RACGP

Royal Australian College *of* General Practitioners

RACGP eHealth & Practice Systems

Submission to the Department of Health on the *Development of a Framework for secondary use of My Health Record data*.

November 2017

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Introduction

The Royal Australian College of General Practitioners (RACGP) is Australia's largest professional general practice organisation representing over 35,000 members working in or towards a career in general practice. General practitioners (GPs) see approximately 85 percent of the population every year and collect, record and store comprehensive patient data. As such, we take the issue of secondary use of data in any context very seriously.

The RACGP welcomes the opportunity to provide written comment to the Department of Health on the development of a framework for secondary use of My Health Record data. We provide both high level feedback and specific comment on the consultation questions.

While there are clearly many potential benefits from using My Health Record data, the My Health Record is the patient's record. Therefore, proper consent procedures must be in place for the use of data not related to individual patient care. Clear and robust processes and systems to ensure appropriate protection for preparation and disclosure of information is essential. These processes and systems must be developed transparently and in close consultation with consumers and health professionals.

Secondary use of My Health Record data relies on the availability of high quality and usable data in My Health Record documents. Healthcare providers, in most cases the person's GP, are required to create quality data sets in local clinical systems and send this information up to the My Health Record. The RACGP has long advocated that there needs to be appropriate incentives in place to ensure this information is of sufficient quality for the intended purpose.

The enthusiasm of researchers to access My Health Record data needs to be tempered by a reminder that the primary purpose of My Health Record is for individual patient benefit. This primary use should not be diminished by secondary use.

The My Health Record opt-out model

The My Health Record consumer opt-out model, due to commence 1 May 2018, will automatically create a My Health Record for every Australian unless they specifically "opt out" of having a record. Under an opt-out system there is a need to ensure patients, especially those who are socially disadvantaged and those with poor health literacy, are made aware of how to opt-out of the system. It needs to be recognised that by not opting out patients provide standing consent for providers to post/upload information into their My Health Record. Clear information should be provided for carers and nominated and authorised representatives for those unable to make opt-out decisions for themselves.

Patient education needs to include a greater focus on access controls and the ability for the patient to limit the number of providers who are able to view their record.

Privacy and consent

One of the sacrosanct edicts of medical care is to protect the patient's privacy. Patients should be able to provide their clinician with all relevant information to enable the provision of high quality healthcare without concern this information could become public. Adequate safeguards and protections need to be in place for the patient and a proper privacy impact assessment should be conducted.

The RACGP believes there is still a lack of informed consent for patients registering for the My Health Record, posing significant risks and the potential for privacy breaches. Patients need to be fully aware of what they are consenting to, and need to be educated that new information may be added to their My Health Record - such as pathology and diagnostic imaging reports.

An appropriate consent model needs to be established for patients when they interact with My Health Record so they can make an informed decision about whether or not their information is used for secondary purposes. Patients need to understand who can apply to access data and how their data is provided and used outside of the My Health Record.

Assisted registration

Many users were provided assisted registration (by GPs as well as other organisations) to sign up for the My Health Record when it was first introduced. GPs participating in the assisted registration process ensured patients were adequately informed about the role and scope of the My Health Record using information provided at the time.

However, the information GP's used and the current *Assisted Registration - Essential Information*: https://myhealthrecord.gov.au/internet/mhr/publishing.nsf/Content/assisted-reg-essential-information does not provide any information on secondary use of data or research or its potential availability for use outside of Australia.

It is essential there is clarity on what information has been provided to patients at the time of registration to ensure patients fully understand what they signed up for. Under the My Health Records Act, Healthcare Identifiers Act and the Privacy Act, patients who have signed up to participate in the My Health Record agree to the use and disclosure of their information in order to populate their My Health Record and to facilitate the retrieval of healthcare information.

In addition, as the My Health Record has expanded patients may not be aware of new information being uploaded to their My Health Record. For example, information from the National Prescription and Dispense Repository (NPDR) commenced uploading from May 2013, and the upload of Pathology and Diagnostic Imaging commenced from April 2017.

Responses to consultation questions

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

Secondary use of My Health Record data should be for:

- public health purposes, such as population statistics showing disease trends and monitoring, prevalence and incidence. This could further the understanding of behaviour and lifestyle factors in disease management and prevention.
- research conducted by institutions with high quality ethics committees, which needs to be regulated by an overarching body independent of the My Health Record.
- clinical decision support.

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

While commercial and non-health related purposes are out of scope for the framework, the RACGP recommends:

- private insurance companies or legal firms should not be able to access My Health Record data
- data should not be used for any commercial purpose including, but not limited to, use for insurance purposes
- no WorkCover access
- no government access to data unless under the auspices of research organisations (as described in Question 1)
- care in how ethnicity data is used.

Data should not be used:

- to measure quality outcomes
- to manage performance by healthcare providers
- for pay-for-performance systems
- for practice or practitioners incentive payments
- for low quality, dubious or unethical research
- for revalidation of health professionals
- for remuneration or rebate claiming patterns
- for increasing competition between health providers.

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

Reputable public health, research and academic institutions and representative health professional bodies.

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

There may be requests for cooperative research from countries Australia has established research relationships with. As an example, the Centre for Disease Control (CDC) in the United States may wish to match Australian data with international data to determine the accuracy of conclusions regarding global population health. The protection of My Health Record data will largely be legislative and not technical and the potential misuse of data by non-Australian entities or researchers needs to be carefully considered.

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?

Release of data should be guided by an independent body with representatives from privacy groups, research institutions, expert medical research and ethics bodies. This independent body should be set up to assess each individual application for access to My Health Record data. The seven high level principles used for the integration of Commonwealth data for statistical and research purposes seem applicable & appropriate for this purpose.

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

Data protection regimes in Scandinavia and the UK are well regarded internationally and we strongly support setting up an independent body as custodian of My Health Record data. This independent body should be separate to government and any of its agencies.

Each application for secondary use of data must go through the relevant approval process and ethics approval prior to the release of any data. An ethics committee, which includes clinicians and consumers, should be part of the governance model.

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?

All requests for My Health Record data should be via an application process to the independent governing body. Applications should include the following information:

- security processes and procedures to ensure the appropriate use and management of the data
- how raw data will be destroyed when no longer required
- risk mitigations to protect against misuse
- compliance with relevant legislation
- any agreements with other organisations that may use the data
- how the data will be transmitted to ensure data security.

Appropriate due diligence needs to be in place to ensure those who have previously been provided data and have used the data unethically/inappropriately are not eligible to receive any further information.

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?

Any requests to use identified data should require the collection of specific informed consent of each individual patient for each use.

The overarching principles outlined in Questions 5 - 7 for the use of de-identified data should be applied to requests for identified data; additional strict data controls will be needed.

The identity and purpose of entities requesting access to identified data should be made publicly available as a means of assuring transparency.

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?

Any linking or combining of data has the potential to re-identify patients. The RACGP believes there should be strict controls to ensure that there is no possibility for re-identification. If data linkages have the potential to re-identify patients, then specific and individual consent should be required for the use of this data.

Using independent data linkage organisations could minimise the risk of data being re-identified if linked to other data sets.

From a healthcare provider perspective, linking datasets should not be used for:

- outcome quality measurements
- performance management
- pay-for-performance systems
- practice or practitioners incentive payments
- certain third parties including insurance companies, legal firms
- low quality, dubious or unethical research
- revalidation of health professionals
- remuneration review or (in)appropriate rebate claiming patterns.

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

An expert body independent of researchers should be established to manage linkage and re-identification purposes, such as the Swedish model mentioned in the report. It is important to maintain total de-identification of data and provide assurance individuals cannot be identified.

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?

An established independent body should have this responsibility as described in Question 10. This body should have special oversight arrangements in place to approve the use of My health Record data for research.

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?

Documents containing patient data in the My Health Record currently come from multiple sources across the healthcare sector. The RACGP believes it is not possible to make a statement about data quality. Data in My Health Record documents should be consistent, legible, accurate, relevant, accessible and timely to ensure high quality. There is at present no system in place to ensure information in My Health Record adheres to these attributes. Entities using My Health Record data need to be aware of this limitation.

The RACGP is particularly concerned data uploaded to the My Health Record by health practitioners will, in the future, become linked to quality criteria incurring penalties or attracting incentives. This would create obligations on health professionals or organisations sending data to the My Health Record and is not supported by the RACGP.

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

There should be very strict monitoring of this process as discussed in questions 5 and 6.

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

Recognising that nothing is guaranteed in the current cyber climate, applications for use of data must include data handling and disposal within their application.

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?

The RACGP believes a public register with the information above is important in the interests of transparency.

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

If the My Health Record Act does not currently explicitly include secondary use, then the penalties need to be updated to include this.

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?

Uncertain.

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?

Health information is regarded as one of the most sensitive types of personal information. The *Privacy Act 1988* (Privacy Act) provides additional protections around its handling. All organisations providing health services and holding health information are covered by the Privacy Act.

Any requests to use identified data should require the collection of specific informed *consent of each individual patient for each use*.