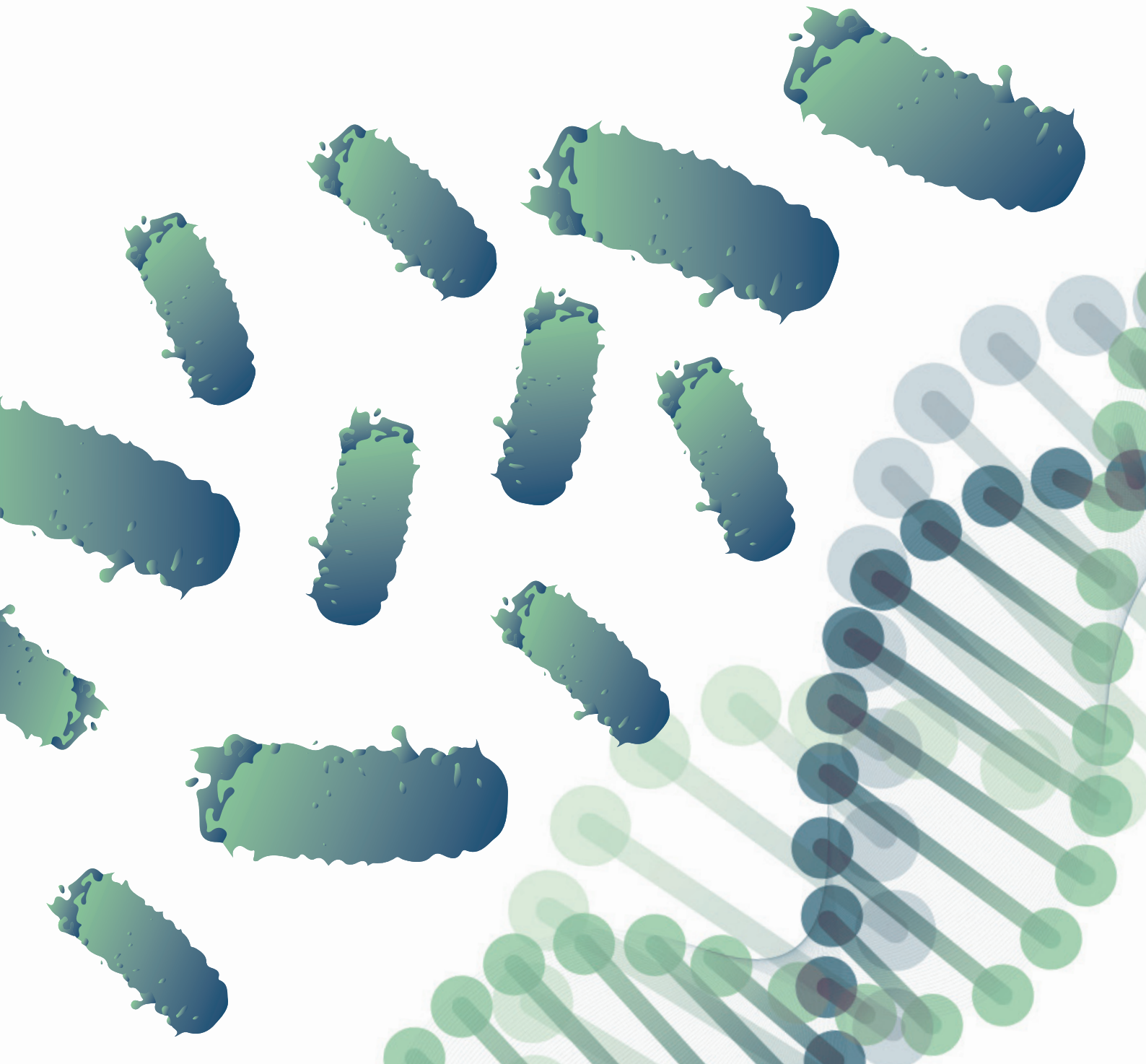




Australian Government
Department of Health

Implementation Plan for the **National Microbial Genomics Framework**

2021-2022



Implementation Plan to the National Microbial Genomics Framework 2021-2022

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Acronyms and abbreviations

ABLN	Australian (Counter) Bioterrorism Laboratory Network
AHMAC	Australian Health Ministers' Advisory Council
AHPPC	Australian Health Protection Principal Committee
AMR	Antimicrobial resistance
ASTAG	Australian Strategic and Technical Advisory Group on AMR
CDGN	Communicable Diseases Genomics Network
CDNA	Communicable Diseases Network Australia
EQA	External Quality Assessment
GHFM	Genomics Health Futures Mission
GMI	Global Microbial Identifier
Health	Australian Government Department of Health
LEADDR	Laboratories for Emergency Animal Disease Diagnosis and Response
MRFF	Medical Research Future Fund
NATA	National Association of Testing Authorities
NHMRC	National Health and Medical Research Council
NPAAC	National Pathology Accreditation Advisory Council
PHLN	Public Health Laboratory Network
PHU	Public Health Unit
PTP	Proficiency Testing Program
RCPA QAP	Royal College of Pathologists of Australasia Quality Assurance Programs
WGS	Whole Genome Sequencing

Introduction

This is the first Implementation Plan (the Plan) prepared to support nationally consistent microbial genomics activities in Australia. It sits under the National Microbial Genomics Framework 2019-2022 (Framework). The Plan seeks to support strategic implementation of, and promote national consistency for, the application of microbial genomics. It will improve national surveillance of and response to communicable diseases and biothreat agents of clinical and public health importance. It recognises and includes microbial genomics activities that states and territories are undertaking across various sectors. These activities support collaboration, coordination and information sharing.

This Plan looks mainly at the use of microbial genomics to build public health capability and improve surveillance of antimicrobial resistance. Opportunities to use microbial genomic data for personalised medicine, hospital care and to guide treatment should be explored in future iterations.

The Australian Government Department of Health (Health) prepared this Plan in consultation with:

- the Communicable Diseases Genomics Network (CDGN)
- the Public Health Laboratory Network (PHLN)
- the Communicable Diseases Network Australia (CDNA)
- other relevant expert groups.

The Plan identifies priority actions that meet the agreed outcomes of the Framework's strategic priority areas:

1. Standardised national approach
2. Technology and data governance
3. Integration into public health
4. Access and workforce
5. Financing

Essential to these priority areas are:

- clear governance arrangements
- a responsible approach to ethical, equity and legal issues
- stakeholder engagement.

BACKGROUND

The Framework provides a consistent, national and strategic view for the integration of microbial genomics into the Australian health system. The Framework also considers microbial genomics policy issues and challenges needing to be addressed. It sets the direction for a nationally co-ordinated approach to microbial genomics which avoids duplication of effort and leverages current activities.

The Framework is a blueprint for coordinated action by governments, health professionals, non-government organisations and industry, working in partnership to embed microbial genomics into the Australian health system. Some states and territories have their own microbial genomics policy strategies. This is the first time a national framework articulates short to long-term goals to strengthen this capability across a number of strategic priority areas. The Australian Government and state and territory governments under the Australian Health Ministers' Advisory Council (AHMAC) governance arrangements developed the Framework.

TRANSLATING THE FRAMEWORK INTO ACTION

The Plan acknowledges that involving all governments, laboratory and public health sectors is key to harnessing the power and subsequent health benefits of microbial genomics. The first Plan will operationalise the Framework. It proposes strategic projects and actions that will drive results over the longer term and high-priority actions for the short term. As the Framework has a long term vision, some actions are expected to go beyond its initial three-year duration.

The Australian Government and state and territory governments have already made large investments into microbial genomics, including research streams. In 2020, the Australian Government announced \$27 million in funding under the Medical Research Future Fund (MRFF). This funding will support large scale pathogen genomics research studies that are late in the research and development pipeline. These projects aim to show clinical and/or public health value, cost-effectiveness and translational capacity. This kind of evidence is key to the adoption of genomics in the mainstream health system.

While the current pilot implementation activities show reasonable evidence of success, governments need to consider and prioritise further investment in microbial genomics-related activities. Investment is needed to support national coordination, standardisation and interoperability, so that the value of microbial genomics can be successfully realised in public health practice.

SECTOR CONSULTATION

A broad range of stakeholders were identified and consulted during the development of the Framework. Consultation with key networks, including PHLN, CDGN, CDNA, state and territory governments and other relevant policy makers have informed the development of the Plan for the Framework.

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, microbial genomics. The Framework does not change the nature of these roles and responsibilities, but looks to create a more cohesive approach across all governments. The Framework and the Plan recognise coordinated and thorough planning is needed between all levels of government and across the laboratory and public health sector. The Framework embodies this approach, with all levels of government involved in both its development and implementation.

The Framework is the responsibility of the federal, state and territory governments under the AHMAC governance arrangements¹. The work and cooperation of pathology laboratories, public health authorities, research organisations and educational leaders is essential to achieving the Framework's overall vision.

PRIORITY KEY

Indicative priorities proposed for each activity are:

- low
- medium
- high

The level of priority is determined through consideration of:

- the need for implementation
- the sequential need for an activity
- the beneficial influence or impact the action will have on national capacity, capability and utilisation of microbial genomics in the public health system.

INDICATIVE ACTION TIMEFRAMES

- Indicative timeframes proposed for each activity are:
- short-term (1 – 1.5 years)
- medium-term (1.5 – 3 years)
- long-term (more than 3 years).

Timeframes show the expected length of time needed to complete the proposed activity. Some activities flagged as long-term are ongoing and likely to go beyond the duration of the first iteration of the Framework and the Plan.

¹ On 29 May 2020, it was announced that the Council of Australian Governments (COAG) would cease and the former COAG Councils and Ministerial Forums would be reviewed and rationalised. The Framework and Plan will be managed under AHMAC equivalent governance arrangements, once determined.

Governance

Governance is key for driving and co-ordinating implementation of the National Framework. To ensure the Australian Government and state and territory governments are all involved and work is progressed in a cohesive way, it is appropriate for the governance arrangements to be established under the AHMAC (or equivalent) structure¹.

NATIONAL ACTION	ROLES	TIMEFRAME	LEAD RESPONSIBILITY
<p>ACTION I:</p> <p>The Australian Government and state and territory governments will establish governance arrangements through the Australian Health Protection Principal Committee (AHPPC) structure. AHPPC will provide advice on the implementation of the Framework, ensuring ongoing national consistency.</p>	<p>Health will discuss available options with relevant committees and networks.</p>	<p>Short-term</p>	<p>Health and relevant committees</p>
<p>ACTION II:</p> <p>The Australian Government and state and territory governments will evaluate the National Microbial Genomics Framework. This evaluation will begin in 2022 to inform the future directions in microbial genomics policy.</p>	<p>Health will lead an evaluation, including development of an evaluation plan.</p>	<p>Medium-term</p>	<p>Health</p>

1. On 29 May 2020, it was announced that the Council of Australian Governments (COAG) would cease and the former COAG Councils and Ministerial Forums would be reviewed and rationalised. The Framework and Plan will be managed under AHMAC equivalent governance arrangements, once determined.

Accountability - measuring and reporting

NATIONAL ACTION	ROLES	TIMEFRAME	LEAD RESPONSIBILITY
<p>ACTION III: Develop an annual report on implementation progress of the Framework.</p>	Health in collaboration with relevant committees and networks.	Short-term	Health and relevant committees
<p>ACTION IV: Develop a national system performance framework (with high level indicators to show what success looks like). This will monitor whether public health microbial genomics is being embedded in the laboratory and public health sectors in an equitable and efficient way. Development and future inclusion of ethical and cost-effectiveness indicators will be encouraged.</p>	Health to support development of a performance framework in consultation with relevant committees and networks.	Medium-term	Health and relevant committees and networks
<p>ACTION V: The Australian Government and state and territory governments will regularly review and report on progress against actions in the Plan. This will occur over the initial two year life span to inform the next iteration.</p>	Health to make arrangements for a regular review of the Implementation Plan.	Short-term	Health and relevant committees and networks

Strategic Priority 1: Standardised National Approach

PRIOR AND CURRENT ACTIVITIES

Many initiatives to support development of a standardised national approach have been completed or are underway. The Australian Government and state and territory governments are supporting microbial genomics research and projects aimed at improving consistency and harmonisation among public health laboratory systems.

- In 2014, PHLN developed recommendations for genomic-guided public health laboratory surveillance. The high priority challenges identified included:
 - harmonisation and evaluation of data analysis pipelines
 - provision of appropriate proficiency testing and quality control for microbial genome sequencing
 - sustainable data governance, storage and sharing
 - workforce development and upskilling.
- In 2016, the Australian Government supported a cross-jurisdictional microbial genomics project, led by the University of Melbourne. This included:
 - preparation of a roadmap for development of an Australian CDGN
 - a pilot project to sequence and analyse two pathogens of public health importance, *Listeria monocytogenes* and selected non-typhoidal *Salmonella* species
 - sequencing a back catalogue of priority pathogens of public health importance. This would provide the critical contextual genomic data to be used in future outbreak investigations.
- In 2017, CDGN and PHLN developed the report '*Data sharing to improve decision making in public health: a case for Australian Public Health Laboratories*'. The report examines foundational approaches for an effective and efficient data sharing scheme in the Australian public health system.
- As part of the 2014-15 budget, the Australian Government announced the establishment of the \$20 billion MRFF. The MRFF provides a sustainable source of funding for vital medical research over the medium to longer term. In May 2018, the Australian Government announced the Genomics Health Futures Mission (GHFM). In 2020, under the GHFM, \$27 million was dedicated to fund translational research projects involving pathogen genomics. The grant opportunity recognises that such evidence is critical to the adoption of genomics in mainstream healthcare.
- Over 2018-19, Health supported the Royal College of Pathologists of Australasia Quality Assurance Programs (RCPA QAP) Biosecurity program to develop a proficiency testing program (PTP) for the whole genome sequencing (WGS) of *Salmonella*. This was offered to interested laboratories for free. The PTP provided important insights into established WGS practices and how performance and standardisation may be improved. Following the successful first pilot WGS PTP, further modules will be offered over 2020-21. These modules monitor the quality of sequencing practices in Australian public health laboratories.

- In 2018, CDGN was formalised as an Expert Reference Panel under PHLN. CDGN aims to create a unified and coordinated public health microbial genomics network. This network will continue to advise and interact with existing laboratory and public health networks, government, policy makers, and other relevant stakeholders. The membership of CDGN was expanded over 2020 to include representation from CDNA. The expansion also allowed associate members to join committee meetings for the COVID-19 response.
- In 2020, to enhance the COVID-19 response, CDGN also fast-tracked implementation of its genomic data sharing platform. The platform enables the fast sharing and analysis of SARS-CoV-2 (the virus that causes COVID-19) sequences. Before the pandemic, the platform was being trialled with a focus on food-borne pathogens (for example, *Salmonella*).

Next steps will include continuing to support CDGN under existing governance arrangements.

This will ensure a national approach to implementation is maintained; raising the profile of this and other participating networks and the work being undertaken. This will encourage the sharing of best practice experience and drive the consistent application of microbial genomics in the public health system.

AGREED OUTCOMES AND PRIORITY AREAS FOR ACTION

Outcome 1.1 – Establishment of standardised policies and procedures

- Develop common standards, nomenclature and reporting outputs and formats that are fit for purpose for public health surveillance and response.
- Agree on a national open-source platform which hosts bioinformatics pipelines and a data repository that is available to all public health laboratories.

Outcome 1.2 – Harmonisation of laboratory-based sequencing and surveillance methods

- Develop harmonised laboratory-based sequencing methodologies.
- Develop standardised microbial genomics surveillance methods.

Outcome 1.3 – Establishment of quality services

- Develop quality assurance and proficiency testing specific to microbial genomics.
- Enhance technical competence and integrity within organisations offering microbial genomics services through collaboration with NPAAC, NATA and RCPA QAP).
- Promote sharing of sequence data nationally and with international laboratories to inform detection and investigation of multi-country outbreaks.

ACTIONS – STANDARDISED NATIONAL APPROACH

NATIONAL ACTION	TIMEFRAME	LEAD RESPONSIBILITY	PRIORITY
OUTCOME 1.1 – ESTABLISHMENT OF STANDARDISED POLICIES AND PROCEDURES			
1.1.1 Consider microbial genomics in the context of any broader review of health technology and systems assessment to support national consistency.	Medium	Health	Medium
1.1.2 Review and update relevant existing guidelines and standards, or develop new ones where appropriate. This is to ensure microbial genomics applications: are evidence-based; nationally consistent (where appropriate); and in line with agreed national approaches.	Medium	CDGN, PHLN	Medium
1.1.3 Build on existing mechanisms, systems and processes (where possible) to ensure nationally adopted supply of service and cohesive approaches to microbial genomic applications.	Medium	Health	Medium
1.1.4 Develop a consistent approach to microbial genomics data analyses across jurisdictions, noting the challenges and approaches in analysis can depend on the organism.	Medium	CDGN	High
1.1.5 Identify and establish national surveillance using genomics for priority organisms of national public health concern.	Short (ongoing)	CDGN, PHLN, Health	High
OUTCOME 1.2 – HARMONISATION OF LABORATORY-BASED SEQUENCING AND SURVEILLANCE METHODS			
1.2.1 Develop and promote laboratory guidelines and decision support tools to clearly describe appropriate referral practices. That is, when should WGS be requested by general practitioners, diagnostic laboratories, or other public health clients to ensure use of resources is efficient.	Medium	CDGN, PHLN	Medium
1.2.2 Encourage engagement between governments, laboratories, public health units (PHUs) and the research sector to discuss, discover and address any ethical and/or legal issues associated with microbial genomics (especially metagenomics).	Medium	CDGN, PHLN, Health	Medium
1.2.3 Involve health sector partners outside of core public health systems to promote awareness and understanding of microbial genomics, such as remote area clinics and hospitals.	Medium	CDGN, PHLN, Health	Medium
1.2.4 Design and provide an annual survey for public health laboratories and public health professionals working with microbial genomics to measure the impact and progress of the modernisation of national microbial genomics capability and capacity. This will also provide a practical evidence base for policy makers, discover areas for improvement, and disseminate best practices and lessons learned.	Medium	Health, CDGN	Medium

NATIONAL ACTION	TIMEFRAME	LEAD RESPONSIBILITY	PRIORITY
OUTCOME 1.3 – ESTABLISHMENT OF QUALITY SERVICES			
1.3.1 Develop nationally consistent protocols. This includes providing input into development of accreditation protocols for public health laboratories working with microbial genomics with NATA and RCPA.	Medium	CDGN, PHLN	High
1.3.2 Continue to support the development and implementation of microbial genomics-related PTP to be offered to laboratories through the RCPA QAP.	Short	CDGN, PHLN, Health	High
1.3.3 Participate in QAP programs (Global Microbial Identifier (GMI), External Quality Assessment (EQA), RCPA) to maintain key microbial genomics-related technical skills and share best practices and lessons learned with other laboratories.	Short	CDGN, PHLN	High
1.3.4 Generate high quality, locally relevant reference genomes for pathogens of public health significance in Australia. This is to be shared among jurisdictional laboratories; and release these genomes to the wider international community.	Short (ongoing)	Relevant PHLN laboratories	High

Strategic Priority 2: Technology and Data Governance

CURRENT ACTIVITIES

Several jurisdictions are investing in developing standards, policies and procedures to support a common infrastructure for managing and using microbial genomics data. However, inconsistencies in the technologies used and data governance, such as data storage infrastructure and bioinformatics analyses, raise challenges for rapid sharing of data. In particular for outbreak detection and the investigation of established outbreaks. Various initiatives are underway to address these challenges and improve data sharing between jurisdictions. These include:

- maintaining data sharing agreements established by CDGN and signed by jurisdictions. These agreements establish trust for cooperative, safe and equitable data sharing between CDGN laboratories
- developing a data sharing protocol and request form that will complement existing internal laboratory processes. The form will give relevant details on the context, type of request, expected outputs and details of relevant contact persons to streamline requests for sequence data from laboratories
- the Microbiological Diagnostic Unit Public Health Laboratory (MDU PHL) at the Peter Doherty Institute for Infection and Immunity on behalf of CDGN, is accelerating implementation of a national system for data storage. The system will store microbial genomics data with (minimal) epidemiological data. This is in addition to a public health bioinformatics platform, allowing standardised analyses across different laboratories.

To completely realise the value of nationally integrated microbial genomics for public health action, proposed next steps include formalising a national approach to the integration of microbial genomics data with relevant contextual / epidemiological metadata in a legally robust, equitable and safe way.

AGREED OUTCOMES AND PRIORITY AREAS FOR ACTION

Outcome 2.1 – Technology

- Acquire and maintain comparable sequencing instruments across jurisdictions which have the flexibility to be configured for use in the Australian setting.
- Develop and maintain high-performance computing infrastructure to support data storage and sharing that can adapt to emerging microbial genomics technologies.

Outcome 2.2 – Data sharing

- Enable multi-directional microbial genomic data and critical metadata sharing across and within jurisdictions, to the Australian Government and internationally. This should include the provision of data and/or isolates to public health laboratories from non-reference laboratories.
- Develop an agreed national protocol for sharing isolates and/or genomic, phenotypic, and epidemiological metadata.
- Ensure data sharing is compliant with the appropriate national and jurisdictional legislation and guidelines. For example, the *Privacy Act 1988*, the *National Health Security Act 2007*, the *National Statement on Ethical Conduct in Human Research (2007)* and any organisational ethical frameworks for public health practice.

Outcome 2.3 – Data storage

- Develop nationally agreed standards for data collection, safe storage, data sharing, custodianship, analyses, reporting and privacy requirements.
- Develop infrastructure to support secure storage of microbial genomic data.

Outcome 2.4 – Use of data

- Agree on common standards for the public health use of microbial genomics data across jurisdictions.
- Agree on common reporting standards for microbial genomics.
- Agree on a common reporting format across laboratories and jurisdictions.

Outcome 2.5 – Data governance

- Review legislation and regulation at both state/territory and federal levels to identify whether there are any impediments to implementation of microbial genomics, particularly in relation to data sharing.
- Ensure microbial genomics outcomes are achieved to the greatest extent possible.
- Support discussions for implementation of a national governance structure.
- Ensure data are being handled in an ethical and culturally appropriate way.
- Ensure meaningful and appropriate recognition of data sources by both primary and secondary users.
- Establish trust between data-sharing entities and encourage further data sharing among active and potential providers.
- Ensure data privacy and security is maintained throughout the data collection, handling and storage process.

ACTIONS – TECHNOLOGY AND DATA GOVERNANCE

NATIONAL ACTION	TIMEFRAME	LEAD RESPONSIBILITY	PRIORITY
OUTCOME 2.1 – TECHNOLOGY			
2.1.1 Develop robust business cases to seek funding opportunities required for the establishment, maintenance and advancement of public health laboratory capacity and capability in microbial genomics.	Short (ongoing)	CDGN, PHLN	High
2.1.2 Create a shared, access-controlled, scalable repository that allows laboratories to upload and share sequence data and associated contextual and epidemiological metadata across jurisdictions and internationally.	Short	CDGN	High
2.1.3 Develop a microbial genomics analysis and visualisation tool for integrated genomics data that can be accessed by public health laboratories undertaking sequencing.	Short	CDGN, MDU PHL	Medium
2.1.4 Establish national agreement on minimum sequence data quality metrics and protocols for sequence quality control.	Short	CDGN	High
2.1.5 Assess the feasibility and costs associated with establishing microbial genomics and bioinformatics capability and capacity in each jurisdiction, in comparison to centralised solutions.	Medium	CDGN, Health	High
OUTCOME 2.2 – DATA SHARING			
2.2.1 Develop a national data sharing agreement and protocol for the sharing of sequencing data, epidemiological metadata and microbial isolates between public health laboratories in all states and territories.	Short	CDGN	High
2.2.2 Support sector engagement with international microbial genomics alliances to promote shared access to data for research and global harmonisation of data where appropriate.	Medium	CDGN, PHLN, CDNA, Health	Medium
2.2.3 Involve the private pathology sector in key data sharing discussions across laboratories through existing networks including PHLN, CDGN and Australian Pathology.	Medium	CDGN, PHLN, Health	Medium
2.2.4 Develop a common process for timely data sharing in the event of an outbreak relevant to Australia. This will complement the <i>WHO's draft code of conduct for open and timely sharing of pathogen genetic sequence data during outbreaks of infectious disease</i> .	Short	CDGN, PHLN, Health	High
2.2.5 Support the integration of microbial genomics data for non-human samples i.e. food.	Medium	CDGN	Medium

NATIONAL ACTION	TIMEFRAME	LEAD RESPONSIBILITY	PRIORITY
OUTCOME 2.3 – DATA STORAGE			
2.3.1 Define minimum security handling requirements, i.e. for microbial genomics data pipelines, systems, data sharing and storage.	Short	CDGN, Health	High
2.3.2 Explore nationally accessible and sustainable data storage and computational infrastructure options, noting these also need to be financially sustainable.	Short	CDGN	High
2.3.3 Establish a reference genome repository that can be accessed by public health laboratories undertaking sequencing.	Short (ongoing)	CDGN	High
OUTCOME 2.4 – USE OF DATA			
2.4.1 Formalise processes to identify, promote, monitor and report best practice in microbial genomics for public health action. This includes the timely sharing of sequencing data and other related information.	Medium	CDGN, PHLN	Medium
2.4.2 For key pathogens, define which public health laboratories are capable of conducting analyses and reporting at a national level. Ideally they could take the lead in the event of a multi-jurisdictional outbreak. This may depend on the organism and the capacity and capability of the laboratory at the time of the investigation.	Short	CDGN, PHLN	High
2.4.3 Establish nationally standardised reporting formats to communicate microbial genomic data to end-users for public health action.	Short (ongoing)	CDGN, PHLN	High
OUTCOME 2.5 – DATA GOVERNANCE			
2.5.1 Review legislation and regulation at both state/territory and federal levels to identify any impediments to implementation of microbial genomics for public health action, particularly in relation to data sharing.	Medium	CDGN, CDNA, Health	High
2.5.2 Develop a national microbial genomics data governance framework that aligns with international frameworks.	Medium	CDGN, PHLN, CDNA, Health	Medium
2.5.3 Develop nationally agreed standards for data collection, safe storage, data sharing, custodianship, analyses, reporting and privacy requirements.	Medium	CDGN, PHLN, CDNA, Health	Medium

Strategic Priority 3: Integration into Public Health

CURRENT ACTIVITIES

There is a collective effort by the Australian Government and state and territory governments to prioritise microbial genomics integration activities to improve public health outcomes. While several microbial genomics activities in surveillance and response are being undertaken in states and territories, there remains significant steps for these to be optimised and fully implemented as routine activities in public health systems. Current efforts include:

- WGS to identify and confirm clusters/disease outbreaks, and sharing of isolates and microbial sequences between jurisdictions in the event of a multi-jurisdictional outbreak
- Jurisdictional implementation of WGS into public health microbiology services for:
 - Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)
 - *Listeria monocytogenes*
 - *Mycobacterium tuberculosis*
 - *Neisseria meningitidis*
 - *Legionella pneumophila*
 - Shiga toxin-producing *Escherichia coli* (STEC)
 - *Salmonella enterica* spp.
 - *Shigella* spp.
 - toxin positive *Corynebacterium diphtheriae*
 - Hepatitis A virus
 - Carbapenemase-producing enterobacteriaceae (CPE) and other antibiotic-resistant pathogens
 - *Candida auris*
- Current implementation is most advanced within the large public health laboratories in Victoria, New South Wales and Queensland. Each laboratory is at a different stage of building sequencing capability for different pathogens.

Research opportunities are also being explored through leading research bodies and consortiums focusing on a range of microbial genomics issues. States and territories continue to engage in collaborative research partnerships to ensure evidence-based integration of public health microbial genomics in Australia. Various research projects currently underway include:

- The Victorian Partnership Project, a NHMRC-funded collaboration between the MDU PHL, the Victorian Department of Health and Human Services and the University of Melbourne
- The NSW Health Public Health Genomics Partnership which comprises NSW Health, NSW Health Pathology, and five different universities based in NSW
- Queensland Genomics Infectious Disease Project, a collaboration funded by QLD Health between the QLD Health Communicable Disease Branch, Pathology Queensland, QLD Health Forensic and Scientific Services, the University of Queensland Centre for Clinical Research and other partners

- CDGN's MRFF grant for genomics research into the behaviour, spread and evolution of the SARS-CoV-2 virus
- CDGN's MRFF grant for a large scale integrated public health pathogen genomics research program. This will show value, cost effectiveness and capacity for translation of genomics into public health nationally.

The next steps are to consider how microbial genomics data for public health could be more broadly integrated into existing animal (One Health), food safety and AMR surveillance systems and networks. This will include identification of priority organisms to take full advantage of microbial genomics for real-time diagnostics, supporting timely outbreak investigation. Greater systemic collaboration with researchers is also required to boost opportunities for improvement and application of microbial genomics for public health action.

AGREED OUTCOMES AND PRIORITY AREAS FOR ACTION

Outcome 3.1 – Integration of microbial genomics data into epidemiological systems

- Facilitate integration into epidemiological and AMR surveillance systems.
- Facilitate integration into laboratory information systems.
- Facilitate integration into food safety and regulatory sector arrangements.
- Facilitate integration into animal health sector arrangements.

Outcome 3.2 – Identification of priority organisms

- Determine a list of priority organisms through consultation and collaboration with PHLN, the Australian (Counter) Bioterrorism Laboratory Network (ABLN), CDNA, CDGN, AHPPC, the Australian Strategic and Technical Advisory Group on AMR (ASTAG), OzFoodNet, the Australian Intelligence Community, research organisations and other relevant stakeholders to identify where sequencing provides an enhanced public health benefit over existing laboratory methodologies.
- Facilitate the rapid detection and characterisation of emerging and/or newly imported pathogens and other bio-threats.
- Improve knowledge on what type of microbial genomics information improves public health disease control and response and how this is applied in relation to priority organisms, particularly its role in maintaining national health security and biosecurity.
- Facilitate and encourage private microbiology laboratories to share microbial genomics-related data for public health and surveillance purposes for priority organisms.

Outcome 3.3 – Prioritisation of public health microbial genomics research

- Enhance communication with microbial genomics researchers to identify gaps for improvement in disease control for public health purposes.
- Maximise microbial genomics research opportunities to enhance public health outcomes.
- Ensure early identification of translational research priorities in microbial genomics.

ACTIONS – INTEGRATION INTO PUBLIC HEALTH

NATIONAL ACTION	TIMEFRAME	LEAD RESPONSIBILITY	PRIORITY
OUTCOME 3.1 – INTEGRATION OF MICROBIAL GENOMICS DATA INTO EPIDEMIOLOGICAL SYSTEMS			
3.1.1 Look into how microbial genomics data and new laboratory information management systems and epidemiological surveillance systems can be integrated to support decision-making. Find out how systems can facilitate seamless notification pathways for effective public health action.	Long	CDGN, PHLN, CDNA	High
3.1.2 Develop and pilot standardised reports and nomenclature for key pathogens that effectively communicates data to end-users.	Short	CDGN, PHLN, CDNA	High
3.1.3 Using pilot implementation projects, look at the possibility of interoperable routine microbial genomics sequencing for surveillance of priority organisms. This will measure and identify local transmissions for outbreak management and control.	Medium	CDGN, PHLN	Medium
3.1.4 Develop exercises to test the use of microbial genomics in the event of a disease outbreak. These will assess and look at strengths and opportunities to improve Australia's integration of microbial genomics into public health responses.	Medium	Health, CDGN	Medium
3.1.5 Develop a streamlined process that facilitates and encourages timely requests for data sharing between jurisdictions to inform public health investigation and action. National epidemiology networks (e.g. OzFoodNet, National Neisseria Network, National Tuberculosis Advisory Committee) and public health laboratories should also be involved in development of this process.	Short	CDGN, PHLN, CDNA	High
3.1.6 Encourage the use of microbial genomics technology and the integration of genomics data from animal and environmental sources. Encourage working towards a cross-sectorial integrated OneHealth approach to surveillance of communicable diseases and AMR. Achieve this through closer engagement with networks such as the Laboratories for Emergency Animal Disease Diagnosis and Response (LEADDR).	Long	CDGN, PHLN	Medium

NATIONAL ACTION	TIMEFRAME	LEAD RESPONSIBILITY	PRIORITY
OUTCOME 3.2 – IDENTIFICATION OF PRIORITY ORGANISMS			
<p>3.2.1 Drawing from national and international experience, decide on a list of priority organisms where sequencing would enhance pathogen detection and public health response. This should be decided through consultation and collaboration with relevant stakeholders. This includes defining appropriate sampling frames, stages of implementation and indicators of effective implementation.</p>	Short	CDGN, PHLN, CDNA	High
<p>3.2.2 Through existing networks, reach out to and encourage private pathology laboratories to share isolates of priority organisms for public health surveillance purposes.</p>	Medium	CDGN, PHLN, Health	Medium
OUTCOME 3.3 – PRIORITISATION OF PUBLIC HEALTH MICROBIAL GENOMICS RESEARCH			
<p>3.3.1 Develop a national research agenda for microbial genomics for public health action. Look at opportunities to link to Australian Government and state and territory government research priorities.</p>	Medium	CDGN, PHLN, CDNA	Medium
<p>3.3.2 Map current public health microbial genomics research activities and explore options to strengthen national coordination. This will inform development of a national research agenda to guide sustainable and strategic research investment.</p>	Medium	CDGN, PHLN, CDNA, Health	Medium
<p>3.3.3 Support translational research opportunities that can improve public health investigation, surveillance and response through commissioning and consulting with relevant academic institutions (i.e. cutting-edge sequencing technologies, clinical metagenomics and application of machine learning/artificial intelligence methodologies).</p>	Medium	CDGN, PHLN, CDNA, Health	High

Strategic Priority 4: Access and Workforce

CURRENT ACTIVITIES

The introduction of microbial genomics in the Australian public health laboratory and public health sector more broadly presents a major workforce development challenge. There is a clear need to upskill the existing workforce through increasing capacity and capability in microbial genomics technologies, as well as bioinformatics. This will help build an appropriately skilled workforce that is literate in microbial genomics sequencing and analysis.

Many states and territories are taking action to better understand how the workforce should evolve to support microbial genomics as an integral part of mainstream laboratory testing. The majority of these activities are currently being supported by existing resources and require sustainable funding to maintain the provision of training, workshops and upskilling. This is true in particular for smaller jurisdictions without dedicated microbial genomics resources.

Health continues to support the CDGN to provide coordination and bioinformatics support to jurisdictions that are developing capability and capacity. The network has used this funding to upskill laboratory staff and improve bioinformatics literacy across jurisdictions that do not have dedicated bioinformaticians or bioinformatics expertise.

The Australian Government is also in the early stages of developing a National Public Health Laboratory Strategy. This is not microbial genomics-specific, however will assist to determine workforce needs more broadly in the public health laboratory system as a first step to understanding gaps and opportunities.

A workforce mapping exercise is needed to understand the specific gaps that need to be addressed to improve access to and build microbial genomics capability and capacity. The workforce mapping exercise should look at mechanisms for safe, equitable, efficient, effective and informed service delivery. There is a pressing need for more bioinformaticians, computer scientists, genomic epidemiologists, translational genomics researchers, genomics-literate microbiologists and data analysts. This will help to meet the growing demand for microbial genomics in the public health system.

The need for improved and standardised education opportunities that cover microbial genomics for laboratory, clinical, public health and government sector staff is widely recognised as being critical to maximising the potential benefits of microbial genomics for public health action.

AGREED OUTCOMES AND PRIORITY AREAS FOR ACTION

Outcome 4.1 – Enhanced capacity and capability

- Assess, foster, establish and maintain national microbial genomics capacity and capability.
- Ensure equitable access to capability, including high-performance computing infrastructure, for all jurisdictions.
- Develop bioinformatics expertise, noting that this cannot be generalised across organism types.
- Maintain and build on engagement with private laboratories.

Outcome 4.2 – Standardised microbial genomics equipment and expertise

- Maintain comparable instrumentation across jurisdictions.
- Maintain comparable levels of expertise across jurisdictions.

Outcome 4.3 – Encourage innovation

- Promote national and international collaboration and innovation across laboratories, PHUs and academia to keep pace with advances in microbial genomics technology, including non-culture based approaches, in future.

Outcome 4.4 – Workforce development

- Promote establishment, improvement and maintenance of genomics literacy and related skills in both laboratory and non-laboratory settings (for example, public health clinicians and epidemiologists) through microbial genomics education, training and quality assurance.
- Promote workforce training strategies and planning to ensure consistent and equal access to upskilling opportunities across jurisdictions and microbiology service providers.
- Facilitate collaboration, partnerships and networks between professional colleges and societies to promote and support the sharing of knowledge.

ACTIONS – ACCESS AND WORKFORCE

NATIONAL ACTION	TIMEFRAME	LEAD RESPONSIBILITY	PRIORITY
OUTCOME 4.1 – ENHANCED CAPACITY AND CAPABILITY			
4.1.1 Build a skilled and literate national public health microbial genomics workforce through development of workforce strategies and planning.	Long	CDGN, PHLN, CDNA, Health	Medium
4.1.2 Improve the microbial genomics literacy and capability of the health workforce. Do this through the development, delivery and ongoing maintenance of appropriate microbial genomics education, training and skills.	Medium	CDGN, PHLN, CDNA, Relevant Training Providers and Institutions	Medium
4.1.3 Assess what bioinformatics support and analytical approaches public and private laboratories need (including public hospital laboratories) across jurisdictions. This will assist to find improvement opportunities that may benefit from national coordination.	Short	CDGN	High
OUTCOME 4.2 – STANDARDISED MICROBIAL GENOMICS EQUIPMENT AND EXPERTISE			
4.2.1 Identify barriers to equity of access for laboratories and develop a national approach to address these. Access is multi-dimensional and includes location, cost, availability and appropriateness.	Short	CDGN, PHLN, Health	High
4.2.2 Develop a public health bioinformatics platform allowing standardised analyses across public health sequencing laboratories.	Short	CDGN, MDU PHL	High
4.2.3 Develop and maintain guidelines on public health microbial genomics testing and research as appropriate and encourage national adoption.	Medium	CDGN, PHLN, Health	Medium
4.2.4 Map the public health microbial genomics workforce initiatives underway, and find opportunities to further develop the necessary capabilities. Also consider strategies to support the equitable supply and distribution of that workforce.	Medium	CDGN	Medium

NATIONAL ACTION	TIMEFRAME	LEAD RESPONSIBILITY	PRIORITY
OUTCOME 4.3 – ENCOURAGE INNOVATION			
4.3.1 Foster partnerships and stakeholder engagement to encourage innovation in microbial genomics to improve public health outcomes.	Medium	CDGN, PHLN, CDNA, Health	Medium
4.3.2 Consult with private industry to explore opportunities for partnerships to support development and sustainable application of public health microbial genomic knowledge.	Medium	CDGN, PHLN, Health	Medium
4.3.3 Explore the field of metagenomics for public health. Harness its ability to investigate unidentified pathogens in clinical isolates or the environment, where standard laboratory practices may fail to detect viruses.	Long	CDGN, PHLN	Low
OUTCOME 4.4 – WORKFORCE DEVELOPMENT			
4.4.1 Involve relevant professional bodies and colleges who oversee and inform workforce training to streamline public health microbial genomics curricula. Ensure a consistent approach to teaching and training of microbial genomic sequencing for use in public health.	Medium	PHLN, CDNA, Health	Medium
4.4.2 Involve relevant stakeholders, sectors and subject matter experts to improve genomics health literacy. Share experiences and lessons learned and raise awareness of the integration of microbial genomics into the Australian public health system.	Medium	CDGN, PHLN, CDNA, Health	Medium
4.4.3 Provide coordination and bioinformatics training and support across jurisdictions to ensure equitable sharing of practices, knowledge and information to all jurisdictions.	Short	CDGN	High

Strategic Priority 5: Financing

CURRENT ACTIVITIES

In May 2018, the Australian Government announced an investment of \$500 million over 10 years for a GHFM under the MRFF. This is to help save or transform the lives of more than 200,000 Australians through research into better testing, diagnosis and treatment. The purpose of the GHFM is to deliver better diagnostics and targeted treatments, avoid unnecessary health costs, and improve patient experience and outcomes.

In April 2019, it was announced that a grant opportunity under the MRFF would be dedicated a GHFM Flagship for pathogen genomics. This flagship recognises the application of genome sequencing technologies to the characterisation and analysis of pathogens. This informs clinical and public health investigations of, and responses to, infectious disease.

An evidence base is slowly being established to understand the value and cost-effectiveness of microbial genomics in the Australian context. This can be done by exploring, evaluating and reporting on economic evidence that supports the integration of microbial genomics into Australian laboratories. This is necessary to inform how a sustainable funding model could be established that considers the cost-effectiveness of services and acknowledges the clinical and/or public health applications of pathogen genomics. These include:

- communicable disease outbreak investigation
- development and use of precision medicine
- identification and surveillance of antimicrobial resistance, noting its role in improving individual patient care
- characterisation of host-pathogen interactions and high-risk microbial populations needed to identify priority pathogens that are important to human health.

The application of microbial genomics in public health has the potential to reduce the financial burden of communicable disease management and outbreak investigation and response. This is through earlier characterisation of outbreaks and implementation of public health intervention measures. Without sustainable funding, laboratories are limited in their capacity to provide microbial sequencing services for the purposes of clinical and/or public health value. Support for, and investment in, advancing technology is needed to drive innovation and capability in this rapidly evolving environment.

AGREED OUTCOMES AND PRIORITY AREAS FOR ACTION

Outcome 5.1 – Establishment of a sustainable funding model

- Develop a sustainable funding model involving a partnership between the Australian Government and the states and territories.
- Improve flexibility to keep pace with technology advances and the expanding role of microbial genomics.

Outcome 5.2 – Establishment of cost-effectiveness

- Ensure the cost of introducing and maintaining microbial genomic technology results in savings accrued from improvement in patient care, and replacement of existing testing technology. Initial establishment of genomics capability will lead to a short-term increase in costs while new workflow processes are developed and outdated testing methods are replaced.

ACTIONS – FINANCING

NATIONAL ACTION	TIMEFRAME	LEAD RESPONSIBILITY	PRIORITY
OUTCOME 5.1 – ESTABLISHMENT OF A SUSTAINABLE FUNDING MODEL			
5.1.1 Look at equitable financing and purchasing models to inform the appropriate integration of safe, effective and cost-efficient public health microbial genomics delivery.	Medium	CDGN, PHLN, CDNA, AHPPC, Health	Medium
5.1.2 Look into funding opportunities at both the national and state and territory level, for example, through grant opportunities, to enhance microbial sequencing capability and capacity. Funding opportunities that focus on public health surveillance and / or to inform individualised patient care should be targeted.	Short	CDGN, PHLN, CDNA	High
OUTCOME 5.2 – ESTABLISHMENT OF COST-EFFECTIVENESS			
5.2.1 Look at suitable indicators to evaluate and report on the value and cost-effectiveness of implemented microbial genomics services.	Long	CDGN, PHLN, CDNA, Health	Medium
5.2.2 Develop partnerships, funding and data sharing approaches for microbial genomics that promote access to safe, efficient and cost-effective services.	Medium	CDGN, PHLN, CDNA, Health	Medium
5.2.3 Collaborate across governments and stakeholders to maximise investment, reduce duplication of effort and to use resources efficiently.	Long	CDGN, PHLN, CDNA, AHPPC, Health	Medium

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All information in this publication is correct as at January 2021