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Your name or the name of your organisation: Australian National Data Service (ANDS)

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

ANDS strongly supports the intention of making data from the My Health Record system available to researchers for secondary use, provided that the usage is consistent with the relevant legislature and code of conduct (e.g. privacy laws and the Australian Code for the Responsible Conduct of Research). We agree that access to this data will contribute greatly to more efficient and new kinds of research, translation of that research into treatment and health service delivery, and, through the research sector, provide benefits to broader public policy, education and business.

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

These data should not be used for marketing purposes, allowing or disallowing access to services and products, and other purely commercial purposes.
Question 3: What types of organisations/individuals should be able to access My Health Record data for secondary purposes?

The international examples given are reasonable.

Section 3.2 states “Data governance should also include the secure destruction of data. It is likely that there will be interest in using data held in the My Health Record data from a similar set of organisations in Australia.” ANDS notes that the Productivity Commission’s Report on Data Availability and Use (pages 278-80) recommends that linked datasets and statistical linkage keys should not be destroyed after each project. ANDS proposes that the Framework for Secondary Use of My Health Record Data should consider internal retention and re-use of the datasets created for secondary use. This would increase efficiency and reduce waste. This approach would need careful management of storage, access and identifiability of the datasets created. However, we are confident that this would be covered by the processes being considered in other sections of the Framework.

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?

Many Australian researchers collaborate with international partners. It would be appropriate to require approval from an Australian Human Research Ethics Committee, and to require the primary investigator to be based in an Australian Institution.

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?

We agree with the principles listed in Section 3.3 and Appendix B of the consultation paper, in particular the Five Safes. We also suggest that the principles from the Australian Code for the Responsible Conduct of Research (which is currently under review) could be incorporated in the Framework.

Additionally, the principle of re-use of research data should be considered by the
Framework. The NHMRC Statement on Data Sharing ([https://www.nhmrc.gov.au/grants-funding/policy/nhmrc-statement-data-sharing](https://www.nhmrc.gov.au/grants-funding/policy/nhmrc-statement-data-sharing)) supports the sharing of data from research projects funded by NHMRC. Additionally there are increasingly many medical journals that require the data underlying papers be made available. We acknowledge that when My Health Record data is made available for secondary use, the ownership does not transfer to the researcher. As such, the researcher cannot pass the data onto others or deposit it in a repository for example. This is already the case for researchers using data obtained by data linkage through PHRN. ANDS suggests that the Framework provides guidance to researchers who are asked to share their data by a research funder or journal. We suggest a standard 'data availability statement' could be developed for use by researchers, and ANDS is willing to assist in the development of this.

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

The Governance models for AIHW and PHRN described in Section 4.2 would provide a good basis for the development of a governance process for application to use My Health Records data. Having decisions made by a committee rather than a single data custodian would be preferable.

There should be consumer representation on any committee making decisions about data release.

Appropriate staffing levels would need to be provisioned for, to ensure that applications are processed in a reasonable time frame (i.e. not years as has been seen by some researchers accessing nationally linked medical data).

Application through a web-based form rather than email would provide a more traceable and manageable record of applications.

The process that DHS undertakes to gain approval for identifiable data, i.e. contact from DHS and never providing identifiable patient data without consent, would need to be carefully balanced with the need to not ‘bombard’ patients with requests for their identifiable data. This may be addressed by allowing the internal retention of datasets (as in our response to Q3). Researchers who have appropriate and relevant ethics approval could potentially then access an identifiable dataset for which patients have already given research use permission.

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?
The principles from the National Statement on Ethical Conduct in Human Research (which is currently being reviewed) should be taken into account.

Appropriate ethics approval should be obtained for the secondary use of de-identified health record data. Different principles may be adopted for different levels of identifiability e.g. aggregate vs individual level de-identified data.

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?

The principles from the National Statement on Ethical Conduct in Human Research (which is currently being reviewed) should be taken into account.

Appropriate ethics approval and consent should be obtained for the secondary use of identifiable health record data.

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?

Appropriate ethical approval should be obtained.

If a researcher/organisation brings their own dataset for linkage, that means that the linked dataset, even if provided to them via PHRN or SURE or other means, would be identifiable to the researcher/organisation. Appropriate agreements should be signed in this case, in order to ensure confidentiality is maintained for the participants being included in the dataset.

Question 10: What processes should be used to ensure that the data released for secondary purposes protects the privacy of an individual?
A risk management framework should be established.

There are many techniques for anonymisation/de-identification of data, as discussed in the Consultation paper. No one technique is suitable for every situation. It may be appropriate to have a range of techniques named in the Framework, and for individual assessments to be made when data is released by appropriately qualified professionals.

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 of the processes named in Section 4.5 could be appropriate for this Framework. The data custodian should be responsible for undertaking and overseeing these arrangements. Appropriate staffing levels would need to be provisioned for, to ensure that applications are processed in a reasonable time frame.

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 data custodian would be in the best position to be able to make a quality statement about the My Health Record data.

Ensuring the data are of high quality would be a large and complicated task, as the data will be entered from many sources. This will probably best be done by the data custodian, however it may be limited by the ongoing cost of such an endeavour.

The RepeAT framework, which is “an assessment tool operationalizing key concepts of research transparency in the biomedical domain, specifically for secondary biomedical data research using electronic health record data”, could be used as a framework for reporting of research practices and outputs using My Health Record Data. McIntosh, LD et al. BMC Medical Research Methodology 2017 17:143 https://doi.org/10.1186/s12874-017-0377-6
Question 13: What monitoring and assurance processes, if any, should be considered to ensure My Health Record data secondary users comply with the Framework?

The processes discussed in Section 5.1 are reasonable. Any reporting and auditing processes should be monitored by the data custodian.

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

No comment

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?

ANDS endorses this suggestion. This information could be greatly enriched by including persistent identifiers (1) such as DOIs for publications and datasets (2), ORCIDIs for researchers (3), and RAIDs for research activities (4).

ANDS endorses the principle of making the publications resulting from use of this data open access in order to maximise research impact, and make research findings as available as possible to the community. Ideally these publications should be linked from the public register using DOIs.

In the case of studies that use My Health Record data but do not find any results that could be published in a peer-reviewed scientific publication, it would be helpful to the research community for a ‘final report’ of the project to be published on the public register. This would assist with (a) reducing bias of non-publication of results, and (b) reducing duplication of effort in an area which has already been found to have no results.

Any derived or related datasets may be able to be described in Research Data Australia (5), a data discovery service for research datasets within Australia. ANDS would be happy to discuss this further.

3. https://orcid.org/
Question 16: Are the existing penalties under the My Health Record Act sufficient?

No comment

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?

No comment

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?

No comment