standard genomic care (i.e., genomic care still considered research or genomic care considered emerging practice)	▪ Risks of insufficient consent, risk of provision of patient care with unknown risk/benefit profile; hospital insurance risks, accreditation risks	

Risks at each step of the genomic care patient journey

This section details the potential risks, consequences and controls specific to genomics at each step of a patient's journey, adapted from **McCorkell, et al. 2024**.

The patient pathway can be considered to include the following steps:

1. Identification of patients who should be considered for genomic testing
2. Referral process for consideration of potential testing pathways
3. Consideration of genomic test options
4. Assessing and undertaking consent; and legal implications
5. Ordering genomic tests
6. Genomic test analysis
7. Interpreting results of genomic tests
8. Clinical application of genomic results in the context of an individual patient
9. Family support considerations and requirements

Review these risks in the context of your hospital and consider:

- Is this risk relevant in your setting?
- How would you risk rate it?
- Do you have any controls/treatment in place? If so, what are these?
- Are any additional controls/treatments required? If so, what are these?
- Are there any additional overarching risks that have not been considered here? And if so, review the risk rating and controls and treatments.

Step #1: Identification of patients who should be considered for genomic testing

Risk	Potential consequence(s)	Potential controls and/or treatments
Relevant patients not identified Inappropriate test ordering Urgency and/or complexity not clearly identified	▪ Delay in diagnosis and/or treatment resulting in harm ▪ Cost and/or waste of resources	▪ Clearly documented and agreed **models of care** ▪ **Credentialling and training** of staff to ensure skills and knowledge in appropriate referral ▪ Design of locally appropriate access to genomics expertise (e.g., genomic champions in clinical units, establishment of multi-disciplinary meetings, laboratory feedback or guardrails) ▪ Clear escalation pathways for questions/concerns including organisational expert backup

Step #2: Referral process for consideration of potential testing pathways

Risk	Potential consequence(s)	Potential controls and/or treatments
Complex patient not referred to expert clinician/department	▪ Care needs not optimally met (under/over treatment) ▪ Validity/utility of result unclear ▪ Delay in diagnosis and/or treatment resulting in harm ▪ Cost and/or waste of resources	▪ Consideration of genomic care within broader hospital capability framework ▪ Clearly documented and agreed **models of care** ▪ Traffic light/flowchart systems ▪ Credentialling and training of staff to ensure skills and knowledge in appropriate referral ▪ Design of locally appropriate access to genomics expertise (e.g., genomic champions in clinical units, establishment of multi-disciplinary meetings, laboratory feedback or guardrails) ▪ Clear escalation pathways for questions/concerns including organisational expert backup
Referral processes not known, and patients not referred appropriately		
Lack of timely referral		
No referral option availability		

Step #3: Consideration of genomic test options

Risk	Potential consequence(s)	Potential controls and/or treatments
Incorrect/inappropriate test ordered (e.g., incorrect gene list selected; test sent to research lab)	▪ Validity/utility of result unclear ▪ Delay in diagnosis and/or treatment resulting in harm ▪ Cost and/or waste of resources	▪ Organisational review of **new tests/models of care** ▪ Test ordering guardrails ▪ **Credentialling of practitioners** ▪ Effective **models of care** including test ordering process ▪ Contracts with specific laboratories for cost-effectiveness ▪ Sufficient pathology expertise ▪ Effective, timely clinician-laboratory communication of key information ▪ Ensuring use of NATA-accredited laboratory ▪ Training and development of relevant staff to ensure skills and knowledge in appropriate test ordering ▪ Design of locally appropriate access to genomics expertise (e.g., genomic champions in clinical units, establishment of multi-disciplinary meetings, laboratory feedback or guardrails) ▪ Clear escalation pathways for questions/concerns including organisational expert backup
Multiple tests being ordered where one might be sufficient to begin		
Lack of awareness about test logistics/test processes		

Step #4: Assessing and undertaking consent; and legal implications

Risk	Potential consequence(s)	Potential controls and/or treatments
Clinician undertaking consent does not fully understand consent and legal implications Patient not appropriately consented	▪ Patient receives insufficient/ incorrect information ▪ Sub-optimal clinical care ▪ Medicolegal and complaints risk	▪ Training and development of relevant staff to ensure skills and knowledge in appropriate test ordering ▪ **Credentialling and special scope of practice** to provide standards for relevant practitioners ▪ Organisational determination of who can order which tests and thus undertake consent (e.g., Junior Doctor needs Consultant approval) ▪ Design of locally appropriate access to genomics expertise (e.g., genomic champions in clinical units, establishment of multi-disciplinary meetings, laboratory feedback or guardrails) ▪ Clear escalation pathways for questions/concerns including organisational expert backup ▪ Point-of-care resources for clinicians

Step #5: Ordering genomic tests

Risk	Potential consequence(s)	Potential controls and/or treatments
Incorrect/ inappropriate test ordered Multiple tests being ordered where one might be sufficient Lack of awareness about test logistics/ test processes	▪ Validity/utility of result unclear ▪ Delay in diagnosis and/ or treatment resulting in harm ▪ Cost and/or waste of resources	▪ Effective **models of care** including test ordering process ▪ Training and development of relevant staff to ensure skills and knowledge in appropriate test ordering ▪ **Credentialling and special scope of practice** to provide standards for relevant practitioners ▪ Organisational determination of who can order which tests and thus undertake consent (e.g., Junior Doctor needs Consultant approval) ▪ Design of locally appropriate access to genomics expertise (e.g., genomic champions in clinical units, establishment of multi-disciplinary meetings, laboratory feedback or guardrails) ▪ Clear escalation pathways for questions/concerns including organisational expert backup ▪ Point-of-care resources for clinicians

Step #6: Genomic test analysis

Risk	Potential consequence(s)	Potential controls and/or treatments
Poor quality of laboratory test (i.e., large numbers of variants of uncertain significance, classification of variants does not follow rigorous process) Poor reporting by laboratory	▪ Validity/utility of result unclear ▪ Delay in diagnosis and/or treatment resulting in harm ▪ Cost and/or waste of resources	▪ Effective **models of care** including test analysis ▪ **Credentialling of practitioners** ▪ (If external) contracts specifies quality metrics for test analysis ▪ Sufficient pathology expertise ▪ Ensuring use of NATA-accredited laboratory

Step #7: Interpreting genomic test results

Risk	Potential consequence(s)	Potential controls and/or treatments
Missed result return to patient Misinterpretation of results by clinicians (e.g., over- or under-calling of variants of uncertain significance) Lack of clarity about management of incidental findings Underappreciation of the difference between quality/reporting from different laboratories Underappreciation of impact on family members	Clinician misinterpretation of result may result in: ▪ Inappropriate/insufficient action ▪ Treatment delay/non-initiation Results not communicated to patient causing: ▪ Inappropriate/insufficient treatment ▪ Treatment delay/non-initiation ▪ Sub-optimal clinical care and attendant clinical, resource and financial risks ▪ Medicolegal risks ▪ Cost and/or waste of resources ▪ Inappropriate/insufficient family screening ▪ Poor family communication and attendant harms	▪ Effective **models of care** including test return and test return monitoring ▪ Training and development of relevant staff to ensure skills and knowledge in appropriate test ordering ▪ **Credentialling and special scope of practice** to provide standards for relevant practitioner ▪ Design of locally appropriate access to genomics expertise (e.g., genomic champions in clinical units, establishment of multi-disciplinary meetings, laboratory feedback or guardrails) ▪ Clear escalation pathways for questions/concerns including organisational expert backup ▪ Flags in electronic medical records to prompt timely result return ▪ Awareness of referral pathways and when to involve genetic counselling ▪ Use of current NPAAC recommendations for management of incidental findings ▪ (If external) contracts specifies quality metrics for test analysis ▪ Sufficient pathology expertise ▪ Ensuring use of NATA-accredited laboratory

Step #8: Clinical application of genomic results in the context of an individual patient

Risk	Potential consequence(s)	Potential controls and/or treatments
Insufficient/ inappropriate consideration of treatment options Insufficient consideration of governance of treatment options that are either emerging practice or research Insufficient/ inappropriate consideration of future assessment needs Lack of appropriate communication about potential risks and next steps in management and support of extended family Lack of resources/ supports for devastating diagnosis	▪ Inappropriate/insufficient treatment ▪ Treatment delay ▪ Sub-optimal clinical care and attendant clinical, resource and financial risks ▪ Medicolegal risks ▪ Cost and/or waste of resources ▪ Inappropriate/insufficient follow up put in place	▪ Effective **models of care** including clinical application of results ▪ Training and development of relevant staff to ensure skills and knowledge in clinical application of results ▪ **Credentialling and special scope of practice** to provide standards for relevant practitioners ▪ Organisational determination of who can order which tests and thus undertake results return and clinically apply results (e.g., Junior Doctor needs Consultant approval) ▪ Design of locally appropriate access to genomics expertise (e.g., genomic champions in clinical units, establishment of multi-disciplinary meetings, laboratory feedback or guardrails) ▪ Clear escalation pathways for questions/concerns including organisational expert backup ▪ Patient profiles established for those undertaking testing that include consideration of future assessments (i.e., young female single patient is reviewed at a later stage when childbearing is more likely) ▪ Where available, consider use of IT systems to support practice (e.g., prompts added to the electronic medical records for follow-up) ▪ Clear guidelines available for management of family members stratified by risk level

Step #9: Family support considerations and requirements

Risk	Potential consequence(s)	Potential controls and/or treatments
Lack of expertise in family follow up requirements Lack of clarity about who is accountable for family management	Appropriate family follow up and support not undertaken resulting in: ▪ Psychosocial harm to patient/family ▪ Inappropriate/insufficient follow up put in place ▪ Insufficient management of family considerations ▪ Medicolegal risks ▪ Sub-optimal care of family members	▪ Clear support details available relevant for the context and patient group (this will most likely vary in each department and within each hospital) ▪ Clear guidelines available for management of family members stratified by risk level

How was this tool developed?

This tool was developed as part of the **Genomics and Your Hospital toolkit** by the Melbourne Genomics Health Alliance, with ongoing input from Victorian healthcare leaders.

Understanding and mitigating risks was identified as a key action for health services when planning for genomic care. Using an iterative, codesign approach, these tools were drafted and reviewed with members from the Melbourne Genomics *Professional Governance Working Group* and *Quality Working Group*. The tool was tested with hospitals to assess their usefulness and utility, and refined over time.

The toolkit remains a living resource that will evolve as genomics becomes more widely integrated into routine care.

GenomicsToolkit.org.au

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