



The Royal Australasian
College of Physicians

**RACP submission: Development of a
Framework for Secondary Use of My
Health Record Data
November 2017**

Feedback

The Royal Australasian College of Physicians (RACP) welcomes the development of a Framework for the secondary use of data held in the My Health Record (My HR) system for research, policy, system use, quality improvement and evaluation activities (hereafter “the Framework”), and appreciates the opportunity to comment on the discussion paper. The development of the Framework is an opportunity to shape an important element of a health system that is capable of effectively and efficiently delivering Australia’s future health needs.

We also appreciate the measured and considered set of issues and options presented in the discussion paper, and commend the Australian Digital Health Agency for the orderly approach being taken at this time; including the appropriate timeframe for consultation.

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

This is an extremely important matter for our members and we would like it noted that we wish to be consulted in future about the Framework’s detail.

Overall, the RACP supports a robust and transparent Framework that permits appropriate access to secondary My HR data and governs its responsible use.

Observations and suggestions

1. The Framework should ensure that we are able to realise the substantial indirect benefits that can be gained from digital health technology, while preserving and enhancing trust and confidence in My Health Record (My HR) itself in both the public as well as in the medical community (including the medical research community).
2. We recommend that the Framework should, at least for the first few years, deliberately and strategically lean towards protecting privacy and away from more liberal provision of data, and that very significant safeguards accompany any release of identifying or potentially identifying information. This would maximise the public and medical profession’s trust in the system, and minimise risk of a privacy breach that would seriously impact confidence not only in My HR but in digital health more generally. For high risk data, we support the use of on-site secure laboratories and remote Secure Unified Research Environments. We suggest that there be a presumption that any identifying or potentially identifying data be categorised as high risk.
3. The broad policy aim of the Framework should be to drive high-quality research to improve health, including by promoting high-value evidence based care. However, within that broad aim and subject to the prohibition on exclusively commercial use, the Framework should permit access to any user that meets its criteria. To foster innovation and avoid the temptation to pick winners, the Framework should be researcher and project-neutral (within the strictures of the Framework’s safeguards). As a resource, aggregate My HR data should be treated as if it were owned by the Australian people whose individual information it is; moreover, they are the ultimate

beneficiaries of secondary use. Similarly, to foster innovation and research, if there are any fees related to access they should be minimal and limited to the administrative cost of providing the data.

4. My HR data can inform population-based health interventions and preventive strategies, and improve the evaluation thereof. For these purposes the Framework is crucial to encouraging a responsive health system that meets the needs of the population and is informed by evidence. In this sense the secondary use of My HR data can assist in linking health care of individuals to overall health of populations. (For a thorough explication of this notion, see the discussion of a “Learning Health System” in [Data for Individual Health](#), prepared for the Agency for Healthcare Research and Quality, particularly its concept of a “closed loop”, a “continuous and transparent cycle of research, analysis, development, and adoption of improvements relevant to health and wellness and to the delivery of health care.”)
5. The role of My HR data in improving medicine safety and vaccine effectiveness is potentially considerable, and it is an invaluable way to improve pharmacovigilance and quality use of medicine, including for biologics and emerging categories such as genomic medicine. Similarly, its relevance in the medium to long term for tracking and containing contagious disease outbreaks (such as Legionnaires’) or public health concerns (such as blood lead levels) is promising. However, we note that My HR is not a purpose-designed medicine safety mechanism or disease register, and that such purposes will remain complementary to existing epidemiological tools.
6. The Framework should facilitate continuous quality improvement—of clinical services and of health system performance more generally. An example of the former is the reduction of avoidable errors and complications. An example of the latter is linking hospitalisation rates with community based care for the purpose of identifying and analysing regional variation (among other variables), which has the potential to encourage better health system planning and more equitable allocation of health resources.
7. The Framework should be formulated in a way that is cognisant of people’s concerns that their data be kept secure and not be used in ways that might impact negatively on them. Public support cannot be assumed, and the impact of data security breaches or inappropriate use of data should not be underestimated. To continue building support for the use of secondary data, there needs to be ongoing communication on the benefits to patients and to Australian society; that extends beyond simple assurances privacy will be preserved. Tailored awareness campaigns should be considered beyond, and perhaps in concert with, 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 patients in a way that drives patient engagement and minimises opt-out. It is not clear from the details that are available whether secondary use of data will be incorporated into the patient consent process for the My Health Record but we strongly recommend that it is. This is irrespective of the move to an opt-out system. Legislative authority for secondary use is inferior to having informed consent from the perspective of patient

trust and confidence. The Productivity Commission includes an instructive discussion on these issues in its 2017 report on [Data Availability and Use](#), and we also found useful a paper by Yasmin Van Kasteren et al, [Consumer Perspectives on My Health Record: A Review](#). The latter includes an important discussion of the implications of personally controlled privacy settings in an opt-out environment for people who lack the means or ability to exercise that control (see 2.4. “Digital Divide: The Views of the Digitally Excluded”).

8. In relation to Question 4 (“[s]hould access to My Health Record data for secondary uses be restricted to Australian users only or could overseas users be allowed access?”), the RACP—being a trans-Tasman specialist medical college with Fellows and Trainees who live, work, teach, and research in both countries—does not favour a restriction of this type. We also note the increasingly international nature of contemporary medical research. Australia already benefits from and contributes to research in other countries and should continue to do so. The data from a more widely used My HR is likely to be highly valued by researchers from across the globe due to the quality and volume of the data, and Australia could and should play a strong role in contributing to increasing medical knowledge and its supporting evidence base. There is also the potential that this could support greater collaboration between the Australasian research community and international research partners.
9. We understand that The Human Genetics Society of Australasia (an RACP affiliated specialty society) is making a submission which notes the need not only to protect individual patients’ privacy but the privacy of their relatives. We endorse that suggestion.
10. We understand that The Australasian Society of Clinical Immunology and Allergy (ASCIA, an RACP affiliated specialty society) has a particular interest in medication allergies/adverse reactions, which is part of the patient-entered “personal health summary” section of My HR. ASCIA therefore supports access to this data by eligible researchers in the non-profit/academic sector with appropriate approvals from ethics panels and other relevant bodies. This information has crucial relevance to drug prescribing, pharmacovigilance and antibiotic stewardship. However, ASCIA has concerns regarding the quality, validity and usefulness of this data, due to the patient-entry model and limited data fields available. Examination of the data will be essential to document quality, and lead to potential improvements in the model of allergy and adverse drug reaction recording in electronic health records. We endorse these sentiments and concerns.
11. The Framework needs specific consideration of principles to guide the secondary use of data pertaining to Aboriginal and Torres Strait Islander peoples. These principles may be informed by the NHMRC’s forthcoming update to its [Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders](#). However, 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) and State and

Territory-based Affiliates of NACCHO, and Torres Strait Islander specific authorities. National governance arrangements may need adaptation at a State and Territory level given the diversity of Aboriginal peoples and Torres Strait Islanders across Australia and consistent with State and Territory legislation and specific HREC arrangements. Where possible, secondary use of data pertaining to Aboriginal peoples and Torres Strait Islanders should require approval from Aboriginal HRECs as these HRECs have specific expertise on these matters. Data custodians should be guided by these specific data governance agreements pertaining to the secondary use of data involving Aboriginal and Torres Strait Islander peoples. Amendments to the My Health Record Rules (2016) to permit secondary use of data involving Aboriginal and Torres Strait Islander peoples, should be developed in collaboration with NACCHO/Affiliates to ensure they offer the required legislative protections.

12. The Framework should incorporate and elucidate issues related to copyright restrictions that attach to the data and do not separate from it just because of de-identification (for example, documents such as specialist letters and digital information such as echocardiography).
13. There should be a public register that shows data requests, their purpose, the status of the request, what's been found by using the data, and any resulting publications. The register should also include denied requests and the reasons for denial.
14. A functional and effective Framework is not a substitute for appropriate ethics approval of particular projects for which data is sought or obtained. Similarly, ethics approval for those projects should not in itself satisfy the requirements of the Framework.
15. Steps should be taken to educate healthcare providers (of all professions) about the distinction between using My HR for its primary purpose-providing health care to an individual patient-and all other purposes, which are secondary. This is particularly important given easy health practitioner access to My HR and the temptation to access it for small-scale non-clinical reasons such as developing case studies and similar activities encouraged by CPD requirements under the National Registration and Accreditation Scheme. This is important because such small scale, low level, but nevertheless unauthorised access to data for secondary use is likely to be accompanied by practitioner non-compliance with the Framework (including out of ignorance), and is also likelier to result in data breaches (because of the informality that accompanies such access and the absence of proper research protocols, such as de-identifying data). This may be less an issue for incorporation into the Framework itself and more for practitioner education about the legitimate and proper use of My HR.
16. We suggest the Framework, in draft form, be well publicised (especially in the research community) and that the RACP be provided with an opportunity for input at that stage.
17. We also suggest the Framework, whatever its final form, should be comprehensively reviewed after three or five years. We also suggest that the responsibility for

ensuring the Framework's ongoing compliance and consistency with Commonwealth and state/territory privacy laws, as they are amended over time, be clearly located.