Commonwealth Department of Health

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

Community Consultation Summary Report

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Abbreviations

AANMS	Australasian Association of Nuclear Medicine Specialists
ABS	Australian Bureau of Statistics
ACAM	Australian Centre for Airways disease Monitoring
ACCHS	Aboriginal Community Controlled Health Services
ACCRM	Australian College of Rural and Remote Medicine
ACHI	Australian College of Health Informatics
ACQHSC	Australian Council for Quality Health Service
ACRRM	Australian College of Rural and Remote Medicine
ACT	Australian Capital Territory
ADHA	Australian Digital Health Agency
AHHA	Australian Healthcare and Hospitals Association
AHMAC	Australian Health Ministers Advisory Council
AIHW	Australian Institute of Health and Welfare
AMA	Australian Medical Association
AMSANT	Aboriginal Medical Services Alliance Northern Territory
ANDS	Australian National Data Service
CALD	Culturally and Linguistically Diverse
CCHRN	Consumer and Community Health Research Network
CHF	Consumers Health Forum
CMCRC	Capital Markets Cooperative Research Centre
DHHS	Department of Health and Human Services
FAIR	Freedom of Access to Information and Resources
FECCA	Federation of Ethic Communities' Council of Australia
GaRDN	Genetic and Rare Disease Network
GPMHSC	General Practice Mental Health Standards Collaboration
HISA	Health Informatics Society of Australia
HREC	Human research ethics committees
JJFC	Johnson Family of Companies
MBS	Medicare Benefits Schedule
MHR	My Health Record
MSIA	Medical Software Industry Association
MHR	My Health Record
NACCHO	National Aboriginal Community Controlled Health Organisation
NAPWHA	National Association of People with HIV Australia
NGO	Non-government organisation
NHMRC	National Health and Medical Research Council
NPS	National Prescribing Service
NSW	New South Wales
NT	Northern Territory
OAIC	Office of the Australian Information Commissioner
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PCEHR	Personally Controlled Electronic Health Record
PHN	Primary Health Networks
PHRN	Population Health Research Network
PLHIV	People living with human immunodeficiency virus
QLD	Queensland
RACGP	Royal Australian College of General Practitioners
RACP	Royal Australasian College of Physicians
RWD	Real World Data

SLK	Statistical Linkage Key
SURE	Secure Unified Research Environment
WA	Western Australia
WAPHA	Western Australian Primary Health Alliance

Executive Summary

HealthConsult, as leader of a Consortium consisting of two commercial Firms and eight subject matter experts, was engaged on 24th June 2016, by the Department of Health (the 'Department') to:

"develop a Framework for the secondary use of data in My Health Record system"

A key task in developing the Framework was to design and conduct a consultation process to facilitate a public conversation about the future possible secondary uses of MHR system data (there is currently no secondary use). Stakeholders engaged strongly with the consultation process, with 714 individuals attending webinars (159), workshops (256), interviews (25), or completing a written survey (274); and 80 organisations/individuals making a written submission. This document summarises the key themes that emerged under each of the consultation questions (grouped as appropriate). **It is only a report of the consultation process, and it should not be read as the likely content of the Framework**.

A thematic analysis of the findings from the consultative process is presented in the Chapters that follow. Key conclusions that can be drawn from the consultation process are:

- There is strong support across all stakeholder groups for the secondary use of MHR data, with a common view being that this emerging public asset must be used for public benefit
- Stakeholders support a wide range of research, policy, program and service development uses, but use for solely commercial or non-health purposes is not supported by the vast majority
- Stakeholders do not support the secondary use of MHR data for the purposes of remunerating or for audits or other processes aimed at evaluating the performance of clinicians
- There is some support for secondary use of MHR data by commercial Firms as long as there is a public health benefit, but there are also some who oppose any secondary use by a commercial Firm
- There is some support for allowing secondary use of MHR data by overseas users (to support international research collaborations), but the prevailing view is that data must be stored in Australia
- Stakeholders have provided guidance on a wide range of principles to be applied to guide the release of MHR data for secondary use, and strongly advocated drawing from the best of existing approaches
- There is strong support for an independent body to govern the secondary use of MHR data, but there is also support for governance by the Department of Health, Australian Institute of Health and Welfare (AIHW) and, to a lesser extent, Australian Digital Health Agency (ADHA)
- Whatever the governance authority, stakeholders want membership of the governance committee to include independent experts, as well as strong consumer and Indigenous representation
- Most stakeholders believe that ethics approval should be obtained for secondary use of de-identified MHR data, and applications for data access should demonstrate a public benefit
- In addition, for secondary use of identified MHR data, most stakeholders believe that informed consumer consent should be obtained
- There is strong support across stakeholders for data linkage of MHR data to other (particularly health) data sets to be done by an Accredited Integrating Authority, to further leverage benefits from the MHR system
- Stakeholders believe that privacy protection is paramount and a 'privacy by design' approach should be adopted in developing the Framework
- Stakeholders have provided guidance on a wide range of approaches to privacy protection and advocated that a 'best of breed' approach is taken in developing the Framework

- Stakeholders believe that MHR data should be released for secondary use using a variety of mechanisms determined using a risk based approach, ranging from publication of key statistics, through to the release of controlled data (data cubes), through to access to unit record data in a secured environment
- Stakeholders strongly support a robust range of monitoring and assurance process from users signing confidentiality undertakings through to random audits of users to ensure that any MHR data released for secondary use is only used for the approved purposes
- Stakeholders have provided guidance on risk mitigation strategies around secondary use of MHR data that includes users meeting minimum standards for data security infrastructure, users being trained and/or accredited, and users providing annual and end-of-project compliance reports
- Stakeholders strongly support a public register that includes details of requests for access to MHR data for secondary use as well as publications reporting the outcomes of the secondary use
- Stakeholders have a mixed view of penalties for misuse of MHR data with some considering the existing arrangements adequate and others advocating a stronger penalty regime
- Stakeholders believe the current policy/legislative environment is complex, and they would like to see changes to harmonise the various polices/legislation to be explicit around secondary use of data

Overall, the stakeholder engagement process has generated considerable and very valuable input into the development of the Framework. There is a widespread recognition of the public good benefits that can be obtained through the secondary use of MHR data. There is also a strong understanding of the risks, and it is clear that the initial Framework must take a cautious approach to ensure that the existing social (and cultural) licence to use the MHR data for secondary purposes is not eroded. Subsequent updates to the Framework may take a more liberal approach, once processes, procedures, mitigation strategies, and so on have been tried, tested and refined. To this end, an evaluation of the effectiveness and impact of the initial Framework after two years or so of operation would be a very worthwhile endeavour.

The stakeholder engagement process also generated a variety of inputs on the next steps in the Framework development process, which can be summarised as:

- Stakeholders advocate the release of a draft Framework for further public consultation, and many of them have expressed a desire to be involved in that process
- Stakeholders advocate much stronger engagement with the Indigenous sector in the development of the Framework, specifically the consideration of a separate Framework and separate governance process for the secondary use of MHR data about Indigenous people
- There is a widespread view amongst stakeholders that development of the Framework should take into account the Government's response to the recommendations of the Productivity Commission's Inquiry into Data Availability and Use (it is understood that this response is not yet available)
- Stakeholders believe that the question of charges for access to MHR data for secondary use should be directly addressed in the Framework
- Stakeholders believe that consumers should be offered the opportunity to expressly consent (dynamic consent is preferred) to, or opt out of, the use of their MHR data for secondary purposes, and that implied consent through an opt out process around primary use is inferior
- A number of stakeholders believe that the final draft Framework should be subject to a full Privacy Impact Assessment
- Many stakeholders advocate for a communications campaign (with tailoring as required for Indigenous and CALD communities) to make the public aware of the intended use of MHR data for secondary purposes (and the associated benefits).

HealthConsult will proceed to develop the draft Framework with regard to the input generated via the stakeholder engagement process. Advice on the process issues raised by stakeholders will be appreciated.

1 Introduction

HealthConsult, as leader of a Consortium consisting of two commercial Firms and eight subject matter experts, was engaged on 24th June 2016, by the Department of Health (the 'Department') to:

"develop a Framework for the secondary use of data in My Health Record (MHR) for research, policy, system use, quality improvement and evaluation activities"

A key task in developing the Framework was to design and conduct a consultation process to facilitate a public conversation about the future possible secondary uses of MHR system data (there is currently no secondary use). This document describes the consultation process, summarises the key themes that emerged under each of the consultation questions (grouped as appropriate).

1.1 BACKGROUND

The Framework will provide a blueprint for the secondary use of data held in the MHR system that might include research, quality and safety measurement, public health, health service development, planning and evaluation. Secondary use of MHR system data can enhance health care experiences for patients, expand knowledge about disease and appropriate treatments, strengthen understanding about effectiveness and efficiency of service delivery, support public health and security goals, and assist public and private health services to meet consumer needs.

In developing the Framework, complex ethical, political, technical, and social issues need to be addressed. While not new, these issues need careful consideration given the expanding volume of health data; the need to improve data access; and to provide coherent policies and standards of evidence-based best practice to support the implementation of secondary use arrangements.

It is intended that the Framework for the Secondary Use of MHR data will provide national guidance on what personal health data may be collected, linked and analysed for research and public health purposes. The Framework will also seek to address the issue of balancing the rights of individual's to privacy and the collective rights of the community to further develop safe and effective health care.

1.2 PURPOSE OF THE PROJECT

As indicated above, there is currently no secondary use of data held in the MHR system. Presently, the system and the data stored within it are only used for the purposes of providing healthcare to individuals. Individuals who have a MHR can set their own personal access controls, and healthcare provider organisations may update and/or access each record accordingly.

Under the My Health Records Act 2012 (the Act), health information in the MHR system may be collected, used and disclosed "for any purpose" with the consent of the healthcare recipient. In addition, one of the functions of the System Operator (the Australian Digital Health Agency, ADHA) is "to prepare and provide de-identified data for research and public health purposes." Before the provisions of the Act will be implemented, a Framework for the secondary use of MHR system data (hereinafter referred to as the 'Framework') must be established. The role of HealthConsult is to develop a draft Framework and an associated draft Implementation Plan for consideration by the Department.

1.3 STRUCTURE OF THE DOCUMENT

The public consultation process was designed to elicit and understand the views of stakeholders, including consumers and healthcare provider organisations about the circumstances in which it would be acceptable to allow the secondary use of MHR system data. This summary report describes those views, which will be faithfully addressed in the development of Framework. The structure of the report includes:

- **Chapter 2:** describes the public consultation process, including details on the volume of data generated by each of the consultation modes
- **Chapter 3:** presents an analysis of what secondary uses the MHR system data should be, and should not be, allowed
- **Chapter 4:** presents an analysis of what types of organisations/individuals should be able to have access to the MHR system data for secondary use purposes
- **Chapter 5:** presents an analysis on the types of principles that should be included in the Framework to guide the release of data for secondary use purposes from the MHR system
- **Chapter 6:** presents an analysis of where the governance committee overseeing the secondary use of MHR system data should be auspiced and the affiliation of members of the governance committee
- **Chapter 7:** presents an analysis on the processes that should be adopted to enable organisations/ individuals to request and gain approval to use data from the MHR system for secondary purposes
- **Chapter 8:** presents an analysis on whether data from MHR should be linked to other data sources
- **Chapter 9:** presents an analysis on what processes should be used to ensure that data released for secondary use purposes protects the privacy of an individual and reduces the risk of re-identification, which incorporates the issue of what precautions should be taken to reduce the risk of de-identified data from the MHR system being re-identified after release
- **Chapter 10:** presents an analysis as to what arrangements should be considered for the preparation and release of MHR system data for secondary use purposes; who should be responsible for overseeing these arrangements; and who should make a quality statement about the data
- **Chapter 11:** presents an analysis on what monitoring and assurance processes should be considered to ensure that users of MHR data for secondary purposes comply with the Framework
- **Chapter 12:** presents an analysis on what risk mitigation strategies should be included in the Framework; whether there should be a public register identifying researchers who have requested access to the data for secondary use; and whether the existing penalties for misuse under the My Health Record Act are sufficient
- **Chapter 13:** presents an analysis of what policy and/or legislative changes, if any, need to be considered to support the release of de-identified MHR system data for secondary use purposes.

It is important to note that in the analysis of the stakeholder views presented in Chapters 3 to 13, only when there are differences in stakeholder group views (e.g. stakeholder groups defined as government agency, healthcare providers, consumer groups/consumers; industry/professional body, research sector or other[1]) are these identified. Otherwise the analysis is not presented by stakeholder group. Additional analysis by stakeholder group is available in the Detailed Community Consultation Summary Report.

[1] Other' stakeholders includes pharmaceutical companies, data analytics and/or IT companies, or self-nominated survey respondents of 'other' etc.

Also as some submission authors requested to remain anonymous, when extracts from their submissions are used they are only referenced by stakeholder group (e.g. consumer, research sector organisations etc).

2
Overview of the Public Consultation process

This Chapter describes the public consultation process, including details on the volume of data generated by each of the five consultation modes.

2.1 OVERVIEW OF THE PUBLIC CONSULATION PROCESS

The public consultation process commenced with the release of a Public Consultation paper on 5th October 2017 and ended at midnight on Friday 17th November 2017 (six week period). Five consultation modes were available, through which all Australians could provide input (not restricted to the issues raised within the Public Consultation paper) into the development of the Framework including:

- attending a national webinar
- attending a workshop in person (there was at least one workshop held in each State/Territory)
- requesting an interview (via the consultation website) with members of the HealthConsult-led team
- completing the online survey (via the consultation website)
- making a written submission (via the consultation website)

2.2 WEBINARS

There were two national webinars held:

- The first webinar, hosted by HealthConsult on 12th October, 2017, explained the public consultation process and presented the issues covered in the Public Consultation paper (117 attendees).
- The second webinar, hosted by the Consumers Health Forum (CHF) on 16th November, 2017, provided preliminary feedback on the outcomes of the Public Consultation process (42 attendees).

2.3 WORKSHOPS

There were 13 workshops held across the country, as per Table 2.1 (total of 246 participants attended).

Table 2.1: Workshop details and number of attendees

Number	Location	Date	Actual Attendees
1	Sydney NSW	16th October 2017 at 10.30 am	30
2	Sydney NSW	16th October 2017 at 3.30 pm	14
3	Cairns Qld	18th October 2017 at 3.00 pm	11
4	Brisbane Qld	20th October 2017 at 10.30 am	28
5	Hobart TAS	23rd October 2017 at 2.30 pm	22
6	Melbourne VIC	30th October 2017 at 2.30 pm	15
7	Melbourne VIC	31st October 2017 at 2.30 pm	29
8	Adelaide SA	3rd November 2017 at 2.30 pm	15
9	Perth WA	7th November 2017 at 10.30 am	17
10	Alice Springs NT	9th November 2017 at 10.30 am	9
11	Darwin NT	10th November 2017 at 9.00 am	22
12	Blue Mountains NSW	13th November 2017 at 10.30 am	6

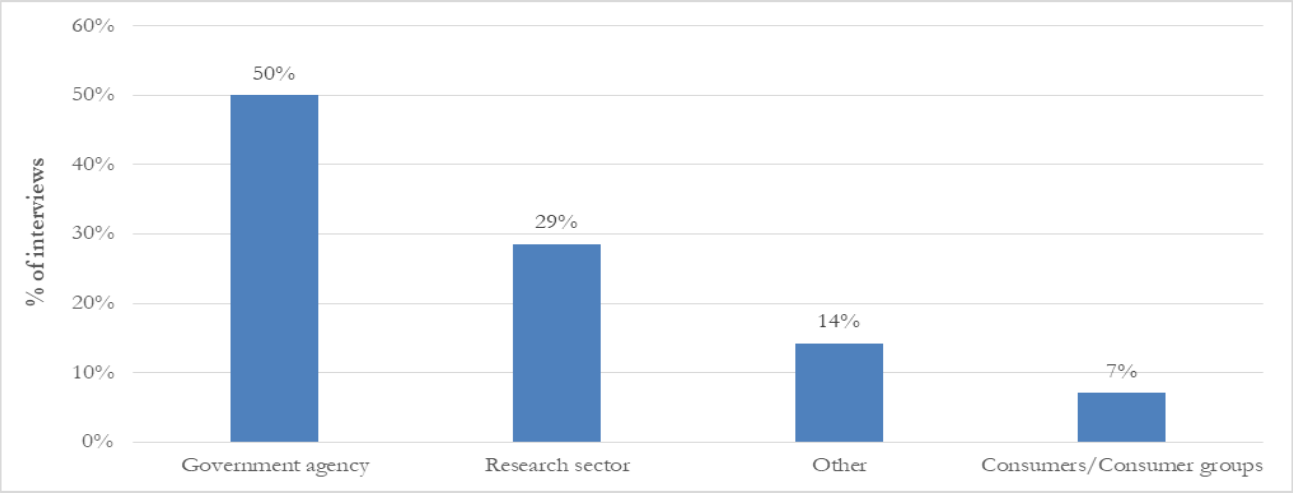
Number	Location	Date	Actual Attendees
13	Canberra ACT	15th November 2017 at 2.30 pm	28
Total Attendees			**246**

At each workshop, a member of the HealthConsult-led team made a short presentation (about 20 minutes) on the Public Consultation Paper. A question, answer and comments session followed, which allowed stakeholders to provide free-form input into the development of the Framework. Stakeholders were strongly engaged in the process, as these sessions lasted between 45 to 75 minutes.

2.4 INTERVIEWS

There were 14 face-to-face interviews conducted, with a total of 25 participants. Figure 2.1 shows that most (50%) of the interviews were conducted with representatives of Government agencies (Federal and/or State) followed by representatives of the research sector (29%).

Figure 2.1: Type of organisations/persons that were involved in the interviews



2.5 ONLINE SURVEY

The online survey, using SurveyMonkey, was conducted from the 9th October until the 17th November 2017. There were 274 survey responses received, although it is important to note that not all respondents answered all survey questions. The majority of respondents (43%, n=119) were individual consumers, for which the organisational affiliation was not recorded. In terms of health professionals, respondents were mainly from health or hospital networks (16%, n =44), private sector, mainly pharma and data analytics (14%, n = 39) and research sector (14%, n = 39).

Figure 2.2: Type of organisation/person completing the survey

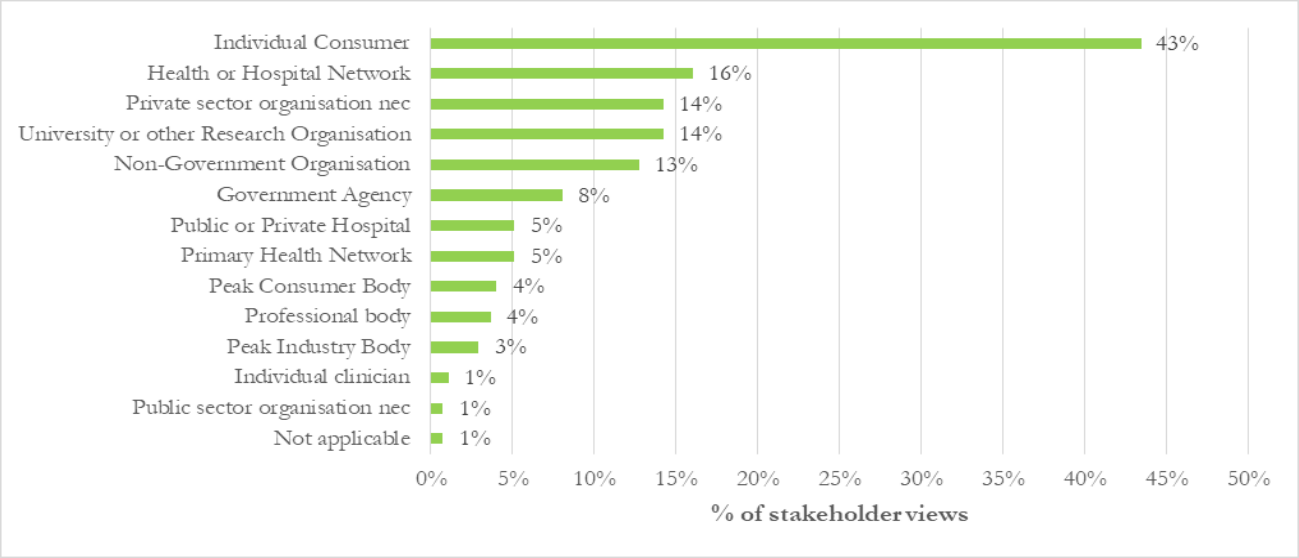


Figure 2.3 shows that majority of survey respondents resided in New South Wales (NSW, 36%) followed by Victoria (19%). The proportions for each State/Territory are very similar to population proportions, particularly when considering the number of responses from national organisations based in the Australian Capital Territory (ACT) and NSW. About 3% of survey respondents were from overseas (e.g. USA, UK, Europe and New Zealand).

Figure 2.3: Location of organisation/person completing the survey

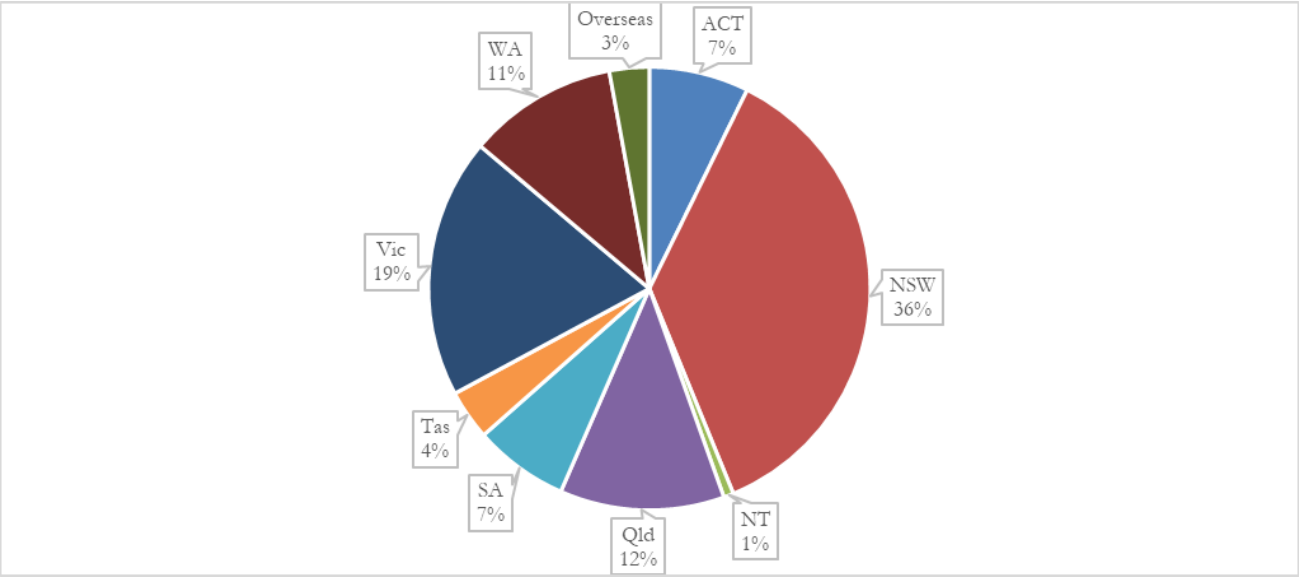
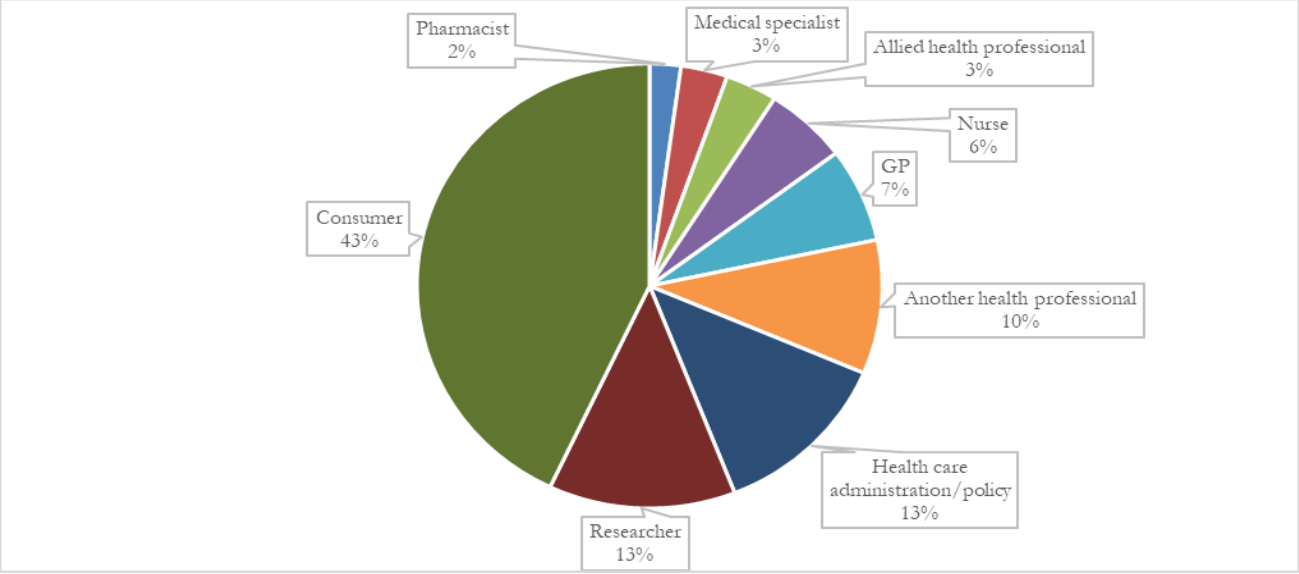


Figure 2.4, consistent with the data reported in Figure 2.2, shows that majority of survey respondents described themselves as consumers (43%); followed by people working in health care administration/

policy (13%) and researchers (13%). Survey respondents also comprised a variety of clinicians, including GPs (7%), nurses (6%), medical specialists (3%) and pharmacists (2%).

Figure 2.4: Category which the survey respondent nominated best described their profession



2.6 WRITTEN SUBMISSIONS

Table 2.2 shows the distribution by organisation/person type and location of authors for the 80 written submissions received. The majority of submissions were made by Industry/Professional Bodies (n=32; 42%) followed by Government agencies (n=10; 13%) and Consumers/Consumer groups (n=9; 12%). Table 2.2 also shows that at least one written submission was received from an organisation/person in each State/Territory, except Tasmania.

Table 2.2: Profile of written submissions made

Type	NSW	VIC	QLD	SA	WA	ACT	NT	Other[1]	Not stated	Total
Government agencies	4	1	2	0	0	3	1			11
Health Care Providers	1	1	1	1	0	0			1	5
Industry/Professional Body	9	4	3	2	0	9			1	28
Consumers/Consumer Groups	5	1	0	1	1	3		2	2	15
Research Sector	3	5	0	1	4	1				14
Other	6	1								7
Total	**28**	**13**	**6**	**5**	**5**	**16**	**1**	**2**	**4**	**80**

[1] Includes one submission from overseas, and one where the author reported their location as unknown.

2.7 KEY ASSUMPTIONS/PROCESSES IN UNDERTAKING THE ANALYSIS

In order to provide an overall analysis of the weight of stakeholder opinion against each of the consultation questions, we have combined the data obtained from all consultation modes. When combining the online survey data with other data sources, we have made the following assumptions:

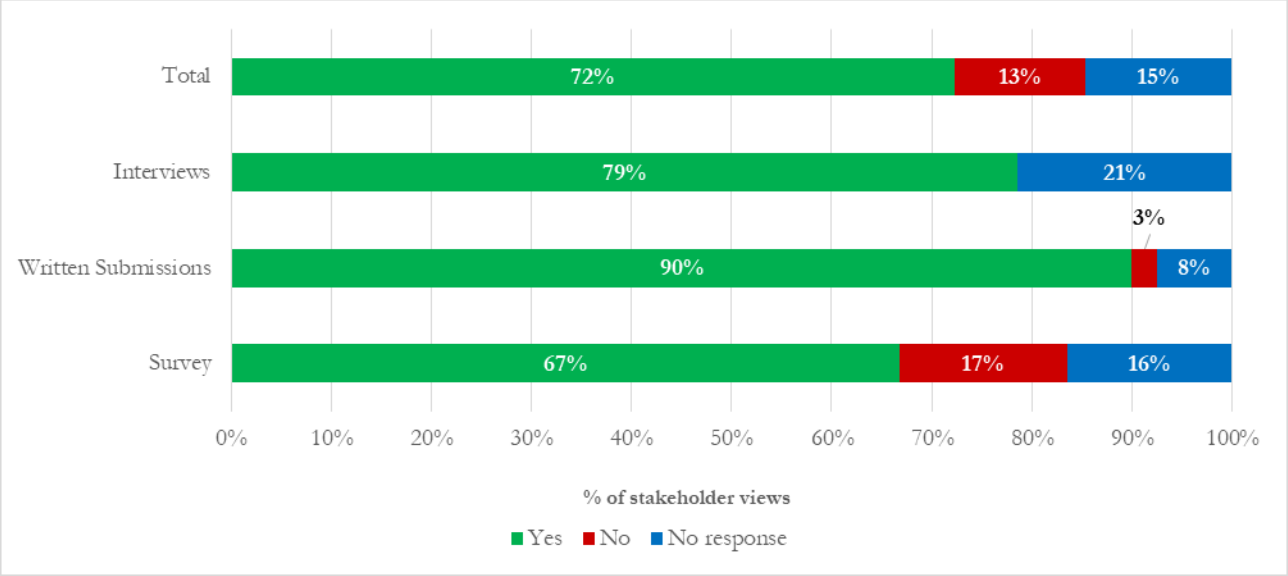
- The online survey respondents who responded *I am a consumer* for their category (question three) were coded to *Individual consumer* for their organisation type (question two), irrespective of what they reported, and were then aggregated into the stakeholder group 'Consumers/Consumer groups'.
- The online survey respondents who responded *Not Applicable* for their organisation type (question two), and any other answer for their category with the exception of *I am a consumer* (question three), have been aggregated to the stakeholder group 'Other'.

Only the data from the on-line survey was received in codified form. Data from all other sources was qualitative, as follows: webinars (consulting team notes from the Q&A), workshops (consulting team notes from the Q&A), interviews (consulting team notes from the discussion) and written submissions (as provided by authors). The consulting team thematically analysed the data from these four sources and assigned codes to the issues raised against each questions that were similar to those used in the survey for the corresponding question. The resultant database was used to summarise the responses to, and the proportion of stakeholders that held a particular view on, each question across all consultation modes.

3
Secondary uses of the My Health Record data

Figure 3.1 shows that, across survey, interview and submission consultation modes, individually and collectively, a significant majority of stakeholders support the MHR system data being used for secondary purposes. As views were not obtained from individual webinar and workshop participants, it is not possible to report the same data for these modes. It is, however, fair to report that, based on the contents of the question, answer and comments session, the views of participants in webinars and workshops mirrored those of participants in other consultation modes (i.e. mostly in favour with some against).

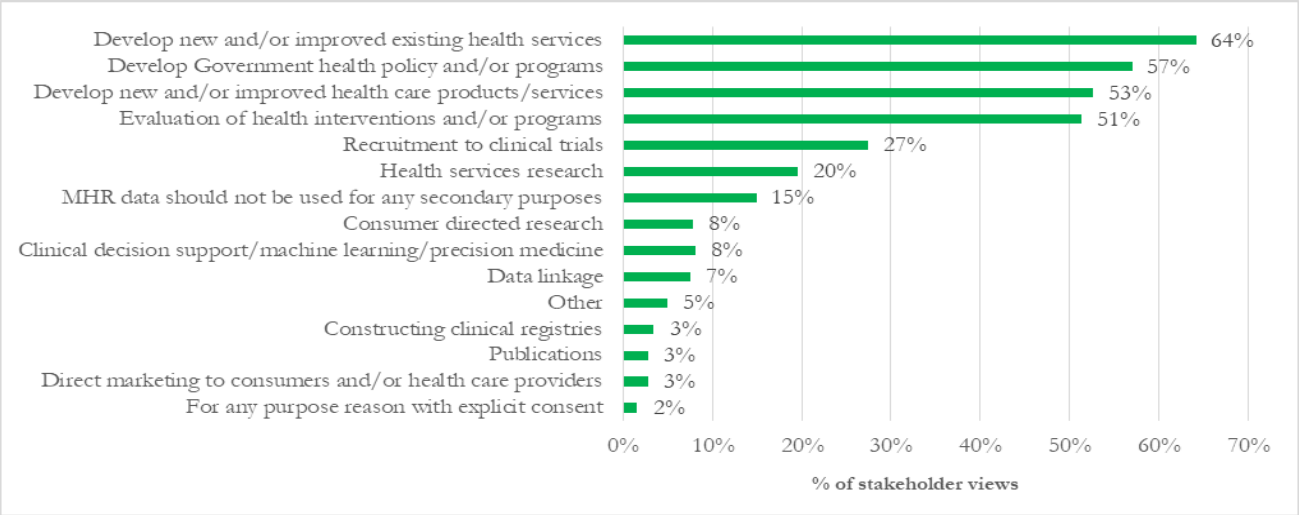
Figure 3.1: Extent to which stakeholders thought MHR data should be used for secondary purposes



Source: Thematic analysis of data generated from interviews, written submission and surveys (n=368)

In terms of purposes for which the MHR data should be used for, Figure 3.2 shows the distribution of responses from all consultation modes (note stakeholders could select more than one option). The data show that there is strong support for the use of MHR data to *develop new and/or to improve existing health services* (64%); *develop government health policy and/or programs* (57%); *develop new and/or improved health care products and services* (53%); and *evaluate health interventions and/or health programs* (51%). Interestingly, there was strong support and opposition (refer to Figure 3.3), across all stakeholder groups, in regards to whether MHR data should be used to *develop new and/or improved health care products and services (e.g. pharmaceuticals, medical devices, diagnostic tests, etc.)* and assist in the *recruitment of suitable patients to clinical trials.*

Figure 3.2: Secondary uses of MHR data that should be permitted



Source: Thematic analysis of data generated from all consultation modes (n=321, nil responses are excluded from denominator)

Typical of the strongly supportive views expressed included those of the Grattan Institute *"Government data holdings should be seen as an important public resource to assist in policy-relevant research that will benefit the Australian community. Failure to harness fully the potential of these datasets represents a significant lost opportunity …"*, and the Australian Healthcare and Hospitals Association (AHHA) *"At present, the secondary use of existing MHR data is not permitted and yet the information held within these records is readily available, inexpensive to obtain, and has boundless potential for improving Australia's health far beyond supporting an individual's clinical care"*.

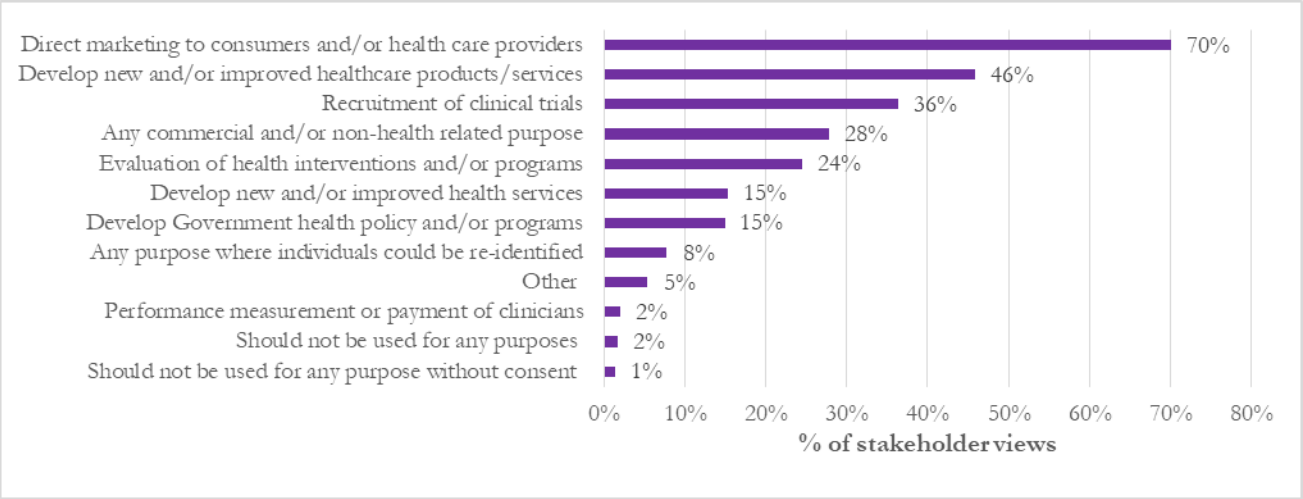
Not all support for secondary use was as strongly expressed, and there were often qualifications, as typified in the submission from the Australian Information and Privacy Commissioner *"Given that the MHR system has the potential to become one of the richest sources of health information in Australia, the benefits that may be derived from the use of the data beyond primary care are significant. At the same time, I am mindful that when considering how the use of sensitive information can be enhanced, it is crucial that privacy remain a central consideration*".

There were also submissions that expressed significant reservations, such as the view of the National Aboriginal Community Controlled Health Organisation (NACCHO), which stated *"We strongly support an approach which prevents secondary use of MHR data (that identifies Aboriginal peoples) for at least five years after the development of systems for secondary use have commenced and until systems and protections have been verified (by NACCHO)"* and the Federation of Ethic Communities' Council of Australia (FECCA), which stated *"while the secondary use of data available through the MHR might be beneficial to the overall population, it can also have negative effects and raise privacy concerns. FECCA urges the government that the needs of vulnerable population groups be taken into consideration when creating the relevant policy"*.

Another important caveat was that many stakeholders believed that consumers should have the opportunity to opt out of secondary use (while still having a record that can be used for the primary purpose), as typified by the submission from the Royal Australasian College of Physicians, which states *"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 MHR 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"*.

In terms of purposes for which the MHR data should not be used for, Figure 3.3 shows the distribution of responses from all consultation modes (note stakeholders could select more than one option). The data show that there is strong opposition (70%) to the use to MHR for direct marketing purposes. There is also significant concern (46%) around the use of MHR data for *developing or improving new healthcare products/services (e.g. pharmaceuticals, medical devices)*, as well as for using the data *to recruit to clinical trials* (36%).

Figure 3.3: Secondary uses of MHR data that should *not* be permitted



Source: Thematic analysis of data generated from all consultation modes (n=294, nil responses are excluded from denominator)

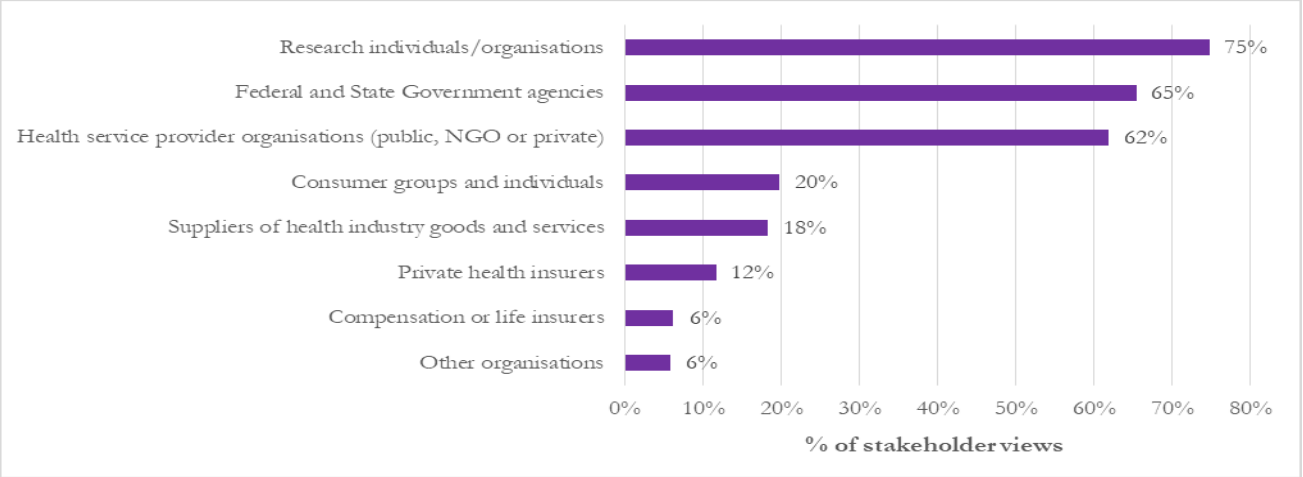
A key issue that needs to be resolved is the boundary between commercial use and public health benefit. Many submissions addressed this issue. A small minority of stakeholders supported commercial use, for example, Research Australia stated *"The consultation paper states 'the use of data solely for commercial and non-health related purposes is considered out of scope'. Research Australia submits that this position is inconsistent with the Australian Government Public Data Policy Statement and the My Health Records Act in respect of the operation of section 15 (ma), and that commercial research should not automatically be excluded. For example, commercial research is 'research' and should be considered in scope. The Data Policy specifically commits the Australian Government and its agencies to 'collaborate with the private and research sectors to extend the value of public data for the benefit of the Australian public'".*

A more common position taken by those in favour of restricted commercial use is typified by the submission from NPS MedicineWise, which states, *"there is a need to address the overlap between commercial and health related uses. … We strongly support the Framework providing clarity on this overlap, so that researchers and other organisations seeking access to MHR data have a clear understanding of what does, and what does not, fall within the scope of the Framework".* However, there was considerable opposition to commercial use, even for some uses that many would consider have a public health benefit. For example, there was opposition to the secondary use of the MHR data for post-market surveillance, as illustrated by Capital Markets CRC stating *"MHR data should not be used by pharmaceutical companies to analyse trends in prescription drug usage or to build pictures of the prescribing patterns of different service providers"* (note that PBS data is already used for the former purpose).

4 Types of organisations/individuals who could access MHR

Figure 4.1 shows that across all consultation modes the most common groups (consultation participants could choose multiple categories) that were supported to have access to MHR system data for secondary use purposes included research individuals/organisation (75% of respondent stakeholders), Federal and State/Territory Governments (65%) and health service provider organisations (62%).

Figure 4.1: Types of organisations that stakeholders felt should have access to MHR data for secondary uses



Source: Thematic analysis of data generated from all consultation modes (n=257, nil responses are excluded from denominator)

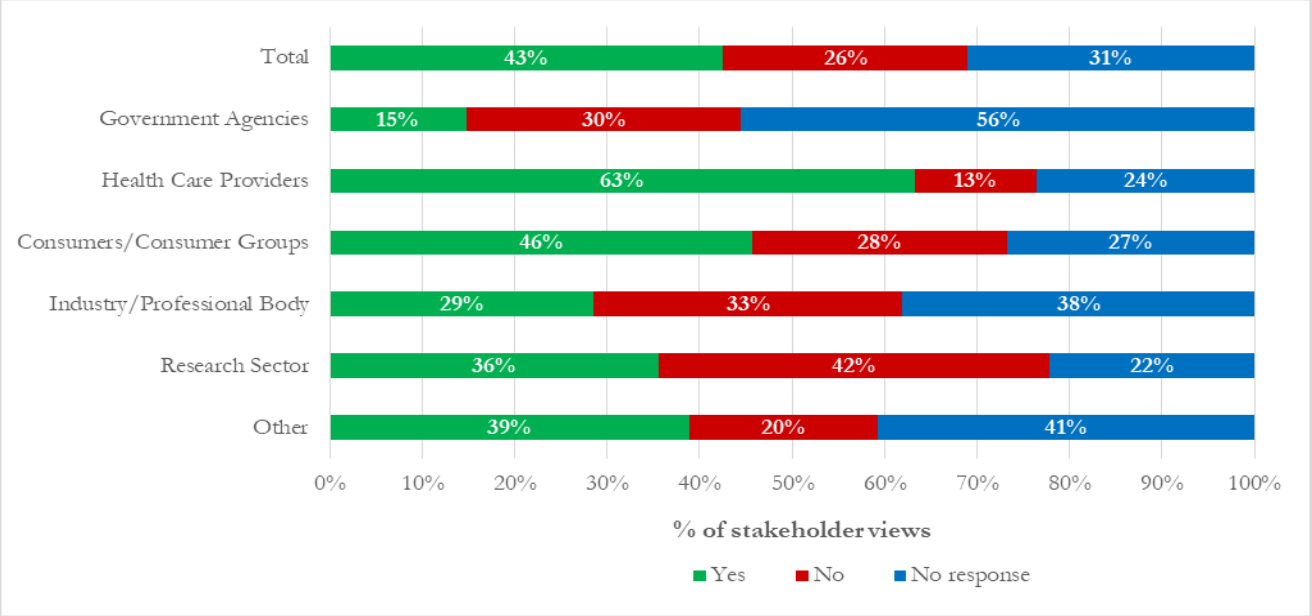
A strong case was put forward by the pharmaceutical and medical devices sector for access to MHR data for secondary use purposes, as typified by the Medicine Australia submission, which stated *"Subject to appropriate controls and governance, Medicines Australia proposes that any such individual or organisation with a demonstrable Health related interest should be able to access the My Health Record dataset"*. The Medicines Australia submission, which is representative of many other sector participants, went onto highlight the benefits associated with having access to real world data (RWD) to support uses such as *"a more nuanced understanding of current drug utilisation to better inform Pharmaceutical Benefits Advisory Committee (PBAC) submissions"*, *"observational research, noting that the MHR dataset could be a valuable supplement to clinical registry data"*, *"more confident monitoring of new drugs"*, *"pharmacovigilance"*, *"improve the efficiency of recruitment into clinical trials"*, and *"Quality of Life in clinical trials"*.

But, Figure 4.1 demonstrates that this view is not supported by the majority of stakeholders. Many submissions expressly stated that MHR data should not be made available to pharmaceutical and health insurance companies. For example, the submission from Future Wise stated "*Secondary use of the data in My Health Record should be explicitly forbidden for organisations whose primary purpose is commercial – specifically pharmaceutical companies and health insurance companies"*, and the submission from the WA Primary Health Alliance (WAPHA) stated *"Sufficient provision must be in the framework to prevent organisations, businesses, in particular insurance companies that are vertically integrated and may own or have investments in primary/secondary health facilities (i.e. dental practise) receiving MHR data and using it for commercial gains. Likewise it is recommended that … clear separation is made between health research to make profit and research for the 'public good'"*.

Figure 4.2 shows that there are varying views by stakeholder group as to whether access to MHR system data for secondary use purposes should be restricted to Australian users only. Of the stakeholders who specifically responded to this question, 43% stated that access should be restricted to

Australian users only, with 26% supporting access by international users. As might be expected, this position was different for stakeholders from the research sector where 42% were in favour of allowing access by overseas researchers, whereas 36% wanted access restricted to Australian users.

Figure 4.2: Should access to MHR system data be restricted to Australian users only



Source: Thematic analysis of data generated from all consultation modes (n=383)

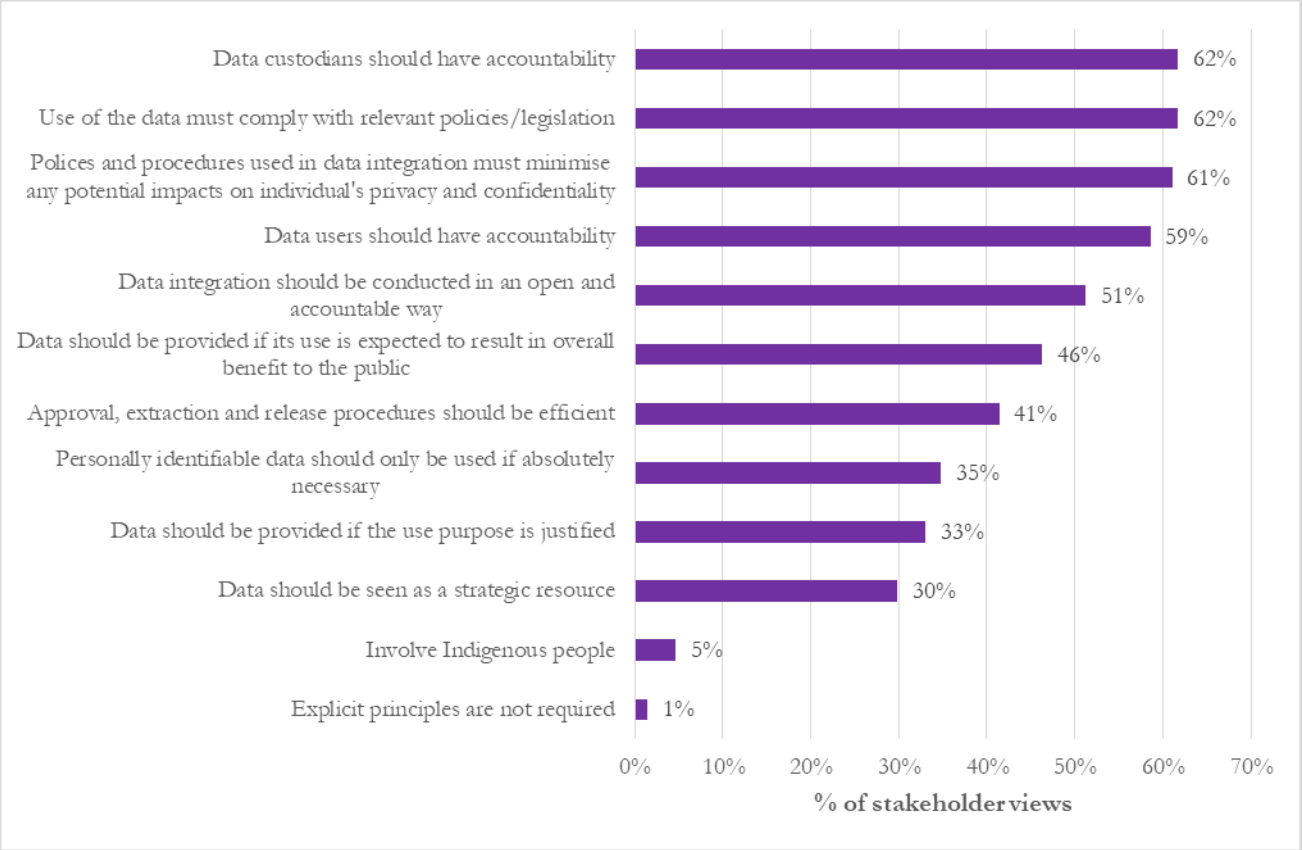
By way of illustration, the submission from the National Health and Medical Research Council (NHMRC) stated that *"international researchers with Australian partners and Australian ethics approvals should be able to access the data within a secure environment, with all data hosted in Australia. The Australian Privacy Principles provide guidance on how personal information can be used and disclosed (including overseas)"*. Other submissions made the very practical point of the need to aggregate data internationally in certain circumstances, as typified by the statement from the Genetic and Rare Disease Network (GaRDN) *"Rare disease research requires international collaboration to obtain sufficient numbers to obtain meaningful research outcomes*". The submission went on to state *"At the minimum at least one Primary Investigator in the research team should be an Australian user. All data analysis conducted on the approved and provided data to be undertaken in Australia"*.

But, as illustrated in Figure 4.2, the contrary view was more prevalent. For example, the Australian Medical Association (AMA) stated *"the AMA does not support the disclosure of MHR data to an overseas user. Overseas entities are not subject to Australian law, there is no way Australia could monitor the secure storage of the data, whether the data user complies with the conditions of data release and destroys the data after use. There is also no realistic way to prevent the data recipient from passing the data to other parties"*. This statement is representative of views put by those who believed that only Australians should have access to MHR data for secondary use.

5 Principles to guide the release of secondary use of MHR data

Figure 5.1 shows that the key principles that stakeholders report should be included in the Framework to guide the release of MHR system data for secondary use purposes are: *data custodians should have accountability* (62% or respondent stakeholders); *use of the data must comply with relevant policies and/or legislation* (62%); *policies and procedures used in data integration must minimise any potential impacts on individual's privacy and confidentiality* (61%) and *data users should have accountability* (59%).

Figure 5.1: Key principles that should be included in the Framework *to guide the release* of MHR data



Source: Thematic analysis of data generated all consultation modes (n=285, nil responses are excluded from denominator)

A key theme from the consultative process is that the Framework for the Secondary Use of MHR data should draw on a set of already well-developed principles that are in place in Australia and elsewhere in the world. For example, the Research Australia submission stated *"Research Australia submits the principles of the Framework for de-identified unit level record data should draw on the Australian Government Public Data Policy Statement"*. A number of other submissions reflected this view including that from Australian College of Nursing which stated *"The following extract from the Data Policy Statement could be adapted for the Framework for de-identified data 'Australian Government entities will:*

- *make non-sensitive data open by default to contribute to greater innovation and productivity improvements across all sectors of the Australian economy*
- *where possible, make data available with free, easy to use, high quality and reliable Application Programming Interfaces*

- *make high value data available for use by the public, industry and academia, in a manner that is enduring and frequently updated using high quality standards*
- *where possible, ensure that non-sensitive publicly funded research data is made open for use and reuse*
- *build partnerships with the public, private and research sectors to build collective expertise and to find new ways to leverage public data for social and economic benefit*
- *securely share data between Australian Government entities to improve efficiencies, and inform policy development and decision making*
- *engage openly with States and Territories to share and integrate data to inform matters of importance to each jurisdiction and at the national level*
- *uphold the highest standards of security and privacy for the individual, national security and commercial confidentiality*
- *ensure that all new systems support discoverability, interoperability, data and information accessibility and cost-effective access to facilitate access to data.'"*

The submission from the Health Informatics Society of Australia (HISA) advocates *"The Freedom of Access to Information and Resources guiding principles, and emerging set of guidelines for the efficient use of clinical and research data, describes four core foundational principles that guide the discovery and reuse of clinical data by the community. The FAIR guiding principles, which stand for Findable, Accessible, Interoperable, and Reusable, offer a theoretical structure and describe not only the data but any algorithm, tool and workflow that led to the creation of that data.* The HISA submission also points to the potential application of the Caldicott principles (which were referenced in the Consultation Paper), and also the NHMRC principles for Accessing and Using Publicly Funded Data for Health Research.

Many stakeholders suggested the use of the five-safes principles (also referenced in the Consultation paper), as typified by the Consumers Health Forum (CHF) submission which stated *"CHF supports the provisions outlined in section 3.3 of the Consultation Paper with regard to data safety, such as the five safes framework currently used by the ABS. An appropriate combination of these existing examples should be included in the Framework".* This statement and many others highlight the need for the Secondary Use Framework to draw on the best of what has already been done, while harmonising, as far as possible, across principles that may already apply to data that finds its way into the MHR system (e.g. Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Schedule (PBS) data).

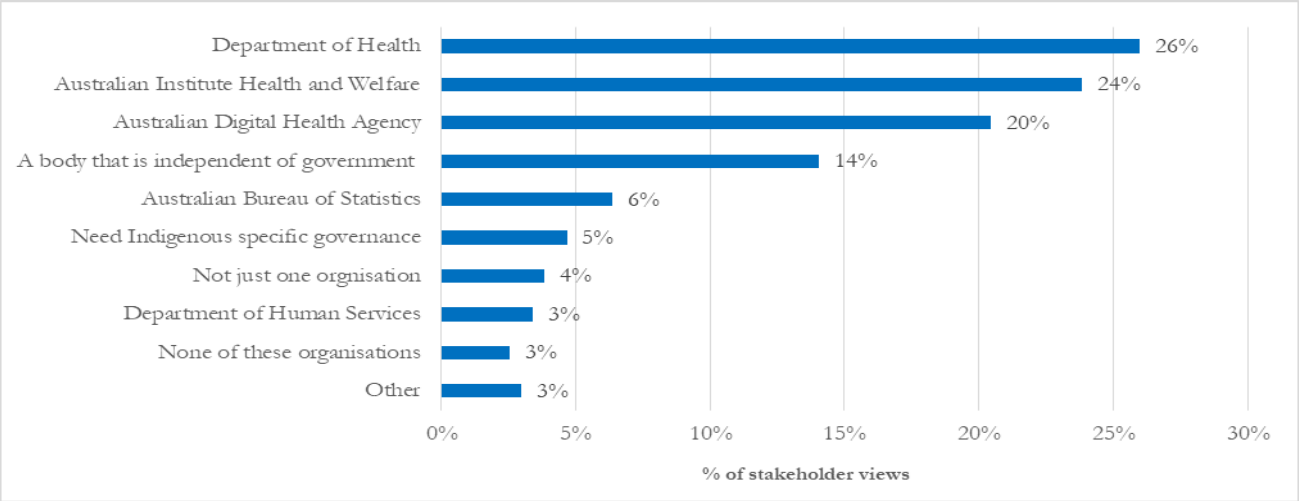
A very important point made by a number of stakeholders is the need to give specific consideration to principles that are appropriate for secondary use of data about Indigenous Australians. The NHMRC highlighted the need to consider the document *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal; and Torres Strait Islander Research (2003).* The submission from the Royal Australasian College of Physicians (RACP) stated *"the Framework needs specific consideration of principles to guide the secondary use of data pertaining to Aboriginal and Torres Strait Islander peoples. These principles and data governance arrangements need to be developed in collaboration with national Aboriginal community representative bodies such as the NACCHO and State and Territory-based Affiliates of NACCHO, and Torres Strait Islander specific authorities".*

This need was strongly highlighted by stakeholders in the Indigenous health sector, as typified by the submission by NACCHO, which stated "*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 (document) 'Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders' (which has been released in draft form), as well as existing Indigenous principles, such as the National Aboriginal and Torres Strait Islander Health Data Principles developed by National Advisory Group on Aboriginal and Torres Strait Islander Health Information and Data (NAGATSIHID) and endorsed by the Australian Health Ministers Advisory Council (AHMAC) in 2006.* This issue will need to be carefully considered in drafting the Secondary Use Framework.

6 Type of governance model

Figure 6.1 shows that, across all consultation modes, the *Department of Health* (26%) gained the most support as the auspice organisation of the governance committee that has responsibility for overseeing the secondary uses of MHR system followed closely by *AIHW* (24%) and *ADHA* (20%). Analysis by stakeholder group showed that representatives from Government agencies were more supportive of a body that is *independent of government* being the auspice organisation of the governance committee. Whereas industry/professional bodies, health care providers and the research sector were more in favour of the AIHW being the auspice organisation of the governance committee. Consumer groups/consumers preferred the auspice organisation of the governance committee to be the Department of Health.

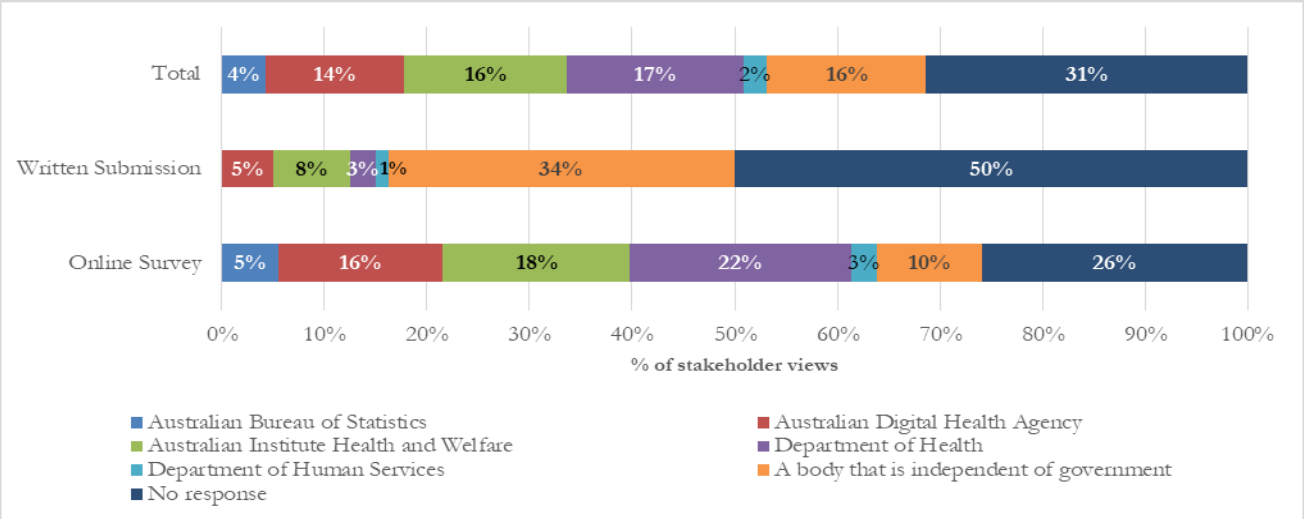
Figure 6.1: Auspice of the governance committee overseeing secondary use of MHR system data



Source: Thematic analysis of data generated from all consultation modes (n=235, nil responses are excluded from denominator)

When looking at Figure 6.2 by consultation mode, a slightly different picture emerges. In the online survey, where *"a body that is independent of government"* was not provided as a closed response option, there is preference for the auspice body to be a Government Agency (Department of Health, AIHW, and ADHA in that order). But, in the written submissions, where no closed response structure was provided, there is a clear preference for the auspice agency for the governance of secondary use of MHR data to be *a body that is independent of government*. This difference is attributable to the structure of the consultations, as well as the fact that there was a much higher proportion of individual consumers responding to the online survey (43%), relative to 19% of the written submission being from consumers/consumer groups.

Figure 6.2: Auspice of the governance committee overseeing secondary use of MHR system data by data source



Source: Thematic analysis of data generated from written submissions and online survey (n=354)

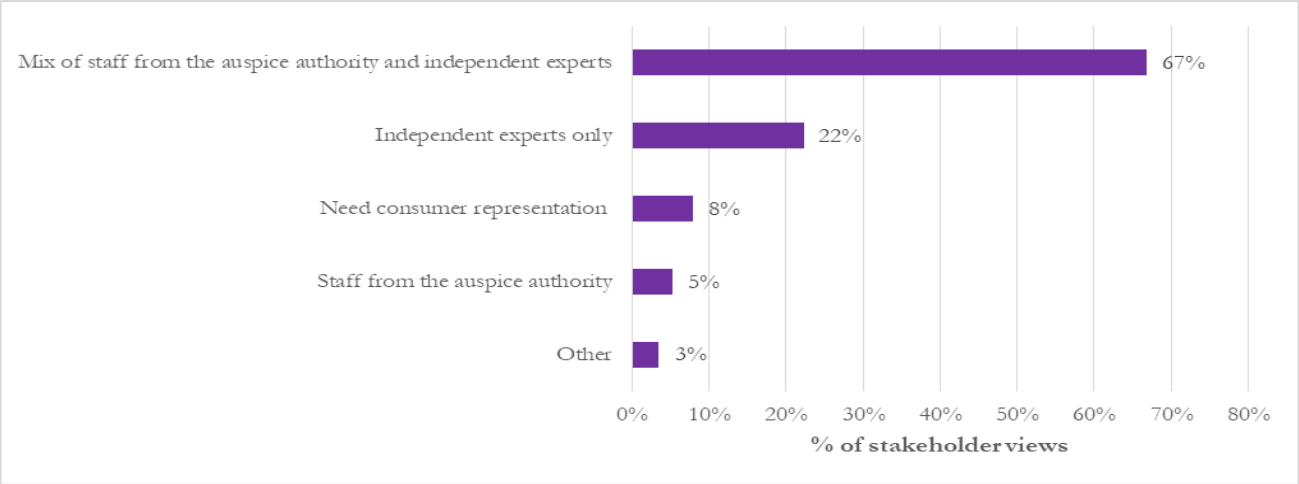
Typical of responses received in written submission was the view put by Royal Australian College of General Practitioners (RACGP) *"We strongly support setting up an independent body as custodian of My Health Record data, which should be separate to government and any of its agencies*". Other groups expressed similar views, for example the Australian College of Health Informatics (ACHI) stated *"Governance should be independent from Government. This is unlikely to be possible initially but we believe this should be a defined goal. Ultimately, independence of governance from Government is crucial to fully realise national trust"*. The submission from Curtin University stated *"A governance model which includes a single governing body for the secondary use of MHR data would be ideal. This independent committee made up of high-level stakeholders and/or experts (including consumer representation and HREC expertise) should provide oversight of research activities"*. And the CHF submission was more explicit stating *"the data custodian and the functions that accompany that role should be undertaken by a single governing body separate to the MHR system operator – the ADHA"*.

In contrast, a number of submission authors expressed strong support for the AIHW to be the auspice authority for governance of the secondary use of MHR data. For example, the submission from the Fred IT Group stated *"A governance structure involving existing organisations such as the AIHW should be used to govern the secondary use of data. Organisations such as AIHW bring a level of impartiality that other organisations could not provide reducing potential conflicts of interest and the potential for unfair commercial or other gains to governing organisations"* and the submission from Australasian Association of Nuclear Medicine Specialists (AANMS) responded *"AIHW, a single governing organisation with experience in relation to medical and health data is required. All decisions to release data must be transparent, consistent, reportable, subject to appropriate scrutiny and auditable. In this regard the governing organisation will be accountable to the Australian community"*.

Consistent with the positions put in response to the questions around release of MHR data for secondary use the Aboriginal Medical Services Alliance Northern Territory (AMSANT) stated *"AMSANT does not believe that a single accountable authority for the management of the secondary use of MHR 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 MHR data that is also represented at the highest governance level"*.

In regards to how the membership of the governance committee should be determined, 67% of the respondent stakeholders thought members should reflect a *mixture of staff from the auspice authority and independent experts* (Figure 6.3). Please note that this question was specifically asked in the survey but not in the consultation paper, although 24 of the 80 submission authors expressed a view on the issue.

Figure 6.3: Membership of the governance committee overseeing secondary use of MHR system data



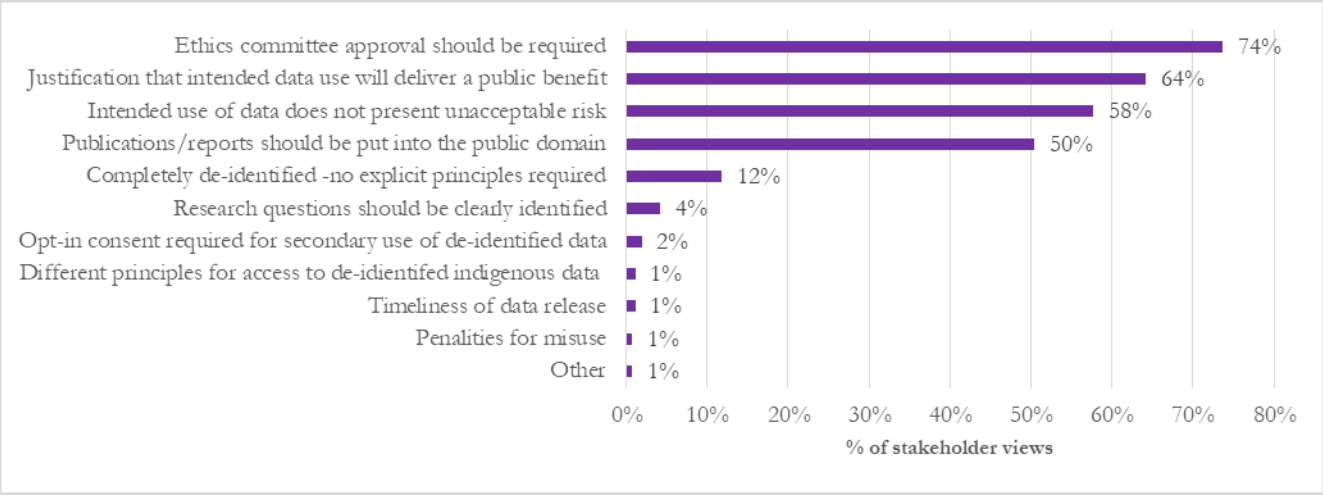
Source: Thematic analysis of data generated from all consultation modes (n=229, nil responses are excluded from denominator)

Typical responses included that of the Consumer and Community Health Research Network (CCHRN) that stated *"An 'independent gatekeeper' committee should maintain control over access to the data. The Committee should consist of members with appropriate expertise including consumers and community members, researchers, government and non-Government agencies"*. Further, a submission from one individual stated *"The Governance Model should include an overarching committee that reports to either AHMAC or the Australian Parliament. The governing board would include representation from Jurisdictions, Public Health, Academics, Private Health, Statisticians, Data Scientists, Privacy Experts and Health Consumers"*. A slightly different view was put in the submission by the Medical Software Industry Association (MSIA), which stated *"to ensure trust there should be independence and avoidance of conflict or the appearance of conflict of interest e.g. despite the benefit that clinical research organisations could bring to the table their involvement could be perceived as motivated by desire to gather as much health data as possible at the expense of individual privacy and dignity"*.

7
Process for requesting and accessing data

Figure 7.1 shows that, across all consultations modes, stakeholders identified the key processes that should be included in the Framework to enable users to request and gain approval **for de-identified data** from the MHR system for secondary use purposes as: *gaining ethics* approval (74%); ensuring there is *justification that the intended end use of the data will deliver a public benefit* (64%); ensuring that the *intended use of the data does not present an unacceptable risk to an individual's privacy* (58%) and *publications/reports on the analysis of the acquired data should be put into the public domain* (50%).

Figure 7.1: Key processes for *users to request and gain approval* for *de-identified* data from the MHR system



Source: Thematic analysis of data generated from all consultation modes (n=262, nil responses are excluded from denominator)

Typical of qualitative comments made in the written submissions was the view put by AANMS *"The release of de-identified data should only occur where appropriate application is made (defined by AANMS earlier in the submission as Ethics Committee approval should be required; Intended use of the data does not present an unacceptable risk to an individual's privacy; Publications/reports describing the analysis of the data should be put into the public domain) and approved, where the use is clearly defined, with a specified timeframe and clear guidelines as to the destruction of the data at the conclusion of the research".*

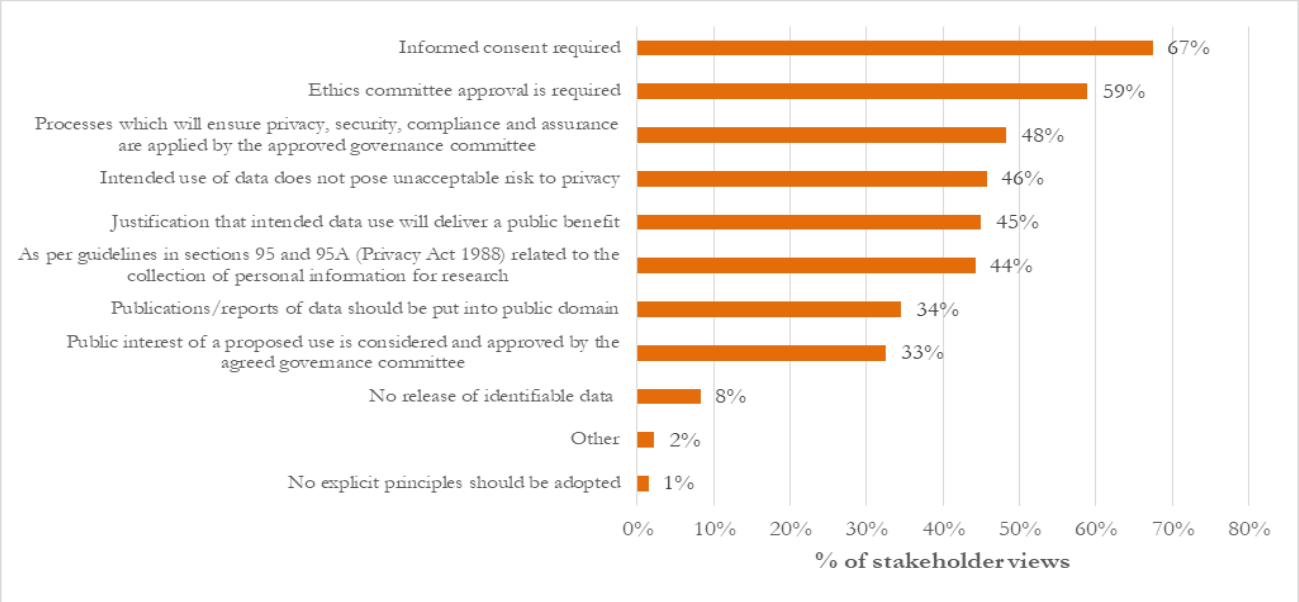
Some written submissions made extra points. For example, the submission from Australian National Data Service (ANDS) stated *"The principles from the National Statement on Ethical Conduct in Human Research (which is currently being reviewed) should be taken into account*". The NHMRC submission stated *"the organisation requesting access to the data having a statement of capacity/training and accreditation as a MHR data user".* And the Australian Information and Privacy Commissioner stated *"I strongly recommend that the Framework consider entities seeking MHR data for secondary use, that are not covered by the Privacy Act or an equivalent privacy law of the State of Territory, to be brought under the coverage of the Privacy Act via sections 6E, 6EA or 6F of the Privacy Act".*

As per Figure 7.1, 12% of stakeholders expressed more liberal views, for example a submission made by a research sector organisation stated *"Confidentialised access should be freely available regularly under license to all bona fide 'trusted' users (Researchers, service providers and policy makers), who should have the same level of access as those who hold/collect the data – this builds trust, ownership and faster output".* And the Research Australia submission stated *"limitations on applications for de-identified unit record level data should only be imposed to meet the requirement that the release is for research or public health purposes, and these terms should be clearly defined. Approval*

of an application should be subject to the capacity of an organisation to comply with re-identification risk mitigation measures, such as the ability to securely store the data and restrict access to authorised personnel".

Figure 7.2 shows that, across all consultation modes, stakeholders identified the key processes that should be included in the Framework to enable users to request and gain approval for **identified data** from the MHR system for secondary use purposes as: *gaining informed consent* (67%)*; gaining ethics approval* (59%); *conditions which will ensure privacy and security are applied in any such approval, and compliance and assurance processes are applied by the approved governance committee providing the approval to ensure the conditions have been applied* (48%); and *intended use of the data does not present unacceptable risk to individual's privacy* (46%).

Figure 7.2: Key processes for users to request and gain approval for *identified data* from the MHR system



Source: Thematic analysis of data generated from all consultation modes (n=267, nil responses are excluded from denominator)

Stakeholders in favour of informed consent put views such as those in one of the industry/professional bodies *"Engagement and communication with community, and informed consent for secondary use of data is a high priority. The consumer needs to be fully versed in the governance mechanisms to have confidence in the privacy and security of their data and its use. A dynamic consent framework is preferred, with options provided to the consumer. Service providers need to enable consumer's informed consent.* A similar view was put in the RACGP submission *"Any requests to use identified data should require the collection of specific informed consent of each individual patient for each use".* And the submission from one of the industry/professional bodies also emphasised *"A principle that should be included in the Framework in respect of identified data should be to ensure that any release of identified MHR data complies with the affected individual's instructions".*

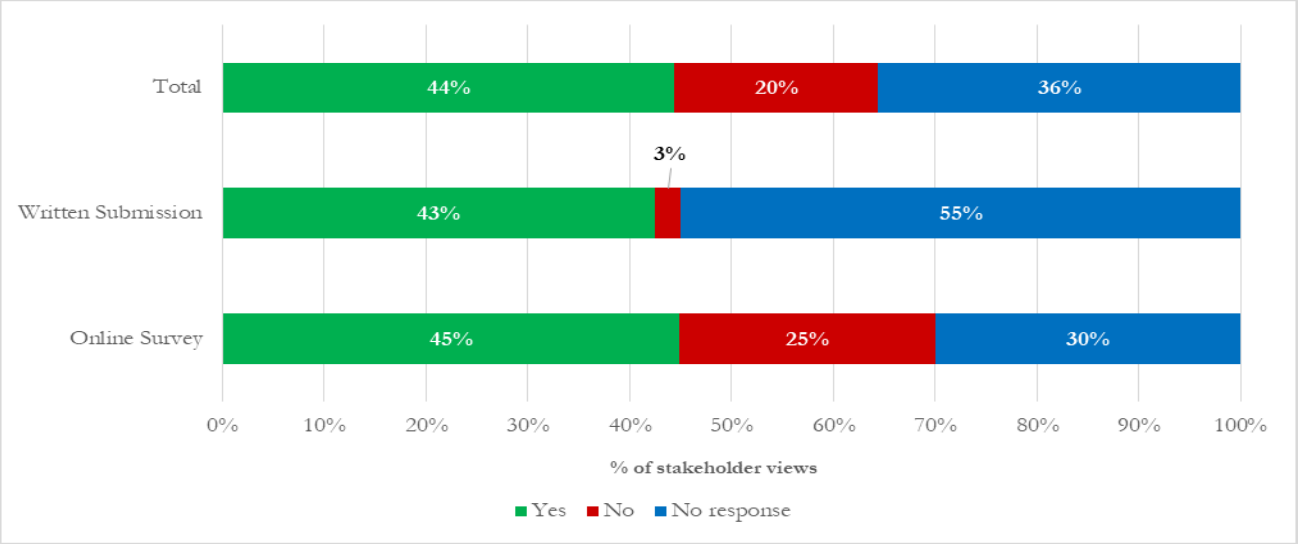
The AHHA submission advised *"The release of data to researchers should adopt a risk management approach that balances the risk associated with the secondary use of MHR data at the level of detail requested with the potential benefits of the research proposal".* A submission from one of the industry/professional bodies also provided important advice *"Consent remains a sensitive issue for Aboriginal and Torres Strait Islander peoples. There needs to be consultation with Aboriginal and Torres Strait Islander communities at each step in the development of the framework before data releases".*

Finally, it is important to highlight 8% of stakeholders believed that there should be no release of identified MHR data for secondary purposes, as typified by the submission from Future Wise, which stated *"Identified data should not be provided for secondary purposes, as the risk to individual privacy is too great".*

8 Data linkage

Figure 8.1 shows that, across the written submissions and surveys, about 44% of stakeholders believed that MHR system data should be able to be linked to other data sources. It is important to note that of those stakeholders who expressed a view, the ratio of those *for linkage* to those *against linkage* was about 14:1 for written submission authors and nearly 2:1 for survey respondents.

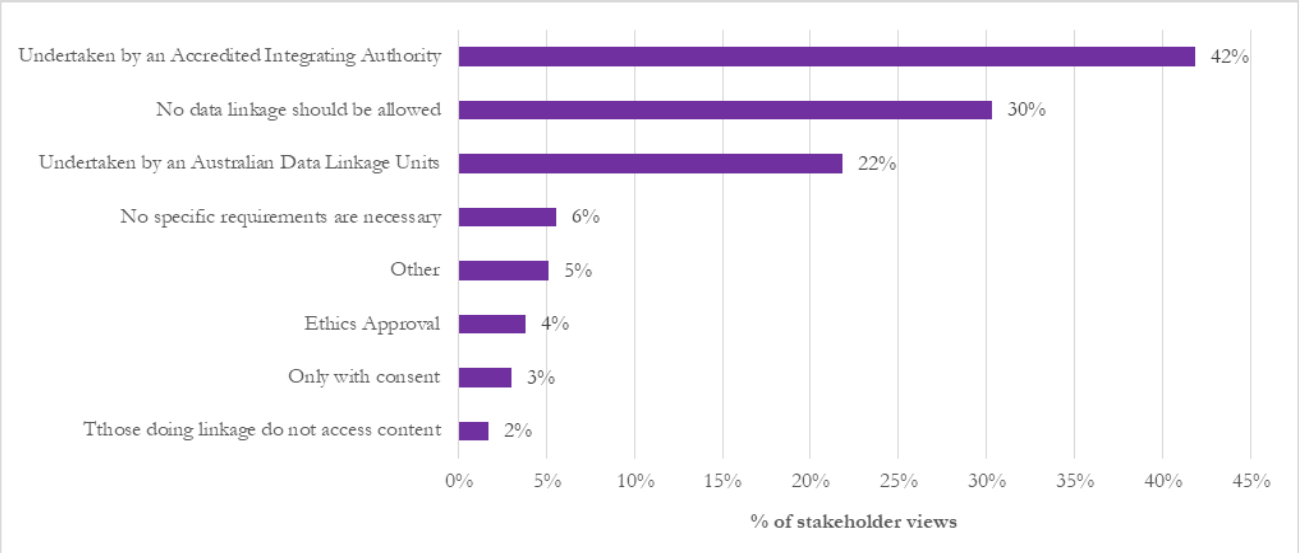
Figure 8.1: Should MHR system data being used for secondary purpose be linked to other data sets?



Source: Thematic analysis of data generated from written submissions and online survey (n=228)

Figure 8.2 shows that the key process that Stakeholders thought should be adopted in the Framework to safeguard the privacy of individuals when datasets involving MHR system records are linked was that data linkages, if undertaken, should be done *by an Accredited Integrating Authority* (42%); an *Australian Data Linkage Unit (i.e. not necessary for it to be an Accredited Integrating Authority)* (22%). However 30% of responding stakeholders thought that MHR system data should be linked to any other data set. Interestingly, all stakeholder groups identified that data linkage should be *undertaken by an Accredited Integrating Authority* except the research sector that preferred it to be *undertaken by one of the Australian Data Linkage Units.*

Figure 8.2: Stakeholder views on how to ensure privacy protection during data linkage



Source: Thematic analysis of data generated from all consultation modes (n=234), nil responses are excluded from denominator)

Many stakeholders recognised the potential value of data linkage, as typified by the submission from the Population Health Research Network, which stated "*Availability of linked population-based data is important because: no single data collection is sufficient to allow an understanding of the complex pathways that result in health or disease and whether Australia's health and social service systems work in optimal ways, and collecting data once and used many times for different purposes e.g. service provision and research is more cost effective than collecting data multiple times*". Similar views were expressed in the submission from the Johnson & Johnson Family of Companies (JJFC) *"Data linkage is essential to health care quality and performance assessment in a decentralised and fragmented health care system such as Australia's. A process based on an "approved research concept" should be followed to create a dataset incorporating information from more than one source. The approach should be able to recognise that research has a legitimate purpose for which health data can be collected, used and linked; and to appropriately balance this use with concerns relating to data security and individual privacy".*

In terms of the linkage process, the NHMRC submission specifically advised *"If ethical clearance and data custodian clearance is obtained to conduct data linkage then linkage must be carried out by an Australian-authorised data linkage hub only".* The submission from HISA put forward a similar view *"We recommend the use of 'safe havens' or accredited linkage units to facilitate the process".* And the AMA submission stated *"Requests to link My Health Record data to another data set should always be subject to human ethics approval and only released to the data applicant in de-identified format after the data is securely linked by one of the three accredited integrating authorities. Use of the de-identified linked data should be subject to the same restrictions as identified data. That is access occurs using a secure on-site data laboratory or within the secure unified research environment (SURE) under a binding agreement of use".*

A consumer view on data linkage was put in the CCHRN submission which stated, *"Data linkage was considered to be of importance to the community as a means of answering important research questions and to better understand unitisation of the healthcare system, 'evidence and research is the key'. It was considered essential that privacy and confidentiality be maintained by using de-identified data, 'Maintaining privacy and confidentiality of my personal records. It would be ok to link my data as long as when it got to the analysis stage it was de-identified'. Linkage should be done by a specific unit such as a data linkage branch that is independent from any of the other users or data custodians".*

When discussing data linkage, stakeholders regularly referred to the need for explicit consent, as highlighted in the submission from Curtin University *"Where researchers require linkage of their own data collections (such as survey or clinical trial data) to MHR data, there are additional risks to privacy. Such linkages should be allowed where researchers can demonstrate that participants have provided informed consent to linkage as part of*

consent to participate in the project. This is what typically occurs for linkage of researchers' data collections to existing administrative data such as hospital admission databases".

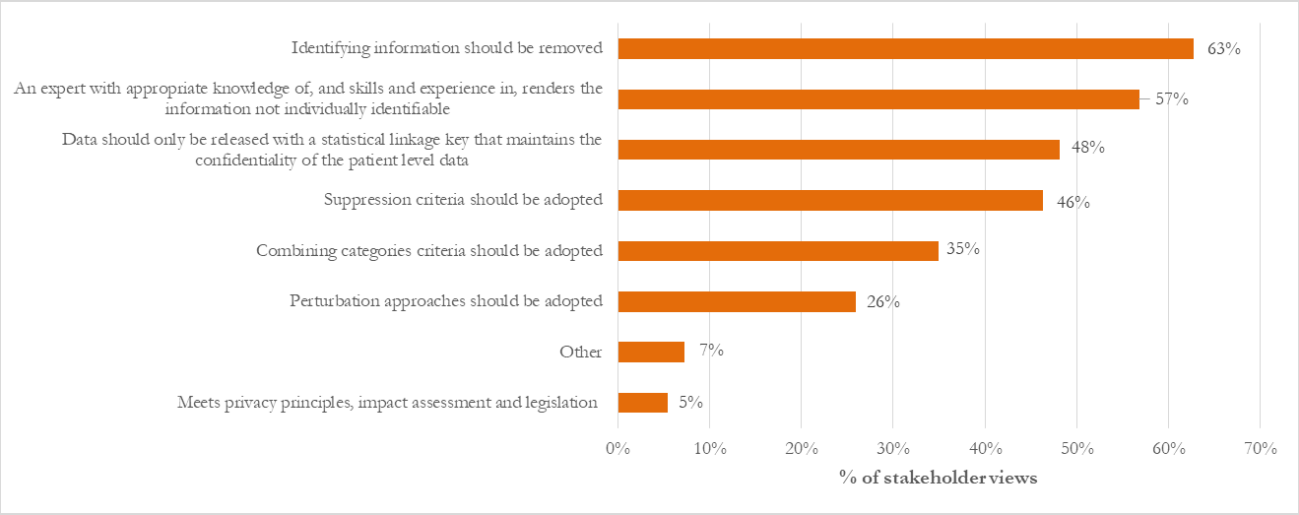
As stated in Figure 8.1, 30% of stakeholders did not support linkage of MHR data to other datasets, as typified in the submission by Positive Life NSW, which states *"People Living with HIV (PLHIV) are a significantly marginalised population and encounter ongoing stigma and discrimination in the community. The linkage of data has the potential to re-identify PLHIV and the risk to safety and wellbeing is considered too high for our peoples. As such, Positive Life does not support the linkage of data between MHR and other datasets, particularly for the purposes of secondary use of that data".* A similar position is put in the submission from the Australian College of Rural and Remote Medicine (ACRRM), which states *"We do not believe at this stage that (MHR) data for this requirement (linkage to other date sets) should be made available. We believe this issue should be reconsidered at a later stage".*

9

Processes to ensure protection of the privacy of individuals

Figure 9.1 shows that, across all consultation modes, stakeholders thought that the arrangements that should be included in the Framework to ensure that the data released for secondary use purposes protects the privacy of an individual include: *ensuring that identifying information is removed* (63%); *an expert with appropriate knowledge of, and skills and experience in, generally acceptable statistical and scientific principles and methods to render the information not individually identifiable* (57%); *data should only be released with a statistical linkage key (SLK) that maintains the confidentiality of the patient level data* (48%) and *suppression criteria should be adopted (i.e. not releasing information for unsafe (small number) cells)* (46%). The use of *an expert with appropriate knowledge of, and skills and experience in, generally acceptable statistical and scientific principles and methods to render the information not individually identifiable* was highly supported by all stakeholder groups except Government agencies where only 8% supported this process.

Figure 9.1: Arrangements to ensure that data released for secondary purposes protects the privacy of an individual



Source: Thematic analysis of data generated from all consultation modes (n=220, nil responses are excluded from denominator)

As per Figure 9.1, stakeholders typically responded using the closed response categories provided in the surveys. The written submission from one research sector organisation echoed these responses stating *"…supports the use of a number of processes that can be used to protect the privacy of individuals, these include but are not limited to Separation principle, Statistical linkage keys, Technologies such as SURE"*. Other stakeholder views included the Australian Centre for Airways Disease Monitoring, which stated *"Researchers / persons who requested use of MHR data should sign a confidentiality agreement outlining their roles and responsibilities in accessing, handling and sharing of confidential information and penalties they can incur if the agreement is breached"*. The NHMRC submission stated *"There should be a mandatory and timely reporting of data breaches/loss and Office of the Australian Information Commissioner advice on remedial actions to be taken (e.g. notifying affected individuals)"*.

Some stakeholders advocated for supporting infrastructure and resources to assist data users to preserve individual's privacy. For example, the submission from CHCRC stated *"A single central agency or resource is required: one that can provide researchers with a comprehensive set of services related to secure data access and secure storage. Ideally, such an agency should be empowered with appropriate regulatory policies and tasked with the responsibility to enable access to high quality de-identified data created for research purposes"*.

Consistent with responses to the question on data linkage, which advocated the use of Accredited Integrating Authorities, many stakeholders pointed to the separation principle as a privacy protection

measure. For example, the submission from AMSANT stated *"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, Statistical Linkage Keys (SLK) in particular, which are potentially re-identifiable and are less accurate for Indigenous populations"*. Other groups expressed concern about the risks associated with the use of SLKs, as evidenced in the submission from SA NT Data Link, which stated *"The SLKs … are not adequate to enable reliable linkages to be undertaken and are also far less likely to protect the privacy of individuals. Such a limited key could not be made to undertake reliable linkage with other jurisdictional data collections"*.

A further issue highlighted in the AMSANT submission was *"The Western interpretation of individual privacy does not take into account Indigenous-specific models of custodianship 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 may not present concerns for non-Aboriginal communities; de-identification for small, remote communities presents different challenges: a community or a person could be identified by a small amount of data, e.g. age range and location"*.

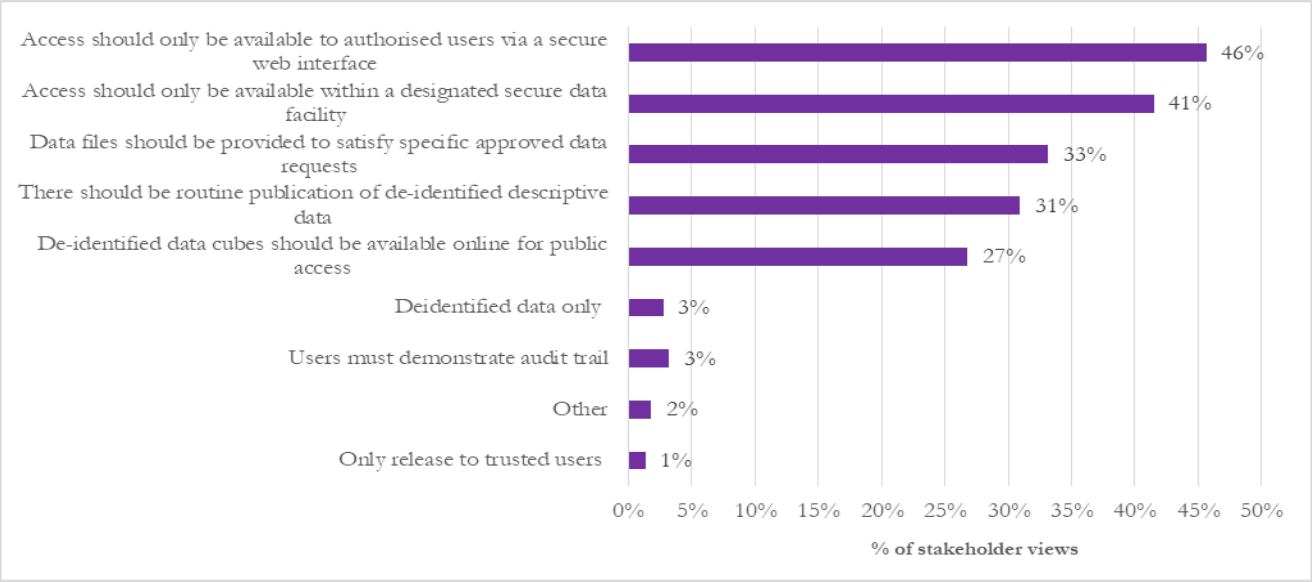
Finally, the submission from ACRRM highlighted the dilemmas associated with under and over aggregation of cells for the protection of privacy by stating *"An organisation decides to use MHR data for analyses of the health of Aboriginal and Torres Strait Islander people.*

- *Go too detailed and you start to get small communities where the concept of identifiable becomes a real risk. Being part of a community identified as having problem X (and therefore the whole community is tarred with the same brush) can be worse than specific identification.*
- *Get too broad and you start to get poor data e.g. the recording of Indigenous status is much more variable in private general practice across Australia.*

10
Preparation, release and quality of data

Figure 10.1 shows that across all consultation modes the most common views (stakeholders could select multiple categories) on arrangements that should be considered for the preparation and release of MHR data were: *access should only be available to authorised users via a secure web interface* (46%); *data should only be available within a designated secure facility* (41%); *data files should be provided to satisfy specific approved data requests* (33%); *there should be routine publications of de-identified descriptive data* (31%) and *de-identified data cubes should be available online for public access* (27%). Interestingly, all stakeholder groups, except research sector representatives, were in favour of MHR system data only being accessible via either *a secure web interface* or a *designated secure data facility*. Whereas research organisations were most in favour of *data files being provided to satisfy specific approval requests*.

Figure 10.1: Arrangements included in the Framework for the preparation and release of MHR data



Source: Thematic analysis of data generated from written submissions and online survey (n=217, nil responses are excluded from denominator)
Other = done by a government agency where employees are accountable and any breaches results in dismissal and banning from the public service (n=1); some raw data and stats should be available real-time (n = 1); and these will likely vary with the circumstances (n=1)

Stakeholders referred to multiple release mechanisms, e.g. the DHHS Victoria submission states *"Victoria envisages that a combination of some or all of the proposed mechanisms for data availability will be required depending on purpose i.e. Routine Publication, Data Cubes, Provision of Data files, Restricted Data Platforms and Safe Havens all have strengths and weaknesses depending on usage. Basic statistical data may be acceptable to be published on a periodic basis. For all other data, a highly secure, controlled access mechanism with full ethics approval must take place"*. Similarly the Grattan Institute submission *"Data release should be facilitated by releasing metadata, developing streamlined and standardised release-approval processes; and developing common-use data sets"*. Other stakeholders supported release of metadata, e.g. Curtin University states *"A clear idea of the underlying metadata and data structures available should be provided publicly, this will provide a clear idea of the information potentially available for research"*.

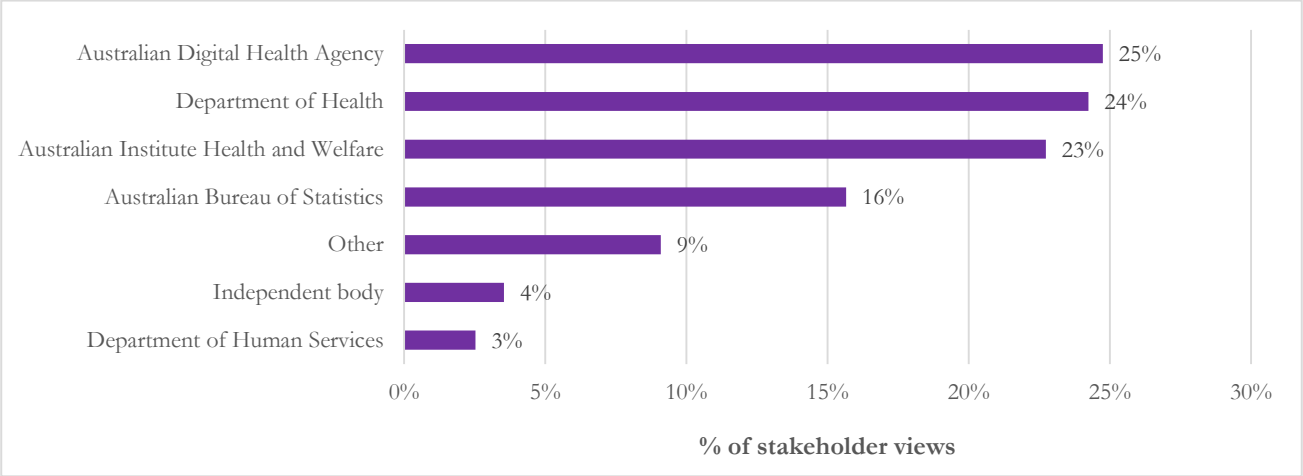
There was also considerable support for the release of data into a Secure Unified Research Environment (SURE) environment or the use of a safe haven as typified by the submission from the Australian Centre for Airways disease Monitoring (ACAM), which states *"Users should only be able to access the data through a secured environment like SURE or the Datalab at the ABS"*. However the submission from one of the research organisations discourages the use of Safe Havens (not SURE) stating *"Having*

engaged widely with our collaborators overseas who use such havens, the use of these severely hampers the benefits that could be realised and the timelines of realising these benefits".

The submission from a number of researchers at the University of Melbourne introduced the concept of differential privacy stating that *"Where aggregate data is released, differential privacy should be considered instead of plain aggregate data"*. Differential privacy is a recent (ten years or so) mathematical development, which effectively involves the use of an algorithm that adds random 'noise' data to the dataset that does not distort the aggregate results, but guarantees that a user *"can learn virtually nothing more about an individual than they would learn if that person's record were absent from the dataset"*[2].

Figure 10.2 shows that across all consultation modes the most common views (stakeholders could select multiple categories) on which organisation should be responsible for preparing and releasing of MHR data for approved secondary use purposes were: *ADHA* (25%) followed closely by the *Department of Health* (24%) and *AIHW* (23%). Consumers/consumer groups, industry/professional bodies and other stakeholder groups were most in favour of the *ADHA* being the responsible agency for the preparation and release of data. Whereas the research organisations preferred the *AIHW* and health care providers preferred the *Department of Health*. Government agency representatives were equally in favour for the responsible agency to be the ADHA or AIHW.

Figure 10.2: Organisation that should be responsible for preparing and releasing of MHR data



Source: Thematic analysis of data generated from all data sources (n=198, nil responses are excluded from denominator).
Other includes: Combination of agencies with consumer input (n=5); Indigenous organisation (n=3); OAIC (n=2); none of these organisations (n=2); one with right skills and resources (n=2); Proposed Health Performance Commission (n=1); Office of the National Health Data Custodian (n=1); and ACCC (n=1)

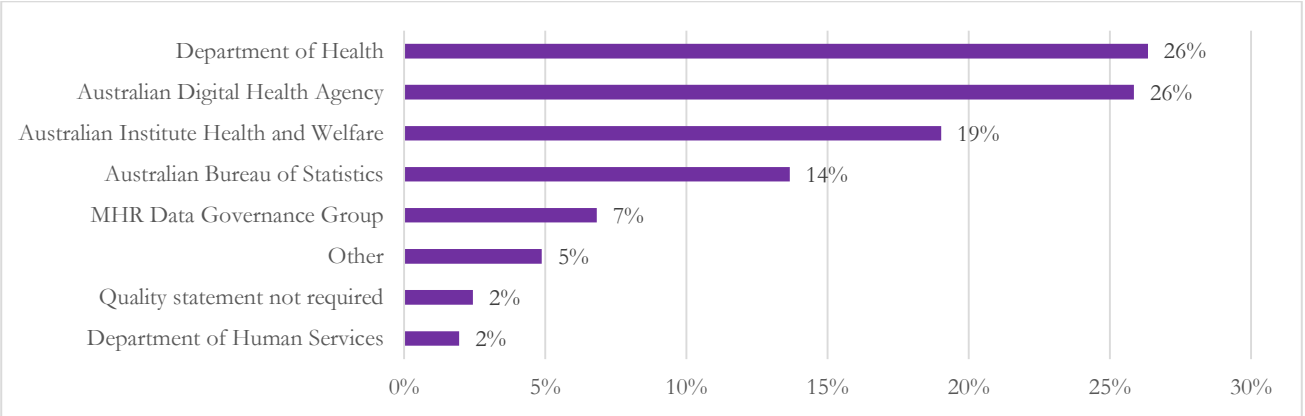
Stakeholder views are typified in the submission from CMCRC, which states *"A single central agency or resource is required: one that can provide researchers with a comprehensive set of services related to secure data access and secure storage. Ideally, such an agency should be empowered with appropriate regulatory policies and tasked with the responsibility to enable access to high quality de-identified data created for research purposes"*. Similarly, the WAPHA submission states *"A central government agency (i.e. The Digital Health Agency, or the Australian Institute of Health and Welfare [AIHW]) should be responsible for releasing MHR data. The approved central agency should stipulate publicly the recommended data sharing arrangements and responsibilities"*. Most stakeholders aligned their views on the governance agency and the release agency.

Figure 10.3 shows that across all consultation modes the most common views (stakeholders could select multiple categories) on which organisation should make a quality statement about the MHR system data being used for secondary purposes were: *ADHA* and *Department of Health* equally favoured (26%) followed by the *AIHW* (19%). When the analysis was done by stakeholder group health care providers, consumers/consumer groups, industry/professional bodies and the research sector were the

[2] Guarantee definition taken from https://www.infoq.com/articles/differential-privacy-intro, accessed 14 January, 2018.

groups in favour of the *Department of Health*. Whereas Government agencies preferred the *"data custodian"* and other stakeholders preferred the *ADHA*.

Figure 10.3: The organisation that should be responsible for making a quality statement about the MHR data



Source: Thematic analysis of data generated from all consultation modes (n=205, nil responses are excluded from denominator)
Other includes: Australian Safety and Quality Commission (n=2); other not further specified (n=2); Indigenous organisation (n=2); Proposed Health Performance Commission (n=1); OAIC (n=1).

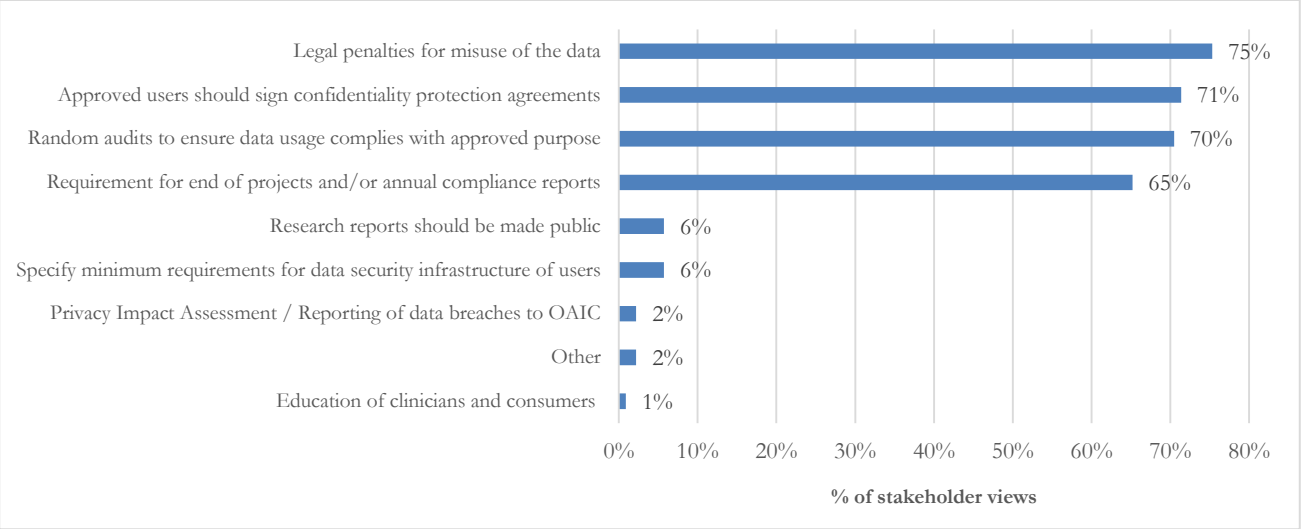
A typical view was put in the submission from one of the industry/professional bodies, which stated *"The System Operator should be responsible for making the quality statement and ensuring the data is of high quality"*. Similarly the WAPHA submission stated *"As custodians of the data, the My Health Record data team should be responsible for providing data quality summaries including metadata associated with the data provided"*. The submission from Australian College of Rural and Remote Medicine (ACCRM) made the additional point around the need for independent assessment of data quality by stating *"The College would suggest that the data custodian is responsible for the quality of the data and the validity of the data should be tested by independent means"*.

The submission from the GaRDN focused on the need to develop a data quality framework by stating *"Data quality is a shared responsibility however a data quality framework should be developed and roles and responsibilities clarified"*. That theme was also present in the submission from JJFC, which stated *"JJFC proposes that the centralised national body … be responsible for the quality of the data and the quality framework"*.

11
Monitoring and assurance processes

Figure 11.1 shows, across all consultation modes, that stakeholders believed that the monitoring and assurance processes that should be considered to ensure MHR system data secondary users comply with the Framework include: *legal penalties for misuse of the data* (75%); *approved users should sign confidentiality protection agreements* (71%); *random audits to ensure data usage complies with approved purpose* (70%) and *requirement for end of projects and/or annual compliance reports* (65%).

Figure 11.1: Monitoring and assurance processes to ensure MHR data users comply with the conditions of release



Source: Thematic analysis of data generated from all consultation modes (n=227, nil responses are excluded from denominator)
Other = data should be time limited and copyrighted (n=2); other not further specified (n=2); ethics and relevant processes when applicants request data (n=1); and data to be destroyed as soon as purpose has been fulfilled or after three months of obtainment, whichever is sooner (n=1)

Stakeholder views on this question were relatively homogenous. Typical opinions were reflected in the submission by the NHMRC, which stated *"An auditing process should be set up and a random sample of about 5% of research projects should be thoroughly audited each year. There should also be annual reporting to the Privacy Commissioner"*. Similar views were expressed by in the submission by one of the research organisations, which stated *"A random audit process as used or in conjunction with ethics committees would support assurance of compliance"*. And again in Positive Life NSW submission *"Every approved user of the MHR system should sign a confidentiality protection agreement and that legal penalties must be strictly enforced for the misuse of data. We support frequent random audits to ensure data usage complies with the approved purpose. Further we support a compulsory requirement for end of project and annual compliance reports from every requesting agency, company or individual that is granted access to the data for secondary use"*.

Similar to the assessment of requests for release of data, the submission from Curtin University advocated a risk based approach stating *"Both monitoring and review should be part of the risk management process and involve regular checking or surveillance. A planned, resourced, approved and documented monitoring and review process is a critical component of the risk management framework and risk process"*.

A robust view that encapsulates many of the stakeholders' thoughts was presented in the submission from CMCRC, which stated *"Sensitive data releases (such as that involving unit record data) should follow a risk management approach. With this in mind, the following monitoring and assurance processes should be considered to ensure data users comply with the Framework implemented:*

- *Individual use agreements and confidentiality undertakings*

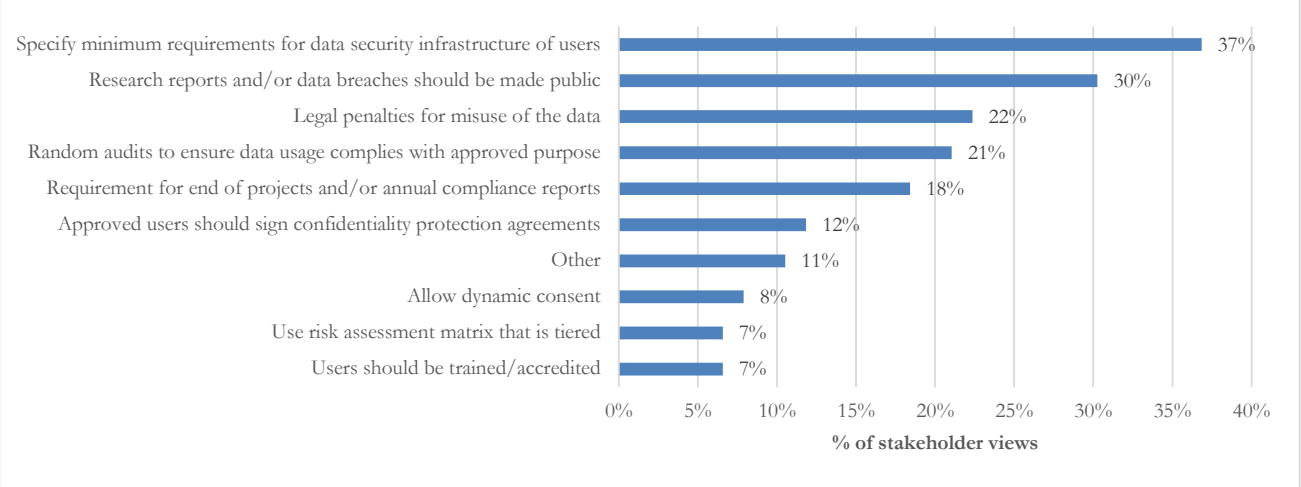
- *Institutional assurances (by the employer of individual users) about data protections in place*
- *Secure access requirements for highly sensitive data (with greater ability for an Accredited Release Authority to oversee and audit use)*
- *Public register of approved programs using MHR data and tracking of publications arising from the use of data.*

There are already examples of these arrangements in place for users of government administrative data – particularly in the health and medical research sector. New arrangements for the secondary use of MHR data should align with existing agreements so as not to impose additional or conflicting requirements on users. However, it should be recognised that existing arrangements for monitoring and assurance were primarily designed for research use of data. The appropriateness of arrangements for other purposes, such as use by private sector companies for eligible commercial uses (if … allowed) would have to be carefully considered and may require more stringent requirements to protect individual privacy.

12 Risk mitigation strategies and imposed penalties

Figure 12.1 shows that, across all consultation modes, stakeholders believed that the risk mitigation strategies that should be included in the Framework are: *specify minimum requirements for data security infrastructure of users* (37%); *research reports and data breaches should be made public* (30%); there should be *legal penalties for misuse of the data* (22%); *random audits to ensure data usage complies with approved purpose* (21%); and *requirement for end of projects and/or annual compliance reports (18%).* The risk mitigation strategy of allowing dynamic consent was only raised by *consumers/consumer groups.*

Figure 12.1: Risk mitigation strategies that should be included in the Framework

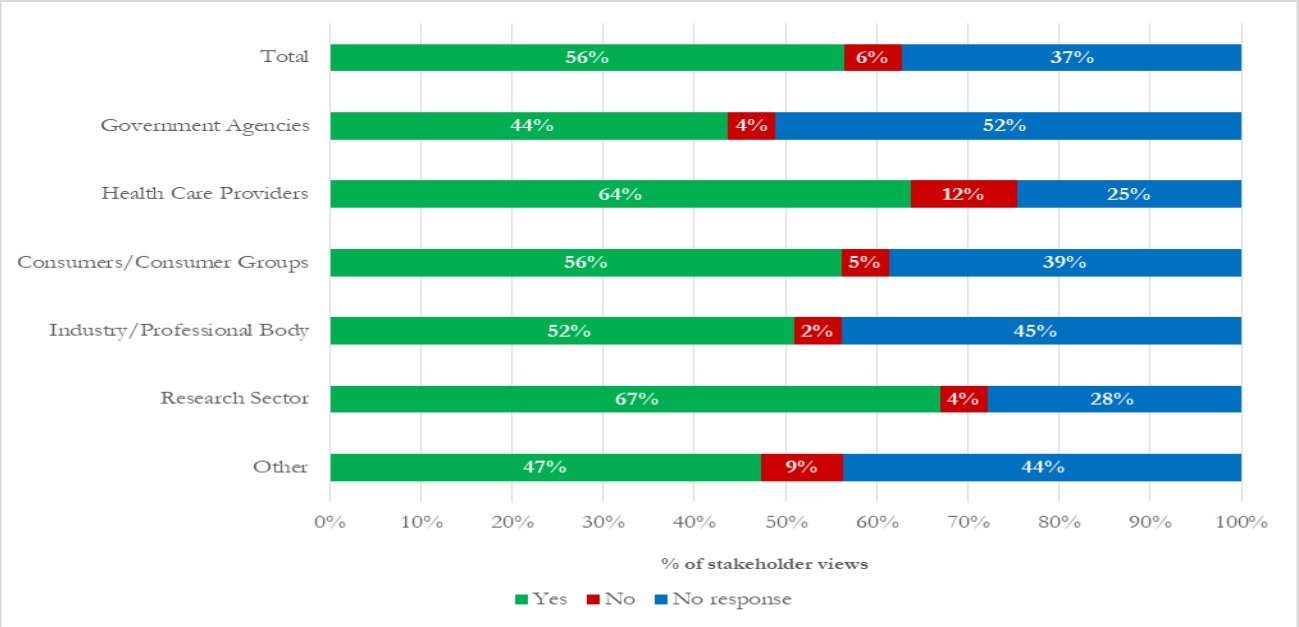


Source: Thematic analysis of data generated from all consultation modes (n=86, nil responses are excluded from denominator)
Other = involve Indigenous bodies to mitigate risks re lack of cultural interpretation of data (n=3); need to ensure that risks are balanced (i.e. stifling innovation, cost-benefit) as don't want to limit research to be undertaken (n=2); implementing a flexible framework responsive to changing technology (n=2); and invite people to attack the system (without publishing the de-identified data of course), and pay them if they succeed (n=1)

Many stakeholders had specified risk mitigation strategies as part of their response to other questions, hence this questions was not directly answered by a number of respondents (n=86). As per Figure 12.1, the views expressed drew on strategies that had been previously reported. Some new ideas were proposed, e.g. the submission from one of the industry/professional bodies stated *"There should be consideration given for the public to have a chance to object to proposed projects prior to access to the data being given within a defined time. The data custodian should consider general public feedback when deciding whether to permit access".* And the submission from the Victorian DHHS stated *"Data users should be required to prepare and submit a risk management plan as part of the application process for data usage, specifically to address risks to privacy, and handling of security breaches including cybersecurity events, and in accordance with ethics review".* These suggestions should be considered for the Framework.

Figure 12.2 shows that, across all consultation modes, individually and collectively, a significant majority of stakeholders (56%) support there being a public register which identifies researchers who have requested access to the data; the purpose, nature and status of the data request, the compliance reports (if used), any publications and/or data breaches that have resulted from using the data. Moreover, of those stakeholders who directly responded to the question, the ratio of those in favour of a public register to those against was over nine to one.

Figure 12.2: Should there be a public register?

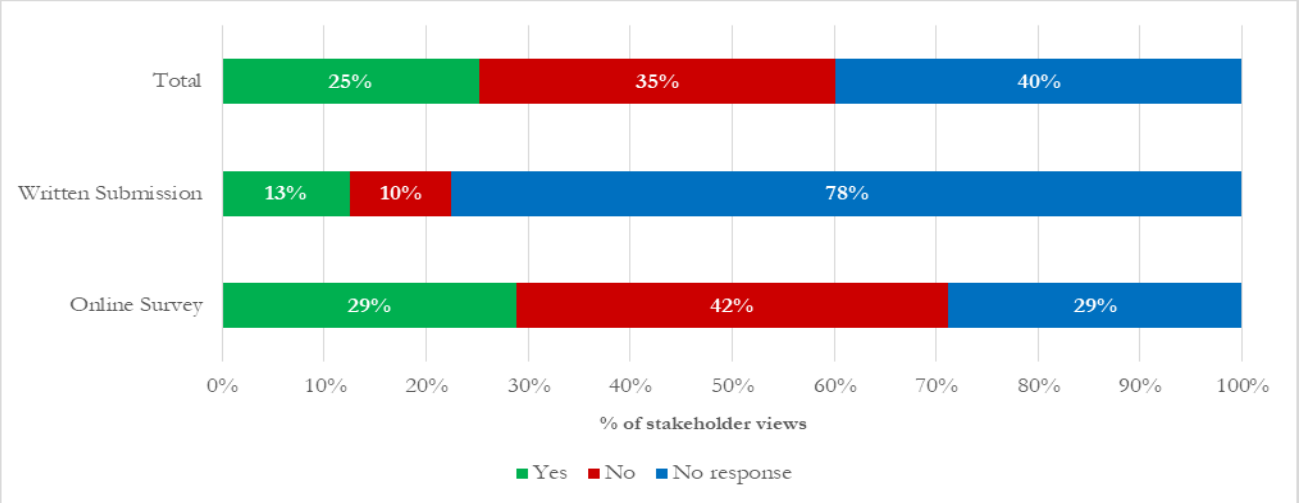


Source: Thematic analysis of data generated from all consultation modes (n=376)

Typical of the supportive comments offered by stakeholders was the submission from HISA, which stated *"The results and benefit of the use of the data should be recorded to better inform patients and the public, help balance the public good versus privacy risk equation and justify continued funding for the management of secondary use of MHR data"*. An important point about using a register to improve transparency was made in the submission by Future Wise *"this sort of publicly-accessible register would increase the transparency of secondary use, and provide reassurance to the public their data is being used appropriately"*.

Figure 12.3 shows that, across written submissions and on line survey respondents, 25% of stakeholders (which represents 42% of those who explicitly responded to the question) believe that the existing penalties for the misuse of data under the MHR Act are *sufficient*. There is a difference in opinion by consultation mode, as 57% of written submissions but only 41% of on-line survey respondents, where a view was expressed, believed the existing penalties are *sufficient*.

Figure 12.3: Are the existing penalties for the misuse of data under MHR Act sufficient to cover secondary use?



Source: Thematic analysis of data generated from written submissions and online surveys (n=354)

Typical of comments from stakeholders who thought the existing penalties are sufficient was in the submission from Roche, which stated *"Roche is of the view that the current penalties are a sufficient deterrent to ensure that the use and integrity of released data is both maintained and used in an appropriate manner. Additional*

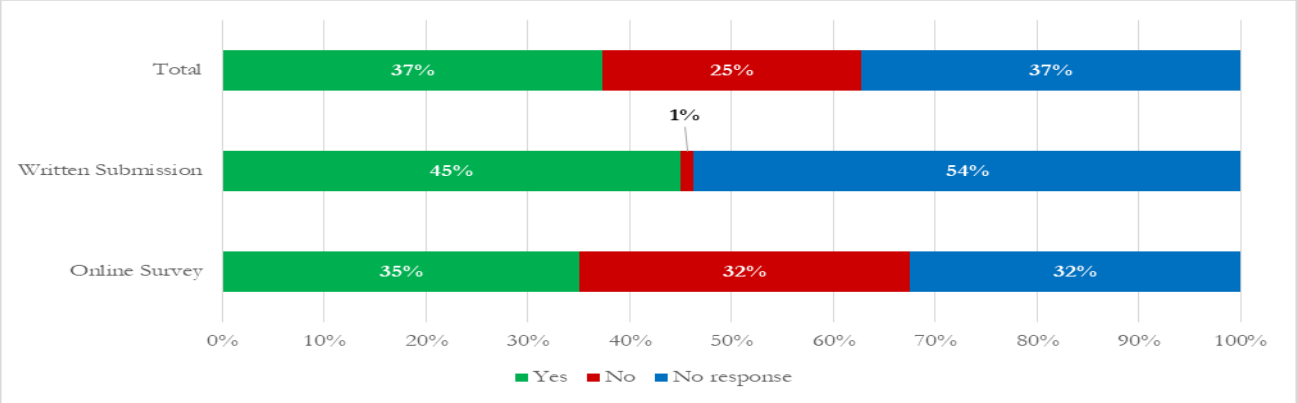
penalties may serve as a disincentive to apply for access to MHR data, and limit the research opportunities and reduce the overall public good". A consumer view, put by CCHRN in its submission was *"Members considered that penalties for misuse of data should be strict and significant in value with people being excluded from accessing the data in future if they have been found to be in breech".* This statement does not comment on existing penalties, but does offer a view on what consumers believe is required of the penalty regime.

Stakeholders who believed the existing penalties were not sufficient raised some important issues. For example, the submission by AMSANT stated *"No, the current penalties are insufficient: government excluded, accidental disclosure … and only individual privacy considered".* The AMSANT submission elaborated *"Currently the Privacy Act exempts statutory Government agencies and accidental disclosure and use in some cases"* and also *"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 in important in cultural security and safety of Aboriginal research".*

13 Suggested policy changes

Figure 13.1 shows that, across written submissions and online survey respondents, 37% of stakeholders reported that *'yes'* there needs to be policy changes against 25% reporting *'no'*, no policy changes are required to support the release of MHR data for secondary use. As also shown in Figure 13.1, there is a difference in opinion by consultation mode, as 98% of written submission authors but only 52% of on-line survey respondents who expressed a view believed that policy changes are needed.

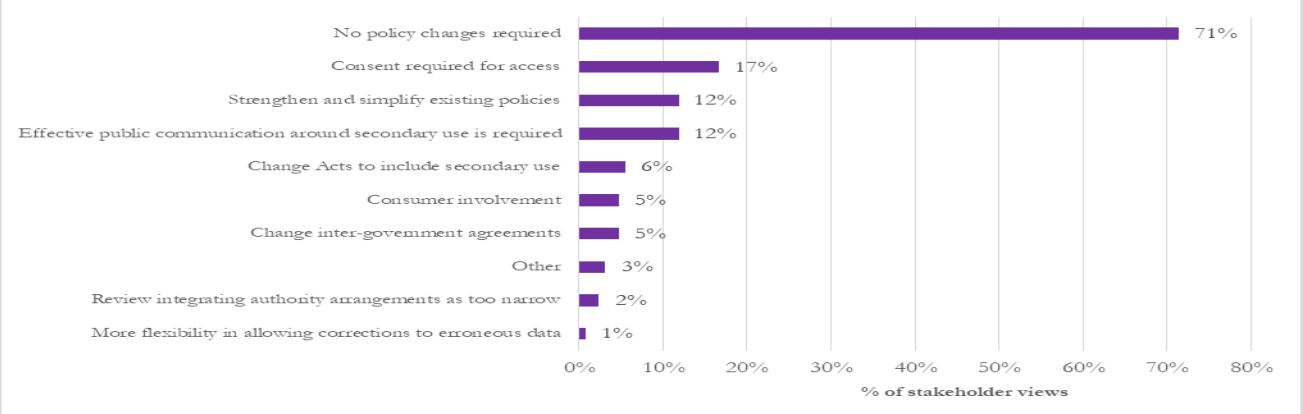
Figure 13.1: Are policy changes needed to support the release of de-identified MHR data for secondary uses



Source: Thematic analysis of data generated from all consultation modes (n=383)

Figure 13.2 shows that although the majority (71% of respondents to the question) of stakeholders felt that there were no policy changes required to support the release of MHR system data for secondary uses there were a number of suggested policy changes made by stakeholders including: *gaining informed consent (i.e. not assumed in the opt out process,* (17%); *strengthening and simplifying existing policies* (12%); and *ensuring there is effective public communication around secondary use* (12%). Representatives from State/Territory Health authorities raised the changes to the inter-state agreements. This was in regards to data access and data sharing. Most felt the current agreements were too narrow. There was also suggestion that MHR system data should be made available to the States/Territories in the same way that MBS and PBS data is currently available.

Figure 13.2: Policy changes suggested by stakeholders to support the release of MHR system data



Source: Thematic analysis of data generated from all consultation modes (n=126, nil responses are excluded from denominator). Other includes: entities seeking MHR data for secondary use that are not covered by the Privacy Act be brought under the coverage of the Privacy Act via sections 6A, 6EA or 6F (n=1); changes needed to address all potential methods of sharing data, especially in light of expanding digital (n=1); legislative changes to be made to Australian privacy principles that fall under the OAIC section 95 and 95A (n=1) and lack of privacy legislation in Western Australia. Note: "Change Acts to include secondary use" include ABS Act prohibits linkage, may need to change (n=2); Change MHR Change Act to include secondary use (n=5)

As implied by the overwhelming large numbers in Figure 13.1, written submissions pointed to a variety of problems with the current policy/legislative framework relating to the release of MHR data for secondary use. Many submission authors pointed to the general complexity of the area, as illustrated in the submission from one of the research organisations, which stated *"The Productivity Commission's Data Availability and Use Inquiry Report highlighted that the legislative environment for secondary use of data was complex and that 'Marginal changes to existing structures and legislation will not suffice. Recommended reforms are aimed at moving from a system based on risk aversion and avoidance, to one based on transparency and confidence in data processes, treating data as an asset and not a threat. Significant change is needed for Australia's open government agenda and the rights of consumers to data to catch up with achievements in competing economies'. …. agrees that the points raised by the Productivity Commission are founded and reflect our experiences in access and using data for secondary uses".*

Further important points were made in the submission from CMCRC, which stated *"It is important to note that the current restrictive data release regime – much of which was imposed decades ago – is patently out of step with the evolving views of consumers regarding use of their own data for the improvement of their own health and healthcare and to support research"* and in the submission from HISA *"harmonisation of legislation and regulation between the federal and differing State jurisdictions. It is unclear if the data stored in the MHR will be considered subject to only Federal legislation as it is held in a national repository, or will it also be subject to the jurisdictional requirements of the state in which it is being requested/used or from where the original records were sourced? … it is unclear why the MHR data should be treated differently to data from the original sources where waiver of consent for purposes relating to healthcare improvement and quality assurance processes as well as certain types of observational research are permitted by law and via authorisation through HREC application. We recommend policy and legislation makers consider how to harmonise and standardise all health data request and authorisation processes".*

In addition to the general concerns, stakeholders made some specific suggestions for change. One government agency submission stated that a key enabler for both primary and secondary use of MHR data was *"Amendment of the My Health Records Act 2012 particularly Part 4 – Collection, use and disclosure of health information included in a healthcare recipient's My Health Record and Part 6 – Enforcement, to enable secondary uses".* Specific to enabling data linkage, the submission from the PHRN stated *"One of the issues that PHRN has experienced … is that the legislative environment for the linkage of data collections is extremely complex and confusing. In part this is due to the fact that the legislation that authorises the collection is not sufficiently clear on the use and disclosure for secondary purposes".*

Finally, the AMA submission emphasises the importance of the Framework in contributing to the resolution of the issues "*Our reading of the My Health Record Act 2012 and its intersection with privacy law, suggests the Framework document bears the full responsibility for setting the parameters and circumstances in which the disclosure of de-identified MHR data for secondary purposes can occur. This confers on the Framework, a substantial responsibility to strike the right balance between secondary disclosures for public good on the one hand, and protecting patient privacy and integrity of the MHR system on the other hand".*