



Australian
College of
Nursing

*ACN feedback on the discussion paper on the development
of a Framework for the secondary use of data held in My
Health Record*

Executive Summary:

The Australian College of Nursing (ACN) welcomes the opportunity to comment on the discussion paper on the development of a Framework for the secondary use of data held in the My Health Record system for research, policy, service planning, system use, quality improvement and evaluation activities. ACN supports these proposed uses of the primary clinical data collected at consumer level and aggregated at population or system level.

Accessing evidence based research from the My Health Record data can be used towards more efficient planning to deliver on Australia's future health needs. The Productivity Commission's 'Shifting the Dial' report¹ recognises the possibilities that the My Health Record presents when the collected data is used rather than just being static stored data. The Australian College of Nursing supports a robust and transparent Framework that permits appropriate access to secondary My Health Record data and governs its responsible use.

Recommendations:

- *ACN recommends that In order to minimise the risks of security breaches, there should only be a single accountable authority for the management of My Health Record data for secondary uses*
- *ACN would support that there should be a public register of requests and users of data, ensuring all data transactions are transparent to the public*
- *ACN strongly agrees that secondary uses of My Health Record Data should not be used for solely commercial and non-health related purposes, and should not be used to identify individuals in any way, for any reason, at any time*
- *In regards to data usage, the consumer should be aware of how the data may potentially be used. This knowledge should inform the framework so that the public benefit of the data can be balanced against commercial benefits*
- *Strong and transparent governance arrangements will ensure public trust and confidence. This will provide greater opportunity for consumers to participate, which will ensure the longevity of the framework.*
- *ACN would suggest that the framework has a time-limited review built into its evaluation, for example a three-yearly review.*

Some of the questions posed are outside the remit of the ACN to comment on, and our response focuses on those areas where our members have expertise and experience.

Australian College of Nursing (ACN) is the national professional organisation for all nurse leaders and its aim is to ensure that the Australian community receives high quality nursing care now and into the future. ACN is a membership organisation with members in all states and territories, health care settings and nursing specialties. ACN is also the Australian member of the International Council of Nurses headquartered in Geneva.

The Australian College of Nursing (ACN) is committed to working with Australian governments to increase engagement with the nursing profession, enhance nursing leadership in reform and maximise nursing potential.

ACN would like the opportunity for further input once the draft Framework is available.

¹ Productivity Commission 2017, 'Shifting the Dial', p. 12, <<https://www.pc.gov.au/inquiries/completed/productivity-review/report>>

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Question 1: What secondary purposes, if any, should My Health Record data be used for?

ACN is supportive of the secondary use of My Health Record data to:

- facilitate research which may contribute to the promotion, protection and maintenance of the health and wellbeing of the public
- facilitate the planning, evaluation and delivery of health services
- contribute to knowledge regarding the health and welfare of the community

The Framework could inform a responsive health system that meets the needs of the population and is informed by evidence. In this sense, the secondary use of My Health Record data can assist in linking health care of individuals to the overall health of populations.

All secondary use of the My Health Record data should be in the public interest. The secondary use of health data has the potential to enhance future health care experiences for patients by:

- enabling the expansion of knowledge about disease and appropriate treatments
- strengthening the understanding about effectiveness and efficiency of service delivery
- supporting public health goals; and
- assisting service providers in meeting consumer needs.

ACN notes that the non-consumer data that already exists in My Health record is:

Discharge Summary	Referral	Pharmaceutical Benefits Report (PBS)	Dispensing record
Event Summary	Pathology Report	Medicare/DVA Benefits Report (MBS)	Australian Organ Donor Register (AODR)
Shared Health Summary	Diagnostic Imaging Report	Australian Childhood Immunisation Register (ACIR)	
Specialist Letter	Pharmaceutical Benefits Report (PBS)	Prescription Record	

Consumer entered Data (that can be added)

e.g.

Advance Care Document	Personal Health Observations	Personal Health Summary
Personal Health Note		

Question 2: What secondary purposes should My Health Record data not be used for?

ACN **would not support** My Health Record data being used for purposes without a likely public benefit e.g. where the sole beneficiary is a private sector entity to use for commercial purposes.

Noting the term:

'Secondary use' is defined as using the information in the My Health Record system for purposes other than the provision of direct health care to the individual person, which is the primary use.

Question 3: What types of organisations/individuals should be able to access My Health Record data for secondary purposes?

Eligible My Health Record data users should include data users with the appropriate experience, qualifications, and facilities to conduct the proposed research or evaluation. This includes students who are part of a research team with appropriate experience and qualifications.

Data users should not be restricted based on the type of organisation as long as all access criteria are met and required approvals received.

Foreign data users who meet all criteria for access should not be excluded subject to the requirements of Australian Privacy Principle 8 — Cross-border disclosure of personal information (Version 1.1, March 2015) and any other relevant legislation being met.²

Question 4: Should access to My Health Record data for secondary uses be restricted to Australian users only or could overseas users be allowed access?

The data should be restricted to Australian users only, who have a physical presence in the country, are regulated by the Privacy Act 1988 and related privacy legislation, and are of good standing. There could also be flexibility for overseas users to collaborate with Australian research organisations, with similar restrictions being applied to these organisations.³

² Office of the Australian Information Commissioner. Australian Privacy Principle 8 – Cross-border disclosure of personal information. Version 1.1, March 2015. <https://www.oaic.gov.au/resources/agencies-and-organisations/app-guidelines/chapter-8-app-guidelines-v1.1.pdf> (accessed November 2017)

³ Office of the Australian Information Commissioner. Privacy Act. <https://www.oaic.gov.au/privacy-law/privacy-act/> (accessed November 2017)

Question 5: What principles, if any, should be included in the Framework to guide the release of data for secondary purposes from the My Health Record system?

The following extract from the Data Policy Statement could be adapted as principles for the Framework for de-identified data:

“Australian Government entities will:

- *make non-sensitive data open by default to contribute to greater innovation and productivity improvements across all sectors of the Australian economy*
- *where possible, make data available with free, easy to use, high quality and reliable Application Programming Interfaces (APIs)*
- *make high-value data available for use by the public, industry and academia, in a manner that is enduring and frequently updated using high quality standards*
- *where possible, ensure non-sensitive publicly funded research data is made open for use and reuse*
- *build partnerships with the public, private and research sectors to build collective expertise and to find new ways to leverage public data for social and economic benefit*
- *securely share data between Australian Government entities to improve efficiencies, and inform policy development and decision-making*
- *engage openly with the States and Territories to share and integrate data to inform matters of importance to each jurisdiction and at the national level*
- *uphold the highest standards of security and privacy for the individual, national security and commercial confidentiality and*
- *ensure all new systems support discoverability, interoperability, data and information accessibility and cost-effective access to facilitate access to data.⁴”*

ACN would suggest that the term "release" should not be used if it applies to identifiable data.

Access may be granted to data with the proviso that:

- there are inbuilt controls over the data
- there is the ability to withdraw access and recall data
- data should be encrypted at rest at all times.

Question 6: What governance model should be adopted to oversee the secondary use of My Health Record data?

The Productivity Commission's 2017 report, 'Data Availability and Use' into data availability and use has looked at this extensively - their recommendations should be considered.⁵

Ethics Approval

All requests to use My Health Records data for research must be reviewed by a Human Research Ethics Committee (HREC) registered with the National Health and Medical Research Council.

⁴ Department of Prime Minister and Cabinet 2015, *Australian Government Public Data Policy Statement*, p.2, <https://www.pmc.gov.au/sites/default/files/publications/aust_govt_public_data_policy_statement_1.pdf>.

⁵ Productivity Commission 2017, *Data Availability and Use*, <<https://www.pc.gov.au/inquiries/completed/data-access/report/data-access-overview.pdf>>.

Question 7: What principles should be adopted, if any, to enable organisations/researchers to request and gain approval for de-identified data from the My Health Record system to be provided for secondary purposes?

See Question 5.

Question 8: What principles, if any, should be adopted to enable organisations/researchers to request and gain approval for identified data from the My Health Record system to be provided for secondary purposes?

Governance:

A principle that should be included in the Framework in respect of identified data should be to ensure that any release of identified My Health Record data complies with the affected individual's instructions.

Question 9: Should there be specific requirements if researchers/organisations make a request that needs the My Health Record data to be linked to another dataset? If so, what should these requirements be?

Linkage:

Linking data significantly increases the risk of re-identification in both of the linked datasets. Linking should only be performed in a controlled environment by a data custodian. The linked dataset should be considered on its own merits, since privacy protections can be weakened by linking, and as such, two seemingly safe datasets may not result in a safe linked dataset.

The linking of My Health Record Data with other datasets requires consideration of the risk that the linkage may enable individuals to be identified. For de-identified unit record level data, the System Operator should specify the processes to be adopted to protect the privacy of individuals in an agreement.

Question 10: What processes should be used to ensure that the data released for secondary purposes protects the privacy of an individual?

Data should be protected by the environment within which it is accessed, with multiple levels of protection.

- secure research environments
- statistical disclosure control processes
- audited access
- vetting of users
- layered protection procedures and processes.

Question 11: What arrangements should be considered for the preparation and release of My Health Record data and who should be responsible for undertaking and overseeing these arrangements?

All approved users/user organisations of My Health Records data should be required to enter into a data transfer/use agreement. The agreement should cover the following:

- details of the data to be supplied/accessed
- authorised use and disclosure
- restrictions on use and disclosure
- information security requirements
- controlled access to the data, as opposed to release
- data should be encrypted at rest

Question 12: Whose responsibility should it be to make a quality statement about the My Health Record data and to ensure the data are of high quality?

The System Operator should be responsible for making the quality statement and ensuring the data is of high quality.

Question 13: What monitoring and assurance processes, if any, should be considered to ensure My Health Record data secondary users comply with the Framework?

Risks mitigation strategies must be in place to prevent compromising the Framework and assuring the community and users that the system is safe.

Ensuring the Framework's ongoing compliance and consistency with Commonwealth and state/territory privacy laws, as they are amended over time will strengthen the Framework.

Question 14: What risk mitigation strategies should be included in the Framework?

The National Statement states that the responsibility for monitoring research lies with the institution conducting the research.⁶

Organisations accessing the data should be required to provide reports to the relevant review bodies e.g. HREC and My Health Record. These reports should include compliance with any conditions of approval e.g. the terms, conditions, maintenance, and security of records.

Auditing of access and queries, and the type of research being conducted should be part of standard operations.⁷

⁶ National Health and Medical Research Council 2007 (updated May 2015), *National Statement on Ethical Conduct in Human Research (2007) – Updated May 2015*, < <https://www.nhmrc.gov.au/guidelines-publications/e72>>.

⁷ National Health and Medical Research Council. Monitoring approved research. <https://www.nhmrc.gov.au/book/chapter-5-5-monitoring-approved-research> (accessed November 2017)

Question 15: Should there be a public register which shows which organisations/researchers have requested data, the status of their data request, what they have found by using the data; and any publications that have resulted from using the data?

Yes, there should be a public register for the purpose of transparency. There should be consideration given for the public to have a chance to object to proposed projects prior to access to the data being given within a defined time. The data custodian should consider general public feedback when deciding whether to permit access.

Question 16: Are the existing penalties under the My Health Record Act sufficient?

Question 17: What policy changes, if any, need to be considered to support the release of de-identified data for secondary uses from the My Health Record system?

The Australian Government Public Data Open Policy Statement takes a 'binary' approach to data (that is, anonymised data should be openly available; access to sensitive data should be restricted). It does not recognise the risk that de-identified data can be subject to re-identification. This risk, and the need to control access to some anonymised data, should be reflected in the Data Policy Statement.⁸

Question 18: What policy or legislative changes, if any, need to be considered to support the release of identified data (bearing in mind that such release is only possible with the informed consent of the person) for secondary uses from the My Health Record system?

Additional comments on the consultation document

Improvement of Definitions

It is important that definitions, particularly around information security, are not ambiguous. For this reason, ACN suggests that the definition of de-identified data, as found in the Privacy Act 1988 (section 6 interpretation) be used in the Framework.

Communication of the Framework

Awareness campaigns should be strongly considered, such as the campaigns envisaged by the Privacy Impact Assessment Report – Personally Controlled Electronic Health Record (PCEHR) System Opt-Out Model. The benefits of secondary use, in addition to those of primary use, should be apparent to consumers in a way that drives consumer engagement and minimises opt-out.⁹

Note: It is not clear from the details that are available whether secondary use of data will be incorporated into the consumer consent process for the My Health Record, if not ACN would recommend that it is.

⁸ Department of Prime Minister and Cabinet 2015, *Australian Government Public Data Policy Statement*, <https://www.pmc.gov.au/sites/default/files/publications/aust_govt_public_data_policy_statement_1.pdf>.

⁹ Australian Government Department of Health 2015, Privacy Impact Assessment Report. Personally Controlled Electronic Health Record (PCEHR) System Opt-Out Model, <[https://myhealthrecord.gov.au/internet/mhr/publishing.nsf/Content/faq-security-410/\\$file/PCEHR%20Opt%20Out%20PIA%20-%202015.pdf](https://myhealthrecord.gov.au/internet/mhr/publishing.nsf/Content/faq-security-410/$file/PCEHR%20Opt%20Out%20PIA%20-%202015.pdf)>.

Engagement and communication with community, and informed consent for secondary use of data is a high priority. The consumer need to be fully versed in the governance mechanisms to have confidence in the privacy and security of their data and its use.

ACN notes the extensive public consultation process being undertaken with surveys, workshops, and webinars in association with the development of the Framework. It is important to ensure that the Framework reflects a truly informed discussion with consumers.

Consent:

A dynamic consent framework is preferred, with options provided to the consumer. Service providers need to enable consumer's informed consent. Communication regarding changes to My Health Record with consumers is needed prior to program expansion in 2018.

Aboriginal and Torres Strait Islander peoples:

The Framework needs specific consideration of principles to guide the secondary use of data pertaining to Aboriginal and Torres Strait Islander peoples. Consideration should be given to social and cultural expectations around management of privacy concerns regarding data of deceased.

Consent remains a sensitive issue for Aboriginal and Torres Strait Islander peoples. There needs to be consultation with Aboriginal and Torres Strait Islander communities at each step in the development of the framework before data releases.

Note: These principles and data governance arrangements need to be developed in collaboration with national Aboriginal community representative bodies such as the National Aboriginal Community Controlled Health Organisation (NACCHO). ACN recommends the Framework adopt *Ethical guidelines for research involving Aboriginal and Torres Strait Islander Peoples* (see <https://www.nhmrc.gov.au/health-ethics/ethical-issues-and-further-resources/ethical-guidelines-research-involving-aboriginal->).

Transparency:

There should be a public register that shows:

- data requests
- their purpose
- the status of the request
- what has been found by using the data, and
- any resulting publications.

The register should also include denied requests and the reasons for denial.

Charging for data:

Publicly available datasets, including aggregated data, should be free to everyone. Cost recovery from organisations should only be considered where a cost is incurred in complying with a data request.

I do not consent to my submission being published on the website