

**DRAFT IMPLEMENTATION PLAN -
NATIONAL HEALTH GENOMICS POLICY
FRAMEWORK**

**DRAFT FOR
CONSULTATION
V1.0**

(1 December 2017)

DRIVING NATIONAL ACTION: 2018-2021

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Introduction

This is the first Implementation Plan under the 2018-2021 National Health Genomics Policy Framework. The National Framework was developed by the Commonwealth and states and territories under the Australian Health Ministers' Advisory Council (AHMAC) governance arrangements. It was agreed by the Council of Australian Governments (COAG) Health Ministers in November 2017.

The National Framework is a blueprint for coordinated action by governments, health professionals, non-government organisations and industry to work in partnership to embed genomics in the Australian health system.

Some States and Territories have individual genomic policy strategies; however, this is the first time in Australia that a national strategy articulates short to long-term goals across a number of key policy areas which impact on the health system and health outcomes. The National Framework provides an overarching framework for state/territory strategies and local hospital networks, with some examples of actions at state/territory level captured in the Implementation Plan.

The purpose of the National Framework is to:

- establish a high level policy Framework to give coherence to, and guide government activity across public genomics policy (noting that the focus of the first iteration is health care applications that are informed by, or based on, human genetic or genomic testing);
- drive improved performance of mainstream genomic services in delivering better health outcomes;
- give visibility to the ethical, legal and social issues associated with genomics and ensure they are included in the development and implementation of all public policy and research; and
- provide national leadership toward embedding genomics in the health system.

The Implementation Plan has been developed by the Commonwealth Department of Health, under the guidance of an AHMAC jurisdictional reference group (reporting through the Clinical Principal Committee) to support the National Framework.

Responding to Consultation Questions

Stakeholders are encouraged to respond to the consultations questions throughout the document which are also compiled together at the end of the document. Respondents are also welcome to provide comments through track changes when seeking to make minor amendments to the current draft text.

The Actions included in this draft are intended to be appropriately led at a national level and achievable. These criteria should be considered when proposing new any new Actions.

Background

The National Framework aims to help people live longer and better lives through harnessing the benefits of human genomics in a cost-effective, equitable, ethical way in the Australian health system. It sets the direction for a nationally co-ordinated approach to genomics which avoids duplication of effort and leverages current activity.

The National Framework identifies five key strategic priority areas for increased national effort:

1	Person-centred approach: Delivering high quality care for people through a person-centred approach to genomics
2	Workforce: Building a skilled workforce that is literate in genomics.
3	Financing: Ensuring sustainable and strategic investment in cost-effective genomics.
4	Services: maximising quality, safety and clinical utility of genomics in health care
5	Data: Responsible collection, storage, use and management of genomic data.

It also recognises that these priorities must be underpinned by clear governance arrangements, a responsible approach to ethical, legal and social issues and stakeholder engagement.

Sector consultation

A broad range of stakeholders were identified and consulted with extensively on the development of Framework. Public stakeholder forums are being held in Sydney and Melbourne, together with an expert roundtable in December 2017 on the draft Implementation Plan. These forums together with written submissions from organisations representing researchers, consumers, healthcare professionals and individuals will inform the Implementation Plan for the Framework.

Translating the National Framework into Action

The Implementation Plan acknowledges that involving all governments and the wider community is pivotal to addressing the challenges associated with harnessing the benefits of genomics for all Australians. The first Implementation Plan establishes the groundwork for the National Framework. It proposes strategic projects and actions that will drive results over the longer term while implementing high-priority actions in the short term. As the National Framework has a long term vision, some actions are expected to go beyond its initial three-year lifespan.

The Commonwealth and states/territories are already making substantial investments in genomic health care, including clinical and non-clinical research streams. While no additional funding is available at this time to take forward new proposed projects and

actions in the Implementation Plan, governments are expected to consider these as priorities for any further investment as resourcing permits.

Some states and territories are developing their own implementation plans that will reflect their priorities that will contribute to delivering on outcomes under the National Framework. These implementation plans are expected to outline the actions already being taken locally and reflect new initiatives being undertaken to support key national priorities.

Purpose and Scope of the Implementation Plan

The Implementation Plan incorporates activities being undertaken across various sectors to encourage and enable collaboration and information sharing.

Roles and responsibilities

Each level of government has specific roles and responsibilities across the range of health policies and programs that involve or are becoming increasingly influenced by, human genomics. The Framework does not change the nature of these roles and responsibilities, but seeks to create a more cohesive approach across all governments. The Framework recognises that coordinated and comprehensive planning is required between all levels of government and across a range of portfolios. The Framework embodies this approach with all levels of government involved in both its development and implementation.

While the National Framework is the responsibility of the Commonwealth and states/territories under the AHMAC governance arrangements, the work and cooperation of research organisations, public and private pathology laboratories, healthcare professional organisations, educational leaders and the private sector are integral to achieving the overall vision of the Framework. Some of the key activities undertaken by these stakeholders are reflected in the Implementation Plan.

Timeframes of the Implementation Plan

Indicative timeframes have been proposed for each activity as:

- short-term (12-18 months);
- medium term (18-24 months); or
- long term (more than 24 months).

Timeframes indicate the expected length of time required to complete the proposed activity, noting some activities that are flagged as long-term are ongoing and are likely to go beyond the lifespan of the first iteration of the National Framework.

Governance

Governance is essential for driving and co-ordinating implementation of the national Framework. To ensure that all governments are involved and work is taken forward in a cohesive way, it is appropriate for the governance arrangements to be established under the AHMAC structure.

National Action	Roles	Timeframe	Lead Responsibility
Action i: Governments will establish governance arrangements through the AHMAC structure to provide advice on the implementation of the National Health Genomics Policy Framework.	The National Health Genomics Policy Reference Group will provide advice to Clinical Principal Committee (CPC) on the options available.	Short term	CPC
Action ii: Governments will evaluate the National Health Genomics Policy Framework. This evaluation will begin in 2020 and be completed during the life of the Framework. It will be completed in time to inform the future directions in health genomics policy.	The Commonwealth will commission an independent evaluation, including development of an evaluation plan.	Long term	AHMAC

Question 1: Do you have any comments on the proposed governance arrangements?

Accountability - measuring and reporting

National Action	Roles	Timeframe	Lead Responsibility
Action iii: Governments will request CPC deliver an annual report for presentation to Health Ministers on the implementation progress of the Framework.		Short term	CPC
Action iv: Governments will develop a national system performance framework* to monitor whether genomics is being embedded in the health system in an equitable, cost-effective, efficient and ethical way.	The CPC will commission the development of a performance framework.	Short term	CPC
Action v: Governments will regularly review and update the Implementation Plan over its three year life span in response to the annual reviews on progress.	AHMAC will put in place arrangements for a regular review of the Implementation Plan, and for advice to be provided on the need for it to be updated.	Short term	CPC

*Performance Framework

This framework is expected to include high level indicators of change as there is currently no nationally consistent dataset on which to build a robust and reliable evidence base. In the longer term, the National Stocktake of Genetic/Genomic Testing will create nationally consistent definitions and collection methods for longitudinal analysis of trends in the uptake of services.

Question 2: *How can the accountability arrangements, for implementation of the Framework, be improved?*

Implementation of Strategic Priority 1: Person-Centred Approach – delivering high quality care through a person-centred approach to integrating genomics into health care

Current government activities

Many initiatives to support person-centred care are underway nationally. Evidence based guidelines are available to consumers and health professionals including the National Health and Medical Research Council guidelines for direct to consumer testing and genetic discrimination. Noting the fast growing domain of genomic knowledge these guidelines may require regular revisions. Various policy, program and communication strategies operate at all jurisdictional levels to support people in the challenges and choices they may face when deciding on their health care. The need for genomic education of families and patients is widely recognised as being critical to maximising the potential benefits to patients while also managing expectations.

The Commonwealth and states/territories are funding research through leading research bodies and consortiums which focuses on a range of related issues including: examining issues in context of genomic data sharing (including legal and non-legal barriers); considering the patient experience and ethical aspects; mapping existing materials; and piloting clinical genomics consent and research genomics consent processes which could be adopted nationally.

Priority areas for action:

[These have been agreed to by Health Ministers and cannot be changed]

- 1.1** Improve support for individuals, and their families, to make informed choices about genomic testing, and take responsibility for those choices and related risks.
- 1.2** Encourage appropriate referrals of genomic testing, that put the welfare and needs of the individual first, thereby avoiding unnecessary testing.
 - 1.2.1** Developing and promoting clinical practice guidelines and decision support tools for engaging with individuals on their personal context and health goals.
- 1.3** Engage relevant community patient advocacy organisations and consumers in discussions of the consumer experience, as well as on the ethical, legal and social issues of genomics.
 - 1.3.1** Developing community engagement strategies to promote an understanding of the application and impact on genomic advances in health care, including the gap between testing and treatment options.
 - 1.3.2** Exploring how the consumer experience can be captured and measured to inform priorities and establish a baseline.

- 1.4** Promote public awareness and understanding of genomics, including through linguistically and culturally safe and appropriate information resources for targeted consumer groups.
- 1.5** Identify barriers to equity of access and develop a national approach to address these, noting that access is multi-dimensional and includes location, cost, availability and appropriateness (including cultural acceptability).
- Explore barriers to the uptake of genomic services including the potential for discrimination (life insurance, employment, lifestyle, access to services etc).
 - Evaluating the delivery of genomic services in terms of being able accessible, appropriate and culturally secure and responsive for Aboriginal and Torres Strait Islander peoples
- 1.6** Investigate how genomics data can be integrated with electronic health records to improve coordination of care, support better clinician decision-making and facilitate seamless clinical pathways.
- 1.7** Explore the potential to develop integrated person and family-centred care delivered by multi-disciplinary teams.
- 1.8** Identify and promote a standard model of consent that is sufficiently flexible to support a person’s understanding of the potential implications of having their genome sequenced, familial aspects and decision-making about any secondary findings, as well as including provision for access by researchers if appropriate.

Implementation Actions

To support people being involved in, and central to, their genome-directed diagnosis, health care and treatment:

National Action	Timeframe	Lead Responsibility
<p><i>Understand the current Ethical, Legal and Social Issues (ELSI) framework environment and identify relevant key issues.</i></p> <p>Action 1: Engage with the Attorney-General’s Department to explore reviewing implementation of the key recommendations of the 2003 Australian Law Reform Commission (ALRC) Report <i>Essentially Yours: The Protection of Human Genetic Information in Australia</i>.</p>	Short term	Commonwealth

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<p>Action 2:</p> <p>A) Identify, map and collate consumer views on ELSI including engaging with Aboriginal and Torres Strait Islander populations and other vulnerable populations to understand their perspective on ELSI (consistent with the principles of the <i>National Cultural Respect Framework for Aboriginal and Torres Strait Islander Health 2016-2026</i>).</p> <p>B) Use the information from 2A to inform strategies and communications around ELSI.</p>	<p>Short term – ongoing</p>	<p>AHMAC - Commonwealth, states/territories</p>
<p>Action 3:</p> <p>A) Develop and promote nationally consistent templates and guidance for consent to clinical genomic testing, and consider the relationship to dynamic consent for data sharing purposes.</p> <p>B) Promote a national approach to managing secondary findings.</p>	<p>Short term</p>	<p>CPC - Commonwealth</p>
<p><i>Improving health genomics literacy in the general community</i></p> <p>Action 4:</p> <p>A) Promote national consistency in content and terminology.</p> <p>B) Review existing materials to identify gaps.</p> <p>C) Prioritise development of new materials.</p>	<p>Long term - ongoing</p>	<p>CPC</p>

Question 3: Are the Actions identified appropriate for delivering on the ‘Person-centred approach’ priority areas for action?

Question 4: Are the timeframes and leads identified for each Action appropriate?

Question 5: Are there any additional actions that would support the implementation of Strategic Priority 1? (Note new Actions can be incorporated by adding rows to the table).

Implementation of Strategic Priority 2: Workforce – Building a skilled workforce that is literate in genomics

Current government activities

Genomic medicine presents a major workforce development challenge. Many states/territories are already taking action to better understand how the workforce needs to evolve to support genomics as an integral part of mainstream clinical practice. For example, NSW commissioned the report in 2017, *The Changing Landscape of the Genetic Counselling Workforce*. The primary healthcare workforce is also expected to take on an increasing role in determining access, linking patients to appropriate genomic services, and help patients understand and deal with findings.

The Commonwealth is funding research into mapping workforce needs (through audits, surveys, interviews etc) as a first step in understanding gaps and opportunities.

Priority areas for action:

[These have been agreed to by Health Ministers and cannot be changed]

- 2.1** Improve the genomics literacy and capability of the health workforce through the development, delivery and ongoing maintenance of appropriate genomic education, training and skills.
- 2.2** Build the capacity for, and promote access to, a skilled and literate genomics workforce, through workforce strategies and planning at the national level.
- 2.3** Facilitate partnerships and networks to promote and support sharing of knowledge.

Implementation Actions

To upskill the broad health workforce through increasing capacity and capability in genomics and bioinformatics:

National Action	Timeframe	Lead Responsibility
<p><i>Building an appropriately skilled workforce that is literate in genomics.</i></p> <p>Action 5:</p> <p>A) Map the genomic workforce initiatives currently underway and identify challenges to further develop the necessary genomic workforce capabilities and consider strategies to support equitable supply and distribution of that workforce.</p> <p>B) Develop and enhance genomic literacy for the broader health workforce including training needs of health sector staff working with Aboriginal and Torres Strait Islander peoples.</p> <p>C) Engage with relevant professional bodies and colleges who oversee and inform postgraduate health workforce training.</p> <p>D) Build collaborative relationships between governments, professional bodies and tertiary education providers to streamline health genomics curricula.</p>	<p>Long term - ongoing</p>	<p>AHMAC - States/territories</p>

Question 6: *Are the Actions identified appropriate for delivering on the ‘Workforce’ priority areas for action?*

Question 7: *Are the timeframes and leads identified for each Action appropriate?*

Question 8: *Are there any additional actions that would support the implementation of Strategic Priority 2? (Note new Actions can be incorporated by adding rows to the table).*

Implementation of Strategic Priority 3: Financing – Ensuring sustainable investment in cost-effective genomics

Current government activities

The Commonwealth is taking a lead role in building capabilities and experience to support the development, submission, and assessment of applications to the Medical Services Advisory Committee (MSAC) for funding of new genetic/genomic testing services.

There is a collective effort by the Commonwealth and states/territories to strengthen the evidence base for demonstrating the cost-effectiveness of genomic services by exploring and reporting on economic evidence that supports the integration of genomics into health care. This includes working with the Global Genomic Medicine Collaborative to review evaluation methods and criteria for genomics tests.

Priority areas for action:

[These have been agreed to by Health Ministers and cannot be changed]

- 3.1** Consider genomics in the context of any broader review of health technology assessment to support national consistency.
- 3.2** Develop partnerships, funding and data sharing approaches for genomics that promote access to safe, efficient and cost-effective services.
- 3.3** Develop a national research agenda for genomics and identify opportunities to link to Commonwealth and state/territory research priorities.
- 3.4** Better understand the role of the private industry, and the opportunities for partnerships to support the development and sustainable application of genomic knowledge.
- 3.5** Collaborate across governments and stakeholders to maximise investments and reduce duplication of resources and efforts.

Implementation Actions

To ensure Australia’s investment in genomic health care and research delivers actionable results that lead to people living better and longer lives:

National Action	Timeframe	Lead Responsibility
<p style="text-align: center;"><i>Sustainable and strategic government investment in clinical services</i></p> <p>Action 6: Leverage existing mechanisms and processes to develop nationally cohesive approaches to Health Technology Assessment (HTA) for genetic and genomic applications.</p>	Short term	AHMAC
<p>Action 7: Examine equitable financing and purchasing models to inform the appropriate integration of safe, effective and cost-effective genomic healthcare delivery.</p>	Medium term	Commonwealth, states/territories
<p style="text-align: center;"><i>Sustainable and strategic research investment</i></p> <p>Action 8: Foster partnerships and stakeholder engagement to drive innovations in genomic health care to support individual and population health outcomes.</p>	Long term - ongoing	Commonwealth, states/territories
<p>Action 9: Map current research activities and explore options to strengthen national coordination of genomic research to inform the development of a national health genomics research agenda.</p>	Medium term	CPC

Question 9: Are the Actions identified appropriate for delivering on the ‘Financing’ priority areas for action?

Question 10: Are the timeframes and leads identified for each Action appropriate?

Question 11: Are there any additional actions that would support the implementation of Strategic Priority 3? (Note new Actions can be incorporated by adding rows to the table).

Implementation of Strategic Priority 4: Services – Maximising quality, safety and clinical utility of genomics in health care

Current government activities

The Therapeutic Goods Administration, within the Commonwealth Department of Health, is responsible for continuing to ensure the quality, safety and performance of genomic tests so that patients and clinicians can receive accurate and meaningful test results. Regulatory approaches enable innovation in testing and timely market access to genetic/genomic tests that are safe and fit for purpose.

The Commonwealth and states/territories are also supporting research to identify appropriate pathways for genomic research to translate into safe, effective, and cost-effective clinical application.

Priority areas for action:

[These have been agreed to by Health Ministers and cannot be changed]

- 4.1** Review and build on guidelines, regulations and standards to ensure genomic applications: are evidence-based; nationally consistent (where appropriate); demonstrate clinical utility; and align with agreed national ethical approaches.
- 4.2** Strengthen processes to identify, promote, monitor and report best practice in clinical genomics, including sharing of data and information.
- 4.3** Maximise genomics research opportunities that aim to resolve clinical uncertainty and improve quality and safety

Implementation Actions

To ensure that the use of genomics in health care is based on the best available knowledge, evidence and research and the outcomes of treatment are used to help improve care:

National Action	Timeframe	Lead Responsibility
<p>Action 10: Update guidelines on genomic testing and research as appropriate including direct to consumer testing, and encourage national adoption.</p>	Short term	Commonwealth, states/territories
<p>Action 11: Provide advice to the Standing Committee on Screening to inform a nationally consistent approach to a position on genomic population screening.</p>	Medium term	Commonwealth, states/territories
<p>Action 12: Support and promote development and sharing of evidence based clinical practice guidelines and decision support tools for referrals to clinically appropriate genomic healthcare services.</p>	Long term	AHMAC
<p>Action 13: Use the National Stocktake of Genetic and Genomic Testing and other data sources to identify potential inequities in service provision and access.</p>	Short term	CPC

Question 12: Are the Actions identified appropriate for delivering on the ‘Services’ priority areas for action?

Question 13: Are the timeframes and leads identified for each Action appropriate?

Question 14: Are there any additional actions that would support the implementation of Strategic Priority 4? (Note new Actions can be incorporated by adding rows to the table).

Implementation of Strategic Priority 5: Data – Responsible collection, storage, use and management of genomic data

Current government activities

A number of jurisdictions are investing in developing standards, policies and procedures to support a common infrastructure for the management and use of clinical genomic data (including genotypic and phenotypic data). The next step is for governments to agree a national approach to sharing health genomics data and arrangements to agree and embed national health genomics data standards (taking into consideration international approaches).

The key contribution of the Commonwealth is to develop a digital health framework that can capture genomics information in a way which ensures that Australia's digital health foundations support the advancement of genomics.

Priority areas for action:

[These have been agreed to by Health Ministers and cannot be changed]

- 5.1** Establish a national genomic data governance framework that aligns with international frameworks.
- 5.2** Explore infrastructure options for national genomic data collection, storage and sharing.
- 5.3** Promote culturally safe and appropriate genomic and phenotypic data collection and sharing that reflects the ethnic diversity within the Australian population, including for Aboriginal and Torres Strait Islander peoples.
- 5.4** Develop nationally agreed standards for data collection, safe storage, data sharing, custodianship, analysis, reporting and privacy requirements.
- 5.5** Promote public awareness of the contribution of all research activities, including those funded through private industry, to advancing the application of genomic knowledge to health care.
- 5.6** Support sector engagement with international genomic alliances to promote shared access to data for research and global harmonisation of data where appropriate.
- 5.7** Strengthen public trust of data systems and mechanisms so that people are empowered to engage with genomic interventions in the health system.

Implementation Actions

To support the collection and analysis of genomic data to drive improvements in health outcomes for all Australians and provide a pathway to truly personalised health care:

National Action	Timeframe	Lead Responsibility
<p>Action 14: Develop a national genomic data governance framework that aligns with international frameworks.</p>	Long term	AHMAC
<p>Action 15:</p> <ul style="list-style-type: none"> A) Develop robust national minimum security standards for genomic data systems and data sharing, including consideration of vulnerable populations. B) Explore opportunities for integration of individual and population genomic information with electronic health records. C) Consider, and nationally adopt, appropriate international standards on phenotype and disease classification systems. 	Long Term	AHMAC / Commonwealth
<p>Action 16: Develop information resources for the general population, and vulnerable groups in the community, on the implications and benefits of genomic data sharing to build community trust.</p>	Long Term - ongoing	CPC – Commonwealth, states/territories
<p>Action 17: Develop a proof of concept for data sharing across systems.</p>	Long term	Commonwealth

Question 15: Are the Actions identified appropriate for delivering on the ‘Data’ priority areas for action?

Question 16: Are the timeframes and leads identified for each Action appropriate?

Question 17: Are there any additional actions that would support the implementation of Strategic Priority 5? (Note new Actions can be incorporated by adding rows to the table).

Question 18: *Are there any other comments you would like to provide on the draft Implementation plan?*

Thank you for taking the time to provide feedback on the National Health Genomics Policy Framework Implementation Plan. Please submit your comments by emailing this document, with your comments compiled below, to Genomics@health.gov.au.

Compiled Responses

Question 1: *Do you have any comments on the proposed governance arrangements?*

Question 2: *How can the accountability arrangements, for implementation of the Framework, be improved?*

Question 3: *Are the Actions identified appropriate for delivering on the 'Person-centred approach' priority areas for action?*

Question 4: *Are the timeframes and leads identified for each Action appropriate?*

Question 5: *Are there any additional actions that would support the implementation of Strategic Priority 1?*

Question 6: *Are the Actions identified appropriate for delivering on the 'Workforce' priority areas for action?*

Question 7: *Are the timeframes and leads identified for each Action appropriate?*

Question 8: *Are there any additional actions that would support the implementation of Strategic Priority 2?*

Question 9: *Are the Actions identified appropriate for delivering on the 'Financing' priority areas for action?*

Question 10: *Are the timeframes and leads identified for each Action appropriate?*

Question 11: *Are there any additional actions that would support the implementation of Strategic Priority 3?*

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Question 12: *Are the Actions identified appropriate for delivering on the 'Services' priority areas for action?*

Question 13: *Are the timeframes and leads identified for each Action appropriate?*

Question 14: *Are there any additional actions that would support the implementation of Strategic Priority 4?*

Question 15: *Are the Actions identified appropriate for delivering on the 'Data' priority areas for action?*

Question 16: *Are the timeframes and leads identified for each Action appropriate?*

Question 17: *Are there any additional actions that would support the implementation of Strategic Priority 5?*

Question 18: *Are there any other comments you would like to provide on the draft Implementation plan?*

Consultation Draft