Development of a Framework for Secondary Use of My Health Record Data

MTAA Submission – December 2017

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

Level 12, 54 Miller St, North Sydney
NSW 2060 Australia
PO Box 2016 North Sydney
NSW 2059 Australia
P (02) 9900 0600
E mtaa@mtaa.org.au
www.mtaa.org.au

Executive Summary

The Medical Technology Association of Australia (MTAA) welcomes the opportunity to make a submission to inform the Department of Health regarding the "Development of a Framework for Secondary Use of My Health Record Data".

The MTAA is the national association representing 71 manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability. The MTAA's objective is to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

MTAA is of the view that there are significant benefits to the healthcare system arising from the secondary use of MyHR data and notes that several OECD countries, including France, Belgium, the UK and the US have already recognised the benefits of the secondary use of personal health data for research to improve patient care and health system performance.

The secondary use of MyHR data can support the implementation of value-based healthcare as it can:

- Inform a patient centric model of care;
- Reward the value, rather than the volume, of healthcare interventions to manage healthcare costs;
- Improve patient outcomes through allowing the identification of valuable medical interventions and informing best practice; and
- Capture data on outcomes that are important to patients.

Additionally, MyHR can collect data on medical devices which has the following patient benefits:

- Earlier identification of performance or safety issues with medical devices;
- Increased capacity to identify the patients that have used or have been implanted with a device the subject of safety concerns;
- Greater assurance about the level of data available to support market access and reimbursement decisions;
- Access to medical devices that enable patients to resume activities of daily living rather than just those which result in a clinical outcome; and
- Identification of better performing medical devices without the need for costly clinical registries and inform their treatment decisions.

MyHR data can also improve Australia's capacity to conduct clinical trials.

Given the above benefits, the framework being established by Government on the secondary use of MyHR data should ensure there is a balance between the capacity to access the data for valid uses that will progress healthcare in Australia and the need to maintain data security and individual privacy.

1. Potential Benefits of Secondary Use of My Health Record Data

1.1. Facilitation of implementation of value-based healthcare

MyHR data is critical to the implementation of value-based healthcare in Australia at a national or jurisdictional level and is consistent with Government's desire to contain healthcare costs and move to a patient-centric approach to healthcare.

Value-based healthcare is a patient-centric way to design and manage health systems that have the potential to deliver improved health outcomes at significantly lower cost.[1] In a value-based healthcare model, value is defined as the health outcomes that matter to patients divided by the costs incurred.[2]

There is currently no nationally consistent approach to deliver or fund value-based healthcare care in Australia, although some States and Territories are considering how this can be integrated into their current healthcare systems and there are even national initiatives (such as the Health Care Homes pilot program) which aim to provide a patient-centric approach to the way that primary health to high demand patient groups is delivered.

MTAA believes that MyHR data can be used to support stakeholders that wish to adopt a value-based approach to healthcare delivery and funding. This is because the use of aggregated MyHR data could allow for benchmarking, identifying population variations, clinical research and development of decision support tools for better patient value.[3]

As a consequence, the secondary use of MyHR data can reward the value, rather than the volume, of healthcare interventions to manage healthcare costs; improve patient outcomes through allowing the identification of valuable medical interventions and informing best practice; and capture data on outcomes that are important to patients.

To maximise the value of the data, MTAA considers that an "opt-out" approach will increase the capacity to provide rich and complete datasets[4] and would be consistent with the UK, where an "opt-out" system has been established for secondary use of electronic health record data, including prevention, diagnosis and medical research.[5]

1.2. Collection of real-world medical devices data with flow-on benefits to patients

Collection of medical device data under MyHR has the potential to transform the Health Technology Assessment *(*HTA)[6] process for medical devices at the marketing approval and reimbursement stages. It can also allow the strengthening of the post-market surveillance system which is intended to monitor for safety once medical devices enter the Australian market. These can have significant benefits for patients, which are discussed further below.

HTA for medical devices is generally more difficult than for pharmaceuticals as some attributes which apply

[1] World Economic Forum, 2017. *Value in Healthcare: Laying the Foundation for Health System Transformation*, Geneva, Switzerland.
[2] Porter, M.E. & Teisberg, E.O., 2006. *Redefining Health Care: Creating Value-Based Competition on Results*. Harvard Business Press.
[3] World Economic Forum, 2017.
[4] Reimer, S., 2012. *Current and Future Settings of Austrian Legislation – Regarding Electronic Health Records (EHR).*
[5] OECD, 2013. *Strengthening Health Information Infrastructure for Health Care Quality Governance: Good Practices, New Opportunities and Data Privacy Protection Challenges*, OECD Publishing, p. 63.
[6] HTA refers to the use of scientific evidence to evaluate the quality, safety, efficacy, effectiveness and cost-effectiveness of health services and health technology and in this submission, refers to the TGA marketing approval process and subsequent reimbursement assessment by the Medical Services Advisory Committee and the Prostheses List Advisory Committee.

to medical devices make the application of the 'gold-standard' trial design (randomised, controlled, double-blind) for pharmaceuticals difficult, inappropriate or not informative. This has been recognised by the Food and Drug Administration in the USA.[7]

Examples of the difficulties in meeting 'gold standard' clinical trial requirement include:

- Blinding of the treatment for the investigator is not feasible nor is it ethical to conduct a trial where the control group includes patients that undergo a sham surgical procedure or are implanted with a sham medical device. These introduce bias.

- Patient numbers recruited to medical device clinical trials are generally low because the number of patients being treated for a condition is generally smaller (due to a lower prevalence of the disease or a reluctance to be the first to undergo a new surgical procedure or be implanted with a new medical device). This makes the conduct of randomised controlled trials with sufficient statistical power difficult.

- The outcomes of clinical trials for medical devices are influenced not just by the device but also by how it is used, particularly where a surgical procedure is involved. Therefore, there is a 'learning curve' effect observed in clinical trials for such devices with outcomes improving the longer the trial continues as surgeons become more familiar with the surgical technique and/or the device. This can confound the effectiveness results reported in a clinical trial setting.

- Medical devices are subject to iterative improvements, based on user feedback. The level of evidence required in these cases is therefore often lower than for the original device and often, bench testing is sufficient to demonstrate the safety and efficacy of the improvements. Conducting costly clinical trials in these instances is not feasible and insistence on these would reduce patients access to improved devices. However, where this occurs, there is limited data of health or other outcomes associated with the changes to the device.

The above challenges can result in patients having market access delayed (or not having access at all) to beneficial treatments as Australian HTA assessors strive to seek the same evidentiary requirements for medical devices as they do for pharmaceuticals.

With access to real world data through MyHR, some of the above challenges can be used to 'fill in the gaps' in information obtained from clinical trials, particularly when it comes to reimbursement decisions. This strengthens the evidence base for decision makers and gives healthcare professionals and patients additional confidence in deciding on the benefits of a particular treatment. This means patients can be better informed of their treatment options and puts them at the centre of the decision making around their care.

Another issue is that the Australian HTA system focuses on the clinical outcomes achieved, with limited, if any, consideration of patient relevant outcomes. This narrow focus is contrary to a patient-centered care model and can deny or delay patients could significantly improve their quality of life. This is particularly important for implantable medical devices as quality of life improvements are a consideration as it is unlikely that a patient would undergo a surgical procedure for a condition where the patient has not symptoms. While patient relevant outcome measures do not supplement clinical outcomes, they do need to be considered in the context of deciding on what treatments should be made available to patients.

[7] U.S. Department of Health and Human Services, 2017. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm579842.htm (23.11.2017)

MyHR data can improve the current system as follows:

- *Strengthen the post-marketing surveillance process through a capacity to identify performance issues with some medical devices earlier and reduce reliance on adverse event reporting[8] to the TGA by healthcare professionals.*
- *Replace the need for costly registries or reduce the number of these which may be required to monitor safety or effectiveness – this will reduce costs to the industry which can flow to purchasers / payers.*
- *Replace the recently TGA mandated patient implant cards which are intended to allow patient to know what devices they have been implanted with. This approach is likely to be more successful in meeting the objectives of the patient implant cards than the cards themselves.*
- *Assist to fill gaps in clinical trial evidence and allow HTA bodies to implement alternative market access arrangements (such as managed entry / coverage with evidence development) to ensure medical devices are made available faster than currently.*
- *Ensure real-world data on health outcomes can be collected to determine the true performance of medical devices, addressing bias and confounding factors which arise in a clinical trial environment.*
- *Conduct secondary observational studies with a qualitative and statistical power to answer clinical questions previously untestable[9] in RCTs. This can be done with increased precision in the evaluation of diagnostics or therapeutics for select sub-populations.[10] It also allows for the investigation of small treatment effects that may be under-reported or even missed in underpowered RCTs.[11]*
- *Fill the gap around the outcomes associated with incremental innovation of medical devices and assist better targeting of areas for innovation.*
- *Capture data, and target commercial solutions, to patient groups experiencing less sthan optimal outcomes.*
- *Capture data on patient relevant measures (such as the International Consortium of Health Outcome Measurement (ICHOM) patient relevant outcome measures (PROMs) and patient relevant experience measures (PREMs)).[12]*
- *Inform the establishment of value based payment programs where payments are made in terms of outcomes observed.*

Patient benefits:

The benefits to individual patients or patient populations of collecting medical device data under MyHR are:

- Earlier identification of performance or safety issues with medical devices;
- Increased capacity to identify the patients that have used or have been implanted with a device the subject of safety concerns;
- Greater assurance about the level of data to support marketing approval or reimbursement decisions;
- Timelier access to a greater range of safe and effective medical devices where outcomes that matter to patients (such as independent resumption of activities of daily living or capacity to return to work), not just clinical benefits, are taken into account;
- Greater capacity to make informed decisions on device performance to inform treatment options;

[8] Reed, T.L. et al., 2016. *Adverse Event Triggered Event Reporting for Devices: Report of a Food and Drug Administration–Supported Feasibility Pilot of Automated Adverse Event Reporting*. Journal of Clinical Engineering, 41(2), pp.83-89.

[9] Untestable, as the exponential combinations of patients, conditions and treatments cannot be exhaustively explored by RCTs due to the large cost of adding even small numbers of patients.

[10] Ghassemi, M., Celi, L.A. & Stone, D.J., 2015. *State of the Art Review: the Data Revolution in Critical Care.* Critical Care, 19(1), p.118.

[11] Nair, S., Hsu, D. & Celi, L.A., 2016. *Challenges and Opportunities in Secondary Analyses of Electronic Health Record Data. In Secondary Analysis of Electronic Health Records*, Springer International Publishing, pp. 17-26.

[12] Van Tuykom, B. & Stoefs J., 2014. *How the NHS is leveraging ICHOM's Standard Sets for Value-Based Purchasing*. Cambridge, MA: International Consortium for Health Outcomes Measurement (ICHOM)

- Access to treatments that have been developed through identification of areas experiencing less than optimal health outcomes.

1.3. Increased capacity to conduct clinical trials

In Australia, clinical trials are facing a number of challenges that could lead to a decline in clinical trials being conducted.[13] Australia is currently the 3rd most expensive country to run a clinical trial and its advantage in terms of quality of healthcare and medical research is diminishing.[14]

In response to these challenges, MTPConnect has been established as one of six Federal Government Industry Growth Centers. Its main growth priorities are to "**Strengthen Australia as an attractive clinical trial research destination**", outlining the required actions in the ecosystem: **"improve the penetration, functionality and usability of national electronic health records"** and **"enabling frameworks to allow industry to have access to de-identified data".**[15]

MyHR data can assist reduce the issues related to patient recruitment and engagement for clinical trials which can delay study initiation and completion. With MyHR data, it will be easier to identify patient profiles which clinicians could then link to trial participation, and to design and assess the feasibility of new clinical trials.[16] It will also be easier to identify areas of clinical need or where suboptimal outcomes are being achieved to inform research and development for new interventions or technologies and then inform the basis of future clinical trials.

2. The MTAA responses to the specific questions:

Below is the MTAA response to some of the specific questions posed in the consultation document.

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

In addition to the opportunities identified in the previous sections, other opportunities include:

- identifying the policy levers from moving from population based healthcare to personalised consumer engaged healthcare; and
- creating transparency and national standards around health delivery and performance which will improve risk management, resource engagement and governance.

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

Data should not be used for:

- individual, political or singular corporate commercial gain; or
- consumer engagement outside personal or carer health goals.

[13] Health, D.o., 2017. *Half Yearly Performance Snapshot 1 July to 31 December 2016*, T.G. Administration, Canberra.
[14] Australia, M., 2011. *Keeping Clinical Trials in Australia - Why Action is Needed Now*, Canberra.
[15] MTP Connect 2017. *Medical Technologies and Pharmaceuticals. A Roadmap for unlocking future growth opportunities for Australia.*

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

In the interests of transparency and in achieving the Data Integration Partnership of Australia goals, there should be no restrictions to de-identified patient data. For example, academics, researchers, policy-makers, healthcare professionals and the healthcare industry all have a capacity to use the data to benefit patient and Australian healthcare outcomes.

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?

Access to overseas users should be allowed but its access should be regulated and monitored.

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?

Principles for data release could include ensuring:

- ethical considerations are met;
- patient privacy;
- data are protected from unauthorised access;
- data are used for benefiting patients and / or Australian healthcare.

Question 6: Which of the governance models described above should be adopted to oversee the secondary use of My Health Record data?

MTAA does not have the necessary knowledge to comment in depth on this. However, it is of the view that the governance processes for the release of the data should ensure the safety and privacy of the data but that it does not result in unduly cumbersome or costly processes.

Question 7: What principles, if any, should be adopted 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 fundamental principle is that the data is being used in an effort to advance patient and / or Australian healthcare.

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 purpose?

The MTAA cannot see the need for the medical device industry, or any other sector, to access identified MyHR data under this framework.

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?

There should be no restrictions on data linkage if the data is de-identified.

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

MTAA does not have a specific response to this question. However, it is of the view that data security and privacy are an integral part of the framework and the process need to be as stringent as possible in this regard.

Question 11: What precautions should be taken to reduce the risk of de-identified data from the My Health Record system being re-identified after release?

MTAA does not have a specific response to this question. However, it is of the view that data security and privacy are an integral part of the framework and high degree of caution needs ot be applied to the release of the data.

Question 12: 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?

MTAA does not have a specific response to this question. However, it is of the view that data security and privacy are an integral part of the framework and therefore the processes to prepare and release the data need to be as stringent as possible.

Question 13: 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 quality statement needs to be made by an entity with sufficient credibility to enable the data to be trusted by all stakeholders, including Government and HTA bodies.

Question 14: What monitoring and assurance processes, if any, should be considered to ensure My Health Record data secondary users comply with the Framework?

MTAA does not have a specific response to this question but acknowledges the importance that processes are put in place to ensure that the secondary use of data complies with the approved purpose for the use of the data and other specific release conditions.

Question 15: What risk mitigation strategies should be included in the Framework?

Risk mitigation strategies should include:

- managing data security;
- using the best practice for sharing, linking and analysing information;
- compliance monitoring.

3. Conclusion

Considering the many significant benefits associated with the secondary use of MyHR data to patients, the MTAA believes that, providing data privacy is secured, access to aggregated healthcare data contained in MyHR by researchers, academics, health professionals and the medical industry should be permitted.

In terms of the medical device industry, this will allow the sector to:

- Prepare submissions for HTA assessment through the TGA and Government reimbursement bodies with more patient relevant data in the 'real-world' setting without the need to establish costly patient or device registries in most instances;
- Facilitate the monitoring of safety and efficacy for medical devices and therefore ensure more timely responses to emerging issues;
- Inform collaboration on outcomes based payment models; and
- Allow for the development of medical device solutions to address areas of health experiencing less than optimal outcomes.