

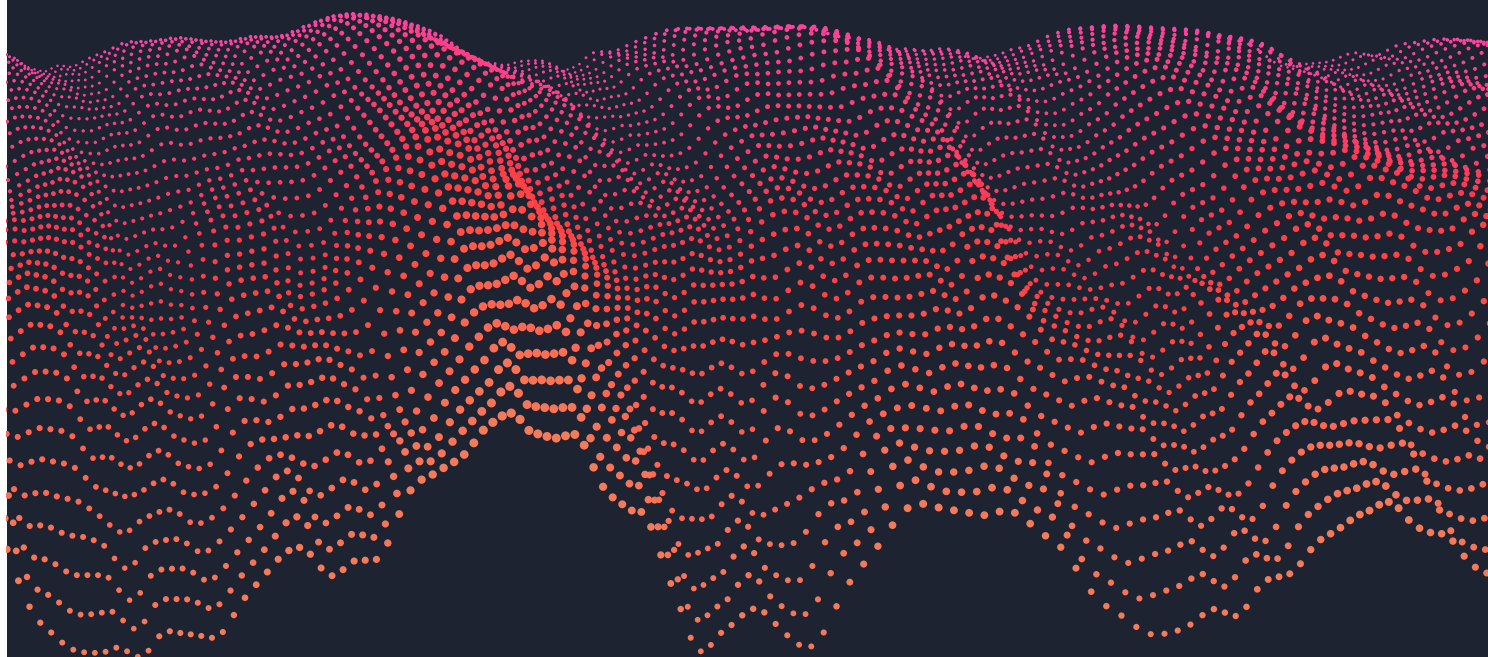


Australian Government

Department of Health

Framework to guide the secondary use of My Health Record system data

May 2018



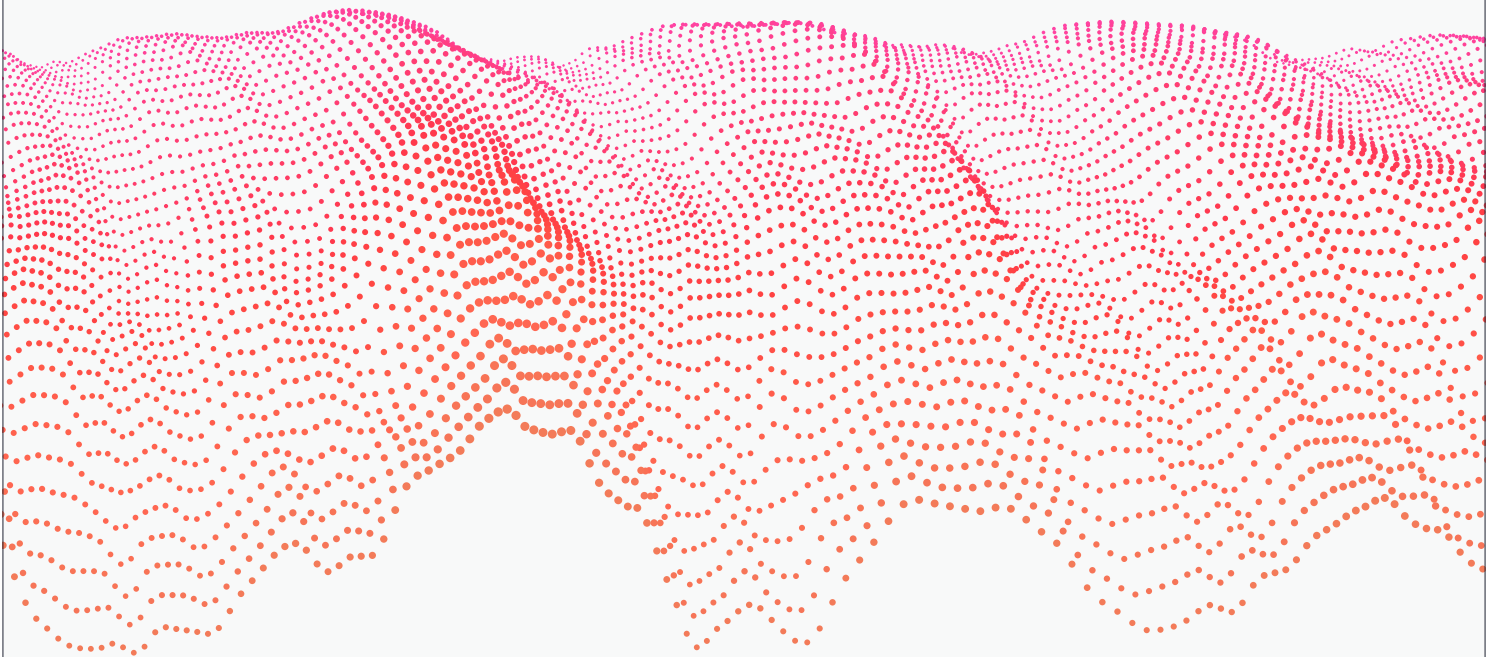


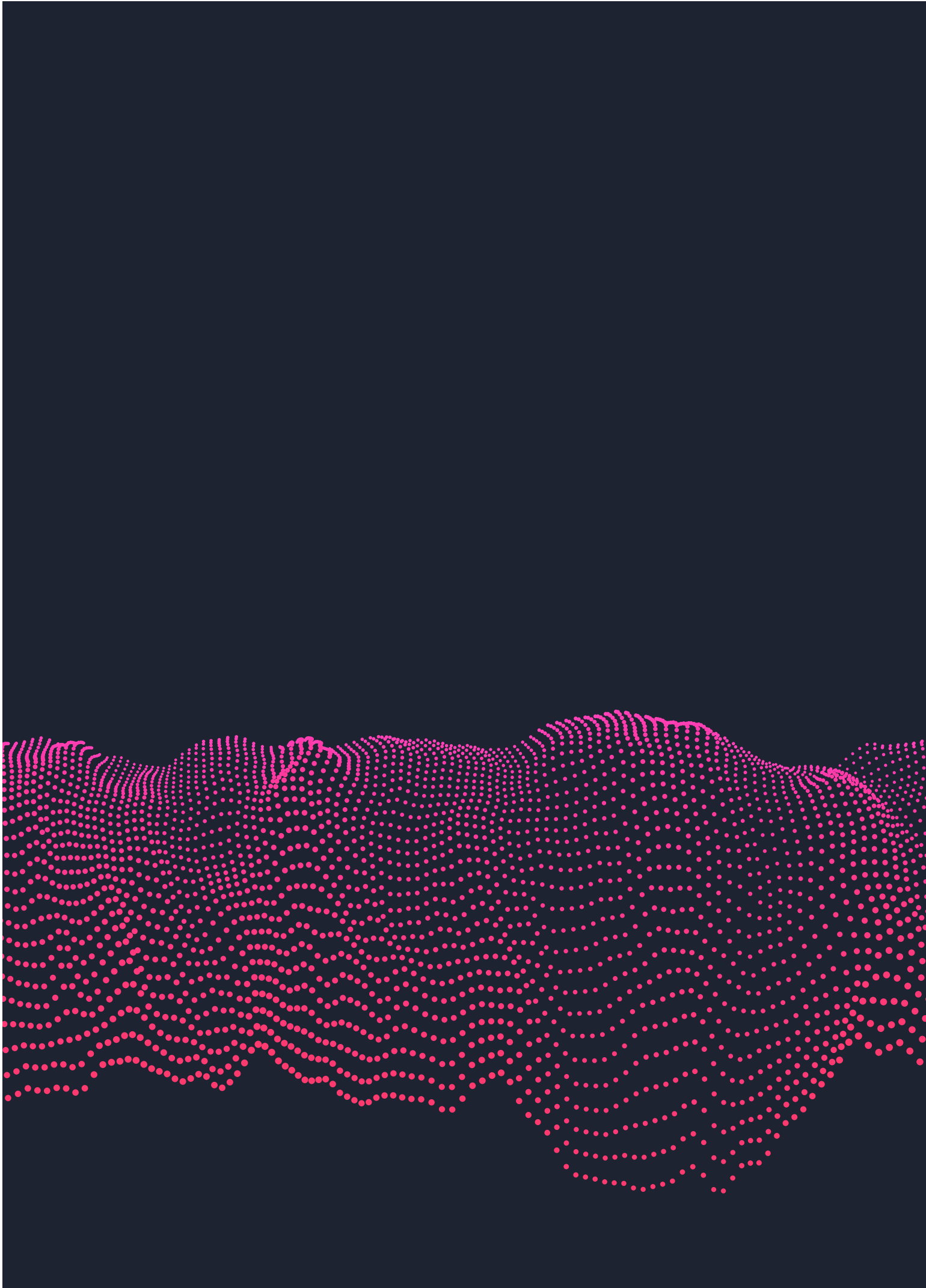
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May 2018





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Introduction

What is 'My Health Record'?

The My Health Record (MHR) system provides Australians with a secure digital health record that supports their clinical care. It is envisaged that a person's MHR will be available to authorised health care providers wherever and whenever they are receiving health services. Keeping the MHR system accurate, relevant and up to date will require the input and cooperation of the individual and the health care providers involved in their care. The MHR system will continue to evolve and the information within it will continue to expand, thereby supporting better care.

Under the *My Health Records Act 2012* (MHR Act), the System Operator (the Australian Digital Health Agency (the Agency)) is responsible for the operation of the MHR system. The System Operator operates the MHR system under a regulatory framework that includes the MHR Act and the *Privacy Act 1988* (Privacy Act).

What is 'secondary use of data'?

In addition to supporting clinical care, the MHR system may progressively provide a valuable source of information on Australia's health system, services being provided and outcomes of care being achieved. Such information can guide service planning, policy development and research to further improve the Australian health system (see case studies on the beneficial use of health and health-related data in **Appendix A**). Making such data and information available and its use by approved users is a secondary use of MHR data, while the *primary use* continues to be supporting the care of individuals.

One of the functions of the System Operator under the MHR Act (section 15(ma)) is 'to prepare and provide *de-identified* data for research or public health purposes'. This document also addresses the secondary use of *identified* MHR data, noting that the System Operator is authorised to collect, use and disclose an individual's health care information (i.e. identifiable information) *with the consent* of the individual (section 66(2)).

In addition to using any publicly available summary reports generated by the System Operator, researchers, policymakers, planners, health care provider organisations and health consumer bodies will benefit from access to more detailed data for research and public health purposes (examples of possible secondary uses of MHR data can be found at **Appendix B**).

Purpose of the Framework to guide the secondary use of MHR system data

This document represents the *Framework to guide the secondary use of MHR system data* (the Framework) for research or public health purposes. It will be used (along with other appropriate materials), interpreted and applied by the MHR Secondary Use of Data Governance Board (the Board) when making decisions about granting access to, and making available, MHR system data for secondary use.

The Framework deliberately takes a cautious approach to the secondary use of MHR data. The aim is to build public trust in the process through transparent decision making and wide sharing of the results of the secondary use of MHR data, including identifying the realised benefits.

The Framework has been developed in the context of the December 2015 policy statement by the Prime Minister, the Hon Malcolm Turnbull MP,¹ and outlines the principles that will be used by the Board to guide the release of data to successful applicants. For example, the Framework stipulates that applicants will be required to sign a legally binding Conditions of Use Agreement (CUA) regarding privacy, assurance and risk mitigation requirements. When the Board considers development of the CUA, it will incorporate the principles of the Framework, which are summarised at **Appendix C**.

Review of the Framework

The Framework will be subject to regular review. Such reviews may identify further beneficial opportunities for secondary use of the MHR system data or they may affirm the need for the current cautious approach.

The first review will occur not more than two years from when the first dataset is released for secondary use under the Framework, and it will take account of the Board's preliminary experiences in its application.

The key principles of this Framework are consistent with the Australian Government's response to the Productivity Commission inquiry report Data availability and use². The technical implications of the Government response will be reflected in the implementation guide for this Framework. The regular review points for the Framework will also provide an opportunity to ensure further developments in this space.

1 Department of the Prime Minister and Cabinet, 'Public data policy' (7 December 2015)
<https://www.pmc.gov.au/public-data/public-data-policy>

2 Australian Government's response to the Productivity Commission inquiry report Data availability and use
<http://dataavailability.pmc.gov.au>

Guiding principles of the Framework

The Framework outlines a series of guiding principles that will be used to guide the release of data for secondary use purposes. Table 1 below contains a summary of the principles that are discussed in more detail throughout the chapters of the Framework.

Table 1: Summary of guiding principles within the Framework

Chapter 1: Governance model for secondary use of My Health Record system data

- | | |
|------------|---|
| 1.1 | The Australian Institute of Health and Welfare (AIHW) is the Data Custodian for the purposes of the Framework. |
| 1.2 | The My Health Record (MHR) Secondary Use of Data Governance Board (the Board) will implement the Framework. |
| 1.3 | The Board has no role around primary use of the MHR system data—this is the responsibility of the System Operator. |
| 1.4 | The Board will comprise representatives from the AIHW, the Australian Digital Health Agency (as the System Operator) and a range of independent experts, including representatives from population health/epidemiology, research, health services delivery, technology, data science, data governance and privacy, and consumer advocacy. |
| 1.5 | The Chair of the Aboriginal and Torres Strait Islander Peoples' Advisory Panel will be a member of the Board. |
| 1.6 | The Board will oversee development and operation of all secondary use infrastructure. ³ |

Chapter 2: Consumer control of data in the My Health Record system

- | | |
|------------|---|
| 2.1 | Consumers can opt out of having their MHR data used for secondary purposes. |
|------------|---|

³ It is important to note that, for the purposes of this Framework, secondary use does not include the uses described in the MHR Act. This means consumers cannot opt out of the use of their MHR system data for uses described in the MHR Act, such as for law enforcement purposes.

Chapter 3: Applying to access My Health Record system data for secondary use

- 3.1** The Board will assess applications primarily based on the use of data, not the user.
- 3.2** The Board will take a 'case and precedent' approach to determining what uses will be permitted and not permitted for secondary use.
- 3.3** Any Australian-based entity (except insurance agencies) can apply to access MHR system data for secondary use, subject to meeting the criteria set out in this Framework.
- 3.4** Applicants that are not based in Australia may, in limited circumstances, be involved in the use of MHR system data for secondary purposes.
- 3.5** The Board will use the 'Five safes' principles to assess applications.
- 3.6** MHR data that has been made accessible for secondary use must not leave Australia; however, there is scope for data analyses and reports produced using MHR system data to be shared internationally.

Chapter 4: Access to, or release of, data for secondary use

- 4.1** The Board will ensure that, where data is in other public datasets, the principles applied to access are consistent with those applied in the other datasets.
- 4.2** The Board will use a 'case and precedent' approach to determine what is 'solely commercial use' of data.
- 4.3** The Board will give specific consideration to use of data pertaining to Aboriginal and Torres Strait Islander people and communities.
- 4.4** Where an applicant seeks access to data from another repository—for example, Medicare Benefits Schedule or Pharmaceutical Benefits Schedule data—they will be referred to the data custodian for those systems.

Chapter 5: Process for requesting and accessing data

- 5.1** For applications involving identified data, subject to the provisions of the *My Health Records Act 2012* and the *Privacy Act 1988*, the Board will require ethics approval to be obtained by the AIHW Ethics Committee before data can be accessed or released.
- 5.2** For applications involving de-identified data, the Board may require ethics approval to be obtained before data can be accessed or released.
- 5.3** The Board will work with related government bodies, data custodians and ethics committee(s) that also have an interest in the particular application to minimise as much as is possible unnecessary duplication of effort, additional cost and/or delays in processing an application.
- 5.4** Prior to data being released, the Board will require the approved applicant to agree to the Conditions of Use Agreement (CUA).

Chapter 6: Data linkage

- 6.1** The Board can permit the linkage of MHR system data with other data sources once the applicant's use is assessed to be of public benefit.
-
- 6.2** Specific processes will apply for data linkage involving identified data for Aboriginal and Torres Strait Islander people.
-

Chapter 7: Processes to ensure protection of the privacy of individuals

- 7.1** De-identification of data is acknowledged to be a dynamic and ongoing process.
-
- 7.2** The Board will strive to stay abreast of changes in technology and data science as they evolve so that, as far as possible, it may anticipate new privacy threats and use this knowledge to inform assessment of applications for the use of data.
-
- 7.3** Proven methods will be used to reduce the risk of breaching an individual's privacy to very low levels.
-
- 7.4** The Board will regularly reconsider the privacy protection processes around secondary use of MHR system data. Particular consideration will be given to circumstances where there is already data in the public domain about individuals.
-
- 7.5** As part of the ongoing process of reviewing the Framework (with the first review occurring after two years of operation), the list of permitted and not permitted uses will be reconsidered and amended with reference to the 'case and precedent' experience of the Board (see Chapter 3, 'Applying to access My Health Record system data for secondary use').
-

Chapter 8: Preparing and making data available, and data quality

- 8.1** The Board will ensure that individuals' privacy is protected in the processes of preparing and making data available for secondary use.
-
- 8.2** The Board will ensure that any data made available is of sufficient quality to expect that the objectives of the project, as stated in the application, can be achieved.
-

Chapter 9: Monitoring and assurance processes

- 9.1** The Board will put in place a set of processes to provide assurance to stakeholders and the public that successful applicants use MHR system data only for approved secondary purposes.
-
- 9.2** The higher the assessed risk of a project, the more detailed the monitoring activities that will be required in the Conditions of Use Agreement (CUA).
-

Chapter 10: Risk mitigation strategies and imposed penalties

- 10.1** The Board will ensure that the risk of a breach of privacy for an individual is reduced to an acceptable level by minimising the risks associated with each application for secondary use and recommending penalties where applicable.
-

Scope

There is a need to balance support for the use of the data for beneficial research and public health purposes against the policy of not using the data for solely commercial purposes. Commercial organisations may propose uses that could be approved so long as it can be demonstrated that the use is consistent with 'research and public health purposes' and is likely to generate public health benefits and/or be in the public interest. Examples are provided at **Appendix D**.

In scope

The Framework covers secondary use of:

- de-identified MHR system data
- identified MHR system data with the consent of the health care recipient.

Out of scope

The Framework does not permit the following secondary uses:

- MHR system data cannot be used solely for commercial and non-health-related purposes.
- The provision of MHR data to insurance agencies will not be permitted (the impact of this exclusion will be considered as a part of the first review).
- The use of MHR data for clinical trials recruitment will not be considered until an explicit consent option is available in the MHR access controls.

The Framework does not apply to uses described in the MHR Act, such as for the purposes of law enforcement or System Operator functions. For a full description of all the circumstances in which identified MHR data can be released, refer to sections 61 to 70 of the MHR Act.

Policy context

There is a significant body of state and federal legislation that is relevant to the secondary use of health data.

The MHR Act, and a suite of regulations (described in **Appendix E**) made under the MHR Act, regulate the collection, use and disclosure of health information contained in a person's MHR. Certain contraventions of the MHR Act will also be an interference with privacy for the purposes of the Privacy Act, which empowers the Office of the Australian Information Commissioner (OAIC) to take a range of enforcement and investigative actions (sections 72 and 73 of the MHR Act).

Specifically, the MHR Act provides that unauthorised collection, use or disclosure, as well as secondary disclosure, of health information in a person's MHR is a breach of the MHR Act and an interference with privacy (sections 59 and 60).⁴ However, where MHR data has undergone an appropriate and robust de-identification process, it is not considered health information and is therefore not subject to the MHR Act or Privacy Act. It is also important to note that MHR data which has not been properly de-identified could be considered health information due to the risk of re-identification.

4 Office of the Australian Information Commissioner, 'My Health Records' <https://www.oaic.gov.au/privacy-law/other-legislation/my-health-records>

The OAIC regulates the handling of personal information under the MHR system by individuals, Australian Government agencies, private sector organisations and some state and territory agencies. The OAIC's role includes investigating complaints about the mishandling of personal information in an individual's MHR. The OAIC can also conduct commissioner-initiated investigations.

Process for accessing My Health Record system data for secondary use

A number of processes will be needed to consider, determine, monitor and report on a request to use MHR system data for secondary purposes. Table 2 below summarises the processes and the roles and responsibilities of the parties involved to assist with the interpretation of more detailed guidance provided in the Framework. The diagram at Figure 1, as well as Tables 2 and 3, describe these processes.

Table 2: Organisations/parties and their roles and responsibilities

| Body | Role and responsibility |
|--|--|
| My Health Record Secondary Use of Data Governance Board | The My Health Record (MHR) Secondary Use of Data Governance Board (the Board) is responsible for the interpretation and application of the <i>Framework to guide the secondary use of My Health Record system data</i> (the Framework) and will use this Framework in making decisions around approving access to MHR system data for secondary use. |
| Applicant | The Applicant is an organisation/individual requesting access to MHR system data for secondary use purposes. The Applicant is responsible for preparing the application and committing to participating in the monitoring and assurance arrangements as stipulated by the Board. |
| MHR Data Custodian for secondary uses (AIHW) | Custodianship of MHR data for secondary uses for research and health purposes rests with the Australian Institute of Health and Welfare (AIHW). The AIHW is established under the <i>Australian Institute of Health and Welfare Act 1987</i> (AIHW Act) as an independent statutory authority to provide independent, reliable, regular and relevant information on Australia's health and welfare. Its responsibilities will include receiving and accessing MHR system data (facilitated by the System Operator) in order to provide data to the applicant as approved by the Board. |
| Data Integrator | The Data Integrator is responsible for conducting the necessary data linkage as specified by the Board. |
| Department of Health | The Department of Health is responsible for legislation and policy related to the MHR system and the release of MHR system data. The Department of Health has policy responsibility for the development and operation of the Framework, including commissioning of a review within two years of the first data being made available for secondary use under the Framework. |
| System Operator | The Australian Digital Health Agency is the designated MHR System Operator. Its role includes 'to prepare and provide de-identified data for research and public health purposes'. Other authorisations provide the basis for the disclosure of identified information for secondary use with individual consent. |

Figure 1: Processes and responsible organisations/parties

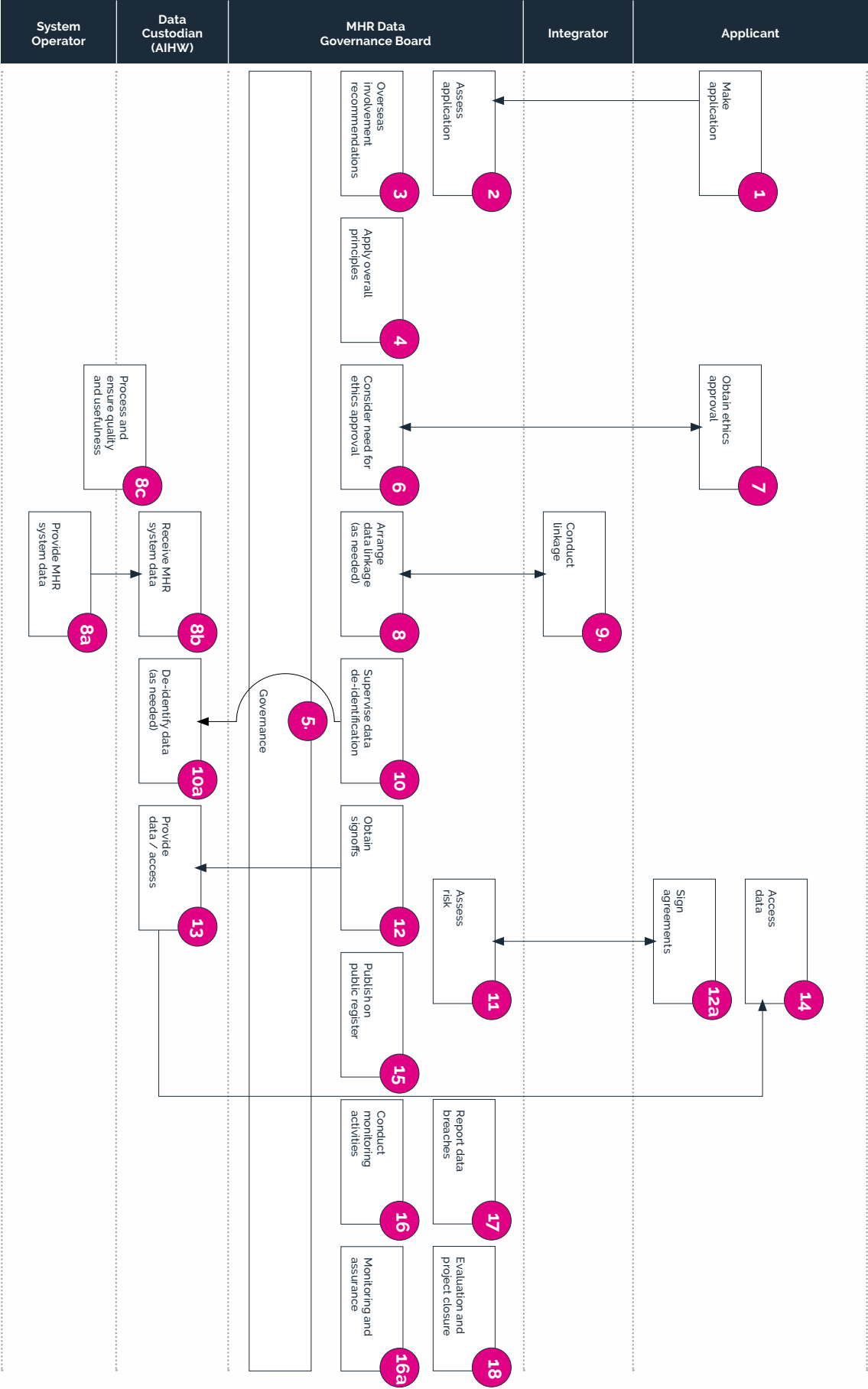


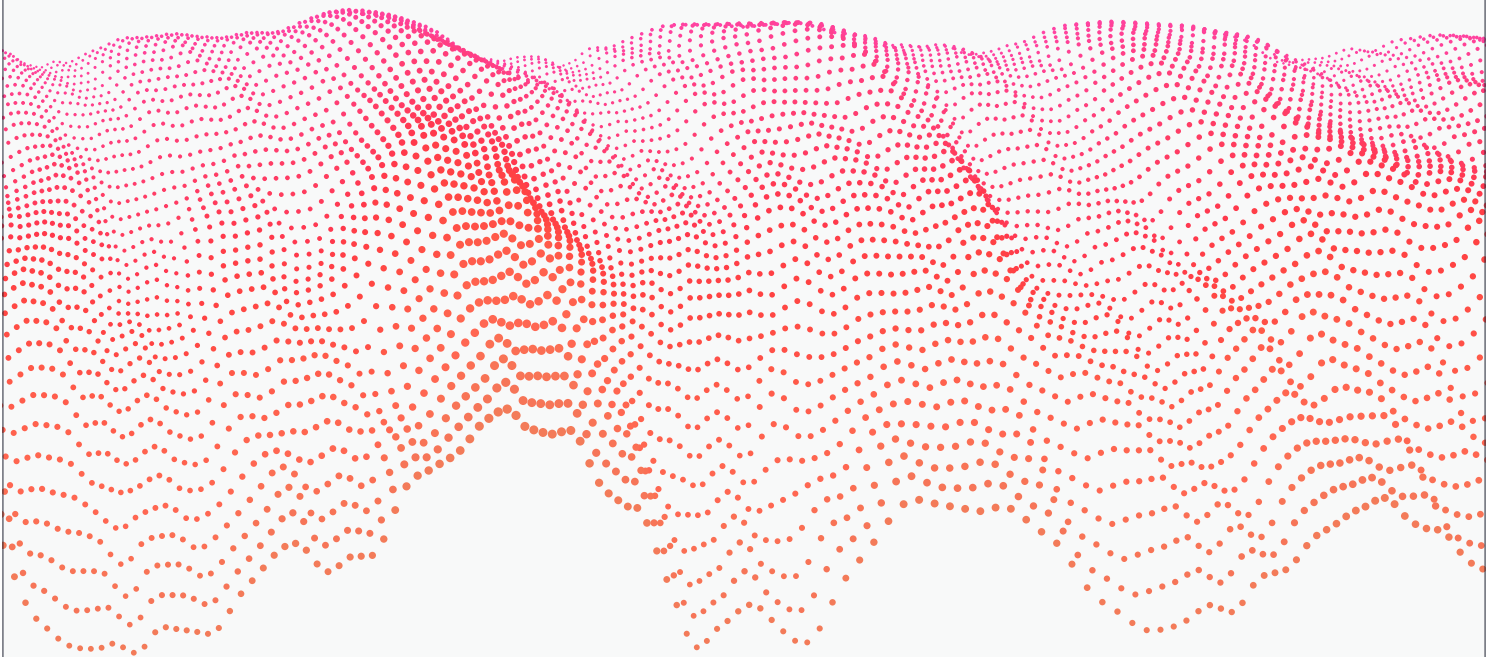
Table 3: Processes in the use of My Health Record system data for secondary purposes

| Description of process | | Responsibility |
|------------------------|---|---|
| Step 1 | Make an application for secondary use of My Health Record (MHR) system data using predefined format/method. Submit a risk management plan with the application. | Applicant |
| Step 2 | Assess application in terms of the intended use. | The Board |
| Step 3 | Consider additional matters for applications involving overseas organisations or individuals. | The Board |
| Step 4 | Apply principles consistent with other health system data bodies. | The Board |
| Step 5 | Manage the availability, access and, where appropriate, release, usability, integrity and security of data. | The Board |
| Step 6 | Identify if ethics approval is required and, if so, request the applicant to obtain it. | The Board |
| Step 7 | Obtain ethics approval (if requested) via a body certified by National Health and Medical Research Council. | Applicant |
| Step 8 | Conditions of Use Agreement (CUA) | The Board |
| Step 8a | Provide MHR system data and/or access to MHR system data as needed to allow approved requests to proceed. | System Operator |
| Step 8b | Receive/access data from the MHR system from the Australian Digital Health Agency in order to prepare it for release to/access by the applicant. | Data Custodian |
| Step 8c | Process, clean and ensure quality and usefulness of data. | System Operator and Data Custodian |
| Step 9 | Conduct data linkage as requested. | Data Integrator |
| Step 10 | Under expert supervision, assess the need to de-identify data using the method deemed most appropriate to protect individuals' privacy. | The Board |
| Step 10a | De-identify data using the method prescribed by the MHR Secondary Use of Data Governance Board (the Board). | Data Custodian |
| Step 11 | Conduct a risk assessment to determine monitoring and assurance processes, including consideration of the published minimum data security requirements. | The Board |
| Step 12 | Ensure CUA has been signed by the applicant. | The Board |
| Step 12a | Sign Conditions of Use Agreement (CUA). | Applicant |
| Step 13 | Make data available to applicant using the method prescribed by the Board. | Data Custodian |

Table 3: Processes in the use of My Health Record system data for secondary purposes (continued)

| Description of process | | Responsibility |
|------------------------|--|------------------|
| Step 14 | Access data through approved means (including linked data as appropriate). | Applicant |
| Step 15 | Publish applications and their outcomes on the Public Register. | The Board |
| Step 16 | Conduct monitoring and assurance processes. | The Board |
| Step 16a | Undertake monitoring and assurance processes consistent with the CUA. | The Board |
| Step 17 | Report any data breaches (as identified) to the Office of the Australian Information Commissioner. | The Board |
| Step 18 | Ensure evaluation and project closure. | The Board |

CHAPTER 1: Governance model for secondary use of My Health Record system data



CHAPTER 1: Governance model for secondary use of My Health Record system data

Governance arrangements will be established to oversee the availability, access and release, usability, integrity, and security of MHR system data for secondary use. Above all, the Board will ensure that MHR data is safe, the quality of the data can be trusted and people can be made accountable for any adverse event that occurs due to inappropriate release of data.

Guiding Principles

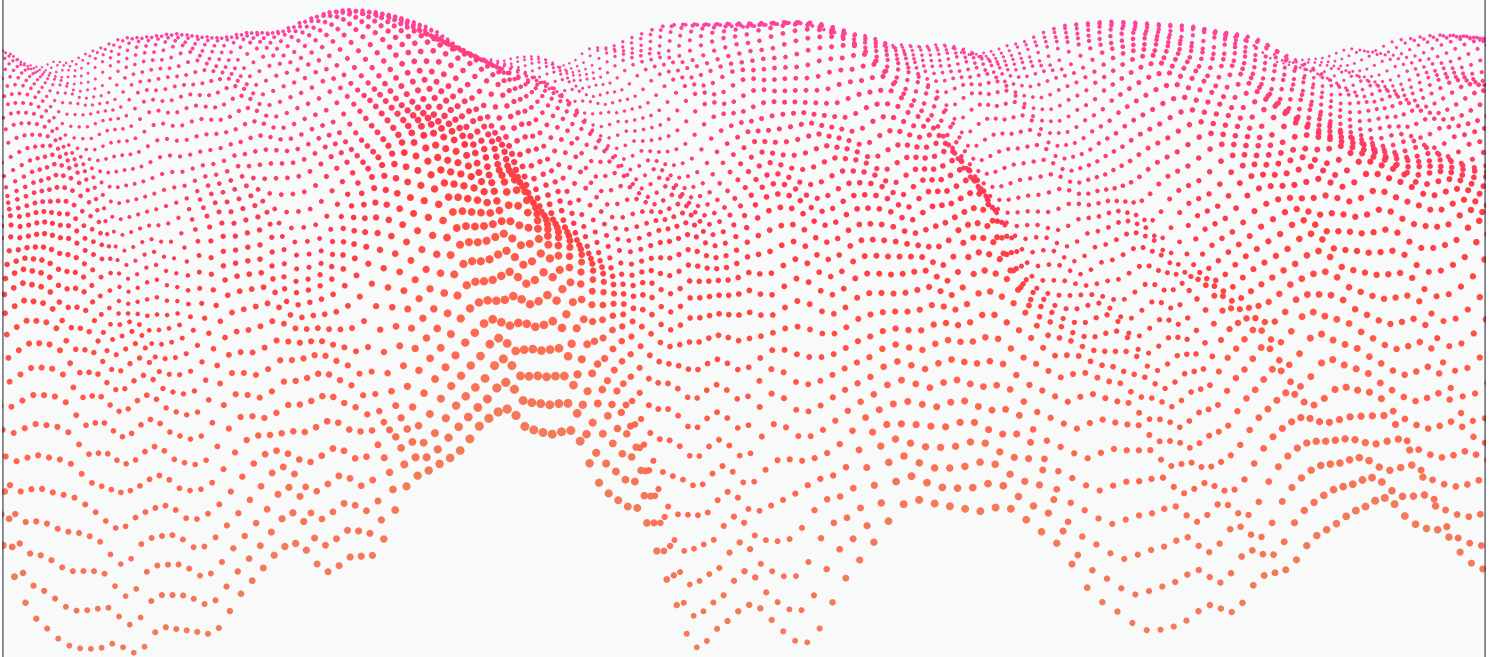
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| 1.4 | The Board will comprise representatives from the AIHW, the Australian Digital Health Agency (as the System Operator) and a range of independent experts, including representatives from population health/epidemiology, research, health services delivery, technology, data science, data governance and privacy, and consumer advocacy. |
| 1.5 | The Chair of the Aboriginal and Torres Strait Islander Peoples' Advisory Panel will be a member of the Board. |
| 1.6 | The Board will oversee development and operation of all secondary use infrastructure. |

The Board will:

- assess applications for access to MHR system data for secondary use purposes only
- comprise representatives from the AIHW and other independent experts from population health/epidemiology, research, health services delivery, technology, data science, data governance and privacy, and consumer advocacy
- wherever possible, consider using existing bodies, after taking account of the remit and functions of those bodies and any limitations that might apply to extending them
- be advised by:
 - » an Aboriginal and Torres Strait Islander People's Advisory Panel to provide expert input regarding all aspects of access and appropriateness of relevant research
 - » a Data Management Committee, which will manage operational issues connected with acquisition, processing and preparation of data. Its functions will include setting priorities for data requests, discussing any issues or difficulties associated with providing data and/or linkage and providing visibility to management of dataset priorities assigned and decisions taken
 - » a Consumer Panel, which will provide a public perspective. Its role will include providing advice on how to engage the public, views on data protection issues and advocacy for consumer-directed research
 - » a Sector Advisory Panel, which will provide strategic input from leaders in the health, research, data management and technology sectors. It will aim to ensure that the potential benefits are maximised.
- have the autonomy and flexibility to establish or access additional panels, committees and other boards for independent and/or expert advice
- have no role regarding the primary use of the MHR system data or uses otherwise authorised by the MHR Act—these are the responsibility of the System Operator.

CHAPTER 2: Consumer control of data in the My Health Record system



CHAPTER 2: Consumer control of data in the My Health Record system

The MHR system was previously known as the Personally Controlled Electronic Health Record (PCEHR) system. It remains 'personally controlled' in that it explicitly supports consumer control of access to the record. Optional privacy features are available to consumers, giving them choice about what information is visible in their record and which health care provider organisations are able to access it.

These features include the capability to remove documents that consumers do not want to share, set a record access code (a code that consumers can give to health care provider organisations to allow them to access their record) and restrict and customise access to particular documents. Consumers may also receive email or SMS notifications for a range of activities, such as when a new health care provider organisation accesses their record for the first time. Consumers who have a MHR can also cancel it at any time.

Guiding Principles

Chapter 2: Consumer control of data in the My Health Record system

2.1 Consumers can opt out of having their MHR data used for secondary purposes.

Individual consumers who have a MHR will be able to opt out of the use of their MHR system data for secondary purposes by using the consumer access control mechanism and clicking on the 'Withdraw Participation' button.⁵ In this way, consumers can choose to have an MHR but elect for their data not to be used for research and public health purposes.

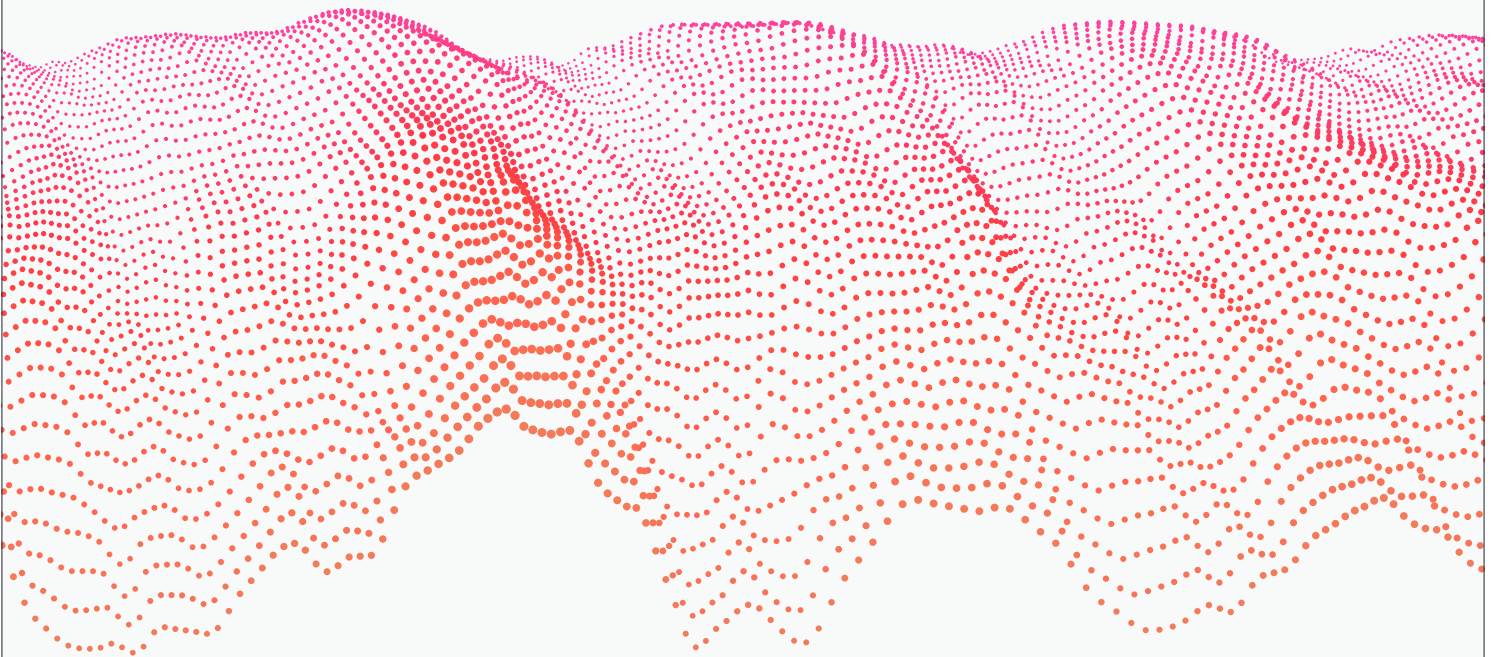
In time, the feasibility of moving to a dynamic consent model will be explored so that consumers may decide to allow or not allow access for defined secondary uses on a case-by-case basis. Even if a consumer chooses to not opt out of secondary use of their MHR system data, any data or document that they have classified (using consumer controls) as being 'Restricted Access' or that they have removed will not be retrieved for secondary use purposes.

Also, where a consumer has initially chosen to have a MHR created for them but has subsequently cancelled their record, the data in that cancelled record will not be retrieved for secondary use purposes.

It is acknowledged that Australian consumers have different levels of health literacy and health system usage. This will be considered when implementing processes to convey consent.

⁵ It is important to note that, for the purposes of this Framework, secondary use does not include the uses described in the MHR Act. This means consumers cannot opt out of the use of their MHR system data for uses described in the MHR Act, such as for law enforcement purposes.

CHAPTER 3: Applying to access My Health Record system data for secondary use



CHAPTER 3: Applying to access My Health Record system data for secondary use

The MHR Act does not specify the types of applicants that may access MHR system data for secondary use. The Framework gives specific consideration to potential access by applicants, including those that are not easily subject to Australian law.

Guiding Principles

Chapter 3: Applying to access My Health Record system data for secondary use

- | | |
|------------|---|
| 3.1 | The Board will assess applications primarily based on the use of data, not the user. |
| 3.2 | The Board will take a 'case and precedent' approach to determining what uses will be permitted and not permitted for secondary use. |
| 3.3 | Any Australian-based entity (except insurance agencies) can apply to access MHR system data for secondary use, subject to meeting the criteria set out in this Framework. |
| 3.4 | Applicants that are not based in Australia may, in limited circumstances, be involved in the use of MHR system data for secondary purposes. |
| 3.5 | The Board will use the 'Five safes' principles to assess applications. |
| 3.6 | MHR data that has been made accessible for secondary use must not leave Australia; however, there is scope for data analyses and reports produced using MHR system data to be shared internationally. |

The Board will:

- apply the 'Safe people'⁶ principle with respect to the applicant, reviewing their knowledge, skills and incentives to store and use the data appropriately
- make a determination as to whether those who will be accessing the data can be trusted to use it appropriately
- apply the following conditions to applications involving overseas applicants:
 - » overseas-based applicants must be working in collaboration with an Australian applicant in respect to the proposed project
 - » the application demonstrates that the proposed data usage will generate public health benefits for Australians
 - » direct access to, or release of, MHR data is only to the Australian entity
 - » MHR data released for secondary use is to be stored in a facility within Australia
 - » overseas-based applicants that are part of the applicant team are party to the CUA and must meet Australian data management and security requirements
- apply these conditions in addition to the relevant clauses in the Privacy Act. For example, Australian Privacy Principle (APP) 8 deals with cross-border (overseas) disclosure of personal information.

6 Desai, T., Ritchie, F. and Welpton, R., Five safes: Designing data access for research (University of the West of England, 2016) <http://eprints.uwe.ac.uk/28124/1/1601.pdf>

the 1990s, the number of people in the world who are under 15 years of age has increased by 1.2 billion, from 1.1 billion in 1980 to 2.3 billion in 1999. The number of people aged 15 years and over has increased by 1.1 billion, from 1.1 billion in 1980 to 2.2 billion in 1999.

There are a number of reasons why the world population is growing so rapidly. One of the main reasons is that the number of children born to each woman has increased. In 1980, the average woman in the world had 2.5 children. In 1999, the average woman in the world had 2.7 children.

Another reason why the world population is growing so rapidly is that the number of people who are surviving to old age has increased. In 1980, the average person in the world lived for 55 years. In 1999, the average person in the world lived for 65 years.

There are a number of reasons why the number of people who are surviving to old age has increased. One of the main reasons is that the number of people who are surviving to old age has increased. In 1980, the average person in the world lived for 55 years. In 1999, the average person in the world lived for 65 years.

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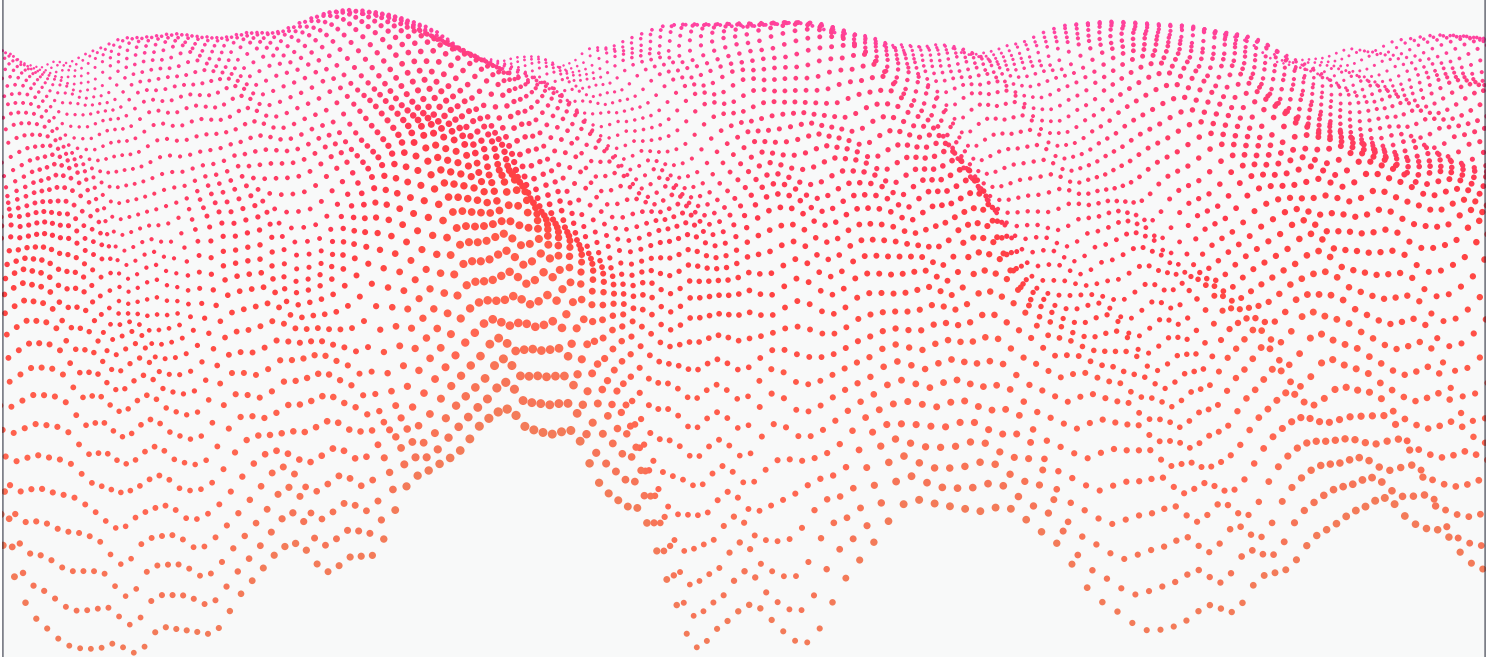
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CHAPTER 4: Access to, or release of, data for secondary use



CHAPTER 4: Access to, or release of, data for secondary use

The Board will ensure that decisions around access to, and release of, data will be made in a manner that is consistent with the principles that guide decisions around other public health system data.

The Information Commissioner has expressed the view⁷ that de-identification of large and rich datasets for publication to the world at large is extremely difficult. Deciding whether information has been de-identified to an extent suitable for public release requires careful, expert and likely independent evaluation. The Framework does not propose to release any MHR unit-level data about individuals to the world at large.

7 <https://www.oaic.gov.au/privacy-law/commissioner-initiated-investigation-reports/publication-of-mbs-pbs-data>
– "Lessons for the Department and other personal information custodians"

Guiding Principles

Chapter 4: Access to, or release of, data for secondary use

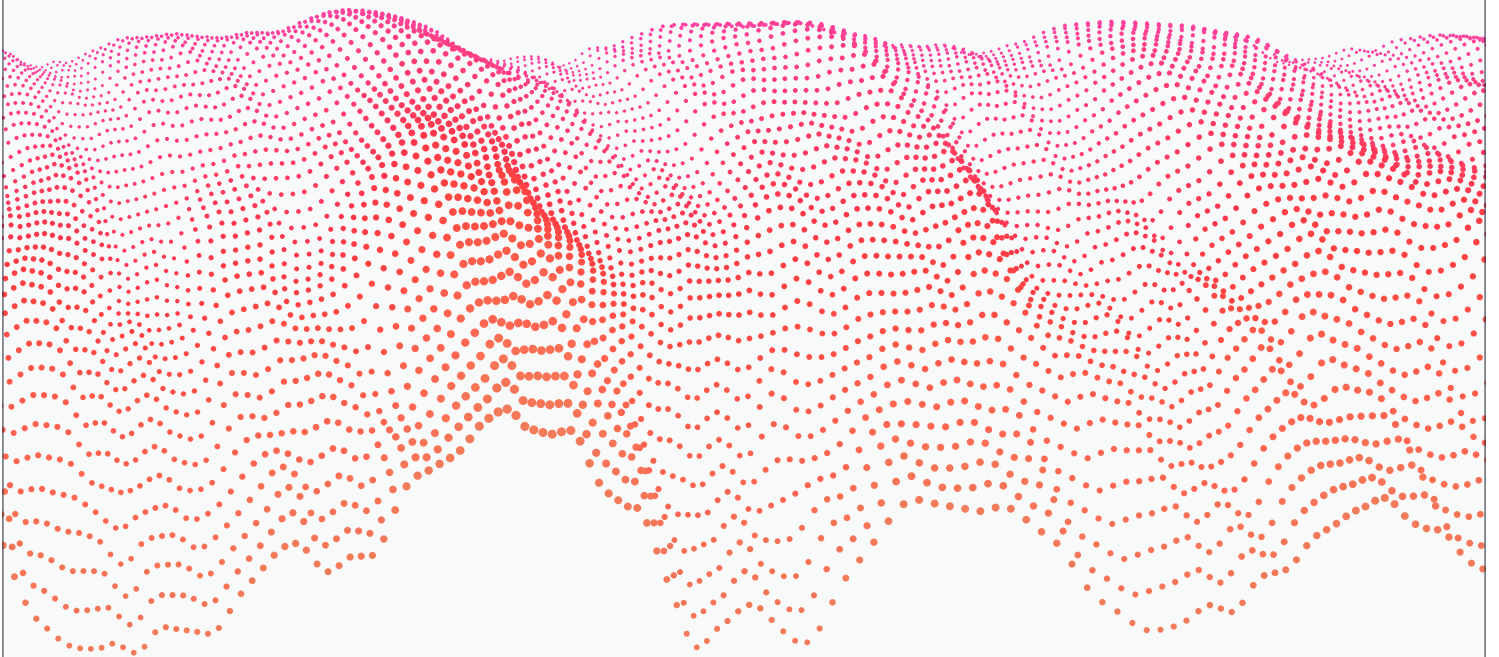
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| 4.1 | The Board will ensure that, where data is in other public datasets, the principles applied to access are consistent with those applied in the other datasets. |
| 4.2 | The Board will use a 'case and precedent' approach to determine what is 'solely commercial use' of data. |
| 4.3 | The Board will give specific consideration to use of data pertaining to Aboriginal and Torres Strait Islander people and communities. |
| 4.4 | Where an applicant seeks access to data from another repository—for example, Medicare Benefits Schedule or Pharmaceutical Benefits Schedule data—they will be referred to the data custodian for those systems. |

The Board will:

- make decisions on applications for access to, and/or release of, data with reference to the Australian Government Department of Health Data Access and Release Policy⁸
- assess the risk associated with each application using the 'Five safes' principles, consistent with the Department of Health Data Access and Release Policy
- assess each application to ensure compliance with all relevant legislation
- have regard for the principles in the National Health and Medical Research Council (NHMRC) document *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders*
- ensure that, where data is in other public datasets, the principles applied to access are consistent with those applied in the other datasets. For example, MBS and PBS data may be viewed in the MHR system and can be found in the public datasets managed by the Australian Government Department of Human Services as the data custodian
- have regard for better practice principles for the use of public data assets from overseas.

8 <http://www.health.gov.au/internet/main/publishing.nsf/Content/Data-Access-Release-Policy>

CHAPTER 5: Process for requesting and accessing data



CHAPTER 5: Process for requesting and accessing data

The Board will ensure that the process for requesting and accessing MHR system data will be enabled in a standardised, efficient and transparent manner.

The AIHW is responsible under the Privacy Act and the *Australian Institute of Health and Welfare Act 1987* (AIHW Act) for the data it holds. The AIHW Act and AIHW Ethics Committee Regulations need to be considered in establishing the appropriate role for the AIHW Ethics Committee in requesting and accessing MHR system data for secondary use.

Guiding Principles

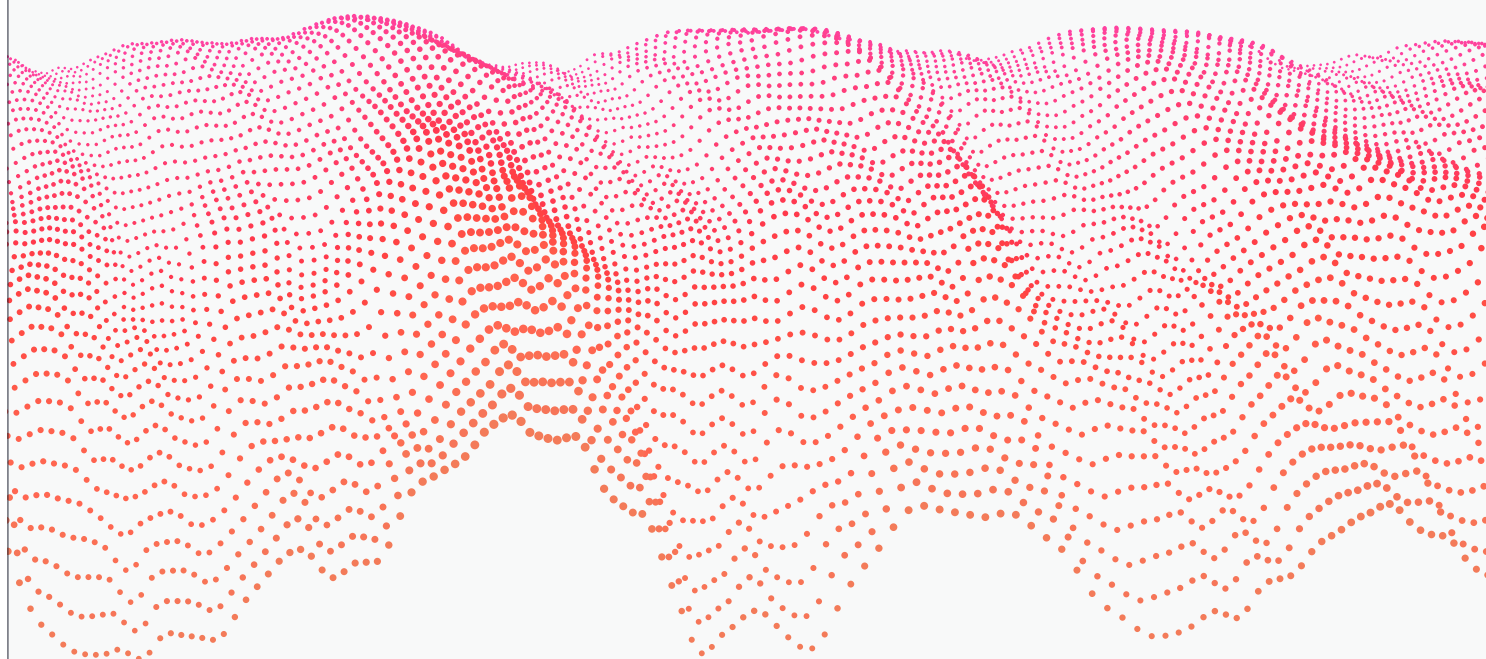
Chapter 5: Process for requesting and accessing data

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| 5.1 | For applications involving identified data, subject to the provisions of the <i>My Health Records Act 2012</i> and the <i>Privacy Act 1988</i> , the Board will require ethics approval to be obtained by the AIHW Ethics Committee before data can be accessed or released. |
| 5.2 | For applications involving de-identified data, the Board may require ethics approval to be obtained before data can be accessed or released. |
| 5.3 | The Board will work with related government bodies, data custodians and ethics committee(s) that also have an interest in the particular application to minimise as much as is possible unnecessary duplication of effort, additional cost and/or delays in processing an application. |
| 5.4 | Prior to data being released, the Board will require the approved applicant to agree to the Conditions of Use Agreement (CUA). |

The Board will:

- work with the AIHW to develop an electronic process to facilitate the consideration of applications to use MHR data for secondary use
- where possible, work with related government bodies, data custodians and ethics committee(s) to minimise unnecessary duplication of effort, cost and/or delays in processing an application
- be satisfied that, following the granting of ethics approval, the applicant has obtained consent for the proposed use from the individuals whose data will be used
- have regard to the various statements, principles and guidelines issued by NHMRC when making determinations about what ethics approvals are required for de-identified use of data
- review applicants' requests to review a decision to reject an application. The outcomes of the review will be published on the Public Register (refer to Chapter 10, 'Risk mitigation strategies and imposed penalties')
- not function as an ethics committee. Should it determine that ethics approval is required, the applicant will be required to obtain that approval from the AIHW Ethics Committee.

CHAPTER 6: Data linkage



CHAPTER 6: **Data linkage**

Data linkage may provide important information about the effectiveness and safety of treatments and clinical care. However, it also poses additional risk to individual privacy. For example, researchers may want to link MHR system data to a database of clinical trial participants to investigate subsequent hospitalisations, morbidity and mortality. Data may also be linked to other datasets such as hospitals, MBS, PBS and registry data.

In Australia, to ensure the privacy of individual consumers, there are a number of accredited Data Linkage Integrating Authorities. These organisations undertake high-risk data integration projects. They are required to provide a summary of all approved projects on their web sites. There are also a number of Data Linkage Units in Australia. The AIHW is both a Data Linkage Unit and an Accredited Data Linkage Integrating Authority.

Guiding Principles

Chapter 6: Data linkage

6.1 The Board can permit the linkage of MHR system data with other data sources once the applicant's use is assessed to be of public benefit.

6.2 Specific processes will apply for data linkage involving identified data for Aboriginal and Torres Strait Islander people.

The Board will:

- involve an expert with appropriate experience and background in data linkage and the subject matter in question to critically assess the application, including:
 - » any data linkage—are there alternative means to achieve the desired project outcomes? Could the project be completed by using existing merged datasets?
 - » the depth and breadth of data that would be integrated—would a lesser level of linkage achieve the applicant's desired outcomes?
- consider privacy risks associated with the application with reference to the Privacy Act and APPs, with particular emphasis on the approach to managing risk
- undertake a risk assessment, following the guidelines provided in the Data integration involving Commonwealth data for statistical and research purposes: Risk assessment guidelines
- ensure that, where data linkage occurs, only the final dataset can be accessed
- determine the most appropriate data linkage method based on the risk assessment
- use an Australian Accredited Data Linkage Integrating Authority where the risk is assessed as high. For all other assessment categories, either an Australian Accredited Data Linkage Integrating Authority or a Data Linkage Unit will undertake the necessary data linkages for the applicant
- require ethics approval to be obtained before approving the provision of any MHR system data for data linkage
- require that the separation principle is used in linking MHR system data with the other approved datasets

the 1990s, the number of people in the world who are under 15 years of age has increased by 1.2 billion, from 1.1 billion in 1980 to 2.3 billion in 1999. The number of people aged 15 years and over has increased by 1.1 billion, from 1.1 billion in 1980 to 2.2 billion in 1999.

There are a number of reasons why the world population is growing so rapidly. One of the main reasons is that the number of children born to each woman has increased. In 1980, the average woman in the world had 2.5 children. In 1999, the average woman in the world had 2.7 children.

Another reason why the world population is growing so rapidly is that the number of people who are surviving to old age has increased. In 1980, the average person in the world lived for 55 years. In 1999, the average person in the world lived for 65 years.

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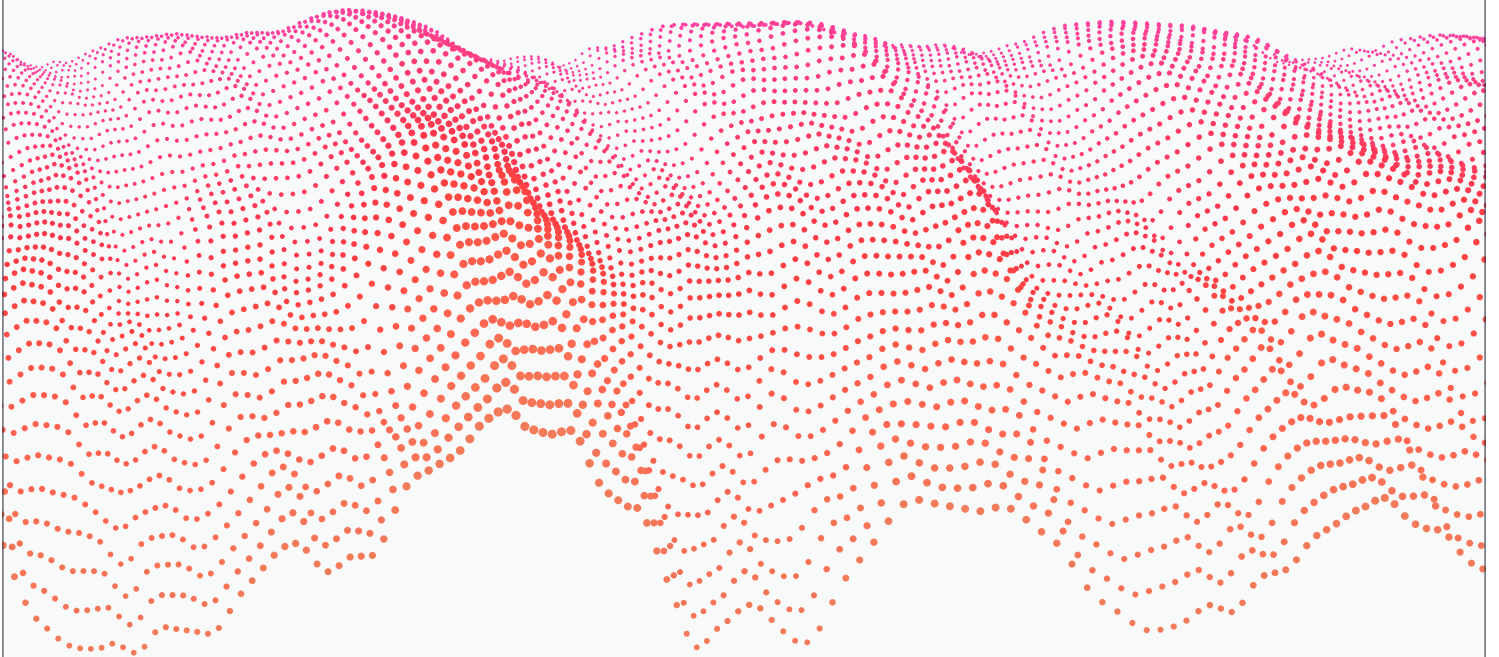
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CHAPTER 7: Processes to ensure protection of the privacy of individuals



CHAPTER 7: Processes to ensure protection of the privacy of individuals

Data re-identification is any process by which data is matched to its true owner after it has been released in de-identified form. In addition to potential harm or embarrassment it can cause to individuals, instances of data re-identification also threaten to erode the social licence of data custodians tasked with facilitating the legitimate secondary use of public data.

There is a need to ensure that individuals' privacy is protected and that de-identification methods render the risk of re-identification as very low (having regard to the relevant release context).⁹ There is also a need to balance maximising the benefits of using the data with the risk of breaching an individual's privacy or causing harm to individuals.

⁹ O'Keefe, C.M, Otorepec, S., Elliot, M., Mackey, E. and O'Hara, K., *The de-identification decision making framework* (CSIRO Reports EP173122 and EP175702, 18 September 2017) <https://publications.csiro.au/rpr/download?pid=csiro:EP173122&dsid=DS2>

Guiding Principles

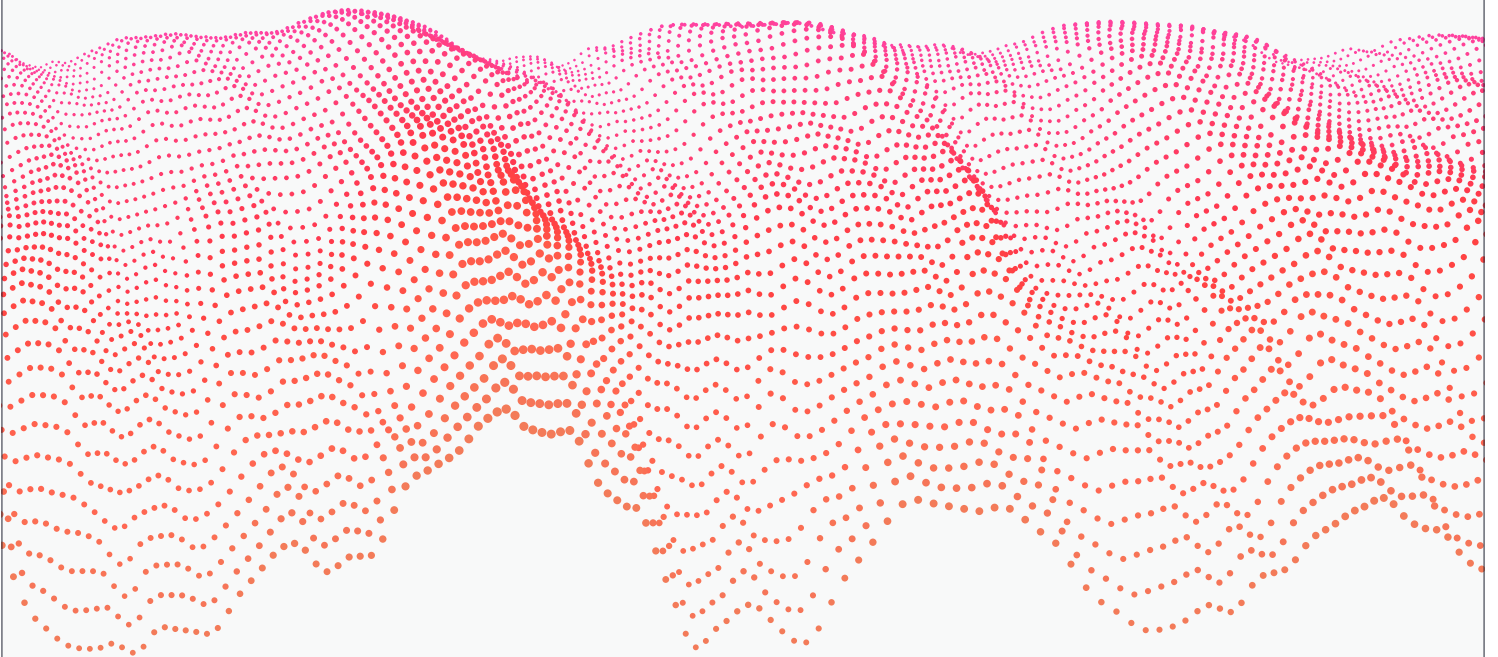
Chapter 7: Processes to ensure protection of the privacy of individuals

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|------------|--|
| 7.1 | De-identification of data is acknowledged to be a dynamic and ongoing process. |
| 7.2 | The Board will strive to stay abreast of changes in technology and data science as they evolve so that, as far as possible, it may anticipate new privacy threats and use this knowledge to inform assessment of applications for the use of data. |
| 7.3 | Proven methods will be used to reduce the risk of breaching an individual's privacy to very low levels. |
| 7.4 | The Board will regularly reconsider the privacy protection processes around secondary use of MHR system data. Particular consideration will be given to circumstances where there is already data in the public domain about individuals. |
| 7.5 | As part of the ongoing process of reviewing the Framework (with the first review occurring after two years of operation), the list of permitted and not permitted uses will be reconsidered and amended with reference to the 'case and precedent' experience of the Board (see Chapter 3, 'Applying to access My Health Record system data for secondary use'). |

The Board will:

- ensure that contemporary de-identification methods and techniques are appropriately applied before any data is made accessible to applicants
- assess each application on its unique characteristics, including consideration of any data linkage that has previously occurred (refer to Chapter 6, 'Data linkage'). The methods and techniques considered will include but will not be limited to:
 - » the Separation Principle (including ensuring that identifiable data is always sent separately to MHR content)
 - » application of the principles provided by the National Statistical Service for ensuring confidentiality of data prior to release—for example, combining or collapsing categories
 - » use of Statistical Linkage Keys and other linkage approaches as they become available
 - » use of a secure environment that enables approved data users to access and analyse requested data in a remote-access secured computing environment
 - » application of the Expert Determination Method
 - » application of the Safe Harbour Method
- obtain an assurance from an expert that the risk of re-identification is very low prior to making MHR data available
- contractually require the timely reporting of any data breaches/loss to the OAIC, including advice on remedial actions to be taken (e.g. notifying affected individuals).

CHAPTER 8: Preparing and making data available, and data quality



CHAPTER 8: Preparing and making data available, and data quality

When assessing each application, the Board will need to decide on the most appropriate method for making data available taking into account the associated risks.

Data quality also has a direct impact on the data user. Incomplete or inaccurate data may result in adverse or invalid findings that have an unexpected or even detrimental impact on public benefit. As the MHR system contains data that is extracted from other systems and free text directly entered, quality will be variable.

It will also be important to be able to assess the bias in the data associated with the evolving dynamic consent arrangements.

Guiding Principles

Chapter 8: Preparing and making data available, and data quality

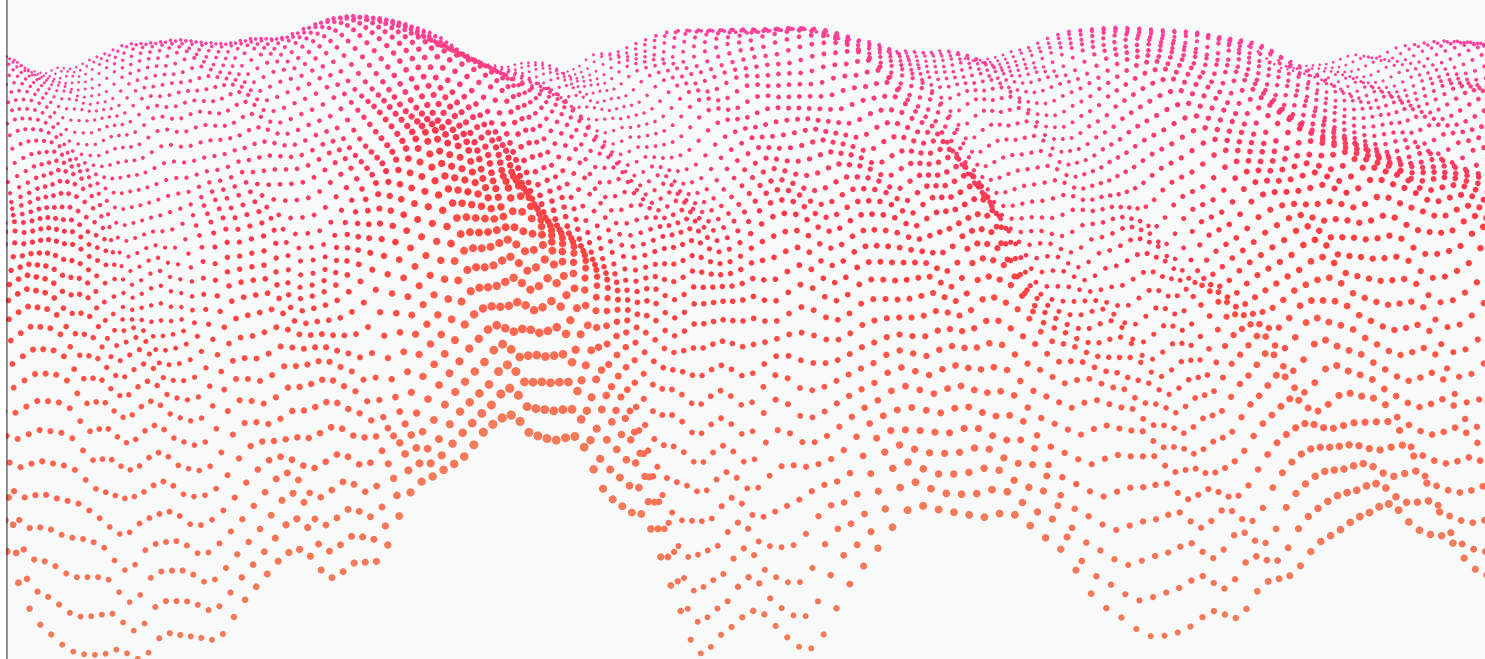
8.1 The Board will ensure that individuals' privacy is protected in the processes of preparing and making data available for secondary use.

8.2 The Board will ensure that any data made available is of sufficient quality to expect that the objectives of the project, as stated in the application, can be achieved.

The Board will:

- ensure that data is made publicly available via regular publications and the development of common use datasets (data cubes containing aggregate data)
- ensure that contemporary methods are used in preparing and making data available
- during the application process, consider any previous data linkage activities (refer to Chapter 6, 'Data linkage') when determining the most appropriate method for the MHR data to be made available
- make regular Data Quality Statements (DQS) about the suitability of the data. The DQS will include information on any known limitations in terms of scope (e.g. time period, data types, coverage levels, completeness and accuracy). For the cohort that withdraws their consent to participate in secondary use, data about their demographic characteristics will be derived from the MHR system to enable the preparation of a DQS.

Chapter 9: Monitoring and assurance processes



Chapter 9: Monitoring and assurance processes

Once MHR system data is made available for secondary use to the approved applicant, it will be important to monitor and assure compliance with the Conditions of Use Agreement (CUA) to ensure that there is no unapproved use or handling of data.

Guiding Principles

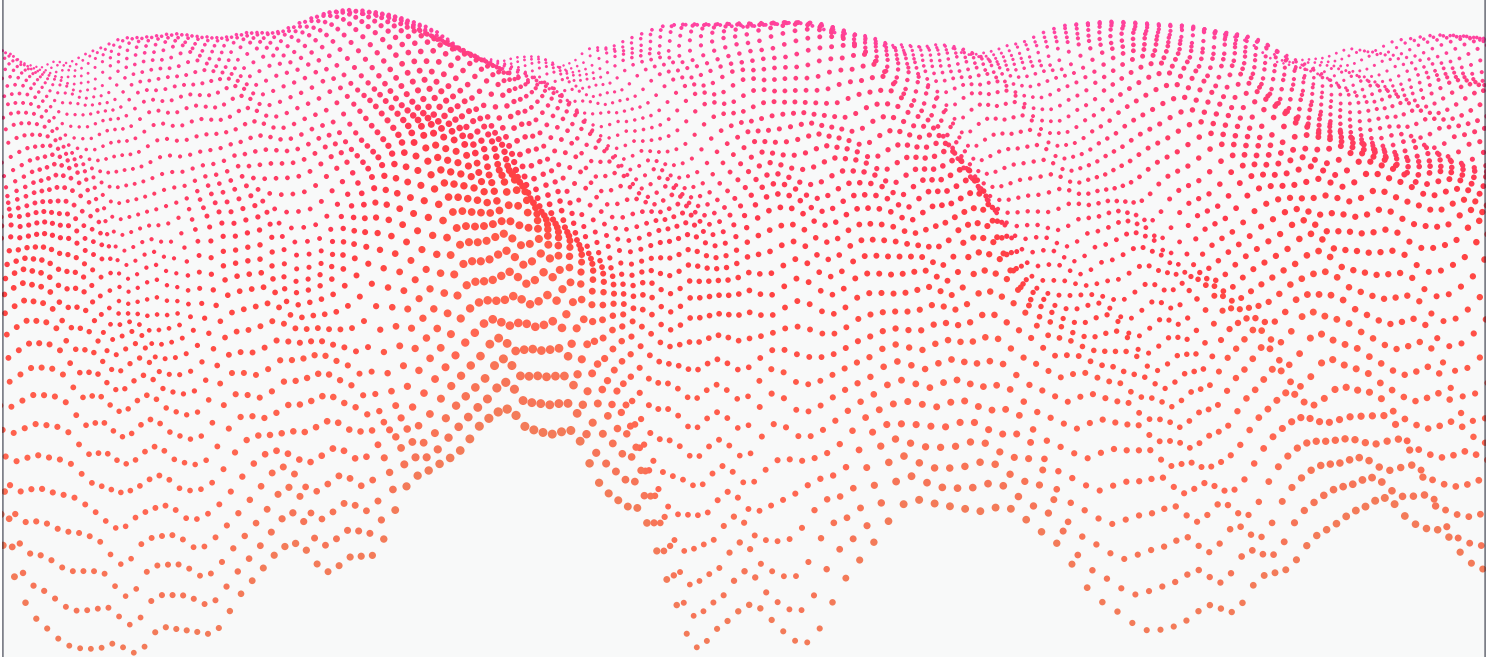
Chapter 9: Monitoring and assurance processes

- 9.1** The Board will put in place a set of processes to provide assurance to stakeholders and the public that successful applicants use MHR system data only for approved secondary purposes.
-
- 9.2** The higher the assessed risk of a project, the more detailed the monitoring activities that will be required in the Conditions of Use Agreement (CUA).
-

The board will:

- require applicants to submit a risk management plan setting out arrangements to ensure secure storage (if transferred) and use of the data
- use the applicant's risk management plan to undertake a risk assessment for each application to inform the nature and extent of monitoring and assurance activities to be executed (in addition to the risk assessment identified in Chapter 6, 'Data linkage'). The risk assessment will also consider but will not be limited to:
 - » arrangements for access to, and storage of, the data
 - » measures to be taken to prevent misuse, loss or unauthorised access to the data
 - » arrangements for the storage and/or destruction of any datasets/information created or generated, including the retention period and method for destruction
- through the CUA, require applicants to cooperate with the process to assess compliance with the approved use. Further information about the development of the CUA is contained at Appendix C
- implement periodic monitoring and assurance to ensure compliance with the CUA. Monitoring of compliance activities may include but will not be limited to:
 - » periodic assessment of each condition within the CUA for compliance. All conditions will be examined at least annually and at the end of the completion of the approved use
 - » the submission by applicants of an annual self-assessment outlining CUA compliance
 - » requiring successful applicants to cooperate with an independent verification of compliance with the CUA by an approved third party who has demonstrated expertise in the field.

Chapter 10: Risk mitigation strategies and imposed penalties



Chapter 10: Risk mitigation strategies and imposed penalties

Where the applicant is covered by the Privacy Act, there are clear obligations for protecting the privacy of individuals and notifying privacy breaches.

Under the MHR Act and the *Healthcare Identifiers Act 2010* (HI Act), the misuse of information in either the MHR system or the Healthcare Identifiers Service as well as other activities that relate to the security and integrity of the MHR system are subject to serious penalties (penalties do not apply to accidental misuse).

In addition, all businesses and not-for-profit organisations with an annual turnover of more than \$3 million have responsibilities under the Privacy Act, subject to some exceptions. The Privacy Act does not cover state or territory government agencies, including state and territory public hospitals and health care facilities (which are covered under state and territory legislation) except where it specifies certain acts and practices related to MHR and Healthcare Identifiers and other applicants prescribed by Australian privacy legislation.

Guiding Principles

Chapter 10: Risk mitigation strategies and imposed penalties

- 10.1** The Board will ensure that the risk of a breach of privacy for an individual is reduced to an acceptable level by minimising the risks associated with each application for secondary use and recommending penalties where applicable.
-

The board will:

- publish minimum requirements for data security infrastructure that must be complied with. Requirements will be risk-based and tiered
- establish and maintain a public register of requests for access to MHR system data for secondary use, which will include:
 - » date of application
 - » details about the applicant
 - » status of application
 - » ethics approval letter (if required)
 - » plain English statements of possible outcomes of the application and the outcomes achieved on completion
 - » monitoring data (e.g. annual compliance reports, data breach reports, independent compliance certificate, end-of-project report)
 - » completion date
 - » publications generated
- include the existing MHR Act penalties in the CUA to ensure there is acceptance and understanding of the conditions, the seriousness of any breach of conditions and the penalties that may apply
- require, as part of the CUA, that any applicant that is not already covered by the Privacy Act (excluding state and territory authorities and instrumentalities) join and remain on the OAIC's opt-in register to be bound by the Privacy Act and the APPs.

List of abbreviations

| | |
|--------------------|---|
| The Agency | Australian Digital Health Agency |
| AIHW | Australian Institute of Health and Welfare |
| AIHW Act | <i>Australian Institute of Health and Welfare Act 1987</i> |
| APPs | Australian Privacy Principles |
| The Board | My Health Record Secondary Use of Data Governance Board |
| CUA | Conditions of Use Agreement |
| DQS | Data Quality Statement |
| Framework | <i>Framework to guide the secondary use of My Health Record system data</i> |
| HI Act | <i>Healthcare Identifiers Act 2010</i> |
| MBS | Medicare Benefits Schedule |
| MHR | My Health Record |
| MHR Act | <i>My Health Records Act 2012</i> |
| NHMRC | National Health and Medical Research Council |
| NT | Northern Territory |
| OAIC | Office of the Australian Information Commissioner |
| PBS | Pharmaceutical Benefits Scheme |
| PCEHR | Personally Controlled Electronic Health Record |
| Privacy Act | <i>Privacy Act 1988</i> |
| SURE | Secure Unified Research Environment |

Glossary of terms

Big data: 'high-volume, high-velocity and/or high-variety information assets that demand cost-effective, innovative forms of information processing for enhanced insight, decision making, and process optimisation'.¹⁰

Data custodian: Custodianship of the secondary use of My Health Record (MHR) data for research and public health purposes rests with the Australian Institute of Health and Welfare (AIHW).

Data linkage: 'the bringing together of two or more datasets to create a new, richer dataset'.¹¹ By bringing together sets of data that were previously isolated, researchers, clinicians and governments can deepen their understandings of the ways people use the health care system.

De-identified data: A process which involves the removal or alteration of personal identifiers, followed by the application of additional techniques or controls to remove, obscure, aggregate, alter and/or protect data so that it is no longer about an identifiable (or reasonably identifiable) individual.¹²

Data Access and Release Policy: Australian Government Department of Health policy.¹³

Data re-identification: Any process by which data is matched to its true owner after it has been released in de-identified form.

Expert Determination Method: A risk-based approach to de-identification that applies current standards and best practices to determine the likelihood that a person could be identified from their de-identified information. This method requires that a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods renders the risk of re-identification as very low (having regard to the relevant release context).

'Five safes':¹⁴ A security framework for maintaining confidentiality around data during research. The basic premise of the model is that data access can be seen as a set of five 'risk (or access) dimensions'—safe: projects, people, data, settings and outputs.

The Framework: This document—the Framework to guide the secondary use of My Health Record system data.

Health uses: These include uses relating to health care and the promotion of public health benefits in areas of social welfare that have health relevance, such as the social determinants of health.

Identifiable data: Where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address.

10 Australian Government Department of Finance and Deregulation, Australian Government Information Management Office, *The Australia Public Service big data strategy: Improved understanding through enhanced data-analytics capability* (August 2013) p. 8 <https://www.finance.gov.au/sites/default/files/Big-Data-Strategy.pdf>

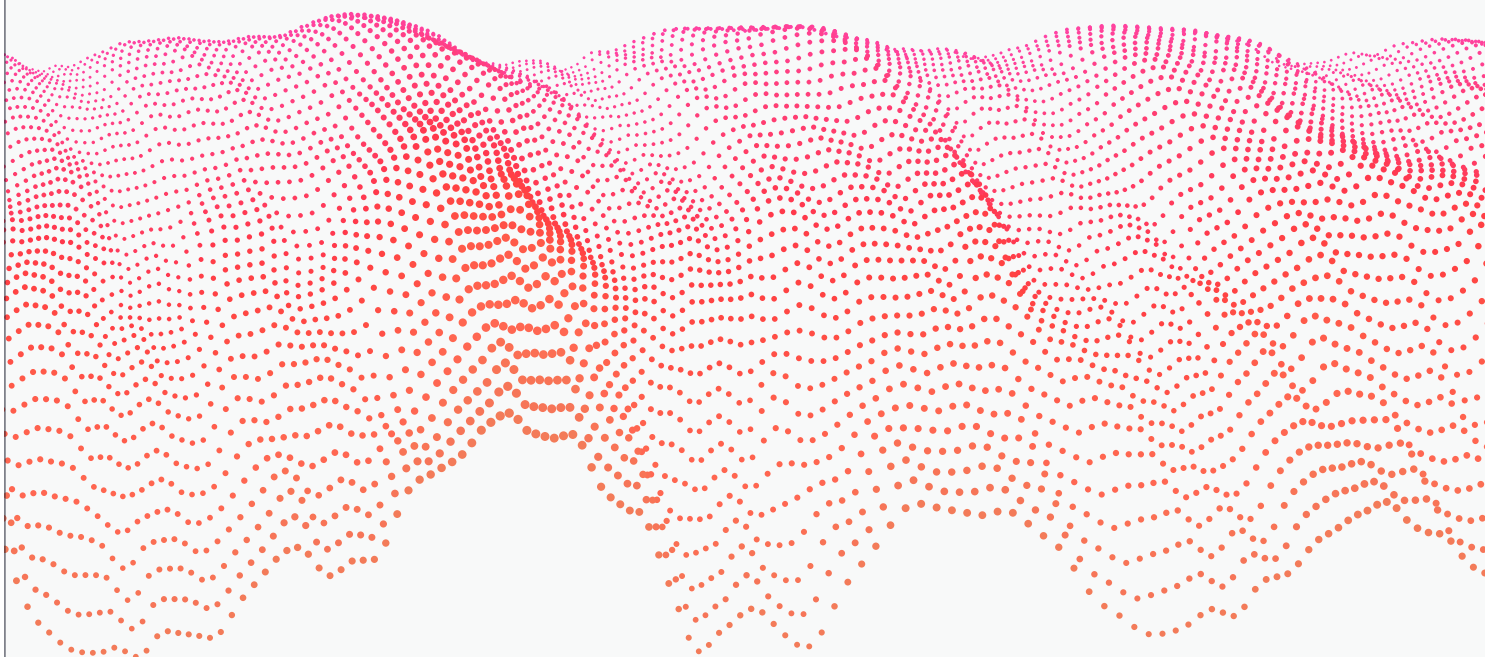
11 The National Statistics Service is a network of Australian Government and state and territory entities led by the Australian Bureau of Statistics that works together to improve Australia's statistics system. National Statistics Service, *Data linking: What is data linking?* (Information Sheet 1) [http://www.nss.gov.au/nss/home.nsf/pages/Data integration - data linking information sheet one](http://www.nss.gov.au/nss/home.nsf/pages/Data%20integration%20-%20data%20linking%20information%20sheet%20one)

12 Office of the Australian Information Commissioner, *De-identification and the Privacy Act* (March 2018) p. 9 <https://www.oaic.gov.au/agencies-and-organisations/guides/de-identification-and-the-privacy-act>

13 Australian Government Department of Health, 'Data Access and Release Policy' (15 February 2018) <http://www.health.gov.au/internet/main/publishing.nsf/Content/Data-Access-Release-Policy>

14 Desai, T., Ritchie, F. and Welpton, R., *Five safes: Designing data access for research* (University of the West of England, 2016) <http://eprints.uwe.ac.uk/28124/1/1601.pdf>

Appendices



Appendix A: Examples of secondary uses of health data

Three examples of the effective use of health data for secondary purposes are provided below.

The folate story

In 1989 Western Australian researchers linked health data from different registries and determined that the inclusion of folic acid in expectant mothers' diets prevents neural tube defects in their babies. This finding was followed by education campaigns to encourage women to eat more folate-enriched foods or take folate supplements during pregnancy.

In 2007 all Australian governments (Commonwealth, state and territory) agreed to introduce the compulsory enrichment of bread making flour with folate, which reduces incidents of spina bifida and other neural tube defects in children. Since this measure was introduced there has been a significant (14.4 per cent) overall decrease in the rate of neural tube defects in Australia. The rate of neural tube defects decreased by almost 55 per cent among teenagers and by 74 per cent for Aboriginal and Torres Strait Islander women.

Assessing the impact of the ABC *Catalyst* program, 'Heart of the Matter'

In 2013 the ABC aired a two-part special *Catalyst* program that questioned the link between high cholesterol levels and cardiovascular disease and suggested that the benefits of statins had been overstated and the harms downplayed. Nearly 1.5 million Australians are estimated to have viewed each part of the program.

Using a 10 per cent random sample of data from the Pharmaceutical Benefits Scheme, a time series analysis was undertaken to assess the impact of the broadcast. The analysis found that, following the *Catalyst* program, there was a 2.6 per cent reduction in statin dispensing, equivalent to 14 005 fewer prescriptions dispensed Australia-wide every week. Further, the analysis found that in the week the program aired there was a 28.8 per cent increase in the discontinuation of statin use (which decayed by 9 per cent per week). These changes in behaviour occurred despite warnings in the *Catalyst* program that its content should not be taken as medical advice and public criticism of the program.

Cost-effectiveness of primary care for Aboriginal and Torres Strait Islander Australians with diabetes

In 2014 researchers matched information from the Northern Territory (NT) primary care information system with hospital admission data. Further analysis of the integrated data was conducted using information about the cost of primary care (from the NT Government accounting system). Patients with diabetes who regularly went to their local doctor were found to have lower rates of potentially avoidable hospitalisations and death and fewer years of life lost.

This research provided new evidence that patients have better health outcomes when their access to primary care is improved. It also provided evidence of significant cost savings to the health system. The savings in hospitalisations provided a measure for the value for money of primary care and created a new, compelling argument for the investment of government funds in primary care in remote Australia.

Appendix B: Examples of potential secondary uses of My Health Record data

Below are three hypothetical examples of the ways in which enabling the secondary use of My Health Record (MHR) data could lead to new insights into the effectiveness and safety of medical treatments and clinical care across Australia's health system.

Enhancing post-market surveillance insights for new products

In Australia, companies that create new pharmaceuticals and medical devices are required to provide provisional evidence of the safety and efficacy of their products. This evidence could be integrated with MHR system data to further monitor how the new product is 'tracking' within the general population and to provide a more comprehensive picture of 'real-world behaviour' (that is, beyond the heavily monitored behaviour of clinical trials) in regard to product consumption. Such analyses might reveal unexpected adverse effects (or benefits) of a new product.

Improvements to patient pathways research

MHR system data will be one of the first datasets to allow analysis around how a person moves through the Australian health system. The application of time series analyses or multi-service provider analyses upon MHR data is likely to yield new insights and even enable a degree of 'forecasting' capacity for health system planners in the future.

Increased visibility and insights into population health matters

De-identified data from the MHR system could be safely integrated with de-identified data from other government systems for public benefit. For example, de-identified MHR data, immigration data and hospital admissions data in a particular city could be safely linked to determine whether or not long-haul flights contribute to higher instances of deep-vein thrombosis.

Appendix C: Developing the conditions of use agreement

When developing the Conditions of Use Agreement (CUA), the My Health Record (MHR) Secondary Use of Data Governance Board (the Board) will include the following elements:

- a requirement for all applicants approved to use MHR data for secondary purposes to be party to a CUA, which will set out the required data management and security standards
- requirements for the timely reporting of any data breach or loss to the Office of the Australian Information Commissioner (OAIC), including advice on remedial actions to be taken (e.g. notifying affected individuals)
- explicit inclusion of existing *My Health Records Act 2012* penalties to ensure that, among approved applicants, there is acceptance and understanding of the conditions, the seriousness of any breach of conditions and the penalties that may apply
- requirements that applicants must cooperate with compliance and approved use processes. It will cover matters relating to data management (e.g. access, storage, security and, where relevant, disposal), confidentiality undertakings, training required for data users, the nature and scope of periodic compliance audits and penalties for non-compliance
- requirements that successful applicants must cooperate with an independent verification of compliance with the CUA by an approved third party. The third party will be agreed as part of the CUA and will have demonstrated expertise in the field
- an undertaking to comply with the *Privacy Act 1988* and the Australian Privacy Principles (APPs) or, if they are not already covered by these, to join and remain on the OAIC's opt-in register and be bound by the *Privacy Act 1988* and the APPs
- a requirement that MHR data released for secondary purposes must not be sold.

Appendix D: Guide to appropriate and inappropriate use of My Health Record data

Secondary uses that are permitted include but may not be limited to:

- development of new health services (e.g. to identify service gaps and/or project demand for health services or workforce)
- improvement of existing health services (e.g. determine effectiveness and/or accessibility)
- development of government health policy (e.g. establish/refine the target population for a publicly funded service)
- development of new and/or improved health care products/services (e.g. use for post market surveillance to analyse the way in which a product (e.g. pharmaceutical, medical device) is used in the real world with a view to improving effectiveness)
- evaluation of health interventions and/or health programs (e.g. determine if an intervention or service is generating outcomes/benefits consistent with funding approvals)
- recruitment to clinical trials (e.g. identify people who may be suitable for a new product/service)
- health services research relevant to public health (e.g. examine the health service utilisation patterns for potentially avoidable hospitalisations; research that leads to changes in other government policies, such as welfare, and ultimately reduces impact on the health system)
- development of clinical decision support systems (e.g. link data on individual's health with best practice to influence treatment choices)
- construction of clinical registries (e.g. create or supplement data in clinical registries to evaluate the effectiveness of interventions)
- develop/enable technology innovations (e.g. develop software applications that support self-care)
- preparation of publications (e.g. on the health status of the population).

Secondary uses that are not permitted include but may not be limited to:

- determination of funds allocation for a health service (e.g. set the level of funds allocated to an individual community health service)
 - remuneration of individual clinicians (e.g. to make/modify payments)
 - individual clinician audit (note: this does not exclude examining practice variations for the purposes of quality improvement or adherence to best-practice guidelines at a health service level).
-

Secondary uses that are solely commercial and hence not permitted include but may not be limited to:

- direct marketing to consumers
 - assessment of insurance premiums and/or claims.
-

Secondary uses that are non-health-related and hence not permitted include but may not be limited to:

- assessment of eligibility for benefits (e.g. use by Centrelink and/or the Australian Taxation Office to make determinations relating to an individual)
- criminal and/or national security investigations, except as required by law (e.g. use to investigate the interactions of individuals with the health system as part of assessing their behaviour).

Appendix E: Legislation that is relevant to the secondary use of My Health Record data

Federal examples

- *My Health Records Act 2012* (MHR Act)
- *National Health Reform Act 2011*
- *Private Health Insurance Act 2007*
- *National Health Security Act 2007*
- *Health Insurance Act 1973*
- *Privacy Act 1988* (Privacy Act)
- *Census and Statistics Act 1905*
- *National Health Act 1953*
- *Australian Bureau of Statistics Act 1975*
- *Freedom of Information Act 1982*
- *Privacy Amendment (Private Sector) Act 2000*
- *Healthcare Identifiers Act 2010* (HI Act)
- *Human Services Legislation Amendment Act 2011*
- *Australian Institute of Health and Welfare Act 1987* (AIHW Act)
- *Australian Information Commissioner Act 2010*

State and territory examples

- In Victoria, New South Wales and the Australian Capital Territory, state/territory health records Acts may apply.¹⁵
- In Queensland, the Hospital and Health Boards Act 2011 applies.¹⁶
- In support of the legislation, there are also guidelines and other documentation at state level—for example, in Victoria, New South Wales and Queensland, responsibilities are further clarified under the Health Services Commissioner (Victoria), NSW Privacy Commissioner and Office of the Information Commissioner (Queensland) guidelines on the collection and use of health information.

¹⁵ *Health Records Act 2001* (Vic); *Health Records (Privacy and Access) Act 1997* (ACT).

¹⁶ *Hospital and Health Boards Act 2011* (Qld) <https://www.legislation.qld.gov.au/view/pdf/inforce/current/act-2011-032>

Framework to guide the secondary use of My Health Record system data

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