

ELECTRONIC HEALTH RECORDS AND HEALTHCARE IDENTIFIERS

Response to the Legislation Discussion Paper

June 2015

**RESEARCH
AUSTRALIA**

AN ALLIANCE FOR DISCOVERIES IN HEALTH



ABOUT RESEARCH AUSTRALIA

Research Australia is an alliance of 160 members and supporters advocating for health and medical research in Australia. Research Australia's activities are funded by its members, donors and supporters from leading research organisations, academic institutions, philanthropy, community special interest groups, peak industry bodies, biotechnology and pharmaceutical companies, small businesses and corporate Australia. It reflects the views of its diverse membership and represents the interests of the broader community.

Research Australia's mission is to make health and medical research a higher priority for the nation. We have four goals that support this mission:

- A society that is well informed and values the benefits of health and medical research.
- Greater investment in health and medical research from all sources.
- Ensure Australia captures the benefits of health and medical research.
- Promote Australia's global position in health and medical research.

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RESPONSE TO THE LEGISLATION DISCUSSION PAPER

INTRODUCTION

Research Australia welcomes the release of the Legislation Discussion Paper and is broadly supportive of the proposals contained therein.

Research Australia's submission focuses on opportunities to improve the usefulness of the PCEHR system for research purposes. Research Australia acknowledges that the PCEHR system's health information has not been used for research purposes to date. However, we expect the value of the system as a source of data for research to increase significantly over the next few years, particularly if it is redesigned as an 'opt out' system. It is important that the research potential of the system is considered now, when the opportunity to amend the legislation has arisen.

The My Health system has the potential to be an important resource for health and medical research, and for this research to be of enormous benefit to the community. This benefit can only be optimised if the data is as complete and comprehensive as possible, is made available for research purposes, and can be linked to other data sources.

The proposed change to an opt out system helps make the data more complete and comprehensive, and is supported by Research Australia. It does not however address the question of being able to link health information from the PCEHR system to other data sources. This submission makes a number of recommendations in relation to better recognising the role of the PCEHR system as a resource for research, and facilitating the linkage of PCEHR data with other data sources.

HEALTH RECORDS AS A RESOURCE FOR RESEARCH

The significant benefits of health records not only to individual patients and their healthcare providers but to the broader health system and community are well recognised, including by the Council of Australian Governments.

Building the evidence base and improving data collections

There is a need to continue research and data development to improve our collective knowledge and understanding of mental health and wellbeing, the many factors contributing to it, their interaction, and effective ways to improve and maintain mental health for people across the population.

For example, current Australian mental health and broader health data collections are inadequate in their description of the mental health and social and emotional wellbeing of Aboriginal and Torres Strait Islander people. Improvement of national data collections in these areas will be critical to the design and refinement of services and supports, and to the identification of service gaps. Similarly, evidence of systematically effective approaches to suicide prevention is scarce, but there is an imperative for governments, service providers and the community to perform better in this area. Suicide is a complex phenomenon and in 2010 was the leading cause of death for men aged 16–44.

New opportunities are enabling us to increase our knowledge of risk and protective factors for mental health in the early years, using data being collected through the national rollout of the Australian Early Development Index and associated research. Work is also starting on the measurement of social and emotional wellbeing and development in middle age. The value of these collections will increase as data accumulates over time and is linked to other data collections.¹

While this statement was made specifically in relation to mental health, the same opportunities to deliver better healthcare, improve health systems and inform prevention exist for all areas of health.

More recently the Productivity Commission has highlighted a role for the better use of data to help improve the efficiency of Australia's health system. Making data available to researchers is central to this task.

More generally, administrative data — including performance data, patient health records and government-held datasets on patients' use of medications or procedures — can support development of a more rigorous evidence base on the clinical and cost effectiveness of health interventions. Among other things, these data (subject to appropriate privacy safeguards) enable researchers to investigate the burden of disease, access to health care across the community, and the effectiveness of specific health interventions. This can help health care providers to choose the best treatments for individual patients. It also helps governments and insurers to make better overall funding decisions by directing funding to where the greatest health benefits can be achieved (including to preventive health measures), and away from interventions with low or no clinical value.²

¹ COAG, *The Roadmap for National Mental Health Reform 2012–22*, page 41

² Productivity Commission 2015, *Efficiency in Health*, Commission Research Paper, Canberra. p.75

THE PCEHR SYSTEM AND THE USE OF DATA FOR RESEARCH

As noted in the introduction, the My Health system has the potential to be an important resource for health and medical research, and for this research to be of enormous benefit to the community.

Use of the data for research purposes is consistent with the objects of the *Personally Controlled Electronic Health Records Act 2012* (the PCEHR Act). In particular, research undertaken using the health information in the PCEHR system can help to:

*... (c) reduce the occurrence of adverse medical events and the duplication of treatment; and
 (d) improve the coordination and quality of healthcare provided to consumers by different healthcare providers.³*

The PCEHR Act also specifies that the provision of data for research or public health purposes is a function of the PCEHR System Operator (section 15), and makes provision for Rules to be made in relation to this function (section 109). Unfortunately these provisions relate solely to 'de-identified data'.

This emphasis on de-identified data is at odds with section 24 of the *Individual Healthcare Identifiers Act 2010* (the IHI Act) which permits an IHI to be disclosed by a healthcare provider as part of the 'communication or management of healthcare information' for the purpose of research (approved by a Human Ethics Research Committee).

Research Australia acknowledges that researchers rarely need to know the identity of individuals, and that these exceptions typically relate to research activities such as clinical trials where the individual's consent to the provision of their health information can be obtained as part of their consent to participation in the trial. The real difficulty with the requirement that only de-identified data can be provided by the PCEHR operator is the limitation this imposes on the ability to link data from the PCEHR system with other data. Data linking is critically important to making the best use of data from different sources.

The recent consultation paper for the development of the Australian National Diabetes Strategy has proposed that data linking should be a key element of the Framework, and has clearly articulated the benefits of doing so.

Data linking

*Healthcare policies relating to chronic diseases such as diabetes should be informed by robust evidence generated for the Australian setting. Since 1992, every Australian who has consulted a doctor, had a medical test or been prescribed a medication has contributed to recorded health data. As a result, there are a number of existing datasets and databases, including the NDSS, the National Diabetes Register, the National Gestational Diabetes register, the Pharmaceutical Benefits Scheme, Medicare records, the AIHW, PCEHR, hospitals, and birth and death registries. Within the recognised legislative and privacy requirements, de-identified aggregate data derived from these **linked datasets** have the potential to provide valuable information about how people develop diseases (including diabetes); how diseases progress under different preventive and treatment strategies; and how health dollars can be more efficiently and effectively focused.⁴*

³ Section 3 of the PCEHR Act

⁴ National Diabetes Strategy Advisory Group, *A Strategic Framework for Action, Consultation paper for the Australian National Diabetes Strategy, 2015 page 32*

Again, while the proposal relates specifically to diabetes, the advantages of data linkage that are identified in this extract have more general application.

While not wanting to understate the difficulties in combining data from various sources across State and Territory boundaries and between separate institutions and systems, it is becoming easier to link existing databases and collections. Advances in data management and computing capacity are making it possible to combine large volumes of structured and unstructured data from multiple sources in ways that allow the data to be analysed to provide useful information.

The Population Health Research Network (PHRN) has been established by the Australian Government to build a nationwide data linkage infrastructure capable of securely and safely managing health information from around Australia. The PHRN is developing and testing leading-edge technology to ensure the safe and secure linking of data collections whilst working to protect individuals' identity and privacy. It is also developing mechanisms for the secure exchange of linkable data between those who hold the data collections (Data Custodians) and the researchers who receive approval to analyse the linked data. A key aspect of these arrangements is that the linked datasets provided to researchers do not contain the identifying information of the individuals whose data is included in the dataset, thus protecting their privacy.⁵

The National Statistical Service provides a Statistical Data Integration Framework for combining information from different administrative and/or survey sources to provide new datasets for statistical and research purposes.

As the PCEHR Act is currently drafted, the PCEHR Operator can only provide de-identified data for research purposes, effectively preventing data in the PCEHR system from being linked to other data sources. This in turn significantly limits the usefulness of the health information in the PCEHR system for research purposes.

Research Australia submits that the PCEHR Act should be amended to explicitly authorise the PCEHR Operator to use and provide identified data for research purposes. The new provisions could operate within the framework provided by the National Statistical Service's Statistical Data Integration Framework and accredited Integrating Authorities.

Research as a 'secondary purpose'

Research Australia accepts that research is a secondary purpose for the PCEHR system but believes that it is desirable that this is more explicitly recognised in the legislation.

Research Australia proposes that the provision of data for research be more explicitly recognised in the PCEHR and IHI Acts. For example, a note could be added to section 3 of the PCEHR Act along the lines of 'The object of the Act can be met in a number of ways including through making health information available for research purposes.'

⁵ Disclosure: Elizabeth Foley, CEO of Research Australia, is a member of the Board of the PHRN.

RESPONSES TO SPECIFIC PROPOSALS

Research Australia provides the following response to specific proposals made in the Legislation Discussion Paper (and uses the Paper's numbering system.)

3.2.1 ACEH Board

The Legislation Discussion Paper proposes

'the ACEH Board and its advisory committees will include individuals with expertise such as:

- (a) healthcare provision;*
- (b) consumer of health services;*
- (c) IT systems and innovation including health informatics;*
- (d) governance;*
- (e) clinical safety; and*
- (f) privacy and security.*

While supportive of the inclusion of these measures, Research Australia believes that the ACEH Board would benefit from the inclusion of one or more individuals with expertise in the use of population health data for research purposes. This would have several advantages, including assisting the Board in considering its strategy and approach to the use of the data for research purposes; strengthening the links to the research community; and supporting better policy development.

Research Australia submits that 'research' should be included as an area of expertise in the above list.

3.3.1 An opt-out PCEHR system

A question that arises with the opt-out system is how to deal with individuals who do not opt out initially but choose to do so at a later time. The Legislation Discussion Paper indicates that 'people will retain their right to cancel their PCEHR at any time.'

Further consideration needs to be given to the form this cancellation will take. Will it mean that all records relating to the individual will be removed from the system? Does it mean that records will be retained but will no longer be able available to the individual or health care providers?

Research Australia proposes that a 'prospective' cancellation, in which existing records are retained but no longer used for clinical purposes is preferable. The health information should remain available for research purposes. In particular, cancellation of a PCEHR must not require the removal of an individual's health information from datasets that have been created for research purposes.

3.4.8 Obligation for System Operator to retain records

Research Australia notes the proposal that:

'In order to help minimise the volume of records retained by the NRS, while still ensuring that records are retained for appropriate periods for clinical and other authorised purposes, it is proposed to amend this requirement so that records are retained for the longer of:

(a) 30 years after date of death; or

(b) if date of death not known, 130 years from the individual's date of birth.'

Providing for the removal of records after they are no longer needed for individual clinical purposes may appear to be good practice but it is not appropriate in this instance. While it is perhaps difficult to envisage at this early stage in its development, in future decades the health records in the PCEHR will form a very valuable source of information about changes over time in Australians' health and Australian health practice. While it may not be necessary for these older records to remain as readily available, the information should be archived in a manner that allows it to still be available for research purposes.

Research Australia submits that rather than retaining records until the longer of 30 years after date of death or 130 years from the individual's date of birth, records should be retained indefinitely.

3.5.3 Collection, use and disclosure of information

Research Australia supports the move to a more principles based approach to the collection, use and disclosure of information.

Research Australia proposes that research should be specifically included as a purpose for which information can be collected, used and disclosed.

The principles should allow information in health records and identifying information to be used and disclosed to the extent that the use and disclosure is necessary to achieve the aims of research. For example, this would allow the collection and use of identifying information by a data linkage unit such as the Australian Institute of Health and Welfare to create a dataset incorporating information from more than one source. De-identified data from the datasets can then be made available to researchers.

The adoption of a principles based approach would also enable a distinction to be made between the identifying information of an individual, an individual healthcare provider and a healthcare provider organisation. There may be circumstances where it is appropriate to provide the identity of healthcare provider organisations to researchers but not the identity of individuals or individual healthcare providers. (Only the latter two are protected by the Privacy Act.) The use and disclosure of health information could be limited to 'approved research', i.e research that has been approved by a Human Research Ethics Committee (HREC). An appropriate definition already exists in the IHI Act and could be replicated in the PCEHR Act.

If considered necessary, organisations able to receive identifying information of individuals and individual healthcare providers for research purposes could be listed in the regulations.

CONCLUSION

Research Australia has appreciated the opportunity to make this submission. The My Health System has the potential to be a very valuable resource for individual health consumers, health practitioners and the wider community, and is greatly enhanced by the proposed change to an opt out model. It is critical that the enormous potential benefits of the My Health System to support research are not lost due to unnecessarily restrictive provisions in the legislation in relation to the provision of data for research purposes. The mechanisms for the secure use of identified data for linking purposes already exist in the broader Commonwealth data management framework, and we urge the Government to take this opportunity to amend the PCEHR Act to ensure that identified data can be provided for research purposes subject to adequate safeguards.

We would be pleased to provide any further information you may require, or to discuss any of Research Australia's proposals further.

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