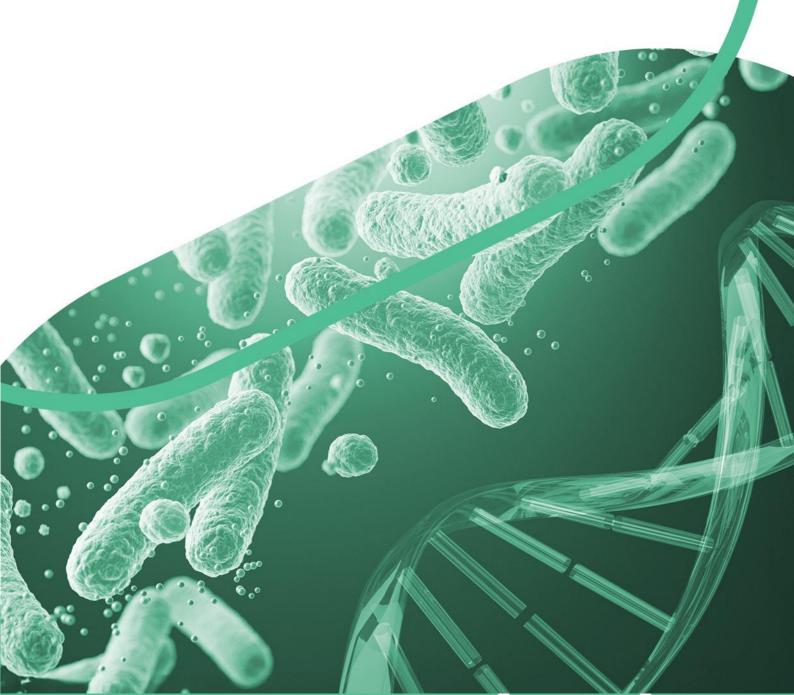




National Microbial Genomics Framework for Public Health 2025–2027



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Title: National Microbial Genomics Framework for Public Health 2025–2027

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Foreword

Microbial genomics is a powerful tool to help us better understand infectious diseases, improve public health surveillance, strengthen public health decision-making, and design vaccines and other treatments. During the COVID-19 pandemic, microbial genomics was essential in detecting SARS-CoV-2 variants of concern, informing public health policy and Australia's response. In Australia we are fortunate to be supported by world renowned experts and an extensive network of public and private laboratories with the capability, capacity and appropriate accreditation to put microbial genomics to its best use.

This national framework for microbial genomics, endorsed by the Australian Health Protection Committee, is now in its second iteration. The framework reinforces our collaborative commitment to integrating microbial genomics into the Australian laboratory and public health system. This will ensure this technology is effectively used throughout Australia, enabling Australia to better respond to public health threats.

Strong collaborative relationships between national, state and territory governments, medical laboratory professionals, researchers and health professionals remain crucial to the successful implementation of microbial genomics safely, ethically and equitably.

I would like to acknowledge those who have contributed to the development of this framework, including the Communicable Diseases Genomics Network, the Public Health Laboratory Network,

and the Communicable Diseases Network Australia.

Professor Anthony Lawler

Chief Medical Officer & Deputy Secretary Health Products

Regulation Group

Australian Government Department of Health and Aged Care

<u>Overview</u>



Purpose

- Provide a consistent, national, and strategic view for integrating microbial genomics into the Australian public health system.
- Identify microbial genomics policy issues and challenges that need to be addressed.



Vision

To protect the health of all Australians from communicable disease and biological agent threats (including foodborne, zoonotic, and environmental).



Guiding principles

- 1. National approach.
- 2. Strategic framework.
- 3. System-focused.
- 4. Evidence-informed public policy.
- 5. Flexible to keep up with scientific advances.
- 6. Identifies priority areas.



Enablers

- 1. Collaborative governance and leadership.
- 2. Stakeholder engagement and action.
- 3. National and international partnerships.



Strategic Priorities

Priority 1:

Harmonised National Approach.

Priority 2:

Technology and Data Governance.

Priority 3:

Integration into Public Health.

Priority 4:

Access and Workforce.

Priority 5:

Financing.

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Glossary of key technical terms

For the purposes of the National Microbial Genomics Framework for Public Health 2025-2027, key terms are defined as follows.

Term	Definition
Bioinformatics	The use of algorithms and software to analyse sequencing data.
DNA	Deoxyribonucleic acid — material which is present in nearly all living organisms as the main constituent of genomes. It is the carrier of genetic information.
Efficiency	A measure of whether health care resources are being used to get the best value for money. Includes technical, productive, and allocative efficiency.
Gene	The basic physical and functional unit of heredity. Genes, which are made up of DNA, act as instructions to make molecules called proteins.
Genome	The complete set of genetic information in an organism.
Genomics	The application of genome-based knowledge through the study of genes and other genetic information, their functions, and its interrelationships for the benefit of human health.
Genomic data	Refers to data produced from nucleic acid sequencing of a genome.
Genomic services	Genome sequencing and analysis available for research, screening, diagnostic purposes, and treatment decision-making.

Genomic surveillance	Involves the use of genomic data to monitor pathogen variants, evolution, transmission, and dissemination, including the distribution and evolution of antimicrobial resistance determinants and lineages. This type of surveillance involves applying the principles of evolutionary biology to determine the relatedness of pathogens.
Governance	The structures and processes by which the health system is regulated, directed, and controlled. It includes the obligations of stewardship—ensuring that the system is well sustained for the future as well as serving the needs of the present.
Lineage	A group of closely related organisms, such as viruses, with a common ancestor (within the same species).
Metadata	A set of data that describes and gives information about other data.
Metagenomics	The study of all genetic material recovered from an environmental or clinical sample. Metagenomics is often used to study a specific community of microorganisms, or to identify an unknown microbial agent(s).
Microbe	A microorganism, such as bacteria, virus, or fungi, that can be seen only through a microscope.
Microbial genomics	The genomic study of microbes or microorganisms.
One Health	An approach to designing and implementing programs, policies, legislation, and research in which animal, human and environmental sectors communicate and work together to achieve better public health outcomes.
Pathogen	An organism that can cause disease.

Pathogen genomics	The genomic study of a pathogen, a category of microbial genomics.
Real-time	The actual time during which a process or event occurs.
RNA	Ribonucleic acid — a nucleic acid present in all living cells. Its principal role is to act as a messenger carrying instructions from DNA to initiate and control the synthesis of proteins, although in some viruses RNA rather than DNA carries the genetic information.
Variant	An organism that is genetically distinct from a main strain, but not sufficiently different to be termed a distinct strain.
Whole genome sequencing	A laboratory process to determine the complete DNA sequence of an organism's genome.

Acronyms and abbreviations

Acronym Meaning

AHPC Australian Health Protection Committee

AMR Antimicrobial resistance

CDGN Communicable Diseases Genomics Network

CDNA Communicable Diseases Network Australia

COVID-19 Coronavirus disease 2019

DNA Deoxyribonucleic acid

EMPaCT Emerging Molecular Pathogen Characterisation Technologies

HCEF Health Chief Executives Forum

Health Australian Government Department of Health and Aged Care

MRFF Medical Research Future Fund

PHL Public Health Laboratory

PHLN Public Health Laboratory Network

PHU Public Health Unit

PTP Proficiency Testing Program

RCPA QAP The Royal College of Pathologists of Australasia Quality

Assurance Programs

UKHSA United Kingdom Health Security Agency

US CDC United States Centers for Disease Control and Prevention

WGS Whole genome sequencing

Background

The genome of a microbe reveals its identity and ancestry, how it differs from other microbes, the ways in which it infects humans, and how it may evade antibiotic and other existing treatment and/or the immune system. Microbial genomics is the study and application of genome sequencing technologies to characterise and analyse microorganisms, including pathogens. It is a powerful and critical tool for the investigation and management of infectious diseases and can be used to improve public health surveillance and inform public health decision-making.

Several potential public health benefits of microbial genomics are identified and will be expanded on in this framework, including the ability to:

- inform public health and infection control and prevention actions for surveillance and outbreak investigations and health care service planning
- provide high-resolution, national, and international compatible typing and characterisation data for communicable disease surveillance and bio-threat detection
- monitor changes in epidemiological parameters, pathogen lineages and other characteristics to inform understandings of disease transmission and risk
- rapidly detect, characterise, and monitor emerging pathogens or new mechanisms of antimicrobial resistance (AMR)
- work collaboratively across the One Health sector using genomic sequencing to enhance outbreak investigations
- monitor and predict the effectiveness of treatments and vaccines for communicable disease pathogens
- inform therapeutics and vaccine development and continuing susceptibility to existing treatment and vaccines
- assist in informing agricultural and water management practices and determining the persistence of microbes in the environment
- inform law enforcement investigations associated with microbial genomic forensic elements.

Noting its utility, integration of whole genome sequencing (WGS) into public health has been gradually building over many years. However, like any integration, there are

challenges that impact the implementation of microbial genomics technology in Australia, including the following:

- There are differences in jurisdictional capacity, expectations, methodology, instrumentation, governance structures and requirements for microbial genomic technologies, information, and funding for pathogen genomic services within both the public health laboratories (PHLs) and public health units (PHUs).
- There is no endorsed approach for PHLs and PHUs to fully integrate microbial genomics data and metadata into existing surveillance systems, networks, and other infrastructure (for example, CARalert, AusTrakka, and the National Notifiable Diseases Surveillance System).
- There is a need to standardise reporting on WGS which is collected in laboratory information management and public health surveillance systems.
- There is an essential need to undertake more extensive workforce planning and training in pathogen genomics for roles including, pathologists, medical, and environmental laboratory scientists, bioinformaticians, epidemiologists, data scientists and software developers.
- There is limited genomic-related infrastructure with sustainable funding models to support public health implementation.
- There is a need to expand upon developed policies and procedures to enable rapid national genomics data sharing and analysis to enhance public health surveillance and responses beyond COVID-19 and across the human, animal, and environmental health sectors.
- There is a need to develop and strengthen national standards and definitions of quality practices to assist accreditation of microbial genomics analysis in Australia.

Failing to address these challenges and areas of interest could result in the potential utility of microbial genomics being not fully realised.

Early work undertaken by the Communicable Diseases Genomics Network (CDGN), an Expert Reference Panel of Australia's Public Health Laboratory Network (PHLN), identified the need to formally establish a nationally agreed and consistent microbial genomics system, to better support coordination and implementation of microbial genomics into Australian PHLs. Acknowledging the variable capability and challenges that existed, it was determined that a national strategic framework would be the most appropriate mechanism to help drive this work forward.

In 2019, the *National Microbial Genomics Framework 2019-2022* (the 2019-2022 Framework) was published as the first national strategic document for microbial

genomics in Australia. The 2019-2022 Framework placed a strong focus on issues that would benefit from collaboration across all jurisdictions and between PHLs and PHUs specifically.

The 2019-2022 Framework was consistent with, and complementary to, the <u>National Health Genomics Policy Framework 2018-2021</u>. The Australian Government is currently working with states and territories through the newly established Health Technology and Genomics Collaboration to update and refresh the lapsed National Health Genomics Policy Framework and Implementation Plan.

An associated implementation plan (the Plan) which operationalised the 2019-2022 Framework was endorsed by the Australian Health Protection Committee (AHPC)¹ in early 2021. The purpose of the Plan was to identify actions, responsibilities, timeframes, priorities, and resourcing requirements for the integration of microbial genomics into the Australian public health system.

Since initial publication, the application of genomic surveillance to support outbreak response has accelerated the development of a nationally coordinated approach to sequencing and analysis. For more information, please refer to Annex A.

-

¹ AHPC is the key decision-making committee for health emergencies, comprising of all state and territory Chief Health Officers and is chaired by the Australian Chief Medical Officer.

Purpose

The purpose of the *National Microbial Genomics Framework for Public Health 2025-2027* (the Framework) is to provide a consistent, national, and strategic view for integrating microbial genomics into the Australian public health system, and identify microbial genomics policy issues and challenges that need to be addressed. The Framework is a high-level document that takes into consideration the various domestic and international public health surveillance plans and strategies, which have public health and genomics intersections.

Specifically, the Framework:

- continues to support better coordination and consistency of action between PHLs and PHUs to ensure the benefits of microbial genomics are harnessed in an efficient, effective, ethical, and equitable way
- provides high-level guidance for the continued progress towards a nationally agreed microbial genomics system that allows organisms of public health importance to be identified within the auspice of a robust quality management system
- highlights that development of both domestic and international linkages for information sharing and communication are essential to drive this important public health initiative
- prioritises issues for consideration and indicates where further work is needed, while also recognising that stakeholders have a role in addressing issues independently
- identifies other emerging issues, in light of rapid developments in sequencing technology, and increased stakeholder access and engagement.

Vision

To protect the health of all Australians from communicable disease and biological agent threats (including foodborne, zoonotic, and environmental) through:

- the equitable and sustainable access to near real-time microbial genomics sequencing, nationally coordinated analysis, and reporting
- the generation of critical research evidence and development of methods
- continued efforts towards timely, responsible, and transparent, bi-directional data sharing and integration into public health surveillance systems

 the continued evolution of use in routine surveillance for pathogens of public health significance.

Audience

This framework is designed as a tool to provide guidance for the development, implementation and funding of microbial genomic related policies, strategies, actions, and services. The Framework is directed at decision-makers, funders and policymakers at state, territory, and national health service levels.

Timeframe

The timeframe of the Framework is three years, with a review anticipated in 2026 to inform the next iteration and to align with the establishment of the standalone Australian Centre for Disease Control (Australian CDC).

Sector consultation

A broad range of stakeholders were identified and consulted during the development of the Framework. This included expert advisory groups under the Australian Government Health Chief Executives Forum (HCEF) committee structure, as well as additional experts, captured through an open public consultation process, which included those from public health and clinical service delivery, research, and private pathology.

Guiding principles

The development of the Framework was supported by the following guiding principles:

1. National approach.

Developed jointly by Australian and state/territory governments, with the Framework facilitating equitable national coordination, government priority setting and decision-making.

2. Strategic framework.

Identification of themes, principles, and considerations for embedding consistency and national coordination as enablers for more efficient, equitable, and effective utilisation of microbial genomics. The Framework is overarching and aligns with existing, or to be developed, regulation, guidelines, and discussion papers addressing specific microbial genomics issues.

3. System-focused.

An understanding of what the system can deliver and consideration of how a change within one system domain can impact, interact with, and change the other domains and affect the entire system. Domains include:

- · leadership and governance
- system financing
- human resources (workforce)
- information systems
- service delivery.

This system is considered within the context of existing capacity and controls to remain consistent with and eventually embedded into communicable diseases surveillance infrastructure.

4. Evidence-informed public policy.

Ensures that the best available research and information is used to guide decisions at all stages of policy processes.

5. Flexible to keep up with scientific advances.

Will contain flexibility to enable it to be adapted to reflect the evolving nature of microbial genomics technology. It considers the latest scientific findings, advances, and potential shifts in microbial genomics policy issues and challenges.

6. Identifies priority areas.

Prioritises the microbial genomics policy issues and challenges that need to be addressed and identifies directions for change, opportunities for action and areas that require further work.

Enablers

To help guide decision-makers, funders, and policymakers in successfully implementing the Framework, three key enablers have been identified:

1. Collaborative governance and leadership.

Joint national and jurisdictional leadership which involves close engagement with the core drivers of the Framework's implementation, including the Australian Government, states, territories, and other identified leads such as relevant government expert advisory groups.

2. Stakeholder engagement and action.

Actively engage and cooperate with public health, research, clinical diagnostic, animal, and environmental laboratories, communicable disease control units, universities, industry, regulatory bodies, relevant networks, and training and quality assurance programs.

3. National and international partnerships.

Establish and maintain genomics collaborations for information sharing, capacity and capability building, with overarching, collective goal progression and attainment between relevant domestic and international entities and initiatives.

Strategic context

Microbial genomics continues to enhance the diagnosis, surveillance, control, and understanding of communicable diseases and AMR. Strengthening Australia's existing national genome sequencing capability and capacity, including workforce, and exploring potential ways for cross-sectoral and microbial-agnostic approaches to data sharing and analysis is essential for disease preparedness.

The One Health principle underpins this renewed Framework, recognising that the health of humans, animals, and the environment are all inter-connected, and there are opportunities to harness expertise across sectors to strengthen response activities. In this framework, consideration is given to current challenges and initial opportunities that could arise from collaboration to improve testing and genomic surveillance procedures, to ensure Australia is prepared to address priority public health and animal health challenges into the future.

Key challenges and considerations when considering the One Health principle in the Framework include:

- variation in the drivers and objectives of sample and data collection, impacting surveillance goals across sectors
- differing maturity in genomic sequencing capabilities and pathogen surveillance systems, with consideration for how to improve networking and resourcing to bridge these gaps
- sensitivities surrounding data and data sharing within and between sectors, impacting the consolidation of genomic information at a national level
- differing levels of integration between jurisdictions across and within One Health sectors.

Funding mechanisms are also reflected within this framework. In Australia, states and territories are responsible for providing microbial WGS capability for the purposes of diagnosis and clinical patient management. Support for surveillance and research is cost-shared between states and territories and the federal government, and the levels of available resources and investments vary between sectors and depend on the objective of the activity. This framework aims to acknowledge the respective responsibilities of state, territory, and federal governments, while outlining the need for a collaborative effort to address gaps and further drive national value.

Consideration has been given as to how this framework may evolve and be integrated into the establishment of the standalone Australian CDC. This is to ensure the challenges, vulnerabilities and areas for improvement identified throughout this process

(including lessons from the COVID-19 pandemic) are explored and supported by sustainable funding mechanisms. The Framework seeks to align with the objectives of the Australian CDC², such as:

- increase independence and strengthen evidence-based and transparent decisionmaking to maintain trust
- improve national coordination of effort and efficiencies, with stronger partnerships, including across Commonwealth agencies and between jurisdictions
- support national action through enhanced national capabilities, underpinned by the distinct and complementary roles and responsibilities of jurisdictions and the Commonwealth
- enhance international connections
- increase and productively use resources to support preparedness and response across all jurisdictions, including nationally.

While diagnostic applications in the clinical space are largely within its early stages, it is anticipated that there will be a rapid emergence of genomics-based diagnostic applications in the coming years. As such, this has been reflected in the Framework.

Finally, this framework seeks to drive national effort on agreed priorities of coordinated sequencing activities across Australia for priority pathogens regardless of organism type—bacterial, viral, fungal, or parasitic. The Framework provides an opportunity to act on divergent approaches to implementing microbial sequencing before they form impediments to successful integration of microbial genomics into the Australian health system. To provide further context, national and international developments can be found in Annex A.

 $\underline{https://www.health.gov.au/sites/default/files/2023-11/australian-centre-for-disease-control-cdc-statement-\underline{of-intent-10-november-2023.pdf}$

² Australian Government (2023). STATEMENT OF INTENT Working together to support the Australian Centre for Disease Control. Retrieved 11 December 2023 from

Implementation

This framework sets out how the Australian Government will work collaboratively with the states and territories to better integrate microbial genomic approaches into public health. The Framework includes actions, responsibilities, timeframes, priorities, and resourcing to measure the progress and success of the Framework and allows for the monitoring of national and jurisdictional progress against activities and milestones. While the Framework outlines an agreed national policy approach to integrating microbial genomics into public health, it does not identify all the specific actions needed to take the Framework forward. The Framework refers to 'actions' as those that monitor/evaluate implementation, and 'outcomes' as implementation activities.

The Framework acknowledges that involving all governments and One Health sectors is key to harnessing the power and subsequent health benefits of microbial genomics. This Framework encompasses a plan to operationalise priority outcomes. 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 two-year duration.

Monitoring Outcomes

It is intended that every three years the Australian Government, with the states and territories, will evaluate the activity outcomes described in the Framework, including the cost-effectiveness, key achievements, sustainability, and challenges of integrating microbial genomics into the Australian public health system. Led by the Australian CDC, this evaluation will be supported by other initiatives such as the AusPathoGen Program, which aims to evaluate the large-scale integration of pathogen genomics, epidemiological and surveillance data at the public health interface. This includes evaluation of the utility and cost-effectiveness of genomics-based public health responses.

Indicative action timeframes

Indicative timeframes proposed for each activity are:

- short-term (0 1.5 years)
- medium-term (1.5 3 years),
- long-term (more than 3 years)
- ongoing.

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 this iteration of the Framework.

Priority key

Indicative priorities proposed for each activity are:

- low
- medium
- high.

The level of priority is determined through consideration of the:

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

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 recognises that coordinated and thorough planning is needed between all levels of government and across the laboratory and public health sectors. 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 HCEF governance arrangements³. The work and cooperation of pathology, animal, and environmental laboratories, public health authorities, research organisations and educational leaders is essential to achieving the Framework's overall vision.

In the proposed implementation activities, 'National Action' infers the collective responsibility of states, territories, and the Australian Government. Where an Action Lead

³ Formerly known as the Australian Health Ministers' Advisory Council (AHMAC).

references 'All', this infers the collective responsibility of states, territories, the Australian Government, and relevant committees.

Governance

Governance is key for driving and coordinating implementation of the Framework. To ensure the Australian Government and state and territory governments are involved, and work is progressed in a cohesive way, it is appropriate for the governance arrangements to be situated under the HCEF structure. In addition, while lead groups are identified against specific responsibilities and actions, in practice these will be completed in partnership with all relevant committees and in consultation with state and territory governments and the Commonwealth, where applicable, whilst also ensuring that approval pathways are adhered to.

Action	Roles	Timeframe	Lead Responsibility ⁴
Action i: The Australian Government and state and territory governments will continue to support governance arrangements through the HCEF structure. AHPC will provide advice on the implementation of the Framework, ensuring ongoing national consistency and transparency.	Australian CDC will monitor this progress.	Ongoing	Australian CDC ⁵ and relevant AHPC subcommittees
Action ii: The Australian Government and state and territory governments will evaluate the Framework ⁶ . This evaluation will begin in 2026 to inform the future directions of microbial genomics policy.	Australian CDC will lead an evaluation, including	Medium-term	Australian CDC

⁴ As described above, when assigning an action lead here and in the strategic priorities, it is important to note that the lead will work on the action in collaboration with relevant parties, as identified by the AHPC.

⁵ When referring to the Australian CDC as an action lead, it is referring to either the interim or standalone Australian CDC, depending on the timeframe and establishment of the standalone Australian CDC.

⁶ Please note that the evaluation report for the 2019-2022 Framework will be completed by the Interim Australian CDC in 2025-2026.

Accountability - measuring and reporting

Accountability requires appropriate risk management frameworks to promote the efficient, effective, economical, and ethical use of public resources. The development of a national system performance framework will ensure implementation activities remain fit for purpose and achieve the defined objectives within the proposed timeframes.

Action	Roles	Timeframe	Lead Responsibility
Action iii: Develop a mid-cycle report on implementation progress of the Framework.	Australian CDC in collaboration with relevant committees and networks.	Short-term	Australian CDC and relevant committees
Action iv: Develop a national system performance framework (with highlevel indicators to show goals have been met). 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.	Australian CDC to support development of a performance framework in consultation with relevant committees and networks.	Medium-term	Australian CDC, AusPathoGen, and relevant committees and networks
Action v: The Australian Government and state and territory governments will individually develop action plans to inform appropriate implementation pathways.	Australian CDC, and state and territories will individually lead their own action plans.	Medium-term	Australian CDC, and state and territories

Strategic priorities

The Framework outlines five strategic priorities that aim to:

- prioritise key microbial genomics policy issues and challenges
- provide directions for change
- highlight opportunities for action
- identify areas that require further work.

The priority areas are not necessarily discrete and there will be interrelationships and interdependencies. The five strategic priorities are as follows:

Strategic Priority 1 — Harmonised National Approach

- Enhance governance arrangements to drive harmonisation on microbial genomics matters of national significance, including rapid national data sharing.
- Grow and apply microbial genomic knowledge that is evidence-based, harmonised, and of high quality.

Strategic Priority 2 — Technology and Data Governance

- Establish and enhance nationally agreed data governance arrangements.
- Promote and practice ethical and equitable data sharing and understanding the risks (or perceived risks) that it may entail.
- Strengthen high-performance computing infrastructure to support data storage and sharing that can adapt to enhance microbial genomics technologies.

Strategic Priority 3 — Integration into Public Health

- Enhance collaboration and strong linkages, as appropriate, between Australian laboratories (including human diagnostic and One Health laboratories) and PHUs to ensure the value of microbial genomics technology is recognised.
- Promote consistent national reporting structures that are compatible with public health surveillance systems.

Strategic Priority 4 — Access and Workforce

- Enhance and maintain a competent multidisciplinary microbial genomics workforce.
- Enhance equity in microbial genomics capacity and capability across jurisdictions.

Strategic Priority 5 — Financing

• Ensure the funding model applied to microbial genomics considers the substantial establishment costs is cost-effective and sustainable into the future.

The following values underpin the strategic priorities of the Framework:

- The application of microbial genomic knowledge is ethically, legally, and socially responsible.
- Access to microbial genomics information is equitable within and between the jurisdictions and the Australian Government.
- The application of microbial genomics knowledge to improve public health outcomes is supported and informed by evidence and research.

Strategic Priority 1 — Harmonised National Approach

Despite rapid advancements and strong jurisdictional collaboration to strengthen microbial genomic capability, some jurisdictional differences remain in laboratory workflow and specimen processing, public health microbiology service reimbursement, and epidemiological typing and characterisation for the purposes of surveillance. These result in national variability in capability, testing practices, turnaround times and reporting.

Without continued progress towards better national coordination and greater standardisation of microbial genomic practices, some of the key risks include, but are not limited to:

- increased burden of disease due to the reduced ability to rapidly identify and characterise emerging infectious disease threats
- reduced impact of surveillance on public health measures due to a limited understanding of disease spread, particularly across jurisdictions
- inconsistency with global best practice for preparedness and response to infectious diseases due to lack of collation and curation of national-level genomic data
- protracted turnaround times for test results if needing to seek other jurisdictional assistance when there is a gap in capability.

In Australia, the current barriers that need to be addressed to support progress towards this strategic priority include:

- limited ability to compare analyses due to incompatible nomenclature
- inconsistency in the application of microbial genomics in public health and bio-threat issues
- fragmentation in data collection and storage
- lack of consistency in data analysis and output, as well as integration into surveillance, investigation, and response efforts.

Some of the key challenges in achieving nationally consistent laboratory-based surveillance have been highlighted in the <u>National Framework for Communicable</u> <u>Disease Control</u>. These include:

• aligning governance and reporting models for PHLs and national centres

- harmonising laboratory-based surveillance methods between jurisdictional public health reference laboratories
- agreeing on ethical and confidentiality principles
- improving information sharing between laboratories, public health authorities and clinicians
- agreeing on sustainable financing mechanisms for PHL activities.

What does the future look like?

- The application of microbial genomics to public health—infectious disease and biological agents of security concern control—is well understood by stakeholders.
- A coordinated and consistent approach has been developed around the application of microbial genomics in public health practice, which increases efficiency and reduces duplication of effort.
- The approach has been adopted at a national level and is supported by all states and territories for communicable diseases and AMRs of public health significance.
- A model has been established that ensures capacity and capability is maintained within PHLs and opportunities are provided and promoted to share their expertise to inform and contribute to nationally coordinated analyses and decision-making.
- The approach is sustainable and well supported by secure information technology (IT) infrastructure, quality assurance pathways, and appropriate financing.

Prior and current activities

Many initiatives to support the development of a harmonised 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, where appropriate, among PHL systems. The majority is being led by CDGN, and the completed activities include:

- the development of a national framework (including SARS-CoV-2 analysis protocols) based on international best practice to facilitate consistency in the use of microbial genomics for public health in Australia
- in 2020, establishing an agreement with the Royal College of Pathologists of Australasia Quality Assurance Programs (RCPA QAP) to support development, analysis, and reporting of proficiency testing programs for WGS, including supporting the analysis of the 2021 SARS-CoV-2 modules

in 2021, developing the <u>CDGN, PHLN and CDNA Sampling Strategy for SARS-CoV-2 Genomic Surveillance</u>, so that Australia remained vigilant in responding to emerging variants.

The following activities are ongoing:

- CDGN continues to promote best practice sequencing methodologies, determined in consultation with internationally established best practices that are both cost and time effective, to garner the most value from microbial genomics sequencing to inform public health action.
- CDGN also continues to provide support to laboratories with sequencing and analysis advice on a range of priority pathogens to ensure capability continues to be enhanced.
- The Salmonella and Listeria Working Group continues to facilitate a national transition to WGS of Salmonella and Listeria for routine public health testing.
- The Tuberculosis Working Group continues to coordinate and standardise approaches to sequencing, analysis, and reporting of Mycobacterium tuberculosis for public health.

Outcome 1.1 — Enhanced harmonised policies and procedures

- Continue to develop and evaluate common standards, principles, and nomenclature that are fit for purpose for public health surveillance and response.
- Progress towards a connected national genomic surveillance platform which hosts bioinformatics pipelines and a data repository that is available to all data custodians.

National Action	Timeframe	Lead	Priority
1.1.1 Continue to ensure microbial genomics is considered in the context of any broader review of health technology and systems assessment to support national consistency, especially in the design of the new Australian CDC.	Short	Australian CDC	High
1.1.2 Review and update relevant existing guidelines and standards or develop new ones (where appropriate) to ensure microbial genomics applications are:			
evidence-based	Medium	AHPC	Medium
 nationally consistent (where appropriate) 			
 in line with agreed national approaches to testing and surveillance (for example, laboratory case definitions and Series of National Guidelines (SoNGs)), and research. 			
1.1.3 Build on existing mechanisms, systems, and processes (where possible) to ensure nationally adopted supply of services and cohesive approaches to microbial genomics applications.	Medium	Australian CDC	Medium
1.1.4 In consultation with relevant AHPC sub-committees, develop a consistent set of principles to guide microbial genomics data analyses and reporting across jurisdictions. This is intended to enable harmonised and centralised national analysis ⁷ for multi-jurisdictional outbreaks and other national investigations, which encourages interoperability noting the challenges and approaches in analysis can depend on the organism.	Ongoing	PHLN	High

⁷ National genomic analysis is not intended to replace jurisdictional analyses or expertise, rather it is considered a complementary action to support and enhance communicable disease surveillance in Australia.

1.1.5 Continue to progress the development of a national genomics surveillance platform for priority organisms of national public health concern.

Ongoing

Australian CDC

High

Outcome 1.2 — Harmonised and ethical methods

- Promote the utility of microbial genomics across sectors.
- Work with stakeholders to ascertain ethical and/or legal issues associated with microbial genomics.

National Action	Timeframe	Lead	Priority
1.2.1 Involve health sector partners outside of core public health systems to promote awareness and understanding of microbial genomics and priority sample referral pathways, such as private pathology, remote area clinics, hospitals, and the general public, with support of PHUs.	Medium	CDGN	Medium
1.2.2 Encourage engagement between governments, laboratories, PHUs and the research sector to discuss, discover, and address any ethical and/or legal issues associated with microbial genomics (especially metagenomics), as they are identified.	Medium	CDGN	Medium
1.2.3 Maintain, develop, and promote processes to identify and monitor best practice in microbial genomics for public health action.	Medium	CDGN	Medium
1.2.4 Continue to develop and promote laboratory guidelines and decision support tools to clearly describe appropriate use of genomics.	Ongoing	PHLN	Medium

Outcome 1.3 — Established quality services

- Continue to develop quality assurance and proficiency testing programs (PTPs) specific to microbial genomics.
- Strengthen technical competence and integrity within organisations offering microbial genomics services for public health purposes.
- Promote sharing of sequence data nationally and to international repositories and/or directly with international laboratories upon request to inform detection and investigation of multi-jurisdictional and multi-country outbreaks.

National Action	Timeframe	Lead	Priority
1.3.1 Continue to develop nationally consistent and best-practice protocols, with support of CDNA and CDGN. This includes providing input into the development of accreditation approaches for public health and One Health sequencing laboratories.	Medium	PHLN	High
1.3.2 Continue to encourage the development and implementation of microbial genomics-related PTPs to enhance laboratory capability.	Ongoing	Relevant Laboratories and Relevant Entities	High
1.3.3 Participate in quality assurance programs to maintain key microbial genomics-related technical skills and share best practices and lessons learned with other laboratories across One Health sectors.	Ongoing	Relevant Laboratories	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 across One Health sectors, and the wider international community.	Ongoing	Relevant Laboratories	High

Outcome 1.4 — Harmonised approaches across the One Health sector

- Work with key stakeholders to develop nationally harmonised laboratory-based sequencing practices and guidelines to promote quality and interoperable One Health services.
- Work with key stakeholders to integrate One Health elements into quality assurance and proficiency testing programs specific to microbial genomics.

National Action	Timeframe	Lead	Priority
1.4.1 Identify and determine ways to enhance collaboration with One Health laboratory stakeholders with the aim of ensuring harmonisation of practices.	Short	Australian CDC	High
1.4.2 Design and administer a triennial survey for relevant One Health laboratories and affiliates, to scope the current state and future opportunities for expanding national One Health microbial genomics capability and capacity. This will provide a practical evidence base for policymakers, discover areas for improvement, and disseminate best practices and lessons learned.	Medium	Australian CDC	Medium
1.4.3 Support the development of cross-sectoral laboratory guidelines and decision support tools to clearly describe appropriate referral and reporting practices, in line with a One Health approach.	Ongoing	Australian CDC	Medium
1.4.4 Explore opportunities to include One Health elements in microbial genomics-related quality assurance and PTPs offered to laboratories.	Ongoing	All	Medium

Strategic Priority 2 — Technology and Data Governance

The public health community recognises the importance of nationally agreed data sharing to improve public health surveillance and response efforts. Identifying suitable approaches to data sharing that ensures sensitive data remains protected and crucial metadata is connected, remains an ongoing challenge. The aim is to achieve real-time sequencing and data exchange to enable both enhanced outbreak detection and response, and complement routine surveillance activities and technological advancements.

International progress to address key issues relating to data governance, including equity of access and benefits arising from the sharing of data, is already being made. International standards and best practice models, including the <u>WHO data sharing principles (2022)</u>, and <u>International Health Regulations (IHR) (2005)</u>, are useful guidelines to help inform the implementation of activities to strengthen Australia's data governance. Nationally, greater alignment of data governance activities with the DATA Scheme, Intergovernmental Agreement on Data Sharing, and other work of the Office of the National Data Commissioner, is imperative.

The Framework acknowledges the value of the <u>FAIR Guiding Principles for scientific data</u> <u>management and stewardship</u>, within the data governance discourse, in which its guidelines seek to improve the 'Findability, Accessibility, Interoperability, and Reusability of digital assets'⁸. While progress has been made to address these principles, effort is still required to ensure data sharing is routine and transparent across Australia.

Australia must continue to support and strive for the timely sharing of data on trusted domestic and international repositories, in line with our international commitment to support pandemic preparedness and response initiatives. The value of genomic data, collected as part of genomic surveillance, for basic research and activities, aligned with the One Health approach, should be also acknowledged⁹.

Jurisdictions continue to invest in developing standards, policies, and procedures to support infrastructure for capturing, analysing, and sharing microbial genomics data. However, inconsistencies remain in the technologies used and data governance practices (for example, data storage, infrastructure, and bioinformatics analyses), raising

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⁸ GO FAIR (2022). FAIR Principles. Retrieved 30 October 2023 from www.go-fair.org/wp-content/uploads/2022/01/FAIRPrinciples overview.pdf

⁹ Though Aboriginal and Torres Strait Islander data sovereignty principles are not explicitly mentioned, the Framework endeavours to meet best standards and practices. There will be continued consultation with relevant stakeholders on how to best navigate this sphere, and its intersections with microbial genomic data governance. Additionally, the Australian CDC plan to develop a framework for governance of First Nations data.

challenges for rapid sharing of data, particularly across One Health sectors. Legislative and regulatory constraints at both the Commonwealth and jurisdictional levels hinder the swift exchange of data and specimens. This impacts test reporting, validation, development, and the consistent maintenance of capacity and capability. Despite the urgency brought by the COVID-19 pandemic, the legislative and regulatory obstacles to data and specimen sharing remain unexplored, revealing previously overlooked system vulnerabilities. The Interim Australian CDC is currently undertaking thorough assessment of legislation and regulations from both the Commonwealth and jurisdictions affecting data and specimen sharing across One Health sectors, where it pertains to human health. By streamlining access to essential data and resources, we aim to facilitate smoother coordination and collaboration across health sectors.

What does the future look like?

- A national data governance mechanism is in place to ensure real-time data sharing and data use in the nationally consistent application of microbial genomics in public health practice.
- Secure systems and IT infrastructure is established to support current and future national and interoperable data sharing and storage requirements.
- Microbial genomics reporting is seamlessly integrated into laboratory and public health information management systems, with clear governance and data sharing processes.

Prior and current activities

Various initiatives are underway to address these challenges and improve data sharing between jurisdictions. These include the following completed activities:

- establishment of the CDGN AusTrakka User Group to:
 - support platform optimisation
 - enhance, coordinate, and support jurisdictional capability and capacity in the implementation of WGS and metagenomics approaches
 - develop procedures and policies allowing rapid national genomic data sharing and analysis, to enhance public health surveillance, outbreak detection and response
 - maintain validated national microbial bioinformatics pipelines
 - develop procedures and policies that allow for rapid national genomic data sharing and analysis through AusTrakka to enhance disease surveillance, outbreak detection and response

 development of AusTrakka Version 2 that aims to be more agile and adaptable to multiple scenarios while maintaining safe data sharing, management, and visualisation.

The following activities are ongoing:

- Maintenance of data sharing agreements established by CDGN, signed by jurisdictions. These agreements establish trust for cooperative, safe, and equitable data sharing between CDGN and its associated laboratories.
- Since January 2022, AusTrakka¹⁰ has focused on developing scalability and sustainability of the platform for the introduction of new pathogens of public health interest, and the governance, data types and requirements that accompany it.
- Development of operational and data governance structures for the ongoing management of AusTrakka for priority pathogens of public health significance.
- Given its success with COVID-19, AusTrakka is currently being explored as a mechanism for the national genomic investigation of Japanese encephalitis virus in Australia as a pilot One Health project.
- Working with AHPC and key stakeholders on the development of a set of guiding principles and an aspirational "end-state" vision for Australia's national genomic surveillance system to ensure it remains secure, fit-for-purpose and reflective of international best practice to support and enhance communicable disease surveillance investigations in Australia.

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¹⁰ For further information regarding AusTrakka's activities, please see Annex A.

Outcome 2.1 — Enhanced technology

- Maintain and enhance comparable sequencing instruments across jurisdictions.
- Continue to develop and maintain high-performance computing infrastructure (and other relevant types of existing and emerging technologies) to support data storage and sharing that can adapt to emerging microbial genomics technologies.

National Action	Timeframe	Lead	Priority
2.1.1 Map current One Health microbial genomic repositories and explore options to strengthen national coordination and interoperability.	Short	Australian CDC	High
2.1.2 Advocate and support increases in microbial genomics, bioinformatics and genomic epidemiology capability and capacity in each jurisdiction.	Medium	Australian CDC	High
2.1.3 Enable and maintain access to nationally agreed minimum sequence quality metrics, and protocols for sequence quality control and analysis for priority pathogens, with support of CDNA and CDGN.	Long	PHLN	High

Outcome 2.2 — Enhanced data sharing and governance

- Maintain and enhance multi-directional, interoperable microbial genomic data and critical metadata sharing across Australian governments, One Health sectors, and internationally.
- Ensure data sharing is compliant with the appropriate national and jurisdictional legislation, guidelines, and ethical frameworks.
- Review legislation and regulation at both state and federal levels to identify
 whether there are any impediments to implementation of microbial genomics,
 particularly in relation to data sharing.
- Ensure meaningful and appropriate recognition of data sources by both data custodian and data requester.
- Establish and maintain trust between data sharing entities and encourage further data sharing among active and potential providers, including in a One Health context.

National Action	Timeframe	Lead	Priority
2.2.1 Endorse a national pathogen-agnostic data sharing framework and protocol for the sharing of sequencing data, epidemiological metadata, and/or microbial materials through Australia's nationally agreed genomics surveillance platform across the human public health sector.	Short	Australian CDC	High
2.2.2 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.	Short	Australian CDC	High
2.2.3 Scope the feasibility of enhanced data integration and/or linkages as appropriate between PHLs and health departments' data management systems and other relevant national databases and surveillance systems.	Short	Australian CDC	High
2.2.4 Explore integrating microbial sequencing data into electronic health records to improve patient care and population health outcomes.	Short	Health	Medium
2.2.5 Harmonise and where possible improve data governance and legal requirements between jurisdictions for sharing sequences and associated metadata.	Medium	Australian CDC	High

2.2.6 Support sector engagement with international data sharing repositories to promote shared access to data for global harmonisation of data, surveillance and where appropriate, research.	Medium	Australian CDC	Medium
2.2.7 Involve the clinical microbiology sector in key data sharing discussions across laboratories.	Medium	Australian CDC	Medium
2.2.8 Encourage the adoption of Open Science principles at organisational and jurisdictional levels.	Long	All	Medium

Outcome 2.3 — Enhanced data storage and use

- Continue to develop nationally agreed pathogen-agnostic standards and minimum storage requirements for data collection, safe storage, and privacy, with consideration to other One Health sector requirements.
- Strengthen infrastructure to support secure storage of microbial genomic data.
- Maintain, develop, and promote common reporting standards for microbial genomics.

National Action	Timeframe	Lead	Priority
2.3.1 Define and communicate mutually agreed data custodianship standards to ensure data and associated metadata is used appropriately with relevant approvals for use sought.	Short	AHPC	High
2.3.2 Support the defining of minimum pathogen-agnostic data security handling requirements and minimum storage requirements for microbial isolates to align with national and international standards and best-practice for microbial genomics data pipelines, systems, data sharing, and storage.	Medium	Australian CDC	High
2.3.3 Explore options for the development of nationally accessible and sustainable data storage and computational infrastructure, which are also accessible to appropriate One Health sector users.	Medium	Australian CDC	High
2.3.4 With support of CDGN, promote and maintain consistent national reporting standards to communicate microbial genomic data to end-users for public health action.	Long	CDNA, PHLN	High

Outcome 2.4 — Enhanced technology and data governance across the One Health sector

- Encourage data sharing across the One Health sector.
- Develop nationally harmonised data governance guidelines to support data sharing across a One Health context.
- Ensure the variances between One Health data privacy and security requirements is acknowledged, and adhered to throughout the data collection, handling, and storage process.

National Action	Timeframe Lead		Priority
2.4.1 Assess the feasibility of national capture, analysis, and reporting of flavivirus sequences across the human, animal and environmental sectors, and action agreed next steps, as part of a One Health pilot project.	Medium	Australian CDC	High
2.4.2 Develop and maintain a common process and guidelines for timely data and information sharing across One Health sectors in the event of a One Health emergency outbreak relevant to Australia.	Medium	Australian CDC	High
2.4.3 Following the evaluation of the One Health pilot project, develop nationally agreed standards for One Health data collection, safe storage, data sharing, custodianship, analyses, reporting and privacy requirements.	Medium	CDGN	Medium
2.4.4 Support the integration of microbial genomics data for non-human samples i.e., food, animal, and environmental into public health outbreak investigations.	Medium	Australian CDC	Medium

Strategic Priority 3 — Integration into Public Health

The COVID-19 pandemic has demonstrated that genomic surveillance is a core pillar of a robust public health system. Microbial genomics generates a vast amount of useful data related to pathogen transmission, resistance, virulence, and evolution. This information enables rapid pathogen detection, identification, and characterisation that can be linked to information on clinical, demographic, and exposure details to form an enhanced picture of the outbreak.

To achieve maximal public health impact, it is critical that genomic data is:

- appropriately integrated and analysed with epidemiological and clinical data
- data and results are rapidly disseminated through bi-directional, interoperable data sharing or integrated systems
- those with expertise in genomic data are integrated into public health planning, response, and decision-making.

Conceptually, this is directly aligned with several of the key outcomes in the <u>National Framework for Communicable Disease Control</u>. To fully achieve this aim requires ongoing strategic coordination and collaboration between existing groups and networks. It is critical that microbial genomics continues to integrate into existing surveillance mechanisms, as this would better enable proactive and coordinated gathering and sharing of information.

However, COVID-19 response activities have highlighted potential risks to the successful integration of complete data for public health response. Sequencing of positive SARS-CoV-2 samples has declined in Australia with many jurisdictions having indicated that there has, or will be, changes to the sequencing strategies for SARS-CoV-2. In those jurisdictions still sequencing, a targeted sequencing strategy is undertaken to achieve the most public health and clinical benefit. These changes are affecting the representativeness of sequences presented in current reporting. It is therefore no longer possible to say with certainty the exact proportions of SARS-CoV-2 variants circulating in Australia.

Reduced sequencing means there is diminished analysis of circulating SARS-CoV-2 lineages, and this risks Australia's ability to:

• prepare and respond to new variants of concern (i.e., increased ability to evade the immune system or increased severity)

- select vaccinations that provide strong protection against common variants circulating in Australia
- ensure diagnostic tests remain accurate at detecting current viral strains in Australia
- analyse mutations to understand how these may influence the behaviour of the infection.

When designing action plans, genomic surveillance objectives and sample needs should be considered when designing public health testing and surveillance strategies, with appropriate input from those with genomic surveillance expertise.

What does the future look like?

- Bi-directional data flows which enable integrated analysis, reporting, and visualisation of genomic, epidemiological, and other surveillance data, to best inform our understanding of disease burden, transmission, and risk.
- Microbial genomics, including wastewater surveillance, is fully integrated into national public health practice and response, and in a One Health context.
- There is evidence from Australia that microbial genomics has contributed to improvements in disease understanding, including detection of outbreaks, and enabled timely response.
- There is greater systematic collaboration with researchers and a process to maximise opportunities for improvement and expansion in the application of microbial genomics.

Prior and 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. Completed activities include the following:

- in early 2021, CDNA endorsed the ongoing sharing of enhanced metadata in AusTrakka for SARS-CoV-2
- in June 2022, CDGN hosted symposia sessions at the Communicable Diseases and Immunisation Conference in Sydney, with a focus on the utility of genomics for COVID-19 and other public health pathogens.

The following include ongoing activities:

- CDGN continues to advise and interact with laboratory and public health networks, government, policy makers, and other relevant stakeholders on pathogens of public health interest, including SARS-CoV-2
- research opportunities continue to be 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
- CDGN regularly contributes to national SARS-CoV-2 surveillance, providing national genomics surveillance reports from data analysed through the AusTrakka platform as part of the Australian National Disease Surveillance Plan for COVID-19
- in March 2021, to support Australia's national response to SARS-CoV-2 variants, activities were undertaken which include the:
 - development and regular update of a Variant of Concern (VoC) literature summary document, a 'live' list of variants and mutations of concern or interest relevant to Australia for surveillance and reporting, based on available literature and international classifications
 - maintenance of the CDGN laboratory case definitions for SARS-CoV-2 VoC
 - collaboration with the Department of Health and Aged Care to develop a harmonised approach for reporting SARS-CoV-2 variants and mutations across jurisdictions and nationally, to support the recording of SARS-CoV-2 variants in the National Notifiable Diseases Surveillance System
 - ongoing review of the CDGN website to ensure content is accurate and aligns with leading international organisations (for example, WHO, UKHSA)
 - monitoring of primers/probes to ensure they can accurately detect the virus and variants.

Outcome 3.1 — Microbial genomics integrated into public health reporting and systems

- Facilitate integration with:
 - epidemiological and AMR surveillance systems
 - laboratory information systems.
- Continue to ensure preparedness to rapidly detect and characterise emerging and/or newly imported pathogens and other bio-threats.

National Action	Timeframe	Lead	Priority
3.1.1 Investigate how microbial genomics data and laboratory information management and epidemiological surveillance systems can be integrated or linked to support unified analysis and decision-making. Determine how systems can facilitate seamless notification and reporting pathways for effective and real-time public health action.	Medium	All	High
3.1.2 Support the development of methodologies for integrated analysis and reporting of genomic, epidemiological, and other surveillance data.	Medium	CDGN	Medium
3.1.3 Develop exercises to test the use of microbial genomics in the event of a human disease outbreak. These will assess and look at strengths and opportunities to improve Australia's integration of microbial genomics into public health responses.	Medium	CDGN	Medium
3.1.4 With support of CDGN, maintain consistent public health reporting standards and nomenclature for key pathogens of public health interest that effectively communicates data to end-users (e.g., clinicians and public health authorities).	Long	CDNA, PHLN	High

Outcome 3.2 — Priority organisms of national significance identified

- 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 refer priority samples for sequencing and/or share microbial genomics related data for public health and surveillance purposes for priority organisms.

National Action	Timeframe	Lead	Priority
3.2.1 Ensure laboratories have the necessary information and resources for the rapid detection and characterisation of emerging and/or newly imported pathogens of public health concern and other bio-threats.	Medium	State and territory governments, Australian Government	High
3.2.2 Drawing from national and international experience, regularly review list of pathogens of public health importance to enable priority sequencing to support and enhance pathogen detection and public health response. This should be decided through consultation and collaboration with relevant stakeholders and include defining appropriate objectives, sampling frames, stages of implementation and indicators of effective implementation.	Ongoing	CDNA, Australian CDC	Medium
3.2.3 Support the development of guidance and partnerships with human diagnostic pathology laboratories to share isolates of priority organisms for public health surveillance purposes.	Ongoing	State and territory governments	Medium

Outcome 3.3 — Prioritised public health research and innovation

- Strengthen communication with microbial genomics researchers to identify gaps for improvement in infectious 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.
- Promote national and international collaboration and innovation across One Health laboratories, public health units and academia to keep pace with advances in microbial genomics technology, including non-culture-based approaches.

National Action	Timeframe	Lead	Priority
3.3.1 Encourage translational research opportunities that can improve public health investigation, surveillance and response, and evaluate the public health integration and utility of microbial genomics through commissioning and consulting with relevant academic institutions (i.e., cutting-edge sequencing technologies, clinical metagenomics, application of machine learning/artificial intelligence methodologies, and mathematical modelling).	Medium	All	High
3.3.2 Map current public health microbial genomics research activities and explore options to strengthen national coordination. This will inform the development of a national research agenda to guide sustainable and strategic research investment.	Medium	CDGN	Medium
3.3.3 Promote the development of a national research agenda for microbial genomics for public health. Look at opportunities to link to Australian Government and state and territory government research priorities.	Medium	Australian Government	Medium
3.3.4 Foster One Health partnerships (both public and private) and stakeholder engagement to explore opportunities for partnerships, to support and encourage innovation in microbial genomics to improve public health outcomes.	Medium	Australian CDC	Medium
3.3.5 Strengthen metagenomic capability 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	Low

Outcome 3.4 — Microbial genomics integrated into One Health sector reporting and systems

• Work with laboratory stakeholders to continue integrating microbial genomics sequencing across One Health sectors to strengthen surveillance activities.

National Action	Timeframe	Lead	Priority
3.4.1 Using pilot implementation projects, such as that for zoonotic flaviviruses, look at the possibility of interoperable One Health routine microbial genomics sequencing and reporting for surveillance of priority organisms to measure and identify local transmissions for outbreak management and control.	Medium	Australian CDC	Medium
3.4.2 Encourage the use of microbial genomics technology and the integration of genomics data from animal and environmental sources.	Long	All	Medium
3.4.3 Support the development of guidance and partnerships with the One Health sector to share isolates of priority organisms for One Health surveillance purposes.	Long	Australian CDC	Medium

Strategic Priority 4 — Access and Workforce

Currently, public health microbiology services are provided by PHLs through a network of jurisdictional specialist microbiology laboratories. These PHLs include dedicated specialist (reference) facilities and laboratories co-located within hospital-based facilities. Depending on jurisdictional size (population and geographical spread) and capacity, PHLs provide a range of specialist functions, including:

- detailed typing and characterisation of communicable disease pathogens, underpinning national surveillance for communicable diseases
- laboratory contribution to outbreak investigation
- specialised microbial reference diagnostics and confirmatory testing
- provision of medical and scientific advice to public health networks and authorities
- state-based and national leadership in standardising the diagnosis and laboratorybased surveillance of communicable disease
- identification and application of new technological and scientific developments to public health microbiology practice.

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.

Despite rapid advances, there remains varying capacity and capability across jurisdictions regarding the implementation of microbial genomics in PHLs, in part due to resource and workforce prioritisation, and expense of equipment needed to fully integrate microbial genomic practices into the laboratory. From a workforce perspective, there also remains challenges in the provision and availability of education and training to support a microbial genomics literate workforce.

To complicate implementation, the increased use of portable sequencing platforms and decentralised molecular diagnostic testing (including personal use in-vitro diagnostic devices) challenges the traditional model of clinical sample referral to PHLs for specialist typing and characterisation as part of surveillance activities. Common protocols and collaboration between the clinical space and PHLs will be key to ensuring quality and portability of genomic data across integrated laboratory information systems for surveillance purposes.

A growing number of pathology providers in public and private sectors are considering different models of genomics testing for hospital infection control and antimicrobial stewardship. 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 meet the growing demand for microbial genomics in the public health system.

The need for improved and standardised education opportunities, which 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.

What does the future look like?

- A robust, sustainable national microbial genomics capacity and capability has been established to meet public health needs, and referral of priority specimens for genomics characterisation is maintained.
- Capacity and capability are well supported and is maintained through required expertise and workforce development.
- Microbial genomics literacy is maintained across all relevant stakeholders and there is national support for innovation.
- The genomics workforce is supported throughout all stages of their careers, building a well-trained and microbial genomics literate workforce to meet the increasing demand for genomics services in Australia.

Prior and current activities

Invigorated by the COVID-19 pandemic, many Australian states and territories have acted to better understand how the workforce should evolve to support microbial genomics as an integral part of mainstream laboratory testing. However, most of these activities are still supported by existing resources and require sustainable funding to maintain the provision of training, workshops, and upskilling. This is particularly true for smaller jurisdictions with limited 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 where there is limited dedicated bioinformaticians or bioinformatics expertise. This is also supported by the CDGN Teaching, Training and Curriculum Working Group.

The Interim Australian CDC is also progressing the development of a National Public Health Laboratory Strategy. While this is not microbial genomics-specific, it will assist to determine workforce needs more broadly in the public health laboratory system as a first step to understanding gaps and opportunities.

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 upon engagement with diagnostic laboratories and One Health laboratories.

National Action	Timeframe	Lead	Priority
4.1.1 Provide outreach and education to end-users (e.g., public health decision-makers) about the availability and utility of genomic analysis.	Short	CDGN	Medium
4.1.2 Establish explicit pathways for requesting genomic analysis to end-users.	Short	CDGN	Medium
4.1.3 Foster bioinformatics and analytical support in public and private laboratories (including public hospital laboratories) across jurisdictions. Find improvement opportunities that may benefit from national coordination.	Medium	CDGN	High
4.1.4 Continue to identify barriers to equity of access for laboratories (including across One Health sectors), in collaboration with state and territory governments, and develop a national approach to address these. Access is multidimensional and includes location, cost, availability, and appropriateness.	Medium	Australian CDC	High
4.1.5 Define and provide adequate resourcing dedicated to establishing surge capacity and pandemic preparedness, across One Health sectors.	Long	All	High

Outcome 4.2 — Enhanced workforce

- Building and maintaining a skilled, multi-disciplinary and cross-trained workforce.
- 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, industry, and societies to promote and support the sharing of knowledge.

National Action	Timeframe	Lead	Priority
4.2.1 Provide coordination and bioinformatics training and support across jurisdictions to ensure equitable sharing of practices, knowledge, and information to all jurisdictions, and help maintain a validated national microbial bioinformatics pipeline.	Medium	CDGN	High
4.2.2 Improve the microbial genomics literacy and capability of the health workforce, through the development, delivery, and ongoing maintenance of appropriate microbial genomics education, training, and skills.	Medium	CDGN	Medium
4.2.3 Involve relevant professional bodies, colleges, industry, and tertiary education sectors, 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	CDGN, RCPA, Health	Medium
4.2.4 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	Medium
4.2.5 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

4.2.6 Maintain and develop a skilled and literate national public health microbial genomics workforce through the development of workforce strategies and planning.

Long

ΑII

Medium

Strategic Priority 5 — Financing

PHLs have identified common challenges to the routine implementation of microbial genomics in their laboratories. These include:

- lack of sustainable funding for maintaining a microbial genomics service in PHLs post COVID-19, particularly in those that receive relatively low specimen numbers, noting also that public expectation regarding service delivery and fast turn-around times remains high
- limited bioinformatics, genomic epidemiology, data science and software engineer expertise in some jurisdictions
- limited infrastructure in some jurisdictions in relation to sequencing, data storage and computational capacity.

The application of microbial genomics in public health has the potential to reduce the financial burden of infectious 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.

An evidence base to support the value of microbial genomics has now been established due to the COVID-19 pandemic, however further work needs to be progressed to understand the cost-effectiveness of microbial genomics in the Australian context for other pathogens of public interest. 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.

While the added value of microbial genomic services for public health has been recognised, agreement needs to be reached between clinical and public health services regarding funding for service development and delivery, where the microbial genomics services have a dual clinical and public health benefit—for example, drug resistance and antimicrobial stewardship.

What does the future look like?

• A sustainable funding model has been established, linked to broader public health laboratory testing, outbreak investigation and public health surveillance response.

• The funding model is agile so it can respond to emerging technologies and expanding application of microbial genomics to public health.

Prior and current activities

The Medical Research Future Fund (MRFF)'s Genomics Health Futures Mission is investing \$500.1 million in genomic research to improve testing and diagnosis for many diseases, help personalise treatment options to better target and improve health outcomes, and reduce unnecessary interventions and health costs for all Australians.

The 2019 Genomics Health Futures Mission: Flagships - Pathogen Genomics grant opportunity provided \$27 million over four years (from 2019-20 to 2022-23) to large scale pilot research studies into pathogen genomics late in the research and development pipeline.

The following grants were awarded:

- Meta-GP: Delivering a Clinical Metagenomics Platform for Australia
- H2Seq: Viral genomics for public health interventions in HIV and HCV
- Genomics Digital Health and Machine Learning: the SuperbugAi Flagship
- Precision Public Health in Australia through Integrated Pathogen Genomics (AusPathoGen).

Starting in 2021, AusPathoGen is undertaking an economic evaluation of genomics-based public health responses. The program aims to compare the incremental cost and effectiveness of WGS compared to current methods of testing and typing, and so assess the incremental cost effectiveness of WGS as the core tool for surveillance of these pathogens.

Outcome 5.1 — Established sustainable funding model

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

National Action	Timeframe	Lead	Priority
5.1.1 Continue to explore and advocate for funding opportunities for storing and managing pathogen sequence data.	Medium	All	High
5.1.2 Continue to explore and advocate for equitable financing and purchasing models to inform the appropriate integration of safe, effective, and cost-efficient public health microbial genomics delivery. This will be particularly important in the context of the establishment of the new Australian CDC.	Medium	All	Medium
5.1.3 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.	Long	All	High
5.1.4 Investigate and advocate for sustainable funding opportunities at both the national and state and territory level, to enhance microbial sequencing capability and capacity.	Ongoing	All	High

Outcome 5.2 — Established cost-effective model

- Ensure the cost of introducing and maintaining microbial genomic technology results in savings accrued from improvement in patient care, prompt public health interventions to infectious disease outbreaks and replacement of existing technologies. Initial implementation will result in a short-term increase in costs while development of new workflow processes and replacement of outdated testing methods occur.
- Establish a mechanism to regularly review risks and challenges associated with the integration of microbial genomics into public health.

National Action	Timeframe	Lead	Priority
5.2.1 Establishing a mechanism to regularly review risks and challenges associated with the integration of microbial genomics into public health.	Medium	All	High
5.2.2 Review the value and cost-effectiveness of implemented microbial genomics services, with the support of CDNA, PHLN and CDGN.	Medium	Australian CDC	Medium
5.2.3 Develop partnerships, funding, and data sharing approaches for microbial genomics that promotes access to safe, efficient, and cost-effective services, including for a One Health context both nationally and regionally, recognising that regional investment mutually benefits Australia.	Medium	All	Medium
5.2.4 Collaborate across governments and stakeholders to maximise investment, reduce duplication of effort, and use resources efficiently.	Long	All	Medium

Future directions

Now is the time to consider how microbial genomics data for public health could be more broadly integrated into both existing and developing animal and environmental (One Health), food safety, wastewater, and AMR surveillance systems and networks. Greater systemic collaboration with researchers, industry and private pathology is also required to boost opportunities for improvement and application of microbial genomics for public health action. By taking full advantage of microbial genomics for real-time diagnostics, this would enable the identification of priority organisms, which supports timely outbreak investigations and preparedness activities.

Annex A

National developments

Since the publication of the *National Microbial Genomics Framework 2019-2022*, the integration of microbial genomics in public health has been fast-tracked due to the COVID-19 pandemic. However, while activities over 2020-2022 were largely focused on the COVID-19 response, developments have been made in other critical areas including training and workforce and establishing sequencing pipelines and methods for other diseases and antimicrobial resistances of public health significance. This progress was largely due to, and facilitated by, the CDGN.

Communicable Diseases Genomics Network

The CDGN was established in 2015 with an overarching aim of implementing genomics into clinical and public health microbiology in Australia. The CDGN includes representatives from PHLs across all jurisdictions in Australia, and New Zealand.

CDGN's vision is to advance public health in Australia and New Zealand through the implementation of microbial genomics to support communicable disease control activities. Since its establishment, CDGN continues to provide PHLN with technical advice on genomics and progress activities under this framework.

To address the aims of the Network, CDGN has established several working groups covering the following topics:

- pathogen and topic-specific expert advisory groups, such as the SARS-CoV-2 variants of concern working group
- workforce training and curriculum development in microbial genomics
- development of a secure platform for rapid, equitable and ethical data sharing (i.e., AusTrakka)
- standardisation and implementation of genomic technologies in laboratories (including clinical metagenomics). This includes development and support for the RCPA QAP in microbial genomics.

CDGN has also played a critical role in Australia's response to COVID-19 and continues to actively monitor and report on domestic and international SARS-CoV-2 variants.

In Focus: CDGN Teaching and Training

Since the formation of CDGN, teaching and training within the field of pathogen genomics for public health has been a central focus for the Network. CDGN's teaching and training activities are undertaken by the Teaching, Training and Curriculum Working Group (TTC WG), established to enhance Australia's genomics capacity through the promotion and implementation of high-quality teaching and training resources across all jurisdictions. The multidisciplinary working group is comprised of members from CDGN laboratories with expertise across microbial genomics, bioinformatics, medical microbiology, and genomic epidemiology, who meet monthly to progress key TTC WG activities.

In 2021, the TTC WG developed a genomics-based end-to-end Training Framework to align training approaches nationally, informed by the group's experience and expertise working within public health and clinical laboratories across Australia.

In 2022, the TTC WG translated the Training Framework into a three-part webinar series titled 'Introduction to Pathogen Genomics for Public Health', which was implemented across the year and covered wet-lab processes for WGS, bioinformatic analysis for clinical and public health, and WGS reporting considerations. Evaluation surveys from the webinar series found participants strongly valued "the up-to-date information on technology changes" and the explanation of "difficult information in a concise manner". The TTC WG activities directly align with Strategic Priority 4 of the Framework, which seeks to foster national microbial genomics capacity and capability and promote improvement and maintenance of genomics literacy in both laboratory and non-laboratory settings.

Microbial genomics and the COVID-19 response

Enhanced expertise was, and remains, essential to guide Australia's national approach to SARS-CoV-2 genome sequencing and analysis to support the Australian Government's response to the COVID-19 pandemic and its transition to management under standard communicable disease control measures. Microbial genomics has been recognised as an important public health tool that can enhance epidemiological investigation of COVID-19 cases by:

- supporting the identification of the source of infection in cases arising without known epidemiological links
- supporting field investigations to identify and more precisely characterise outbreaks
- identifying clusters of infection

 defining possible transmission networks to enhance targeted implementation of public health measures and prevent or slow onward transmission.

Integration and implementation of a nationally coordinated approach to sequencing was accelerated and became a critical pillar in Australia's public health response to the COVID-19 pandemic. The need to rapidly characterise SARS-CoV-2 lineages using genome sequencing was apparent early in the pandemic, due to the virus's ability to quickly evolve and impact transmissibility, severity, immune evasion, and treatment efficacy.

With support of Australia's collaborative network of PHLs and CDGN, all states and territories were able to quickly increase their sequencing capability and capacity in the early stages of the pandemic. Over the course of the pandemic the outputs of sequencing analysis influenced decision-making in different ways; for example, informed decisions to introduce public health and social measures, such as mask wearing, social distancing, or lockdowns.

With increased sequencing capability arose the need for more effective management and harmonisation of sequencing information, and the establishment of a nationally coordinated approach to genomic surveillance. In early 2020, a nationally agreed approach to sequence and share minimal metadata for SARS-CoV-2 was established, led by CDGN. This included the development of a governance framework for data sharing, which was critically public health focussed and enabled custodianship of the data to remain with contributing sequencing laboratories.

SARS-CoV-2 Variants of Concern

As SARS-CoV-2 variants began to emerge in late 2020, the international public health community rallied to determine the impact of circulating variants on current diagnostics and therapeutics, disease severity, and overall transmissibility. In response, CDGN identified the need for a dedicated taskforce to provide Australia with a nationally coordinated mechanism for understanding and responding to emerging variants. The CDGN multi-disciplinary Variant of Concern Working Group (VOC WG) was formed to address this need, comprising of medical microbiologists, virologists, bioinformaticians, genomic epidemiologists, phylodynamic modelers, and government representatives.

The CDGN VOC WG has:

- supported a nationally coordinated response to SARS-CoV-2 variants
- implemented near real-time genomic surveillance and consistent reporting of circulating lineages, particularly through regular publication of a VOC Literature Summary containing up to date information on lineages circulating nationally and globally

- maintained a national VOC Laboratory Case Definition
- provided regular briefings on emerging lineages in response to requests from governments and key stakeholder groups.

The CDGN continues to provide expert advice to the Australian Government on SARS-CoV-2 variants and mutations of interest relevant to Australia for surveillance and reporting based on available literature and international classifications.

Due to the broader circulation of COVID-19 in the community in late 2021, Australia's sequencing laboratories moved from a comprehensive sequencing strategy (attempt to sequence every case) to a targeted surveillance approach, focussed more on surveillance and detection of variants or mutations of concern. This led to the publication of the <u>CDGN, PHLN and CDNA Sampling Strategy for SARS-CoV-2 Genomic</u>
<u>Surveillance</u>. The Strategy aimed to ensure the data collected:

- is representative of the available confirmed cases
- has the ability to identify new SARS-COV-2 virus variant introductions
- provides reliable findings that impact public health action.

The Strategy outlined suggested priority groups for targeted sampling, this included patients admitted to hospital and/or intensive care, to identify whether any virus lineages are associated with increased disease severity¹¹.

WGS Proficiency Testing for SARS-CoV-2

To ensure capability was developed and maintained across jurisdictions, over 2019-2022, Health supported the <u>RCPA QAP</u> Biosecurity program to develop a PTP for SARS-CoV-2 WGS. 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 of the WGS PTP, further modules were offered over 2020-21. These modules monitored the quality of sequencing practices in Australian PHLs.

AusTrakka

AusTrakka was developed in response to key reports to the Office of Health Protection on the need to better facilitate public health genomics data sharing and analysis in

¹¹ Australian Government Department of Health and Aged Care (2021). CDGN, PHLN and CDNA Sampling Strategy for SARS-CoV-2 Genomic Surveillance. Retrieved on 21 August 2024 from https://www.health.gov.au/sites/default/files/documents/2021/11/cdgn-phln-and-cdna-sampling-strategy-for-sars-cov-2-genomic-surveillance_0.pdf

Australia in a nationally coordinated way. In 2020, national endorsement was provided for the use of AusTrakka, as Australia's national genomic surveillance system for SARS-CoV-2. AusTrakka provides for near real-time analysis of integrated pathogen genomic data for public health across Australia, providing a central, secure, and private online location to share, store, analyse and view aggregated national and jurisdictional data. As of 2024, AusTrakka is contracted as Australia's national genomic surveillance system for SARS-CoV-2 until mid-2025, with the inclusion of additional pathogens yet to be determined.

In September 2020, AHPC endorsed the <u>Framework for data sharing and analysis for SARS-CoV-2 in the AusTrakka system</u>. This framework provides a mechanism for rapid data sharing and genomic analysis within and between jurisdictions, and nationally. While not legally binding, it formalised the endorsement for public health laboratories to rapidly share all SARS-CoV-2 genomics data to the AusTrakka platform through their nominated public health laboratory for national near real-time surveillance. This enabled the public health system to track transmission and identify new and emerging SARS-CoV-2 clusters to improve surveillance of COVID-19. This rapid sharing of genomic data now consistently, meaningfully contributes to response activities and informs decision-making on public health interventions, where required.

AusTrakka has been involved in the rapid and coordinated responses in four areas of national need:

- foodborne diseases (see Case Study 1, 2 and 4, pages 64, 65 and 74),
- respiratory and vaccine-preventable diseases (see Case Study 3, page 66),
- sexually transmitted infections (see Case Study 2, page 65)
- AMR (Case Study 2 and 3, page 65, 66) and emerging pathogens (biothreat agents).

Case Study 1: Multijurisdictional outbreak of *Salmonella* Typhimurium

In 2021, a national genomic surveillance investigation of *Salmonella* Typhimurium cases across Australia was conducted in AusTrakka, triggered by an increasing number of Typhimurium outbreaks across jurisdictions. For this outbreak, traditional epidemiological approaches were unable to identify clear links between clusters or potential sources as differing typing methods in each state prevented comparison based on laboratory results alone. OzFoodNet Australia requested a national comparison of all genomic sequences collected within a six-month period be conducted in AusTrakka. This included samples that were part of separate outbreaks in Queensland and Victoria.

An initial comparison identified 32 multi-jurisdictional genomic clusters of varying sizes within the 629 sequences submitted. In-depth genomic analysis revealed highly related groups within clusters that would not have otherwise been discovered. This enabled the identification and exclusion of suspected transmission chains between jurisdictions and potential sources. This was one of the first large-scale genomics-led exploratory investigations into *Salmonella* Typhimurium transmissions across Australia. The outcomes of this investigation informed OzFoodNet of potential links between cases and sources for further investigation, enabling a more targeted approach to the response. This is an example of an innovative response to national surveillance and outbreak investigation in line with the <u>Australian Foodborne Illness Reduction Strategy</u>.

Case Study 2: Monitoring multi- and extensively-drug-resistant Shigella species

The emergence and increased circulation of multi- and extensively-drug-resistant (MDR/XDR) *Shigella* strains across the globe means there is a significant risk of the introduction and establishment of these highly resistant pathogens in Australia. Genomic studies undertaken in Victoria and Queensland has provided key insights to the different aspects of this threat: the introduction and transmission of XDR *Shigella sonnei* among gay, bisexual, and other men who have sex with men (GBMSM) in Australia^{12,13}, cocirculation of multiple MDR *Shigella* species in Australia¹⁴, and the transfer of a MDR plasmid to an endemic strain of *Shigella flexneri* that disproportionally affects Aboriginal and Torres Strait Islander children¹⁵. This expertise now underpins the efforts towards real-time, nationally harmonised surveillance of *Shigella* species, undertaken as one of the key pathogens in the MRFF funded national AusPathoGen program; directly meeting the priority area of using evidence-based surveillance and monitoring data to inform action and responses outlined in Australia's National Antimicrobial Resistance Strategy.

¹² Williamson DA, Ingle DJ, Howden BP. (2019) Extensively drug-resistant Shigellosis in Australia among men who have sex with men. New England Journal of Medicine.

¹³ Ingle DJ, Andersson P, Valcanis M et al. (2020) Prolonged outbreak of multidrug-resistant Shigella sonnei harbouring blaCTX-M-27 in Victoria, Australia. Antimicrobial Agents and Chemotherapy.

¹⁴ Ingle DJ, Easton M, Valcanis et al (2019) Co-circulation of multidrug-resistant Shigella among men who have sex with men in Australia. Clinical Infectious Diseases.

¹⁵ Guglielmino CJD, Kakkanat A, Forde BM et al (2021) Outbreak of multi-drug-resistant (MDR) Shigella flexneri in northern Australia due to an endemic regional clone acquiring an IncFII plasmid. European Journal of Clinical Microbiology and Infectious Diseases.

Case Study 3: Clinical and public health utility of *Mycobacterium tuberculosis* whole genome sequencing¹⁶

For patients with *Mycobacterium tuberculosis*, WGS has been shown to be of real value as it enables patients to receive tailored treatment and is able to differentiate between relapse and re-infection. Contamination, mixed infections, clusters, and transmission pathways can also be determined more accurately using WGS compared to traditional methods. Surveillance of AMR is an additional advantage, particularly for high-burden countries.

In Australia, WGS of *Mycobacterium tuberculosis* for the purpose of drug susceptibility testing at the time of diagnosis and in the event of a recurrence has been added to the Medical Benefits Scheme on advice from MSAC¹⁷.

Translational research initiatives

In 2020, the Australian Government announced \$27 million in funding under the MRFF through the Genomics Health Futures Mission to support large scale pathogen genomics research studies that are late in the research and development pipeline. These projects aim to demonstrate clinical and/or public health utility, cost-effectiveness, and translational capacity, in recognition that such evidence is critical to the adoption of genomics in the mainstream health system.

AusPathoGen

The Australian Pathogen Genomics (AusPathoGen) Program aims to deliver precision in public health for Australia through integrated pathogen genomics. Commencing in 2021, AusPathoGen, a consortia of program partners led by CDGN, aims to build on the success of the COVID-19 genomics response to further implement and evaluate large-scale integration of pathogen genomics, epidemiological and surveillance data at the public health interface.

The AusPathoGen program aims to address the rise in infectious diseases and AMR, adhering to international models for optimal use of pathogen genomic data.

¹⁶ Gordon, A. K., Marais, B., Walker, T. M., & Sintchenko, V. (2021). Clinical and public health utility of Mycobacterium tuberculosis whole genome sequencing. International Journal of Infectious Diseases, 113, S40-S42.

¹⁷ Australian Government (2022). Medical Services Advisory Committee, Public Summary Document, Application No. 1646 – Whole genome sequencing of antimicrobial-resistant pathogens. Retrieved 3 March 2025 from https://www.msac.gov.au/sites/default/files/documents/1646%2520- %2520Final%2520PSD_Mar-Apr2022.pdf

This includes:

- accelerating translational research to inform the establishment of genomicsenabled surveillance and public health interventions
- evaluation of its cost-effectiveness and public health impact
- strengthening the pathogen genomics community in Australia and internationally.

The Program also aims to reduce the impact of infectious diseases and AMR on public health by improving pathogen characterisation and optimising responses, to enhance public health action and patient care in Australia. This work will support activities under this framework.

H2Seq

Human immunodeficiency virus (HIV) and hepatitis C (HCV) are among the most rapidly mutating, genetically diverse, pathogenic RNA viruses. Mutations observed in circulating viruses are influenced by challenges posed by the human immune system and antiviral treatments. Transmission is mainly influenced by human behaviour and constraints associated with efficient viral replication. Understanding the interaction of viral mutations and each of these influencing factors are key to informing preventive and therapeutic strategies for HIV and HCV.

H2Seq, as a MRFF-funded initiative, has a vision to develop, implement, and evaluate a national system for near real-time molecular epidemiology of HIV and HCV in Australia. The goal is to assess the efficacy and cost-effectiveness of targeted public health interventions for newly acquired HIV and HCV infections informed by phylogenetic analyses annotated with epidemiological data. Public health applications of the molecular epidemiology of HIV and HCV will only be implemented when it is deemed ethically, legally, and socially responsible.

In relation to microbial genomics and molecular epidemiology for HIV and HCV, H2Seq has achieved the following:

- Consulted widely across the pathogen genomics and blood borne virus (BBV)
 public health sectors in each state and territory via national stakeholder working
 groups to establish the feasibility of the H2Seq molecular epidemiology
 framework.
- Developed and implemented algorithms enabling reliable subject level linkage of viral sequences and public health metadata without storage of any potentially identifying information by systematic anonymisation at data source. Given the concerns relating to individual privacy and confidentiality for these infections this

approach uses cryptographic hashing to enable linkage without compromising the information used in the linkage.

• Evaluated legal and ethical considerations around setting up centralised pathogen genomic databases, linked to public health metadata, data sharing with key stakeholders, as well as development of strategies to mitigate such risks.

Metagenomics Platform (Meta-GP)

Clinical metagenomic next-generation sequencing is a transformative approach in microbial diagnostics and patient care, due to its use in detecting and characterising all known pathogens – bacterial, viral, fungal, parasitic – in one single test. Meta-GP, a MRFF funded national multi-centre cohort study, aims to develop and implement clinical metagenomic diagnostics for infectious diseases in Australian clinical and public health laboratories.

At the conclusion of Meta-GP, Australia will have a nationally accessible network of laboratories that can apply metagenomic approaches in patient care to rapidly detect, prevent, and respond to infectious threats, including AMR.

Meta-GP aligns with the Framework's strategic priorities and principles by delivering the following objectives:

- the ability to rapidly identify the cause of any infectious disease within a clinically actionable timeframe and hence transform individual patient care
- a clear understanding of the range of microbial pathogens that impose a major disease burden in Australia
- ensure public health surveillance can occur in the face of culture independent diagnostic tests.

International developments

Due to the emergence of SARS-CoV-2 and its rapidly emerging and evolving variants, the ability to perform genome sequencing has now been established in more than two-thirds of WHO Member State countries¹⁸. However, there remains marked variation between different countries regarding the degree to which:

¹⁸ World Health Organization (2022). Global genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032. Retrieved 17 February 2023 from

https://www.who.int/initiatives/genomic-surveillance-

strategy#:~:text=Global%20genomic%20surveillance%20strategy%20for%20pathogens%20with%20pande mic,detection%2C%20monitoring%20and%20response%20to%20public%20health%20threats.

- infrastructure and systems enable nationwide genomic surveillance of communicable diseases
- genomic data is able to be shared for public health purposes.

Below is a brief snapshot of activities undertaken by key organisations, collaborations, and countries to enhance pathogen genomic capability and capacity.

World Health Organization

The WHO acknowledges that the application of microbial genome analysis has emerged as an essential feature in infectious disease control, with the intention of:

- · identification and diagnosis of infectious diseases
- demonstrating infection movement between human and/or animal hosts, including:
 - evolution mapping of infectious agents
 - gene phenotypic properties assignment, such as infectivity and pathogenicity
 - drug sensitivity or resistance evaluation of an infectious agent.

To drive the progression of its integration, the WHO has released the <u>Global genomic surveillance strategy for pathogens with pandemic and epidemic potential 2022-2032</u> which urges Member States to strengthen their genomic surveillance capacity and capabilities. It aims to address public health needs while recognising that most countries will require assistance to develop their own capabilities. The five objectives of the strategy are to:

- improve access to tools for better geographic representation
- strengthen the workforce to deliver at speed, scale, and quality
- enhance data sharing and utility for streamlined local to global public health decision-making and action
- maximise connectivity for timely value-add in the broader surveillance architecture
- maintain a readiness posture for emergencies¹⁹.

strategy#:~:text=Global%20genomic%20surveillance%20strategy%20for%20pathogens%20with%20pandemic,detection%2C%20monitoring%20and%20response%20to%20public%20health%20threats.

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¹⁹ World Health Organization (2022). Global genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032. Retrieved 17 February 2023 from https://www.who.int/initiatives/genomic-surveillance-

This global strategy aims to guide countries in their expansion of genomic surveillance efforts and promote a harmonised local-to-global approach. Supporting the Strategy's mandate is the recently formed WHO Western Pacific Region (WPR) Emerging Molecular Pathogen Characterisation Technologies (EMPaCT) Surveillance Network. The Network identifies that there is a need for a systems approach to re-visit and re-organise available resources to meet new demand for surveillance to include genomic information in the WPR. A seven-step approach was proposed to facilitate this vision which strives to support the development of sustainable, resilient, and nationally coordinated in-country genomic surveillance systems which have the potential to detect and characterise new threats²⁰.

Understanding the complexities of genomic integration, in July 2022 WHO published the *Accelerating access to genomics for global health: promotion, implementation, collaboration, and ethical, legal, and social issues: a report of the WHO Science Council.* The report acknowledges the impediments to integration of genomics in low- and middle-income countries include the high cost of equipment and reagents, and lack of trained personnel. In this report, fifteen actions are recommended to achieve the goal of accelerating access to genomics for global health under four themes:

- promotion of genomics through advocacy
- implementation of genomic methodologies
- collaboration among entities engaged in genomics
- attention to the ethical legal, and social issues raised by genomics²¹.

Recognising the global response to the COVID-19 pandemic was disjointed and hindered by inadequate sharing, WHO published the <u>WHO guiding principles for pathogen genome data sharing</u> in November 2022. The guidance acknowledges pathogen genomics capacity is advancing rapidly and recognises risks created by gaps in global surveillance. New technology is not equally accessible and potentially negative effects from reporting the emergence of new and dangerous pathogens can act as a deterrent to data sharing. WHO encourages timely pathogen genome data sharing, and the guidance suggests 13 foundational principles on which pathogen genome data sharing should be based:

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World Health Organization: Regional Office for the Western Pacific (2022). Meeting Report: Inaugural Meeting of the Western Pacific Region Emerging Molecular Pathogen Characterization Technologies (EMPaCT) Surveillance Network. Retrieved on 17 February 2023 from https://iris.who.int/handle/10665/352822

²¹ World Health Organization (2022). Accelerating access to genomics for global health: promotion, implementation, collaboration, and ethical, legal, and social issues. A report of the WHO Science Council. Retrieved 17 February 2023 from https://www.who.int/publications/i/item/9789240052857

- capacity development
- collaboration and cooperation
- high quality, reproducible data
- global and regional representativeness
- timeliness
- acknowledgement and intellectual credit
- global and regional representativeness
- equitable access to health technologies as a benefit
- as open as possible and as closed as necessary
- interoperability and relevance for national, regional, and global decision-makers
- trustworthiness and ease of use
- transparency
- consistency with applicable law and ethical regulations
- compliance and enforcement²².

To facilitate pathogen genomic surveillance, in May 2023 the WHO launched the International Pathogen Surveillance Network (IPSN), a global network of pathogen genomic stakeholders, hosted by the WHO Hub for Pandemic and Epidemic Intelligence. The IPSN aims to accelerate progress on the deployment of pathogen genomics and improve public health decision-making. To achieve its mission, the IPSN has identified five areas of work:

- 1. Communities of practice to solve common challenges.
- 2. Country scale-up accelerator to align efforts and enable South-South exchange.
- 3. Funding to improve equity and to power IPSN projects.

²² World Health Organization (2022). WHO Guiding principles for pathogen genome data sharing. Retrieved 17 February 2023 from https://www.who.int/publications/i/item/9789240061743

- 4. High-level advocacy and communications to keep genomic surveillance on the agenda.
- 5. Global partners forum for pathogen genomics to bring partners together²³.

The Quadrilateral Security Dialogue and the G20

The Quadrilateral Security Dialogue (the Quad) is a strategic security dialogue between Australia, India, Japan, and the United States (US). On 24 September 2021, the Quad committed to better preparing member countries and the world for the next pandemic, as part of the Build Back Better Health Security initiative²⁴. In its commitment, the Quad agreed to continue building multi-lateral COVID-19 response and health security efforts in the Indo-Pacific, and further strengthen science and technology cooperation. This included support for the development of a "global pandemic radar" to improve viral genomic surveillance, and working to strengthen and expand the WHO Global Influenza Surveillance and Response System (GISRS). Through the Science and Technology cooperation, genomic surveillance was, and continues to be, a key priority of the Quad to accelerate efforts to end the COVID-19 pandemic and build better health security.

The Group of Twenty (G20) is an intergovernmental forum comprising of 19 countries and the European Union. It works to address major issues related to the global economy, such as international financial stability, climate change mitigation, and sustainable development. The G20 Bali Leaders' Declaration of 15-16 November 2022 assured that the G20 remained committed to embedding a multisectoral One Health approach to enhancing global surveillance, including genomic surveillance, to detect pathogens and AMR that may threaten human health. In addition, the G20 encouraged sharing of pathogen data in a timely manner on shared and trusted platforms in collaboration with WHO to enable global pathogen surveillance as part of our commitment to implement the IHR (2005) and encourage sharing of benefits arising from the utilisation of pathogens consistent with applicable national laws.

Centre for Pathogen Genomics

In 2022, the <u>Centre for Pathogen Genomics</u> was launched by the University of Melbourne as an academic and training hub for infectious diseases genomics in the Asia-Pacific region. It brings together experts to optimise the use of pathogen genomics through:

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²³ World Health Organization (2024). International Pathogen Surveillance Network (IPSN). Retrieved 21 August 2024 from https://www.who.int/initiatives/international-pathogen-surveillance-network.

²⁴ The White House (2021). Fact Sheet: Quad Leaders' Summit. Retrieved 10 January 2024 from https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/24/fact-sheet-quad-leaders-summit/

- research across infectious diseases, metagenomics, data analytics and visualisation
- implementation and evaluation science
- public health
- clinical practice.

The Centre for Pathogen Genomics has a large, international capacity and capability building program to support genomic surveillance and response across the Asia-Pacific. It focuses on engagement and partnerships with public health laboratories, research institutions, and support for global initiatives to promote communities of practice and equitable access to pathogen genomic surveillance.

In addition to the global networks and organisations described above, countries around the world have established frameworks and ambitious programs to progress pathogen surveillance. While this framework focuses on programs based in the UK, Canada, US and Singapore, this list is not exhaustive and provides only a small snapshot of activities underway.

United Kingdom

In September 2020, the UK published <u>Genome UK: the future of healthcare</u> which aims to extend their leadership in genomic health and research over the next ten years. The three pillars of the Strategy are defined as: diagnosis and personalised medicine, prevention, and research²⁵. Recognising the critical role of surveillance in responding to the pandemic²⁶; in 2021 to 2022 the UK committed to progress on the following ambitions relating to pathogen genomics:

- deliver and analyse SARS-CoV-2 viral genomes together with genomes from affected individuals to inform diagnostics, vaccines, prevention, and containment strategies in response to the global pandemic
- expand viral genome sequencing and analysis capacity and capability to establish a world leading pathogen genomics system to detect and provide local, regional,

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²⁵ Department of Health and Social Care. (2020, September 26). Genome UK: the future of healthcare. GOV.UK. Retrieved 21 August 2024 from <a href="https://www.gov.uk/government/publications/genome-uk-the-future-of-healthcare

²⁶ The COG-UK consortium a national pathogen sequencing service was rapidly formed in March 2020 to provide SARS-CoV-2 genome sequencing and analysis to inform public health policy and action.

and national surveillance of infectious threats with strategies to provide this capability within the regional and national health and public health framework²⁷.

In January 2024, the UK Health Security Agency (UKHSA) published the <u>UKHSA</u> <u>Pathogen Genomics Strategy</u> which outlines how it will invest in pathogen genomics to mitigate public health threats from infectious diseases over the next five years. The Strategy includes seven strategic aims, such as:

- using pathogen genomic data to optimise clinical/public health decision-making, from local to global settings
- using pathogen genomic data to drive improvements in diagnostics, vaccines and therapeutics
- providing a nationally coordinated, scaled-up pathogen genomics service
- supporting a pathogen genomics workforce transformation within and beyond UKHSA
- committing to pathogen genomic data sharing and global collaboration
- driving innovation in pathogen genomics
- building high-impact pathogen genomic services that are good value for money²⁸.

Case Study 4: Multi-country outbreak of Salmonella Typhimurium²⁹

In 2021, the UK used WGS to link a geographically dispersed cluster of cases of *Salmonella* Typhimurium with unknown origin. Based on the data generated, a further connection was then established between the human outbreak of cases and *Salmonella* Typhimurium contamination identified in a buttermilk tank at a chocolate factory in Belgium. Investigations found that the implicated food products had been distributed to at least 113 countries and led to more than 300 cases of infection in 16 different countries. Information provided by investigations informed public health control measures.

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²⁷ GOV.UK (2021, May 19). Genome UK: 2021 to 2022 implementation plan. Retrieved 26 October 2022 from https://www.gov.uk/government/publications/genome-uk-2021-to-2022-implementation-plan#pillar-1-diagnosis-and-personalised-medicine

²⁸ UK Health Security Agency. UKHSA Pathogen Genomics Strategy. Retrieved 5 August 2024 from https://assets.publishing.service.gov.uk/media/65aff68ef2718c000dfb1bd8/Pathogen_Genomics_Strategy_2024.pdf

World Health Organization (2022, April 26). Disease Outbreak News; Multi-country outbreak of Salmonella Typhimurium linked to chocolate products – Europe and the United States of America. Retrieved 30 September 2022 from https://www.who.int/emergencies/disease-outbreak-news/item/2022-DON369

Canada

Canada acknowledges that global interest in genomics has increased, and precision health, environmental protection, food, and energy security are just some examples of where genomics research can be utilised and combined with other fields³⁰. To prevent falling behind other countries, more than \$400 million dollars over 6 years was proposed during Canada's 2021 Budget to fund the development of a Pan-Canadian Genomics Strategy (PCGS) which aims to increase the implementation of genomics and related technologies in Canada and progress genomics commercialisation.

United States

In March 2022, the US CDC announced \$90 million in funding for a new competitive agreement that will support the establishment of the US Pathogen Genomics Centers of Excellence (PGCoE). The PCGoE network provides an opportunity for genomic surveillance advancement through partnerships between academic institutions and health agencies and aims to improve public health response to infectious disease threats. Recipients of the 5-year awards were announced in September 2022, with all five centers consisting of a health department and one or more academic institutions. Working as a network, the PGCoE's intend to:

- perform a landscape analysis of gaps, needs, and opportunities for pathogen genomics in the United States public health system
- pilot and implement genomics technologies and applications for public health
- provide training in pathogen genomics for the public health workforce
- prepare for and respond to infectious disease threats³¹.

In addition to the creation of the PGCoE, US CDC's Advanced Molecular Detection program effort has been expanded by a \$1.7 billion multi-year US government investment from the American Rescue Plan Act of 2021 to help prepare states,

³⁰ Government of Canada (2022, June 29). Consultation Paper: Developing a Pan-Canadian Genomics Strategy. Retrieved 20 February 2023 from https://ised-isde.canada.ca/site/genomics/sites/default/files/documents/2022-05/Consultation-Paper-Developing-a-Pan%E2%80%91Canadian-Genomics-Strategy.pdf

³¹ Centers for Disease Control and Prevention (2022, September 22). CDC announces \$90M funding to support new Pathogen Genomics Centers of Excellence network. Retrieved 20 February 2023 from https://www.cdc.gov/amd/whats-new/PGCOE-announcement.html

communities, and the nation for future disease outbreaks by investing in computer power, data sharing, and education³².

Singapore

In June 2022, the Centre for Outbreak Preparedness (COP) was launched by the Duke-NUS Medical School to strengthen regional research capacity and capabilities. A partnership with Bill and Melinda Gates Foundation was also announced to develop the Asia Pathogen Genomics Initiative (APGI)³³. The Duke-Nus COP aims to enhance regional health security across South and Southeast Asia by working to improve regional surveillance and laboratory capacity for early detection of disease threats and supporting other countries in the region in early detection and variant analysis through enhanced genomic surveillance and data sharing via the APGI.

³² Centers for Disease Control and Prevention (2022, January 26). Investments in AMD. Retrieved 20 February 2023 from https://www.cdc.gov/amd/investments/index.html

³³ Duke-NUS Medical School (2022, June 10). Duke-NUS Centre for Outbreak Preparedness launched in Singapore to enhance regional capacity for future health threats. Retrieved 20 February 2023 from <a href="https://www.duke-nus.edu.sg/about/media/media-releases/centre-for-outbreak-preparedness#:~:text=SINGAPORE%2C%2010%20June%202022%20%E2%80%93%20Leveraging%20the%20research%2C,to%20regional%20pandemic%20preparedness%20by%20improving%20genomic%20surveillance.

