

Submission on consultation paper for the development of a framework for secondary use of My Health Record data

November 2017

Introduction

Thank you for the opportunity to provide a submission to the Development of a Framework for Secondary use of My Health Record Data. The main section of the submission is followed by responses to the consultation paper questions.

The Aboriginal Medical Services Alliance NT (AMSANT) is the peak body for Aboriginal community controlled health services (ACCHSs) in the NT. Our members are located right across the NT from Darwin to the most remote areas. The ACCHSs sector is the largest provider of primary health care to Aboriginal people in the NT. ACCHSs deliver comprehensive primary health care in an integrated, holistic, culturally secure framework which combines a population health approach with primary health care service delivery, and are also involved in diverse health research activities.

AMSANT considers that the timeline and scope of the consultation and Framework development process is inadequate and does not allow for meaningful engagement with our sector on such a complex and important matter. In addition, the questions posed by the consultation do not afford an opportunity to articulate fully the essential requirement for an Indigenous governance structure for the secondary use of My Health Record data.

AMSANT's concerns regarding the secondary use of My Health Data are focused on the need for strong protection of the rights and interests of Indigenous people in relation to their health data. The consultants should be aware that there are many examples of Aboriginal health data being misused or misinterpreted to the detriment of our communities. Strong safeguards are required to prevent unintended consequences of misconceived, culturally unsafe research, inaccurate interpretation and reporting, or the possible misuse of Aboriginal health data derived from the My Health Record. **Our strong view is that there needs to be a separate Indigenous controlled data governance structure for My Health Record data.**

Public consultation and engagement process

Given that the Commonwealth Government has been preparing for the development of this framework for over two years, the six weeks' timeframe of the consultation is inadequate and precludes effective information-sharing and consultation with ACCHS members across the NT, including in some of the remotest parts of Australia. The consultation forums which took place in Alice Springs on the 9th November and Darwin on the 10th November, were the only face to face opportunities to discuss the framework, with final submissions due by the 17th November, one week later.

The lack of opportunity for input is particularly disappointing given the expert knowledge and experience of our sector in the fields of electronic health records, data management, research and

governance of Aboriginal health data, and our contribution to the development and implementation of the My Health Record.

Our experience has highlighted the need for culturally competent and safe processes for consulting and engaging with Aboriginal patients about the My Health Record. The “Plain English” labelled version of the consultation paper is unsuitable for cross cultural and multi-lingual contexts where English is not a first language.

Indigenous governance

It is essential that the framework includes a strong Indigenous data governance structure to safeguard against the risks of inappropriate research as mentioned above, and also as an expression of the inherent rights we hold as Indigenous peoples. Development of the principles of Indigenous data governance has been contributed to from a range of sources including international instruments such as the UN Declaration of the Rights of Indigenous Peoples (UNDRIP) and the work of national Indigenous data bodies including the National Advisory Group on Aboriginal and Torres Strait Islander Health Information and Data (NAGATSIHID), and the Maiam nayri wingara Indigenous Data Sovereignty Network. A number of the Articles of UNDRIP, including Article 31, define rights to Indigenous autonomy in relation to internal and local affairs and in relation to our cultural, human and genetic resources. NAGATSIHID developed the National Aboriginal and Torres Strait Islander Health Data Principles endorsed by AHMAC in 2006. The Maiam nayri wingara Indigenous Data Sovereignty Network represents a growing Indigenous movement which asserts rights and control over data and how it is used in research. Emerging standards require Indigenous people to have the power to: (1) determine who is included and who should be excluded as Indigenous for the purposes of data collection; (2) ensure that data reflects our interests, values and priorities and (3) determine the content of data collected about us and who has access to these data. (Adapted from: Tahu Kukutai and John Taylor (eds). “Indigenous Data Sovereignty”.)

This in turn builds on existing longstanding Aboriginal action to take control of health services and health research that affect us, exemplified by the Aboriginal community controlled health sector. Our sector in the NT led development of electronic health records that are the forerunner of the My Health Record and we have used such records for over a decade to take control of our health and to improve the quality of our health services. Our existing ownership of our own health data through Aboriginal community controlled health services (ACCHSs) has driven our sector’s longstanding involvement in health research and AMSANT and a number of our member ACCHSs have our own widely recognised processes for assessing and approving health research projects, including projects that seek access to data held by ACCHSs. We have developed standards for the collection and use of data that are used in the assessment of health research projects and we also collect and use our own data for health research within the sector to improve the quality of service delivery.

This record of self-determined achievement will be compromised by the Commonwealth’s proposal for the secondary use of the My Health Record data should the framework for its use fail to include adequate provision for Aboriginal involvement in its governance. AMSANT’s understanding is that all data relating to Aboriginal people irrespective of where it is stored (in ACCHSs’ or Government databases) should be managed under Indigenous data governance principles, and the data contained in My Health Records and any consideration of its secondary use is no exception.

It is AMSANT's strong view that there is the need for a robust governance and ethics process in relation to My Health Record which is controlled by Aboriginal and Torres Strait Islander people. However, this is nowhere foreshadowed in the consultation discussion paper. The Commonwealth Department of Health appears to have overlooked the existing significant processes and standards in relation to the use of Indigenous data described above, and risks adopting an inadequate, backward-looking approach to dealing with data about Indigenous people's health.

This is also exemplified by the fact that in other comparable nations with Indigenous populations, Indigenous data governance standards are far in advance of those in Australia.

- In Aotearoa NZ, the Te Mana Raraunga Charter (an audit tool to assess frameworks) states principles of data sovereignty as they apply to Maori data. The charter was born in 2015 when the NZ Government launched two initiatives: the IDI (Integrated Data Infrastructure) which is a longitudinal dataset (and infrastructure) which links data across administrative systems (tax, health, education, justice, migration, benefits) with little Maori governance and likely to replace the census. Another is the New Zealand Data Futures. Strong links exist internationally with Indigenous data sovereignty networks in Australia, and many similarities apply.
- In Canada, OCAP® (Ownership, Control, Access, Possession) is a set of standards that establish how First Nations data should be collected, protected, used or shared. Since 2010, the First Nations Information Governance Centre (FNIGC) has operated on behalf of First Nations to ensure that OCAP is applied through a certification process for research projects, surveys and information management systems. More information on OCAP® can be located on the FNIGC website (<http://fnigc.ca/ocap.html>).
- Also in Canada, the Institute for Clinical Evaluative Sciences (ICES) in Ontario uses governance processes for use of routinely collected health data with Indigenous identifiers:
 1. Access to and use of data with Indigenous identifiers is approved by data governance committees organised and populated by the relevant Indigenous organisations.
 2. Linked datasets with Indigenous identifiers are not routinely available to researchers and analysts, who must make specific application and seek approval from the relevant data governance committee before they can access them.
 3. Researchers are required to discuss their projects with Indigenous community representatives, who may collaborate in the planning conduct and reporting of the studies.
 4. Researchers and staff at ICES participate in ongoing initiatives to orient them to Indigenous worldviews, research principles, and historical and social contexts.
 5. Staff at ICES are working with representative organisations to build capacity among Indigenous organisations and communities to train Indigenous analysts and epidemiologists.
 6. Study results are co-interpreted with the communities and their representatives, who have a lead role in deciding how the results will be communicated more widely.
- In the British Columbia First Nations' Data Governance Initiative (BCFNDGI <http://www.bcfndgi.com/>), First Nations across Canada are focusing on data governance and collaborating with the Canadian Government. Alberta has established a Regional First Nations Information Governance Centre which is primarily funded by Health Canada. Quebec First

Nations are working collaboratively to build data governance and information management capacity, working with their government partners to address their unique needs.

Developing a framework that includes strong Indigenous data governance

The international examples and Indigenous data governance initiatives in Australia referred to above, point to what is current and emerging best practice in data governance and should provide impetus for the Commonwealth to work collaboratively with relevant Indigenous organisations and community representatives on developing an appropriate governance structure for the use of Indigenous data in My Health Records. This will not be possible under the current limited consultation process and timeline.

Development of an Indigenous data governance structure will maximise the benefits of the secondary use of My Health Record data for Aboriginal and Torres Strait Islander peoples as well as for all Australians. Such a structure could build on the work of the Maïam nayri wingara Indigenous Data Sovereignty Network. Strong links exist internationally between Indigenous data sovereignty networks in Australia, the US¹ and Canada where data integration has created an opportunity to demonstrate the benefit of collaborating with first nations to improve national research standards.

It would also include Aboriginal peak body organisations, including the National Aboriginal Community Controlled Health Organisation (NACCHO), AMSANT, Aboriginal Peak Organisations of the NT (APO NT) and peak bodies from other jurisdictions. For example, AMSANT and our members have developed NT-specific/ service-specific Indigenous research governance processes, for assessing and contributing to cutting edge health research projects.

Initiatives by national research institutions can also provide guidance for developing the framework. The South Australia Research Accord developed by the Wardliparingga Aboriginal Research Unit of SAHMRI provides a set of principles that is relevant to the framework development:

Priorities: Research should be conducted on priorities arising from and endorsed by the Aboriginal community to enhance acceptability, relevance and accountability.

Involvement: The involvement of Aboriginal people and organisations is essential in developing, implementing and translating research.

Partnership: Research should be based on the establishment of mutual trust, and equivalent partnerships, and the ability to work competently across cultures.

Respect: Researchers must demonstrate respect for Aboriginal knowledge, Aboriginal knowledge systems and custodianship of that knowledge.

Communication: Communication must be culturally and community relevant and involve a willingness to listen and learn.

Reciprocity: Research should deliver tangible benefits to Aboriginal communities. These benefits should be determined by Aboriginal people themselves and consider outcomes and processes during, and as a result of, the research.

¹ <http://usindigenousdata.arizona.edu/>

Ownership: Researchers should acknowledge, respect, and protect Aboriginal intellectual property rights and transparent negotiation of intellectual property use and benefit sharing should be ensured.

Control: Researchers must ensure the respectful and culturally appropriate management of all biological and non-biological research materials.

Frameworks are also being developed for culturally safe and relevant practices in relation to emerging and advanced technologies such as genomics, genetic research and bio banking. SAMHRI has developed a South Australia research accord about bio repository, while the ANU National Centre for Indigenous Genomics (NCIG) is developing a framework to ensure Indigenous governance of, and the application of best practice for, the conduct of genomics research using the collection. NCIG has an Indigenous-majority Board. The significance for the My Health Record is underscored by recent approval of the National Health Genomics Policy Framework 2018-2021, by the COAG Health Council Ministers, which specifies a high-level national approach to policy, regulatory and investment decision-making for genomics.

These emerging and advanced technologies provide an important example of why strong Indigenous governance is needed to be included in the My Health Record secondary data use framework.

In contrast, it is of concern that the Commonwealth currently has limited mechanisms for accessing advice about Indigenous data issues. AMSANT is concerned that the National Advisory Group on Aboriginal and Torres Strait Islander Health Information and Data (NAGATSIHID) has been abolished, reducing Indigenous influence on data and how it is used.

These limitations are also apparent in the current consultation paper. Indeed, none of the framework development governance models presented in the consultation discussion paper (UK, Sweden, Scotland etc.) are from countries which have recognised and interact with indigenous population data and sovereignty principles and where governments successfully collaborate with first nations to improve national research standards.

Quarantining Indigenous data for a period of five years

AMSANT supports the suggestion of NACCHO and others that Indigenous My Health Record data should be quarantined from secondary use for at least five years after the initial development of systems for secondary use have commenced, and until systems and protections have been verified. This would allow sufficient time to enable the Commonwealth to work collaboratively with relevant Indigenous organisations and community representatives on the development of an Indigenous data governance structure for My Health Records. It would also allow for appropriate consultation with Indigenous patients on secondary use issues and to provide the necessary reassurance that their data is safe and will not be subject to inappropriate use.

Some specific concerns

Ethics

The consultation paper's proposed access and data release frameworks are all based on Commonwealth DOH, AIHW and PHRN models and processes, all of which provide for some form of ethics clearance but no actual Indigenous decision-making (as opposed to advisory) role,

represented at the highest level of governance within the framework. Rather, the emphasis is on ethical guidelines at the state and territory level or reference to ethics committees within government departments.

Human research ethics committees are important mechanisms for ensuring the ethical conduct of research. Secondary use of data pertaining to Aboriginal and Torres Strait Islander people should require approval from Aboriginal HRECs where these exist, as these hold specific cultural expertise. Approval should also be required from regional HRECs to ensure that use of data is subject to existing processes and regional expertise.

However, it is important to note that there is considerable variation in HRECs and limitations on their role. Aboriginal and regional HRECs on their own are insufficient to ensure cultural safety and appropriate Indigenous governance in relation to secondary use of data. HRECs are not a substitute for an Indigenous data governance structure.

Privacy issues and the public good

The model and rationale behind secondary use of My Health Record data is based on the Australian Privacy Act 1988. According to the Act, consent can be waived if it is impractical to gain consent and the public good outweighs the risk to an individual's privacy. In deciding what constitutes the public good, however, there is currently minimal opportunity for Indigenous community engagement or control.

Moreover, the Office of the Australian Information Commissioner, who is the independent regulator of the My Health Record, only protects "the privacy of the individual". Individual privacy is an inadequate standard in relation to Indigenous interests in data and does not take into account Indigenous-specific concepts of custodianship of information and knowledge and collective privacy that are important in cultural security and safety of Aboriginal research.

Further concerns relate to the proposed de-identification model, which is based on four principles which we are told guarantee privacy including Statistical Linkage Keys (which we understand to be easily breakable, re-identifiable, unsafe) and SURE (Secure Unified Research Environment based on US and UK privacy). Re-identification risk can threaten the social licence of data custodians but most relevant for Aboriginal data is the cultural licence to manage and use the data.

Opt out

The changes to My Health Record to opt out in 2018 have significant implications, including the need for robust Indigenous governance on the use of data and the need for appropriate processes to opt out. AMSANT believes the planned process for opt out are not adequate. Informed, prior consent is a key principle to Indigenous participation in research. Information about opt out and secondary use of data needs to be accessible, appropriate and meaningful.

The current, successful model being used in ACCHSs to register patients for the My Health Record is the assisted registration functionality built into Communicare and other clinical information systems (CISs). Assisted Registration allows health service patients to create a My Health Record with support from those whose health and wellbeing guidance they trust the most. The known customer model can be used to verify identity thereby removing the need for patients to provide 100 points of documented identification which is often difficult or impossible. Patients can elect, via a simple tick

box, to include or not, both the past two years' and future MBS and PBS data and linkages to the Australian organ donor register and the Australian immunisation register. With the support and guidance of trained health services staff, information can be translated into language to ensure patients are informed and understand the My Health Record. This registration process could be altered to assist clients to opt out, and also include an option for those that want a My Health Record, to opt out of secondary use of data, or for specific controls on their use of data.

Data linkage

The consultation paper suggests defining a role for a single accountable authority for the management of My Health Record data for secondary uses to minimise the risks associated with privacy and security breaches such as re-identification of data.

Current national principles require that high-risk datalinkage projects will be handled by an accredited Integrating Authority, currently limited in Australia to three bodies: AIHW, ABS and Australian Institute of Families Studies. Approval from an Integrating Authority requires the approval of all data custodians and relevant HRECs and data is only available through a Secure Unified Research Environment (SURE) and only to researchers who have signed an agreement of use and undertaken SURE training.

AMSANT does not consider the current and proposed arrangements are adequate to properly protect Indigenous interest in linked data. Where Indigenous people are not data custodians (as will most often be the case) or where there is not strong Indigenous representation in the governance of a project, there is no guarantee of ensuring the cultural safety and security of research.

AMSANT does not believe that a single accountable authority for the management of the secondary use of My Health Record data can adequately incorporate a sufficiently strong Indigenous data governance role. Our view is that there needs to be a separate Indigenous controlled data governance structure for My Health Record data, that is also represented at the highest governance level.

Research transfer, data quality, compliance and monitoring

Research or knowledge transfer is a key aspect of Indigenous research, however, it is not addressed in the framework consultation paper. This includes the need for publications protocols and review rights and processes in relation to research involving Indigenous data.

The consultation paper mentions raw data transfer platforms, but no processes for monitoring of data analysis and quality.

There is also no consideration of monitoring or enforcement mechanisms to address non-compliance or mishandling of data or data results in ways which can be detrimental to Aboriginal people.

These issues need to be fully explored and incorporated into the development of the framework.

Response to Public Consultation Questions

<p>Question 1: What secondary purposes, if any, should My Health Record data be used for?</p>
<p>Valid population level health research providing solid Indigenous governance structures in place (government custodianship to research institutions, analysis and ethics) and guided by National Indigenous data sovereignty principles.</p>
<p>Question 2: What secondary purposes should My Health Record data not be used for?</p>
<p>Commercial uses, corporate uses, international researchers Individual personal financial (ie tax, Centrelink etc) cross referencing/data linkage with other compliance related services. Small geography/cultural cohort analysis.</p>
<p>Question 3: What types of organisations/individuals should be able to access My Health Record data for secondary purposes?</p>
<p>Research institutes Aboriginal-led research institutions, ACCHSs and organisations that demonstrate adherence to Indigenous data governance principles.</p>
<p>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?</p>
<p>Australia only. It is impossible to monitor and control use of data outside of national legislation and guidelines.</p>
<p>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?</p>
<p>The framework should include principles of Indigenous data governance, the development of which has been contributed to from a range of sources including international instruments such as the UN Declaration of the Rights of Indigenous Peoples (UNDRIP) and the work of national Indigenous data bodies including the National Advisory Group on Aboriginal and Torres Strait Islander Health Information and Data (NAGATSIHID), and the Maiam nayri wingara Indigenous Data Sovereignty Network. A number of the Articles of UNDRIP, including Article 31, define rights to Indigenous autonomy in relation to internal and local affairs and in relation to our cultural, human and genetic resources. NAGATSIHID developed the National Aboriginal and Torres Strait Islander Health Data Principles endorsed by AHMAC in 2006. The Maiam nayri wingara Indigenous Data Sovereignty Network represents a growing Indigenous movement to assert rights and control over data and how it is used in research. Emerging standards require Indigenous people to have the power to: (1) determine who is included and who should be excluded as Indigenous for the purposes of data collection; (2) ensure that data reflects our interests, values and priorities and (3) determine the content of data collected about us and who has access to these data. (Adapted from: Tahu Kukutai and John Taylor (eds). "Indigenous Data Sovereignty".)</p> <p>This in turn builds on existing longstanding Aboriginal action to take control of health services and health research that affect us, exemplified by the Aboriginal community controlled health sector. Our sector in the NT led development of electronic health records that are the forerunner of the My Health Record and we have used such records for over a decade to take control of our health and to</p>

improve the quality of health services. Our existing ownership of our own health data through Aboriginal community controlled health services (ACCHSs) is now compromised by the Commonwealth's proposed secondary use of the My Health Record data should there be inadequate provision for Aboriginal involvement in its governance.

The ACCHS sector has also long been involved in health research and AMSANT and a number of our member ACCHSs have our own widely recognised processes for assessing and approving health research projects. We have developed standards for the collection and use of data that are used in the assessment of health research projects and we also collect and use our own data for health research within the sector to improve the quality of service delivery.

AMSANT'S understanding is that all data relating to Aboriginal people irrespective of where it is stored (in ACCHSs' or Government databases) should be managed under Indigenous data governance principles, and the data contained in My Health Records and any consideration of its secondary use is no exception.

The Commonwealth Department of Health appears to have overlooked the existing significant processes and standards in relation to the use of Indigenous data described above and risks adopting an inadequate, backward-looking approach to dealing with data about Indigenous people's health.

This is also exemplified by the fact that in other comparable nations with Indigenous populations, Indigenous data governance standards are far in advance of those in Australia.

- In Aotearoa NZ, Te Mana Raraunga Charter (an audit tool to assess frameworks) states principles of data sovereignty as they apply to Maori data. The charter was born in 2015 when the NZ Government launched two initiatives: the IDI (Integrated Data Infrastructure) which is a longitudinal dataset (and infrastructure) which links data across administrative systems (tax, health, education, justice, migration, benefits) with little Maori governance and likely to replace the census. Another is the New Zealand Data Futures. Strong links exist internationally with Indigenous data sovereignty networks in Australia, and many similarities apply.
- In Canada, OCAP® (Ownership, Control, Access, Possession) is a set of standards that establish how First Nations data should be collected, protected, used or shared. Since 2010, the First Nations Information Governance Centre (FNIGC) has operated on behalf of First Nations to ensure that OCAP is applied through a certification process for research projects, surveys and information management systems. More information on OCAP® can be located on the FNIGC website (<http://fnigc.ca/ocap.html>).
- Also in Canada, the Institute for Clinical Evaluative Sciences (ICES) in Ontario uses governance processes for use of routinely collected health data with Indigenous identifiers:
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 8. Linked datasets with Indigenous identifiers are not routinely available to researchers and analysts, who must make specific application and seek approval from the relevant data governance committee before they can access them.

9. Researchers are required to discuss their projects with Indigenous community representatives, who may collaborate in the planning conduct and reporting of the studies.
 10. Researchers and staff at ICES participate in ongoing initiatives to orient them to Indigenous worldviews, research principles, and historical and social contexts.
 11. Staff at ICES are working with representative organisations to build capacity among Indigenous organisations and communities to train Indigenous analysts and epidemiologists.
 12. Study results are co-interpreted with the communities and their representatives, who have a lead role in deciding how the results will be communicated more widely.
- In the British Columbia First Nations’ Data Governance Initiative (BCFNDGI <http://www.bcfndgi.com/>), First Nations across Canada are focusing on data governance and collaborating with the Canadian Government. Alberta has established a Regional First Nations Information Governance Centre which is primarily funded by Health Canada. Quebec First Nations are working collaboratively to build data governance and information management capacity, working with their government partners to address their unique needs.

These international examples and Indigenous data governance initiatives in Australia referred to above point to what is current and emerging best practice in data governance and should provide impetus for the Commonwealth to work collaboratively through appropriate engagement processes with relevant Indigenous organisations and community representatives on developing appropriate principles for the use of Indigenous data in My Health Records. This will not be possible under the current limited consultation process and timeline.

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

This is a leading and inappropriate question: the Framework, set of principles, and definitions of governance and processes which are proposed in this document are derived from AIHW, ABS, DHS and DOH and models in UK, Sweden, Finland, and Scotland. These sources adopt a dominant culture framework and do not incorporate Indigenous data governance principles. See Q6 above for suggested more relevant Indigenous models.

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?**

It is surprising that the question contemplates not adopting any principles in relation to accessing de-identified data. This is an unthinkable option.

The releasing of de-identified My Health Record data for secondary undetermined purposes including such high-risk activities linked to new technologies as data linkage, genomics, commercial uses and even international research as suggested by the consultation document, is extremely complex and multilayered.

AMSANT’s view is that the principal means of ensuring appropriate access to de-identified data is through a strong Indigenous data governance structure.

There are many existing national and international principles which are relevant here. They have been discussed in Question 5 and will not be repeated here. These apply to data access and approval as well as to data release.

A core principle in research is that of prior and informed consent, that applies in much broader contexts as well as to the very process of engagement for the secondary use consultation.

It is unclear how the process of opting out of having a My Health Record in 2018 can be separated from the opting out of secondary use of data. There must be a clear opt out process specifically for the secondary use of data from a person’s My Health Record. There are additional risks for Indigenous Australians who experience multiple barriers to access, including a lack of or unreliable online access, remoteness and language barriers. Requiring online access to create or access their MyGov account and opt out, or dropping into their local Medicare service centre or call a 1800 helpline are not sufficient mechanisms to address these barriers.

Widespread community information and education must take place on the ground about the opt out of My Health Record and secondary uses of data. A strategy must be developed collaboratively with our sector and services on the ground, that is culturally appropriate and includes use of interpreters where necessary. This would need to occur after the overarching framework has been developed.

Informed consent is included as a principle in the National Aboriginal and Torres Strait Islander Health Data Principles:

***Principle 5:** In general, free and informed consent should be obtained from Aboriginal and Torres Strait Islander peoples prior to any information management activities, except where mandatory reporting or legislative provisions apply. Otherwise, where there is a proposal to initiate an information management activity without the consent of Aboriginal and Torres Strait Islander peoples, it must be clearly demonstrated both that the activity will advance the interests of Aboriginal and Torres Strait Islander peoples and that it is impractical and infeasible to obtain further specific consent.*

Informed consent in the context of the My Health Record:

- **must be** obtained at point of contact/service delivery
- in the ACCHS sector that may entail additional resources be developed collaboratively to ensure consent processes are appropriate in an intercultural and multilingual context
- requires understanding who has access to his/her data, and for what purpose/s
- requires understanding when their data is aggregated and summarised and for what purpose/s; and understand how the data is protected from inference or misuse
- understanding how long data is retained, and how is data is protected when shared.

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?**

Only Informed consent should apply.

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?

Datalinkage is a particularly powerful methodology and should be considered high-risk (the proposed framework identifies only limited cases when it may be high-risk).

It is essential that Aboriginal research criteria should apply and specific project governance strengthened so that there is Indigenous oversight of the research results and any ongoing storage or use of the data.

There are added risks associated with ‘big data’ and linked data including:

- Data is mostly owned by government with no Indigenous input into what data are shared and for what purpose/s;
- Indigenous methodologies are not normally used for project design, data collection and analysis;
- Most big data sets are collections of deficit data, particularly as these data relate to Indigenous people, and lack data on cultural and community characteristics. The lack of contextual data and understanding regarding cultural and community matters means there is a high risk of misguided research and/or inaccurate interpretation of data and reporting of research relating to Indigenous people;
- Complexity limits analysis to elite of non-Indigenous analysts;
- As secondary data, consent is usually not considered necessary.

Linked datasets should never be used to track or trace individual patients for compliance purposes. We are concerned about the safety of linkage processes, SLK in particular, which are potentially re-identifiable and are less accurate for Indigenous populations. Re-identification of individuals should as far as possible not be technically possible and should be subject to legal sanctions if breached.

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

For protection of an individual’s privacy, the processes provided should be used in particular the separation principle. We are concerned about the safety of linkage processes, SLK in particular, which are potentially re-identifiable and are less accurate for Indigenous populations.

The Western interpretation of individual privacy used here does not take into account Indigenous-specific models of custodianship of information and knowledge and collective privacy. These include:

- collective governance and privacy concerns, leadership and decision-making.
- Aboriginal communities may view the publication and use of aggregate data as an invasion of communal privacy in circumstances where the same type of data use may not present concerns for non-Aboriginal communities.
- De-identification for small, remote communities presents different challenges: a community or person could be identified by a small amount of data, eg, age range and location.

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?

This situation should be captured by post research auditing processes as a monitoring mechanism.

We support the Privacy Amendment (Re-identification offence) Bill 2016 that is currently before the Senate, that will make re-identification a criminal offense.

See above: separation principles, issues with collective privacy and SLKs.

The document mentions re-identification as presenting a risk to the social licence of data custodians. However, emerging Indigenous data sovereignty principles require asking data custodians to also assess cultural licence criteria, as social licence is not sufficient when dealing with the cultural dimensions of Indigenous data. This Framework does not address cultural licence in any way.

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?

As above, an appropriate Indigenous data governance model should oversee these arrangements for any data release relating to Indigenous peoples.

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?

There are a number of data quality issues. This document doesn't present a clear evaluation of the data quality issues to be considered.

ACCHSs have a high degree of expertise regarding their patient's data and data quality issues associated with My Health Record data. The ACCHS sector should be involved in developing processes for ensuring data quality.

Indigenous identifiers are incomplete in many data collections including Medicare, and this needs to be addressed as a first step in ensuring good data quality.

Undercounting of Indigenous people in the Census needs to be addressed to ensure accurate denominators. If an individual has duplicate My Health Records, there needs to be a mechanism to merge them.

Statistical records in various datasets also do not reflect the diversity in language, tribal and country affiliations of the many Aboriginal and Torres Strait Islander nations in Australia.

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

It is surprising that this question contemplates not applying any monitoring or assurance processes. Compliance is a key component of any research but in particular Aboriginal research.

Currently, the Privacy act exempts statutory government agencies and accidental disclosure and access and use in some cases.

The document gives a very rough outline of the risk mitigation strategies, and it is therefore difficult to assess what means there are to ensure compliance by law.

Strict legislated guidelines are needed, rather than relying on researchers to self-monitor and self-evaluate.

External independent overseeing and monitoring is required.

Legal penalties, Random audits, periodic reporting, ongoing evaluation.

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

The principal means of risk mitigation should be a sound Indigenous governance process, spanning data collection to storage, use, analysis and publication.

Commercial interests should not have access to data.

Integrated data authorities should only be used for data linkage. However, it is necessary to include Indigenous governance mechanisms, which are not presently in place.

Need for independent legal opinion.

The framework should be developed with an Indigenous data specific risk strategy.

Tailored threat risk and privacy impact assessments need to be conducted:

- For example, the recent addition of genomics to the secondary use of data (recent COAG announcement) raises additional risks for Indigenous people in Australia.
- Genomics is a particularly sensitive and controversial area of medicine which requires strong safety and risk mechanisms that include solid Indigenous governance.
- For example: Indigenous experience worldwide with the Human genome project showed widespread exploitation by multinational drug companies with little benefit or control for the Indigenous populations subject to material and data collections.

Question 16: Should there be a public register which shows which organisations/researchers have requested data, the purpose, the status of their data request, what they have found by using the data; and any publications that have resulted from using the data?

Yes, with the ability to comment and contribute to the process of evaluating quality, value, impact and relevance.

There needs to consultation about the location and governance of the public register and whether it should also include a monitoring role.

The register should be accessible and relevant to community organisations.

Question 17: Are the existing penalties under the My Health Record Act sufficient?

No, the current penalties are insufficient:

- government excluded, accidental disclosure etc
- only individual privacy considered

Legal advice should be sought.

Question 18: 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?

A national policy on Indigenous data governance and research should be developed specifically considering the proposed future National data infrastructures.

Question 19: Additional points

Missing from the framework and questions is research dissemination, knowledge transfer and research into practice processes and framework.

The framework must include a research dissemination strategy which demonstrates benefit, engagement with data custodians and communities, capacity building for Aboriginal people and organisations in the new fields of data knowledge such as data linkage, genomics and quantitative research.

The following principles should to be considered in relation to these issues:

Principle 9: Aboriginal and Torres Strait Islander communities should be provided with feedback about the results and possible implications arising from data analysis. *(National Aboriginal and Torres Strait Islander Health Data Principles)*

Principle 10: Information collections require regular review and refinement in order to ensure ongoing relevance to service delivery and the potential for improved health outcomes. *(National Aboriginal and Torres Strait Islander Health Data Principles)*

Principle 13: Plans should be agreed for managing use of, and access to, research results.

- Identify at the start of a research project all Indigenous people, organisations and communities who will need to be involved in determining strategies for access to research results.
- Agree on the rights to research results, their forms and presentation, and individual or community use of them.
- This may involve ongoing access to data or representations of the results of research through digital media. ...”

(Guidelines for Ethical Research in Australian Indigenous Studies. AIATSIS, 2nd ed., 2011, pages 15-16.)