MEDICINEINSIGHT

CONSENT MODEL REVIEW

A report for the Department of Health

February 2021 | v2.0

Independent, not-for-profit and evidence based, NPS MedicineWise enables better decisions about medicines and medical tests

Level 7/418A Elizabeth St
Surry Hills NSW 2010
PO Box 1147
Strawberry Hills NSW 2012

P. 02 8217 8700
F. 02 9211 7578
info@nps.org.au
www.nps.org.au

Stock code (if required)

Suggested citation

MedicineInsight Consent Model Review. NPS MedicineWise, February 2021

Contents

Foreword 4
Executive Summary 5
Context of the the consent model review 8
The MedicineInsight Opt out Approach 9
Our consultation approach 10
Consultation themes and insights....11
Recommendations 18
Next steps 20
Appendix 1. Stakeholder engagement 21
Appendix 2. Draft costings....22
Appendix 3. Draft implementation plan....26
Appendix 4. Digital Health Cooperative Research Centre Collaboration....27
Appendix 5 Opt out approach features....33
Appendix 6 Participant information sheet....35

FOREWORD

Over the past eight years the Australian Government has made a significant investment to support the creation of a unique health data asset – MedicineInsight. MedicineInsight collects deidentified patient data from General Practices to provide a national longitudinal data set for Australia, with cleansed, structured and interrogable clinical data on 3.3 million Australians.

Since 2012, MedicineInsight has supported the Quality Use of Medicines agenda and National Medicines Policy. The data is extracted weekly from clinical information systems (CISs), providing close to real-time insights, and is sourced nationally from 697 participating practices representing 4,966 general practitioners as at December 2020. The Department of Health and associated agencies are using MedicineInsight for a range of purposes and are highly supportive of its capabilities as are academic researchers, epidemiologists and the General Practice community which benefits from this dataset.

The MedicineInsight program uses an opt out approach, which is the basis on which patient data is collected. This approach is overseen by the Royal Australian College of General Practitioners (RACGP) National Research Evaluation Ethics Committee (NREEC), and the MedicineInsight independent Data Governance Committee. Over time, both have endeavoured to ensure the opt out approach is consistent with best practice privacy approaches, and ethical requirements as required by the National Health and Medical Research ethics guidelines.

It is important to note that, while there is no legal requirement to obtain consent for the use of deidentified data, an opt out model must appropriately fulfil ethical obligations and ensure it maintains the social licence to operate. The MedicineInsight program strives to ensure transparency of its governance and consent approach with stakeholders, however as sentiment continues to shift towards health data sharing and data linkage it is appropriate that the opt out approach and alternative models are continuously reviewed.

This review found that there is an opportunity for practical enhancement of the opt out approach which underpins MedicineInsight data collection. These recommendations are aimed at ensuring MedicineInsight retains the support of its stakeholders and may continue to support the quality use of medicines in Australia.

EXECUTIVE SUMMARY

Issue

Since the commencement of the MedicineInsight program, the opt out approach to consent and governance of the program has evolved based on researcher needs, human research ethics guidance, and increasing consumer engagement. However, there has not been a dedicated review of the opt out approach since the program commenced.

In order to ensure best practice, ongoing confidence in the MedicineInsight program and demonstrate transparency in its governance, the current grant agreement between NPS MedicineWise and the Australian Government Department of Health (Department) requires a review of the MedicineInsight consent framework.

Accordingly, a review of the MedicineInsight consent model has been undertaken by staff at NPS MedicineWise. The purpose of the review, in accordance with the project scope approved by the Department (Scope), was to consider whether the consent model is appropriate, and to make recommendations to ensure consent is obtained in line with contemporary best practice.

Methodology

The review was led by an experienced Research Ethics and Data Governance Specialist with significant experience of large health datasets in Australia. In order to assess whether the current consent model represents best practice, current and emerging legislative and ethical standards were considered, and wide consultation was undertaken.

The activities that informed the review included a comprehensive desktop review of stakeholder submissions to other reviews (including legislative reform), a review of Commonwealth programs concerning consent and review of the documentation listed in Attachment 4 of the approved review Scope document.

From the desk top research evaluation principles were established which informed consultation questions for stakeholders designed to help identify best practice practices that could be applied to MedicineInsight. Twenty-two individual consultation sessions were held with academics, MedicineInsight partners, Primary Health Networks, government stakeholders, as well as advisory group discussions with general practitioners (GPs), researchers and academia, health consumers and representatives of the Digital Health Cooperative Research Centre.

From the different activities, insights were drawn about contemporary best practice. These are stated throughout the report and formed the basis of the report recommendations.

Findings and Analysis

Based on analysis of current legislative, ethical requirements and a comprehensive stakeholder consultation, the opt out model is consistent with contemporary best practice and is currently the most appropriate model.

However, four areas for improvement were identified to enhance the current opt out approach. These have resulted in 18 recommendations. The four areas of improvement are:

1. **Communication and transparency** - The MedicineInsight program should do more to ensure informed choice underpins the opt out consent approach by explaining opt out, data linkage, and deidentification processes to heath consumers, practice staff and managers.
2. **Governance and consumer oversight** - The MedicineInsight program should revise and clarify its governance processes to ensure ongoing consumer input and oversight of procedures to enhance trust in the opt out approach.
3. **Collaboration and partnering** – The MedicineInsight program should further align with current and emerging Commonwealth requirements regarding consent and consider partnering on research and monitoring of consumer sentiment to data sharing.
4. **Evaluate complimentary consent models** – The MedicineInsight program should continue to monitor emerging evidence that may demonstrate alternative and practical consent approaches and, if feasible, implement appropriate changes (with the approval of the Department).

Recommendations

1. Communicate the review findings to participants in the consultations, GPs, Health Consumers and MedicineInsight customers as part of a coordinated communication plan incorporating the Privacy Impact Assessment findings and revised MedicineInsight Strategy.

2. Revise the MedicineInsight website to provide easier to understand information, including the use of pictograms, infographics visual aids and summaries of data use and participating practices.

3. Work collaboratively with technical experts and partners to develop public communications on data linkage processes, including clarifying the scale of data sharing, linkage variables, and legal authority.

4. Produce video resources and case studies highlighting the benefits of the program, including how MedicineInsight contributes to understanding the impact of Covid 19, bushfires and other health issues.

5. Provide further information around how to opt out, including how to access opt out forms so health consumers may make an informed choice to opt out if desired.

6. Use quarterly MedicineInsight communications channels to General Practices to proactively promote the opt out approach.

7. Continue to ensure MedicineInsight data is only released in line with the Commonwealth data sharing principles and the Five Safes Framework.

8. Release a plain language consumer version of the governance framework on the NPS MedicineWise website.

9. Provide summaries of data governance assessments and more transparent information about the Data Governance Committee and members.

10. Develop or make available and promote resources for researchers about how to engage consumers in MedicineInsight projects.

11. Promote the use of consumer advisors within research studies, and internal communication between consumer and data governance advisory groups.

12. Ensure the cultural safety and data sovereignty of consumers is respected by maintaining tailored culturally appropriate materials and undertaking dedicated Indigenous research and proactively engaging community in study design.

13. Seek accreditation under the National Data Access and Sharing arrangements and ensure the risks and benefits of alternative data sharing arrangements are fully understood and communicated.

14. Actively seek to collaborate with areas of the Department which are monitoring and evaluating consumer sentiment towards opt out approaches to data sharing.

15. Explore mechanism for direct consumer dialogue with MedicineInsight participants.

16. Continue, and strengthen RACGP ethics oversight of the opt out approach.

17. Persist with the opt out approach, support specific studies which involve individual consent, and evaluate the evidence for dynamic consent as it emerges.

18. Explore a national and coordinated approach to dynamic consent implementation and review the success of similar projects in obtaining opt-in consent for record linkage.

Summary Next Steps

The Department is requested to consider this report and to:

1. Accept the report as meeting the MedicineInsight Maintenance milestone that requires NPS MedicineWise to complete a review of the consent model.

2. Communicate back to NPS MedicineWise which of the recommendations it accepts and which it requires NPS MedicineWise to implement

3. NPS MedicineWise to implement those recommendations accepted by the Department either as part of the existing MedicineInsight Maintenance workplan and budget or as art of the workplan and budget to be submitted for Department approval for the period commencing 1 July 2021.

CONTEXT OF THE CONSENT MODEL REVIEW

Relevant NPS MedicineWise review recommendations

The third recommendation of the NPS MedicineWise Review[1] commissioned by the Department and undertaken by Professor Lloyd Samson, outlines that NPS MedicineWise should strengthen governance of the use of MedicineInsight data including greater transparency to ensure ongoing confidence in the processes and to ensure data are not used in a manner contrary to NPS MedicineWise's mission.

Current Grant Agreement objectives

The current grant agreement provides, as a performance indicator (see 1.3), that during the term of the Agreement the Grantee must ensure there is transparency in MedicineInsight data governance; and the use of the dataset is consistent with the National Strategy for Quality Use of Medicines (NSQUM) through the quarterly publication of projects on the NPS Website. In addition, the Grantee must conduct and complete a review of the current MedicineInsight Consent Framework.

How does this report fit within the overall workplan?

This report is a review of the current consent framework for MedicineInsight with recommendations, which form a deliverable of the NPS MedicineWise Grant Agreement under Schedule 8a, MedicineInsight Maintenance; *"A review of the current Consent Framework. This includes provision of a framework for considering consent model revisions".*

This report and its recommendations are aligned with and compliment other workplan deliverables under Schedule 8a MedicineInsight Maintenance, which include the delivery of a Privacy Impact Assessment which has some overlapping recommendations. Recommendations of this report have been mapped to actions under the MedicineInsight strategy to ensure consistency.

What is the Scope of the consent model review?

On 7 September 2020, the Department approved the project Scope for this review. The Scope of the review is to ensure that consent is obtained for the program, not only in accordance with relevant legislation, but in line with contemporary best practice. The specific aims of the review are to provide recommendations on how the opt out model may be improved, particularly to further support data linkage of MedicineInsight.

[1] https://www1.health.gov.au/internet/main/publishing.nsf/Content/0145E7AFBF01648ACA25852200051C9C/$File/Public-Report-of-the-Review-of-QUM-Program-Delivery-by-NPS-MedicineWise.pdf

THE MEDICINEINSIGHT OPT OUT APPROACH

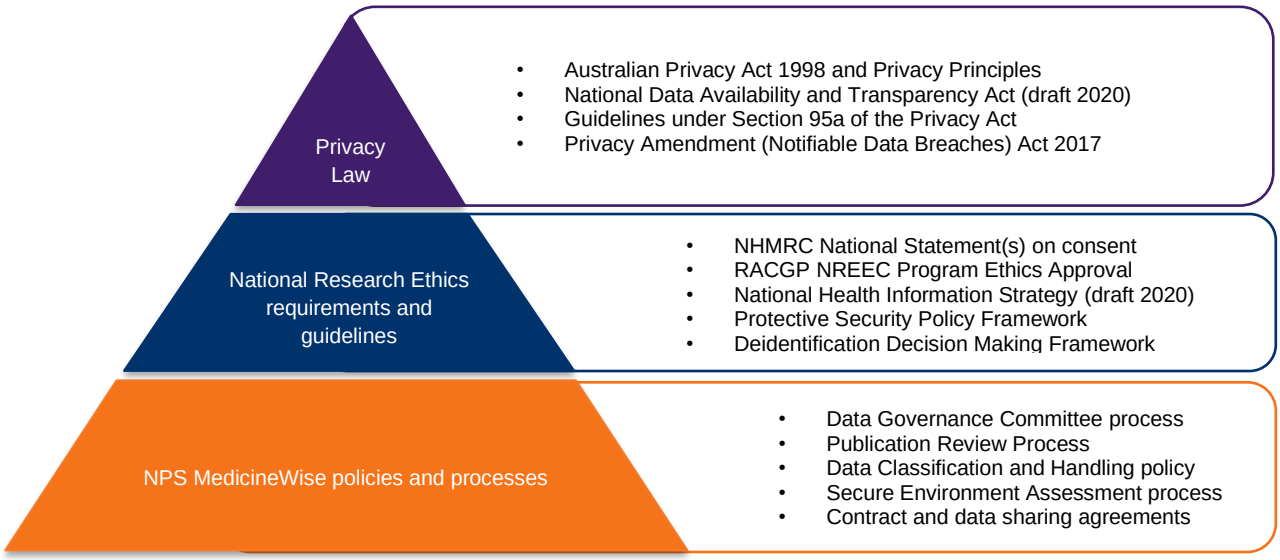
The opt out approach is a method used in the recruitment of participants into research where information is provided to the potential participant regarding the research and their participation is presumed unless they take action to decline to participate[2].

An opt out approach to data handling may only be lawfully applied when certain criteria and assessment processes are met in accordance with National Health and Medical Council guidelines and Privacy Act requirements. While an opt out approach makes it possible for people to make an informed choice about their participation, this choice can only be made if participants in MedicineInsight receive and read the information provided, and they understand that they are able to act on this information in order to decline to participate. Informed choice through the MedicineInsight program relies on the display of patient information at the practice and through communication of the program activities including research outputs.

The opt out approach and the requirements that MedicineInsight must satisfy are described in National Guidelines[3], which includes exemption requirements and that the suitability of an opt out approach for research purposes may be assessed and approved by a properly constituted Human Resource Ethics Committee (HREC). MedicineInsight received HREC approval from the Royal College of General Practitioners in 2014 and this is updated from time to time.

A key aspect of the opt out approach is that patient data is collected on a deidentified basis, and therefore some Commonwealth Privacy Act mechanisms are not applicable such as ethical considerations of waiving consent. Further as the data is deidentified the opt-out approach does not constitute a consent model when applying the criteria of Commonwealth privacy legislation. The MedicineInsight opt out approach relies on providing health consumers with reasonable attempts to make an informed choice to participate and implements several controls (see **Appendix 5** for more information)**.** The opt out approach to consent also sits within a broader framework of MedicineInsight governance as follows;

FIGURE 1: MEDICINEINSIGHT KEY GOVERNANCE CONCEPTS



[2] See NHMRC National Statement on Ethical Conduct in Human Research definition of opt out section 2.2
[3] See NHMRC National Statement on Ethical Conduct in Human Research section 2.3

OUR CONSULTATION APPROACH

Twenty-two one-hour sessions were held with individual participants via teleconference. Each participant's session was prefaced with an information sheet and a semi-structured questionnaire to guide the consultation conversation (**See Appendix 6**).

In addition, several targeted sessions were held with NPS MedicineWise advisory groups, including the independent MedicineInsight Data Governance Committee, the NPS MedicineWise Consumer Advisory Group, the MedicineInsight Data Development Advisory Group and the MedicineInsight General Practice Advisory Group.

Data linkage was discussed with representatives of Curtin University, Western Australian Data Linkage Branch, La Trobe University, the Unit Head of the Australian Institute of Health and Welfare Data Linkage Unit, the Director of the Australian Bureau of Statistics Multi Agency Data Integration Partnership (MADIP) and representatives of the Department of Health's Data Access and Release Panel.

In October 2020, NPS MedicineWise staff participated in a roundtable webinar with the Office of the National Data Commissioner (ONDC), and provided a consultation submission to the ONDC, and received written feedback from the ONDC regarding this review.

Through September and October 2020, several ongoing discussions occurred with the Medical Software Industry Association, the Australian Bureau of Statistics, and Australian Institute of Health and Welfare. In addition, a six-week collaborative design process was undertaken by NPS MedicineWise staff with the Digital Health Collaborative Research Centre and the Royal Melbourne Institute of Technology which explored the feasibility for implementing a dynamic consent model within population health datasets (see **Appendix 5**)[4].

A desktop review of public submissions was undertaken to the Data Access and Transparency draft bill (closed November 2020), the consultation paper of the National Data Sharing and Transparency Bill submissions (closed March 2020) and the National Health Information Strategy (closed March 2020).

All consultation sessions aimed to identify and discuss stakeholder views on the MedicineInsight consent model, the appropriateness of the current opt out approach, and potential alternatives and/or enhancements. Each of the sessions provided valuable feedback about MedicineInsight consent processes and future directions.

In accordance with project Scope, all stakeholders were consulted except for the NSW Data Linkage Unit (CHeReL) which declined, and the Therapeutic Goods Authority which felt that as they are not data custodians, input into this review was beyond the remit of their expertise. The Consumers Health Forum (CHF) and the RACGP considered they both had an ongoing role in the oversight of the consent approach and assessing ethical issues regarding the use of MedicineInsight data.

It is proposed that consultation themes and insights of this report are provided back to participants pending approval of the report and the implementation plan by the Department. A full list is participants involved in the consultations is attached at **Appendix 1.**

[4] This exercise incurred no costs. Staff time of approximately 15 hours was approved and accounted for as a professional development opportunity with direct relevance to grant funded activity.

CONSULTATION THEMES AND INSIGHTS

1. Communication and transparency - the MedicineInsight program, opt out approach and data linkage

A reoccurring theme raised throughout consultation sessions, was that transparency and effectiveness of communication is essential for building public trust in the opt out approach.

The NPS MedicineWise Consumer Advisory Group noted that the MedicineInsight program website is an important channel of information, and that this generally contained comprehensive information. However, some consultees considered this text heavy and dense. Stakeholders, including GPs, suggested information about the opt out approach and the program could be better tiered or layered based on the level of interest, attitudes towards data sharing[5] and user design principles. We were advised that the structure of the website and program information should be amended so that it is tailored to provide discoverability of information that best informs the opt out choice.

Stakeholders also suggested that the website could provide more understandable content, and some considered the current information too complex. It was suggested the program employ pictograms, infographics and summary information for those who do not wish to read.

Types of information which could underpin the opt out approach information may include 'report cards', video or podcast resources or provide summary '*at a glance*' statistics on the MedicineInsight program. Several participants suggested vignettes, or case studies as a powerful way to highlight the public good aspects of the program. It was suggested that data insights should be presented graphically as trends and complemented by hyperlinks and electronic resources for those that wish to discover more.

Most stakeholders considered that NPS MedicineWise is quite transparent about the use of data as approved projects are listed on the website. Participants noted the Office of the National Data Commissioner is advocating strongly to highlight the benefits of sharing data for health research[6] and many health consumers consulted suggested the program be more explicit in highlighting the benefits of MedicineInsight research, with relevant and current information about topics supporting public health in areas such as bushfires and COVID-19.

The Department of Health Data Release and Access Panel (DRAP) Committee representatives noted the importance of communicating the basis and benefits of, data integration. We were advised that the current project summaries provided on the website could be improved on to 'tell the patient's story' and how the positive use of health data improves health and supports health care planning.[7]

INSIGHT: Get the balance and structure of information right on the website, use visual communication methods and focus on the benefits of MedicineInsight including specifically the benefits of data linkage

[5] See Research Australia 2020 polling which indicates 82% of the public are supportive of sharing their health data for research purposes,
[6] See Office of the National Data Commissioner discussion paper on the benefits of data sharing
[7] See the UK National Health Service Caldicott principle seven, which states that 'The duty to share information can be as important as the duty to protect patient confidentiality'

Communication of the opt out approach

Almost all stakeholders recommended that the basis of the opt out approach needs to be clearly described. This was seen by many as a high area of need, as the concept behind opt out relies on informed choice. Therefore, communication about the programs opt out approach is critical.[8]

Participants suggested that consent is an area not well understood by consumers or even those conducting health research.[9] We also found significant confusion about the lawful basis of the consent model approach. Representatives of the Department suggested we reference specific Commonwealth advice on communicating the opt out approach[10]. It was further noted that the Privacy Commissioner and National Data Commissioner are increasingly expressing the view that the lawful basis of opt out approaches should be more fully relied upon and communicated[11].

Participants suggested that MedicineInsight should strengthen communication around:

- That a 'consent model' for the use of patient data is not employed or appropriate
- That legal mechanisms and waivers of consent under the Privacy Act do not apply
- The program uses deidentified information of patients and must abide by ethical principles for conducing human research
- That the opt out approach requires consumers to have genuine informed choice

Many participants acknowledged that the success for an opt out approach and measuring informed choice is hard to quantify. While opt out benchmarks exist[12] it is important to proactively promote opt out mechanisms that are available to consumers to ensure genuine 'informed choice'. General Practice Advisory Group members and other GPs suggested that the MedicineInsight program could explore working with the RACGP to better communicate the opt out approach at the point of practice registration. Members with affiliation with RACGP felt they had an organisation role on behalf of members to assist with the communication as this impacts all data extractors not just MedicineInsight. Participants noted that a form of consent to data sharing is often provided when signing up a new patient with a general practice. However, this is not always provided in a coordinated way or necessarily extends to secondary use purposes[13].

It was further suggested that primary care data extraction programs should work towards efficiencies in seeking 'informed choice' for their disparate programs, as genuine informed choice will be more difficult to obtain as multiple data extraction programs compete for patients' attention.

INSIGHT: Clarify the basis of the opt out approach, promote additional mechanisms for informed choice, and explore with partners how best to coordinate opt out approach notifications related to data sharing

[8] See NHMRC National Statement on Ethical Conduct in Human Research section 2.3
[9] CHF submission to the Ooffice of the National Data Commissioner Data Availability and Transparency Bill: Exposure Draft Consultation
[10] This was recommended to be the Office of the Australian Information Commissioner guide to health privacy
[11] See the Privacy Commissioner's submission to the review of the Privacy Act 1988 (December 2020) which recommends the Act preserves the use of consent for high privacy risk situations, rather than routine personal information handling, and that consent notices express requirements more concisely.
[12]. For example, according to the 2018 My Health Record inquiry .5% of participants see preferences for secondary use of their patient information, while 9.9% opted out of program. Similarly, 10% of patients polled by Research Australia in 2019 indicate they would not be comfortable sharing their health data.
[13] See RACGP guidelines for the Secondary Use of General Practice Data

Communicate data linkage processes

The Department of Health DRAP committee representatives noted a previous proposal, assessed in 2018, regarding a proposed data linkage of MedicineInsight to the PBS was not approved. In this instance the DRAP committee had questioned whether the MedicineInsight program had fully informed consumers of the intention, risks and benefits of MedicineInsight data linkage occurring.

The DRAP committee representatives agreed that appropriate communication of data linkage purposes is important and recognised that the MedicineInsight program has subsequently increased its transparency by informing consumers via patient notification forms[14] that data linkage is a proposed use for MedicineInsight data.

It was further suggested that, confirmation of privacy compliance together with communication to consumers about data linkage processes, would assist considerations by data custodians with respect to approving linkage of MedicineInsight with their datasets.

It was also noted, the DRAP committee has, on many occasions, considered and approved the use of PBS data by NPS MedicineWise to support post market medicines surveillance and evaluation studies, and that the risk assessment information provided by MedicineInsight staff in these instances has been robust.

The DRAP Chair noted separately that data linkage is complex and misunderstood and that the members don't feel confident making decisions about linkage studies. They are looking to lift the general level of knowledge with the committee to support future applications.

Consultation with the Australian Bureau of Statistics (ABS) MADIP program regarding data linkage, suggested that the MedicineInsight program consider and share the findings of the current Privacy Impact Assessment. The ABS also referred to recommendations that partners develop clear public communications on data linkage processes, including clarifying the scale of data sharing, linkage variables, and the legal authority for data linkage[15].

The need for clear explanation of data linkage processes was described as a shared problem and echoed by experts in the field with several suggesting that NPS MedicineWise further collaborate with technical experts on methods to explain complex data linkage processes and newer technology such as bloom filters to a lay audience. Examples of best practice were discussed and provided by technical experts.[16]

INSIGHT: Provide the DRAP Committee communication of the MedicineInsight opt out approach recommendations and the MedicineInsight Privacy Impact Assessment

INSIGHT: Work with technical experts and consumers to further develop public communication on complex data linkage processes

[14] See Patient notification forms and posters available at https://www.nps.org.au/medicine-insight#patient-and-provider-information

[15] ABS Multi-Agency Data Integration Partnership – Privacy Impact Assessment recommendations

[16] See Lumos technical information for General Practices as an example

2. MedicineInsight governance – revise processes to build greater consumer trust in the opt out approach

Most stakeholders recommended that consumer and stakeholder trust in the program would be enhanced if assessment processes for the release of MedicineInsight data aligned further with the Five Safes Framework.[17] This framework is the emerging best practice guide utilised to assess data release by both the Department and the Office of the National Data Commissioner.

In March 2020, the MedicineInsight program refreshed its Data Governance Framework and subsequently aligned its risk assessment criteria with the Commonwealth data sharing principles and Five Safes Framework.[18] While this was well received by participants in the consultation, it was noted that the MedicineInsight assessment criteria for data release was not widely known as the MedicineInsight Data Governance Framework is not a public document. It was strongly recommended that a consumer-friendly version of the Data Governance Framework, including the assessment criteria incorporating the Fives Safes Approach, be made publicly available to build greater trust in the program.

INSIGHT: Ensure MedicineInsight data is released in line with the Commonwealth data sharing principles and the Five Safes Framework and release a consumer-friendly version of the Data Governance Framework.

Stakeholders raised the transparency of MedicineInsight governance as an important element of ensuring informed choice exists within the opt out approach. For example, discussions referred to recent submissions by the Consumers Health Forum concerning the draft national data sharing laws which mandate data access agreements being accessible and in the public domain.

The Department consultations noted that approved uses of its data assets are not currently made publicly available. However, the Department is exploring these transparency measures. All approved use purposes of MedicineInsight data are currently made available on the NPS MedicineWise website, including links to research outputs. However, some stakeholders suggested that NPS MedicineWise should, in addition, specify decisions made, appeals and amendments approved.[19] For example, participants noted that the NHS Health Research Authority provides public summaries of the rationale of each data release.[20]

INSIGHT: Ensure open access of research outputs and consider making publicly available summaries of data governance assessments, decisions or research agreements, which may contribute to providing more informed choice to opt out.

The NPS MedicineWise Consumer Advisory Group and many other participants suggested the MedicineInsight program should further promote consumer involvement in its governance processes. Several stakeholders suggested materials should be made available for prospective researchers which promote consumer engagement. Some academic GPs and members of the independent Data Governance Committee advocated for greater consumer co-design and oversight of MedicineInsight individual research projects

[17] See the Office of the National Data Commissioner best practice data sharing principles
[18] The DRAP Committee risk assessment process to approve data linkages studies requires risk assessments conducted against this criterion.
[19] Council of Australian Tribunals Administrative Appeals Councils best practice guidance
[20] See the Health Research Authority, Confidentiality Advisory Group decisions register

Consultation with the National Aboriginal Community Controlled Health Organisation (NACCHO) and Maridulu Budyari Gumal collective explained that the cultural safety and data sovereignty of consumers should be further respected by maintaining tailored culturally appropriate materials and undertaking dedicated Indigenous research[21].

It was recommended that the MedicineInsight program work with Indigenous Research Ethics Committees, peak bodies and organisations to ensure community engagement and codesign of any planned program of work and conducting research that complies with relevant for Aboriginal and Torres Strait Islander Research Ethics frameworks[22]

INSIGHT: Promote consumer involvement in MedicineInsight research and Governance processes and explore Indigenous specific research pathways for the program to enhance trust in the opt out approach.

3. Align with national directions and consumer attitudes towards data sharing

NPS MedicineWise attended a roundtable webinar and provided a written submission in response to the draft National Data Access Sharing Laws to the Office of the National Data Commissioner (ONDC).[23] Feedback from the ONDC to NPS MedicineWise included that national accreditation requirements are designed to extend to not for profits and that MedicineWise should consider accreditation as a Commonwealth Data User and Provider. The ONDC indicated that consent to data sharing remains one the most divisive topics discussed and are of the view that consent should remain one of several of the 'lawful basis of data processing'.

Consultation with Information Integrity Solutions, who undertook the Privacy Impact Assessment on the proposed national scheme, further identified the approach to consent as a potential obstacle in developing public trust, confidence and acceptance for the National Commonwealth Data Sharing and Release Framework.[24] The Department of Health representatives and other stakeholders recognised concerns that there is some ambiguity as to whether MedicineInsight or other health data sets may be considered public health data under the new proposed laws.

INSIGHT: NPS MedicineWise should obtain legal advice and consider accreditation under National Data Access arrangements to strengthen stakeholder trust in the program and align with the emerging national public interest tests for data sharing.

Stakeholders also raised the issue that it is important to understand why some Australian patients decide not to share, access, and allow the use of their health data by others. Health consumers reiterated that the willingness of health consumers to share data was not assured. Several stakeholders recommended the MedicineInsight program do more to test and validate public sentiment towards the program.

[21] As described in the Communique of the Indigenous Data Sovereignty Summit held in June 2018, Indigenous Data Sovereignty refers to the right of Aboriginal and Torres Strait Islander peoples to exercise ownership over information which is about and affects Aboriginal and Torres Strait Islander people.
[22] See AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research and the NHRMC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)
[23] See the Office of the National Data Commissioner; Data Transparency and Availability draft exposure bill submissions
[24] See Information Integrity Solutions Privacy Impact Assessment on the Data Transparency and Availability Draft Exposure Bill

Consultation with the Digital Health Cooperative Research Centre (DHCRC) and Monash University noted that the Department of Health are currently seeking industry partners, and have offered research funding to explore and examine a range of potential factors, barriers or

enablers to the provision and use of health and medical data by the public and health providers.[25,26]

The Australian Digital Health Agency have a long-term strategy to move towards dynamic consent. for the Secondary Use of the My Health Record[27] Dynamic consent is a personalised, communication interface to enable greater participant engagement in clinical and research activities. It is a participant-centred initiative that places patients and research participants at the centre of decision making, providing an interactive IT interface to engage with participants[28]. Some participants recommended that the MedicineInsight program should seek to align its consent approach with national strategic directions, such as the Digital Health National Infrastructure Modernisation Scheme, the National Heath Information Strategy, and National Health Information Strategic Asset.

INSIGHT: Long term collaborative engagement is needed to understand consumer attitudes to data sharing. The MedicineInsight program should align its consent approach with the Department of Health national health information governance strategies.

Health consumers and stakeholders indicated universal support and endorsement of the RACGP Ethics Committee role in providing ongoing oversight of the MedicineInsight opt out approach to consent. This was considered important and necessary to maintain trust of both GPs involved in the program and health consumers trust in the opt out approach. Participants indicated that any proposed change to the opt out approach should be reviewed by the RACGP Ethics Committee. In general, stakeholders encouraged the MedicineInsight program to maintain an ongoing dialogue with the RACGP and Human Research Ethics Committees around the feasibility, and practicableness of actively seeking patient consent.

4. Evaluate complimentary consent models as evidence emerges

Stakeholders described the evidence base for alternative consent models as mixed. Dynamic consent platforms were also not well known in Australia and many stakeholders described the CTRL platform[29] implemented via the Australian Genomics Health Alliance as the flagship dynamic consent platform used in health research.

Many stakeholders, including health consumers, recognised the difficulty in managing dynamic consent preferences in large population datasets, with most stating this is impractical, complicated and was designed for other purposes such as clinical trials (or genomics research). With the exception of three stakeholder groups, all others noted that moving to dynamic consent would mean the suitability and utility of MedicineInsight data would be comprised and not fit for research purposes. Many participants stated that consideration of alternative opt out

[25] See Digital Health Cooperative Research Centre flagship program on trust and consent in general practice and related health care settings
[26] See Dept of Health commissioned research in 2020; Understanding trust in digital health among communities affected by BBVs and STIs in Australia
[27] See the Framework to guide the Secondary Use of the My Health Record
[28] Kaye J, Curren L, Anderson N et al: From patients to partners: participant-centric initiatives in biomedical research. Nat Rev Genet 2012; 13: 371–376.
[29] The CTRL Platform lead participated in consultations and provided input on requirements gathering of the CTRL dynamic consent platform.

approaches needs to be practical; balanced with the potential benefits and harms and follow the National Health and Medical Research Ethical Guidelines assessment criteria.

Academic researchers studying dynamic consent noted that these platforms are under development and only limited empirical evidence is available regarding consumer experiences[30]. Another issue noted is that no single, standardised measure of "informed consent" exists.

Many participants echoed views expressed by the OAIC, ADHA, CHF and others that health consumers should in principle be given the chance to provide dynamic consent to the use of their health data where feasible, however no viable models were identified for this to occur.

Through September and October 2020, NPS MedicineWise staff undertook a six-week collaboration with the DHCRC and Royal Melbourne Institute of Technology (RMIT) to investigate the implementation of precision (dynamic) consent within population health datasets. Through this work, MedicineInsight staff proposed and received iterative feedback on an exploratory conceptual model for implementing dynamic consent in population health datasets.

Participants described evaluation principles for dynamic consent platforms, a mapping of Department of Health stakeholders and enablers, and the creation of potential conceptual models for implementing dynamic consent. The outcome was that the opt out approach was still considered the most feasible and appropriate model for large longitudinal health datasets. However, two models a low cost and full solution, were identified which may be feasibly implemented as a proof of concept, and which support the ability of health consumers to specify their consent preferences within large population health data sets (**Appendix 4**).

Some participants noted that complimentary consent models have been employed within MedicineInsight before. For example, the EquipGP Trial[31], Health Care Homes and proposed IMPLORE trial[32] provide study designs where research participants (whether health consumers or GP clinics) must provide their consent. The MedicineInsight data collection is then used to identify and facilitate consented participation and support for these studies. These study designs operate in a third space between the binaries of an opt out approach and informed consent but provide models for potential dynamic consent to operate[33].

INSIGHT: Persist with the existing opt out approach, participate where complementary consent models are proposed and actively evaluate emerging dynamic consent approaches.

Feedback was also provided that in order for complimentary or dynamic consent preferences to be a specified within population health datasets, a national approach should be implemented. For example, stakeholders described the national opt out approach employed within the UKs National Health Service where consent preferences are appended to the patients NHS number – the equivalent of the Medicare spine. This is relevant to Australia as

[30] See work by Dr Megan Prictor such as the Dynamic Consent: An Evaluation and Reporting Framework
[31] See the EQuiP GP Trial for further information on this model
[32] Painaustralia and the University of Sydney have proposed the use of MedicineInsight data, which involves identification of consented participants through *the IMPLementing an Opioid stewardship intervention to REduce opioid use* (IMPLORE) trial.
[33] Studies that necessitate multiple consent approaches are permissible under the NHRMC national statement see element three: description of consent

specifying consent preferences via a national identifier is technically feasible and has been suggested as a future consideration of the national digital health ecosystem[34]

Similarly, in mid-November the Australian Digital Health Agency released a future state concept for national digital health infrastructure. This concept, endorsed by the Department of Health, suggests that foundational and interoperate building blocks such as the National Authentication Service for Health (NASH certificates) and Public Key Infrastructure (PKI) services will underpin the long-term operation of dynamic consent within the future digital health ecosystem[35].

INSIGHT: Align with the national approach towards dynamic consent where personal information is used and ensure MedicineInsight has the interoperability foundations in place to participate for relevant studies, although this is not required for deidentified data.

[34] See API Gateway Request for Tender - Appendix B Future State Concept National Digital Health Ecosystem which describes future plans to embed dynamic consent within national access and identification services in a similar manner to the NHS

[35] See API Gateway Request for Tender - Appendix B Future State Concept National Digital Health Ecosystem

RECOMMENDATIONS

Communication and transparency - improve understanding of the opt out approach and data linkage

Get the balance and structure of information right on the website and further describe the benefits of participation

1. Communicate the consent review findings to participants in the consultations, GPs, Health Consumers and MedicineInsight customer, as part of a coordinated communication plan incorporating the Privacy Impact Assessment findings and revised MedicineInsight Strategy.

2. Revise the MedicineInsight website to provide easier to understand information, including the use of pictograms, infographics, visual aids and summaries of data use and participating practices.

3. Work collaboratively with technical experts and partners to develop public communications on data linkage processes, including clarifying the scale of data sharing, linkage variables, and legal authority.

4. Produce video resources and case studies highlighting the benefits of the program, including how MedicineInsight contributes to understanding the impact of Covid 19, bushfires and other health issues.

Increase transparency around the of the opt out approach to consent and data linkage

5. Provide further information around how to opt out, including how to access opt out forms so health consumers may make an informed choice to opt out if desired.

6. Use quarterly MedicineInsight communications channels to General Practices to proactively promote the opt out approach.

MedicineInsight governance – ensure processes build greater consumer trust in the opt out approach

Ensure data governance release principles are best practice and provide more information on data governance assessment processes.

7. Continue to ensure MedicineInsight data is only released in line with the Commonwealth data sharing principles and the Five Safes Framework.

8. Release a plain language consumer version of the governance framework on the NPS MedicineWise website.

9. Provide summaries of data governance assessments and more transparent information about the Data Governance Committee and members.

Promote consumer involvement in research to enhance trust in the opt out approach

10. Develop or make available and promote resources for researchers about how to engage consumers in MedicineInsight projects.

11. Promote the use of consumer advisors within research studies, and internal communication between consumer and data governance advisory groups.

12. Ensure the cultural safety and data sovereignty of consumers is respected by maintaining tailored culturally appropriate materials and undertaking dedicated Indigenous research and proactively engaging community in study design.

Align with national directions and consumer attitudes towards data sharing

Alignment with national standards and accreditation requirements

13. Seek accreditation under the National Data Access and Sharing arrangements and ensure the risks and benefits of alternative data sharing arrangements are fully understood and communicated.

Long term collaborative engagement is needed to understand consumer attitudes to data sharing.

14. Actively seek to collaborate with areas of the Department which are monitoring and evaluating consumer sentiment towards opt out approaches to data sharing.

15. Explore mechanism for direct consumer dialogue with MedicineInsight participants.

16. Continue, and strengthen RACGP ethics oversight of the opt out approach.

Evaluate complimentary consent models as evidence emerges

17. Persist with the opt out approach, support specific studies which involve individual consent, and evaluate the evidence for dynamic consent as it emerges.

18. Explore a national and coordinated approach to dynamic consent implementation and review the success of similar projects in obtaining opt-in consent for record linkage.

DETAILED NEXT STEPS

How will recommendations be progressed?

Recommendations and improvements to the existing opt out approach will be further documented, prioritised and scheduled for implementation as part of the MedicineInsight work plans to be submitted and approved by the Department under the Grant Agreement.

The draft implementation plan (**Appendix 3**) whilst subject to approval by the Department, has been aligned with the broader MedicineInsight Strategic plan and includes indicative costs (**Appendix 2**). A draft communication plan to stakeholders has been proposed which incorporates those consulted as part of the consent model review (see **Appendix 7**). A coordinated strategic approach will be taken to implement recommendations with parallel work including:

- The implementation of the MedicineInsight Strategy and MedicineInsight communication plan
- Timely implementation of the MedicineInsight Privacy Impact Assessment recommendations
- The current Digital Strategy and Communications website work plan
- Alignment with the external Evaluation Review underway regarding the MedicineInsight program.

Some recommendations such as exploring the future feasibility of dynamic consent models and undertaking Indigenous specific research will require further input from key stakeholders and end-users to ensure that the planned improvements are acceptable. The generation of any workplan changes will also involve a range of internal teams to both ensure the changes are achievable, such as;

- Full cost benefit of any assessment of emerging dynamic consent models, or Proof of Concept if the Department would view a need for this
- Benefits and risks of implementing each activity
- Linkage and/or inclusion within other Grant workplans
- Outline of key stakeholders to be engaged during development
- Recommendations will be assigned an owner, and progress against the plans will be monitored by the NPS MedicineWise Senior Leadership Group
- The progress of implementation of the recommendations will be reported to the Department via the established grant quarterly reporting process. Feedback on the implementation of recommendations provided by the Department will be incorporated into implementation plans.

APPENDIX 1. STAKEHOLDER ENGAGEMENT

NPS MedicineWise internal advisory groups	General Practice Advisory Group	August & Oct
	Consumer Advisory Group	August
	Data Governance Committee	August & Oct
	Data Development Advisory Group	August & Oct
External consultation	Australian Bureau of Statistics MADIP program	August & Oct
	Australian Institute of Health and Welfare (AIHW)	Aug – Nov
	Australian Digital Health Agency	September
	La Trobe University	September
	Curtin University Centre for Data Linkage	September
	Sydney Local Health District*	September
	Galexia – data linkage privacy impact providers*	September
	Consumers Health Forum	Ongoing
	The Office of the National Data Commissioner	October & Nov
	The Dept of Health Data Release Assessment Panel	October
	The Digital Health Co Operative Research Centre	October
	National Aboriginal Community Controlled Health Organisation	October
	Health, Law and Emerging Technology School of Law University of Melbourne	October
	Royal Melbourne Institute of Technology digital strategy and change subject matter experts*	October
	Medical Software Industry Association*	October
	Monash University*	October
	Royal Australian College of General Practitioners	Ongoing
	WA Primary Health Alliance	November
	Australian Commission on Safety and Quality in Health Care	November
	Telstra Health*	November
	Australian Genomics Health Alliance	November
	Maridulu Budyari Gumal (SPHERE)*	November
	Western Sydney University*	November

* Indicates additional consultation not listed in original Scope

- The NSW Centre for Health Record Linkage (CHeReL) and the Therapeutic Good Association were initially identified in the project Scope to be consulted with however declined to participate
- RACGP and Consumers Health Forum – referred to previous and ongoing consultation
- Consultation occurred with MedicineInsight Privacy Impact Assessment providers - Information Integrity Solutions on an ongoing basis. Discussions regarding the consent review report and privacy impact assessment on MedicineInsight overlapped.

APPENDIX 2. DRAFT COSTINGS

These following costings are indicative and are aligned to the MedicineInsight Strategy. Note all indicative hours/costs are one off costs, apart from indicative hours/costs for consumer engagement under recommendations 11 and 15, which represent annual external consumer engagement costs.

Key to Cost impact: No additional cost anticipated | Requires further scoping of costs | Additional external costs or staff hours identified

Improvement area	MedicineInsight Strategy action	Consent review report recommendation	Cost impact	Skillset or capability	Indicative hours	Indicative cost
Communication and transparency - improve understanding of the opt out approach and data linkage	Pillar 3, objective 1, initiative 2, action 3 Transparent communication of data linkage methods, variables and projects, and production of supporting materials to improve data linkage literacy of consumers, clinicians and stakeholders	1. Communicate the consent review findings to participants as part of a coordinated communication plan incorporating the Privacy Impact Assessment findings and revised MedicineInsight Strategy.	To be delivered under existing approved workplan with no additional cost to the Department	Design Accessibility Review Marketing Review Consumer review Review Website structure	Approx. 57 hours of staff time senior specialists, manager) Approx. 10 hours of consumer review	FTE .04 $5,322 Sitting fees $2,200
		2. Revise the MedicineInsight website to provide easier to understand information, including the use of pictograms, infographics, visual aids and summaries of data use.	Additional external costs or staff hours identified			
		3. Work collaboratively with technical experts and partners to develop public communications on data linkage processes, including clarifying the scale of data sharing, linkage variables, and legal authority.	Additional external costs or staff hours identified			

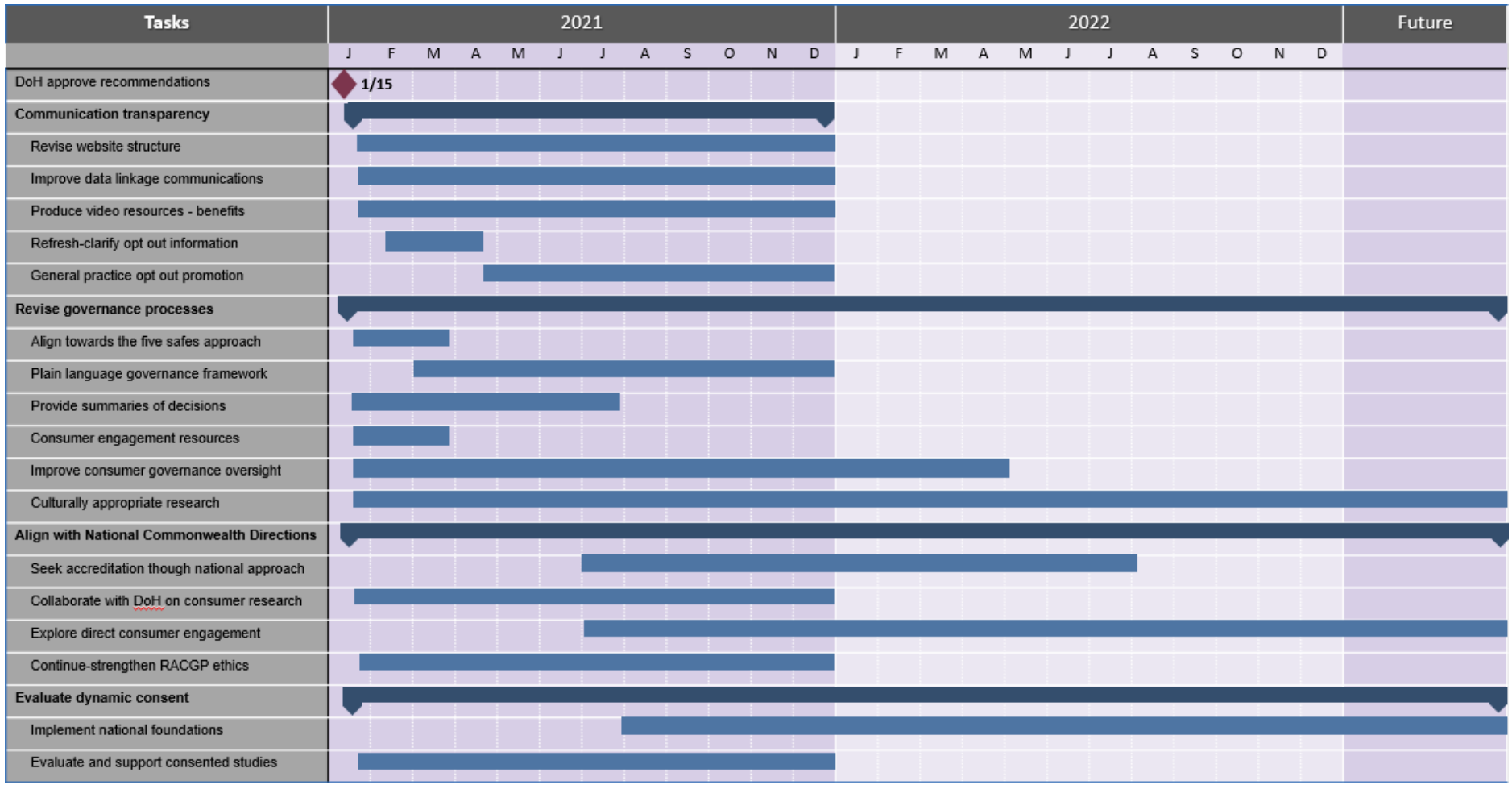
Improvement area	MedicineInsight Strategy action	Consent review report recommendation	Cost impact	Skillset or capability	Indicative hours	Indicative cost
	Pillar 2, objective 1, initiative 1, action 8 Ensure governance and ethics models are contemporary and managed effectively to overcome identified barriers, including ongoing monitoring and assessment of implications from legislation and accreditation reforms, use of Commonwealth data access sharing agreements, and compliance with data release principles	4. Produce video resources and case studies highlighting the benefits of the program, including how MedicineInsight contributes to Covid 19 bushfire health research studies.	Additional external costs or staff hours identified	Internal production of two videos Editing Scoping of script	Approx. 45 hrs staff time (senior specialist, manager)	FTE .03 $3,991
		5. Provide further information on opt out requests and the opt out forms so health consumers may make an informed choice to opt out if desired.	To be delivered under existing approved workplan with no additional cost to the Department	Policy update Digital team website updates		
		6. Use quarterly MedicineInsight communications channels to General Practices to proactively promote the opt out approach.	To be delivered under existing approved workplan with no additional cost to the Department	Policy updates Content updates		
MedicineInsight governance – ensure processes build greater consumer trust in the opt out approach	Pillar 2, objective 1, initiative 1, action 8 Ensure governance and ethics models are contemporary and managed effectively to overcome identified barriers, including ongoing monitoring and assessment of implications from legislation and accreditation reforms, use of Commonwealth data	7. Ensure MedicineInsight data is only released in line with the Commonwealth data sharing principles and the Five Safes Framework.	To be delivered under existing approved workplan with no additional cost to the Department	Policy updates		
		8. Release a plain language consumer version of the governance framework on the NPS MedicineWise website.	Additional external costs or staff hours identified	Consult with CAG Consumer to review Accessibility	Approx. 10 hours consumer review	Sitting fees $2,200
		9. Provide summaries of data governance assessments and	To be delivered under existing approved workplan with no	Policy and reporting updates		

Improvement area	MedicineInsight Strategy action	Consent review report recommendation	Cost impact	Skillset or capability	Indicative hours	Indicative cost
	access sharing agreements, and compliance with data release principles	make biographical details of data governance members available	additional cost to the Department			
	pillar 2, objective 1, initiative 1, action 5 Continue to seek consumer input into all projects – as per NPS consumer engagement strategy.	10. Develop or make available and promote resources for researchers about how to engage consumers in MedicineInsight projects.	To be delivered under existing approved workplan with no additional cost to the Department	Policy and website updates		
		11. Promote the use of consumer advisors within research studies, and internal communication between consumer and data governance advisory groups	Additional external costs or staff hours identified	Consult with CAG External consumer review	Approx. 30 - hours external consumer review time per/annum	Sitting fees $12,200 (over three years)
	pillar 1, objective 2, initiative 2, action 2, Codesign frameworks for collection, use and management of Aboriginal and Torres Strait Islander data	12. Ensure the cultural safety and data sovereignty of consumers is respected by maintaining tailored culturally appropriate materials, and undertaking dedicated Indigenous research	To be costed in future workplan once scoped	Consult with CAG Consult with NACCHO		
Align with national directions and consumer attitudes towards data sharing	pillar 2, objective 1, initiative 1, action 3, Agree parameters with Department of Health for engagement with government within and beyond the grant.	13. Seek accreditation under the National Data Access and Sharing arrangements and ensure the risks and benefits of alternative data sharing arrangements are fully understood and communicated.	To be costed in future workplan once scoped	Consult with ONDC (once accreditation costs announced) Consult with Department		

Improvement area	MedicineInsight Strategy action	Consent review report recommendation	Cost impact	Skillset or capability	Indicative hours	Indicative cost
		14. Actively seek to collaborate with areas of the Department which are monitoring and evaluating consumer sentiment towards opt out approaches to data sharing.	To be costed in future workplan once scoped	Consult with Department		
	pillar 2, obj 1, initiative 1, action 9, Continue to seek consumer input into all projects – as per NPS consumer engagement strategy.	15. Explore mechanism for direct consumer dialogue with MedicineInsight participants.	Additional external costs or staff hours identified	Consult with Consumer Advisory Group	FTE .001 staff time (senior specialist, manager)	Stakeholder relationships $5,214 over three years)
	pillar 1, obj 1, initiative 1, action 4, Clarify and confirm governance requirements with the DGC and low risk ethics review mechanism with RACGP to streamline approvals.	16. Continue and strengthen RACGP ethics oversight of the opt out approach. .	To be delivered under existing approved workplan with no additional cost to the Department	Data governance staff		
Evaluate complimentary consent models as evidence emerges	pillar 3, obj 2, initiative 3, action 1 Evolve and implement a fully scoped, costed and prioritised technology roadmap that drives adoption of innovative, fit-for-purpose technology to streamline and enhance data	17. Persist with the opt out approach, communicate the lawful basis of the model and evaluate the evidence for dynamic consent platforms as it emerges.	To be costed in future workplan once scoped	Data warehouse staff Business analyst Data governance staff		
		18. Advocate for a national and coordinated approach to dynamic consent implementation and monitor and review the success of	To be costed in future workplan once scoped	Data warehouse staff Business analyst		

Improvement area	MedicineInsight Strategy action	Consent review report recommendation	Cost impact	Skillset or capability	Indicative hours	Indicative cost
	management, data quality, utility and useability	similar projects in obtaining opt-in consent for record linkage		Data governance staff		

APPENDIX 3. DRAFT IMPLEMENTATION PLAN



APPENDIX 4. DIGITAL HEALTH COOPERATIVE RESEARCH CENTRE COLLABORATION

What was undertaken?

A six - week short course was undertaken between September and November 2020[36], which NPS MedicineWise staff member participated in conjunction with the Digital Health Co-operative Research Centre and the Royal Melbourne Institute of Technology. The collaboration was sponsored by the Australian Institute of Digital Health. The purpose of the collaboration was threefold;

1. To identify enterprise digital health technologies, evaluate their features and benefits, and consider how these may be adapted or joined up to provide dynamic consent within population health datasets.
2. To evaluate the readiness for a dynamic consent to be implemented within population health datasets as a complimentary approach.
3. To formulate a case for this digital health initiative to be considered by healthcare business stakeholders, including an approach to change management and adoption.

The focus of the collaboration was to scope and provide a high level 'exploratory' business case of how dynamic consent may operate with population health datasets. Particularly the project considered sought to identify investment has already occurred through an array of national health infrastructure, and how these may be connected and leveraged.

This implementation model of complimentary dynamic consent exists in a third space between the legal constructions of informed consent and an opt out approach, where mechanisms are provided for consent preferences to be specified to data use, but these do not replace the opt out approach to consent.

The principles of this third space model draw on the following prior work;

1. User Experience design of the Australian Genomics Health Alliance CTRL platform
2. The complimentary opt out service of the UK's National Health Service
3. The information architecture of the EnCoRe dynamic consent platform
4. The ability for consumers to specify secondary use preferences and tailored health information provision within the My Health Record.
5. NPS MedicineWise experience in identifying consented patients within an opt out population health dataset through the EqUIP GP Trial.
6. The foundational, interoperable building blocks specified in the Australian Digital Health Agencies future state health ecosystem documentation

While an exploratory business case was undertaken, a formal cost-benefit was not proposed as the benefits of dynamic consent and its outcomes are difficult to quantify. Should the Department of Health require costings, participants considered these must be assessed in accordance with existing NPS MedicineWise processes, Department of Health grant, and broadly the Commonwealth Grant Guidelines Value for Money criterion.

[36] This exercise incurred no costs. Staff time of approximately 15 hours was approved and accounted for as a professional development opportunity with direct relevance to grant funded activity.

DYNAMIC CONSENT AT A POPULATION LEVEL

There is widespread—though conditional support among patients and the public for data sharing for health research.
Consumers recognise the actual and potential benefits of health research; however they report significant concerns.
Public health data custodians must do more to ensure its social license is maintained to collect population health data

THE MISSION: Health consumers must retain the right to access and control their health data for purposes they decide.

THE SPECIFIC PROBLEM:

- No options exist for health consumers to provide dynamic consent for large population health datasets
- Binary and legalistic views on consent are confusing everybody
- The risk appetite is low for health data custodians.
- Piecemeal dynamic consent initiatives are undertaken, which are costly and inefficient for the Department of Health.

CONSEQUENCES:

- Secondary use of health datasets are underutilised and translational research that may benefit society is not undertaken.
- Social license is not obtained, and health consumers maintain a trust deficit for the use of their data by government
- Solutions funded by the Department of health to explore consent preferences are fragmented.

VISION:

- To enable large (opt out) population health datasets funded by the Department of Health to adopt scalable, cost effective and robust consent and revocation methods for controlling the use of consumer health information.
- To benefit individuals by providing a meaningful, intuitive mechanisms which will allow control over the use of their personal health information held by government.

EXPLORATORY DESIGN

Dynamic consent for population health datasets

DIGITAL HEALTH TECHNOLOGIES IDENTIFIED

- Dynamic consent platform plug-in web application
- Privacy preserving data linkage and hash key generator
- Consent reconciliation and data use reporting portal

DESIGN PRINCIPLES

- Consumer co-design
- Light touch simple
- Uses existing health funded data infrastructure
- Extensible to public health data custodians - record once use many
- Utilizes privacy preserving linkage
- Is based on interoperable standards and a national data sharing ontology

NEEDS ANALYSIS

- Between 4-15 accredited linkage authorities
- Between 15-40 public health university research teams
- Less than 200 accredited data users
- Between 0.5 – 2% population willing to set preferences for secondary use
- 9.9% opted out of the My Health Record
- 20% of enrolled patients in dynamic consent platforms
- 24% population surveyed unwilling to consent to health data release
- MedicineInsight patients (3.2M/2-5%) = 160,000 consent preferences

PROBLEM STATEMENT

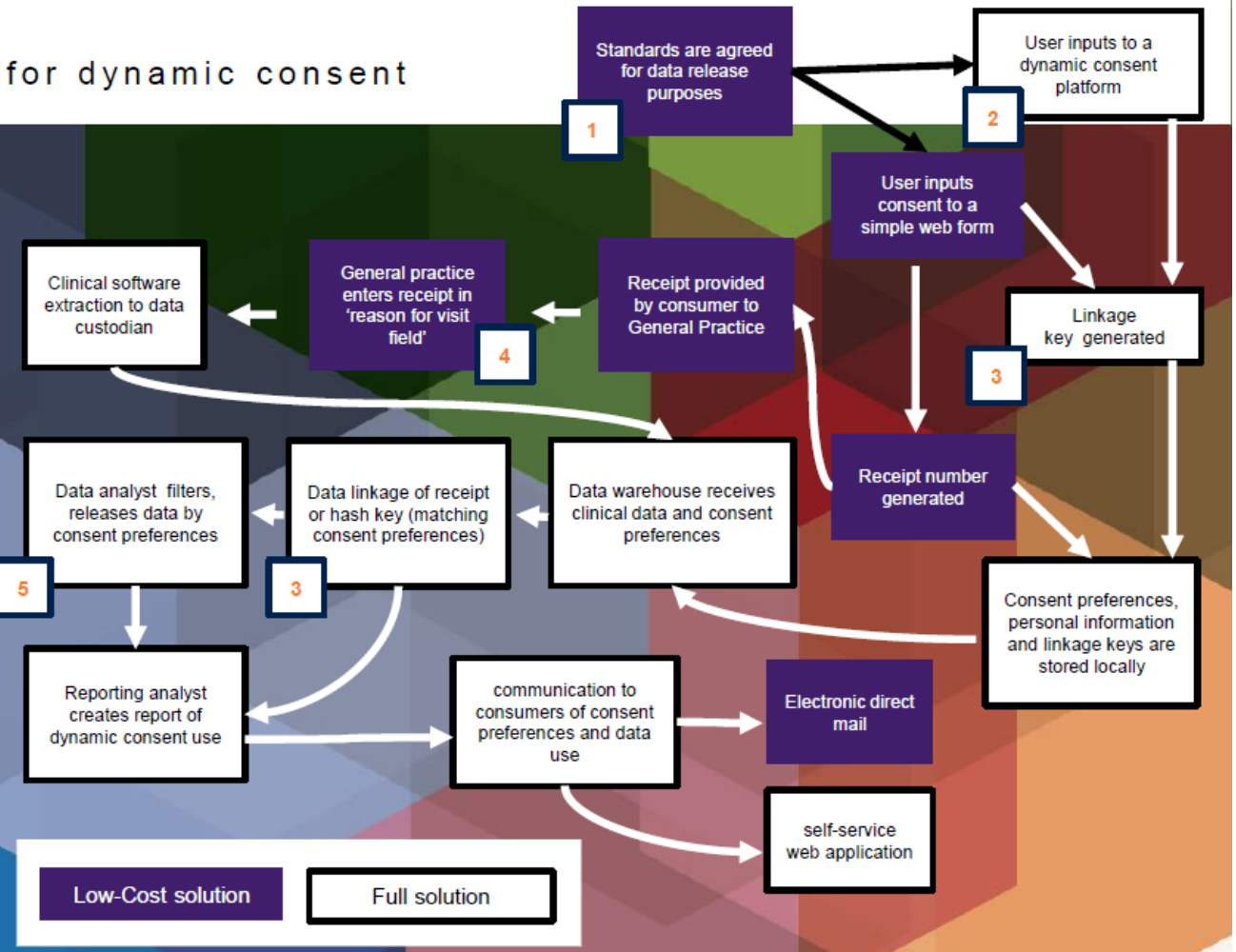
- **To enable large (opt out) population health datasets** funded by the Department of Health to adopt scalable, cost effective and robust consent and revocation methods for controlling the use of consumer health information.

- To **benefit individuals** by providing a meaningful, intuitive mechanisms which will allow control over the use of their personal health information held by government.

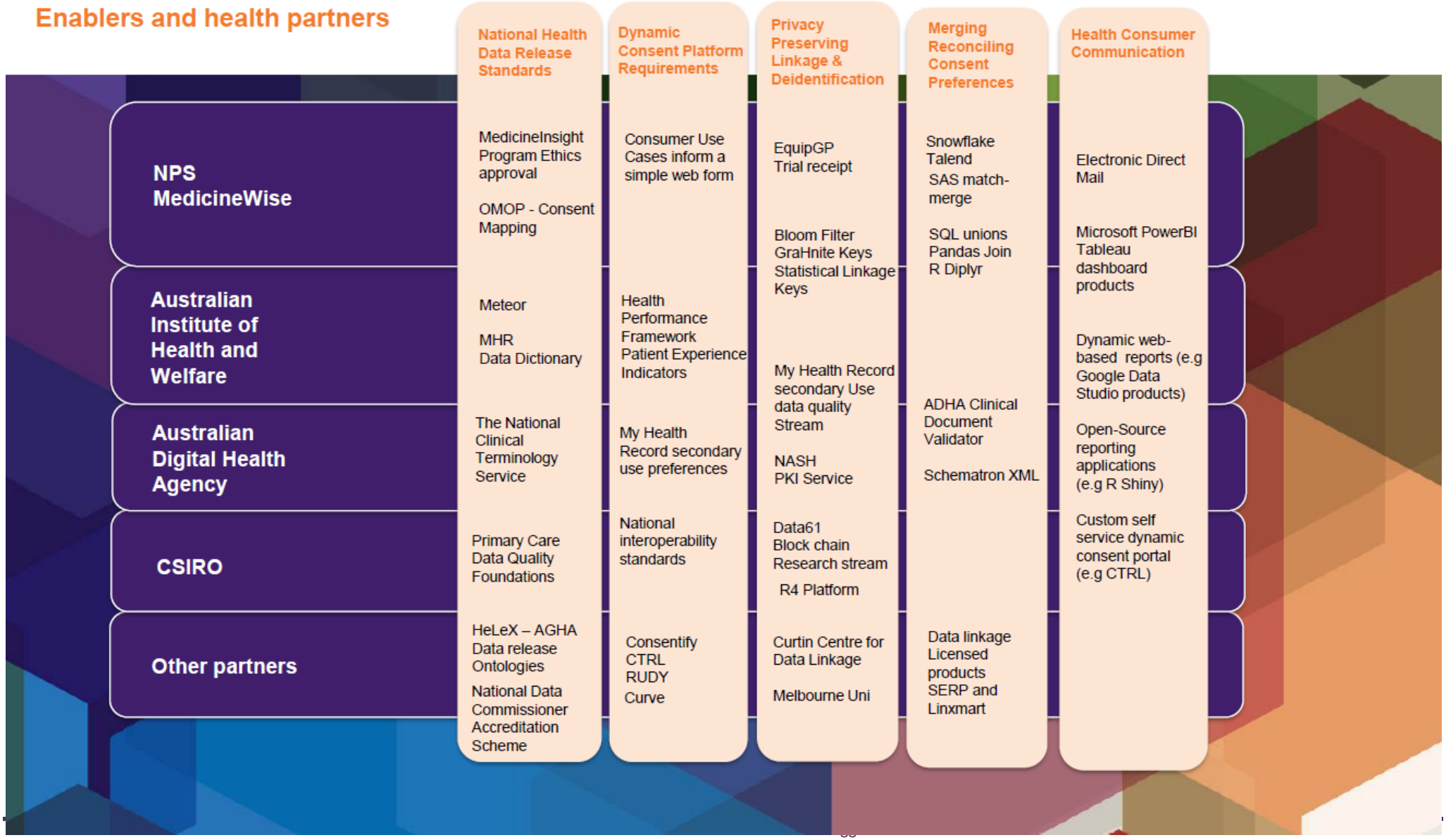
Conceptual models

Connected infrastructure for dynamic consent

1. The Office of the Australian Data Commissioner will finalise standards for data sharing through national legislation and accreditation
2. A front-end dynamic consent platform has been user tested and may be licensed through the Australian Genomics Health Alliance
3. Curtin University have developed privacy preserving linkage products built for this purpose
4. NPS MedicineWise have trialed this method to identify consented patients
5. NPS MedicineWise and AIHW analysts routinely write code to extract, transform, slice, dice, filter, population health data extracts

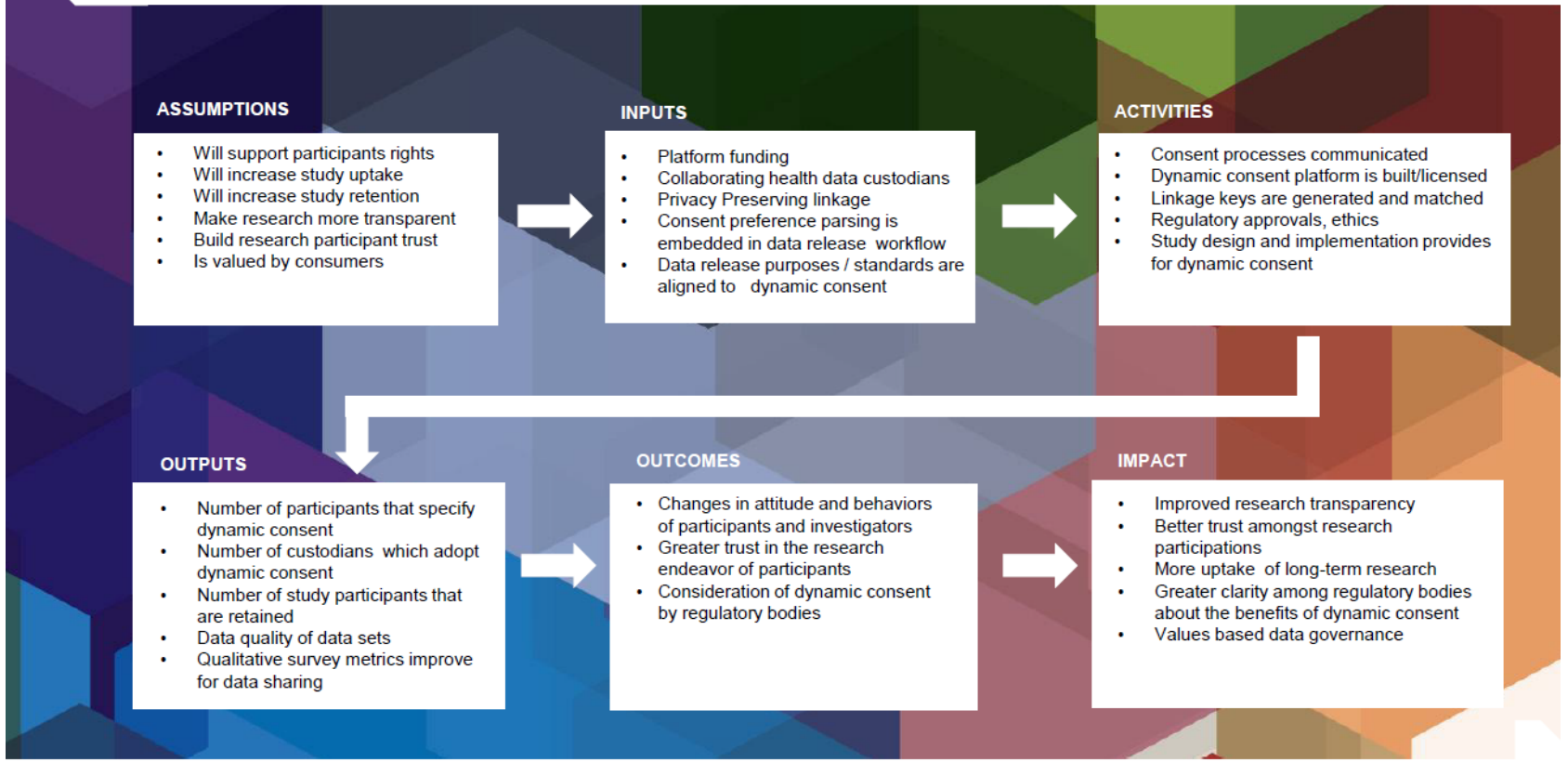


Enablers and health partners



Evaluation framework

Assessment principles for dynamic consent within population health datasets



Adapted from the Department of Health Program Evaluation Framework recommendations, and Prictor M, Lewis MA, Newson AJ, et al. Dynamic Consent: An Evaluation and Reporting Framework. *Journal of Empirical Research on Human Research Ethics*. 2020;15(3):175-186

NPS MEDICINEWISE

APPENDIX 5 OPT OUT APPROACH FEATURES

What are the key features of the MedicineInsight opt out approach and consent model?

The consent model controls complement existing RACGP advice, and General Practice policies, procedures and processes which govern how patient data is to be used for approved secondary use and quality improvement purposes. Sit within a policy framework. Changes to any of these requires amendment to the MedicineInsight program ethics approval provided by the RACGP NREEC.

The MedicineInsight consent model and opt out approach controls include:

1. NPS MedicineWise provides practices with a Practice Kit, including a Practice Agreement, which transparently identifies how we collect, use and share MedicineInsight data. Transparency within the Agreement is ensured through user friendly notes to assist practice staff to understand the language of the Agreement.

2. The principal of the practice (or other legally responsible representative) provides express written consent for the use of identifiable practice information within the MedicineInsight program, and for the collection of de-identified patient information for secondary use (except where patients have opted out).

3. General Practitioners may additionally provide written consent to the use of their identifiable information to enable insights at provider level in tailored practice reports for practices in which they work (note a further control that this is only technically possible within the authoring practice).

4. To ensure consent remains current and specific, the MedicineInsight program reviews and reconsents all practices involved in the program from time to time.

5. Patients are made aware of the MedicineInsight program through the Patient Poster and displayed within the waiting room of all participating practices. Patients are advised they can opt out of the program through notification forms available at all participating practices and online, meaning their deidentified data will not be collected once they have opted out. NPS MedicineWise Educational Visitors when visiting participating practices check to ensure posters are displayed in line with the practice agreement which obligated the display of posters and facilitation of opt out.

6. We respect the choice of individual patients to opt out of the program at any time and provide a technical solution and supporting resources to facilitate this opt out process which is handled at the practice independently of NPS MedicineWise.

7. NPS MedicineWise has committed to ensuring a continued public presence for the program and an ongoing public profile of MedicineInsight data use. To ensure transparency in each approved use of MedicineInsight data, information is made publicly available via the NPS MedicineWise website.

What key processes have been undertaken to review the MedicineInsight opt out approach?

In 2012, the MedicineInsight consent model and controls formed part of the original program governance framework. At this time, NPS MedicineWise conducted an internal Privacy Impact Assessment (PIA which was reviewed by legal experts. The PIA review, endorsed the consent model and controls as compliant and appropriate under the Australian Privacy Act and Privacy Principles.

RACGP National Research and Evaluation Ethics Committee approval

The pilot stage for the MedicineInsight program (2012-14) trialled and established the stability of the methods and materials used to recruit and support general practices to participate. Once the pilot was completed, the program transitioned to a quality improvement activity. At this time (January 2014) the consent model was approved by the RACGP NREEC. In December 2017, the RACGP NREEC granted ethics approval for the standard operation and use of the MedicineInsight program. At this time the consent model was reaffirmed as both ethical and appropriate.

Practice reconsent process and collection notices updates

In 2019, NPS MedicineWise undertook a reconsent process with each practice involved in the MedicineInsight program. This process was necessary to ensure that the express consent provided by practices remained current and specific. All MedicineInsight practices were approached to reconsent to the program, and minor updates to collection notices were made. These processes were undertaken with the approval of the RACGP NREEC.

NPS MedicineWise literature review of consent models (2019)

In 2019, NPS MedicineWise undertook a literature review of consent models. The scope of this review focused on the specific context of using deidentified and identifiable data obtained from general practice settings. The report included the following:

Literature review: Forty-one articles (peer reviewed and grey literature) were reviewed that explored models of consent for health research (including secondary research) using deidentified and/or identifiable data. Models were categorised as broad consent, opt out consent, dynamic consent and meta consent.

Stakeholder scan: Six comparable programs in the Australia general practice setting were found that utilise a consent model to obtain data for medical and health research purposes. Six of these were found to use an opt out consent approach.

Best practice model for research consent: The review affirmed that the opt out consent model is appropriate in situations where obtaining consent from individuals is impracticable and where public interest outweighs the risk to privacy. It was also found that dynamic consent approaches, while not widely implemented, should be further explored as these models mature.

APPENDIX 6 PARTICIPANT INFORMATION SHEET

What is the aim of the review?

The aim of a review of the MedicineInsight consent model, is to ensure that consent is obtained for the program, not only in accordance with relevant legislation, but in line with contemporary best practice, and to ensure the program meets current and emerging public interest criterion. The specific aims of the review are to provide recommendations on how the opt out model may be improved to further support data linkage of MedicineInsight. This will consider amongst other things;

- Privacy and governance issues identified in data linkage proposals
- Best practice recommendations, and privacy impact assessments relevant to projects undertaken by Commonwealth and State data linkage authorities
- The views of General Practice and Health Consumers.
- Consideration of how MedicineInsight may best align with emerging Commonwealth consent requirements, such as data access and sharing principles, proposed changes to the public interest test for data access and release, and new data linkage accreditation requirements.

What has informed the review?

- In December 2017, the Royal Australian College of General Practitioners Ethics Committee (RACGP NREEC) granted ethics approval for the standard operation and use of the MedicineInsight program. The RACGP NREEC confirmed the consent model as ethical and appropriate and provides ongoing oversight of the program operations.

- Through 2016-18, the Consumers Health Forum of Australia was commissioned by NPS MedicineWise to conduct research about consumers' attitudes to health data. The project culminated in a thought leadership roundtable. A summary report of the roundtable discussion was made public in 2018.

- In 2019, NPS MedicineWise undertook a literature review of consent models. The objective of this review (funded by the Department of Health) was to provide evidence-based recommendations on eliciting consent for health research.

- NPS MedicineWise are now undertaking a review of the current consent model which will be completed by December 2020 with a report and recommendations provided to the Department of Health.

Who are NPS MedicineWise consulting with?

Through September to December 2020 external consultation will occur with stakeholders including consumer representatives, government and non-government data linkage authorities, MedicineInsight users, and technical experts. The purpose of consultations is to test best practice recommendations for improving the MedicineInsight opt out approach.

What will we do with consultation feedback?

The consent model review will be completed by December 2020 with a report and recommendations provided to the Department of Health. We may share the findings of the consent model review and recommendations with all participants involved in the consultations (likely in early 2021). Please advise us if you would like your organisation or participation anonymised.

APPENDIX 7 INDICATIVE COMMUNICATION PLAN

Date December 2020

Purpose

To provide ongoing transparency about MedicineInsight governance, data privacy and data utility to a range of key stakeholders, users, partners and advisors

Summary approach

1. Targeted Electronic Direct Mail (EDM) communications to key stakeholders to communicate/provide access to consent and privacy impact statement recommendations. This will be implemented as soon as possible in Q3 FY2021 following approval of recommendations. NB. Specific recommendations and information will be uploaded/made available on the MedicineInsight site section
2. Regular EDM communications/newsletters to the same audience over the long term to communicate a comprehensive range of MedicineInsight subject matter including
    - Implementation progress and updates
    - MedicineInsight strategy
    - Strategic implementation progress updates
    - Paxton/external review findings
    - On-going case studies or examples of data utility

    These will be distributed on a quarterly or biannual basis subject to progress
3. Media outreach to trade and consumer titles; social media promotion via LinkedIn and Twitter;
4. production of a range of digital and multi-media assets including video interviews or information graphics which can be uploaded to the website and promoted through EDM, social and through media

EDM targeting summary

We have identified 27 priority organisations who believe need to receive ongoing information about MedicineInsight developments. These are split across 6 rudimentary segments and are indicated below. This is a flexible distribution list and we can add to it at any time

	Segment	Organisation
1	Partner user	
		Western Australia Primary Health Alliance
		Tasmania Primary Health Network
		Central & Eastern Sydney Primary Health Network

	Segment	Organisation
2	Partner	
		Royal Australian College of General Practitioners
		The Digital Health Cooperative Research Centre
		The Australian Institute of Health and Welfare
		National Aboriginal Community Controlled Health
		The Australian Digital Health Agency
3	Specialist advisors	
		Drug Utilisation Sub-Committee
		Sydney Local Health District
		Australian Genomics Alliance
		Data Governance Committee
		Consumer Advisory Committee
		General Practice Advisory Committee
		Data Development Committee
		SPHERE NSW
4	Consultees	
		Australian Commission for Safety and Quality in Health Care
		Therapeutic Goods Authority
5	Departmental	
		Department of Health - Health Analytics Projects and Futures Section and Digital Infrastructure Branch
		Data Release and Access Committee
6	Researchers and data linkage experts	
		University of Tasmania
		University of New South Wales
		University of Melbourne
		University of Adelaide
		Monash University
		La Trobe University
		Curtin University
		Australian Bureau of Statistics

EDM/email formats

- We will utilise a combination of

- Personalised traditional emails through Microsoft outlook to primary contacts and HTML emails via a bespoke email template see appendix for reference
- The choice of format is based on the nature of the relationship i.e.
    - Outlook emails will be utilised where there is a senior staff relationship and/or receipt of the email is anticipated or where we anticipate that tonally a more sober tone is required
    - The HTML template will enable colours imagery and is likely to stand out and get noticed and will be sent to recipients so that they can forward it to a wider group of internal networks with optimal impact
- Content will be tailored appropriately by segment and relationship

EDM calls to action and fulfilment

- Calls to action within emails will include website links to relevant uploaded documentation including:
    - Consent model feedback full report
    - Consent model feedback key points (for ease of reading)
    - Privacy Impact statement full report
    - Privacy Impact statement full report
    - Recipients will be asked to forward to relevant internal colleagues or networks

EDM Contact strategy Q3 FY20/21 (recommendations)

	Segment	Organisation	Timing	Content		Email Format
				Consent report and privacy impact	Strategy	
1	Partner user					
		WAPHA	FY2021	✓		HTML
		TAS PHN	Q3	✓		HTML
		CEPHN		✓		HTML
2	Partner					
		RACGP	Q3	✓		HTML

	Segment	Organisation	Timing	Content		Email Format
				Consent report and privacy impact	Strategy	
		The Digital Health Cooperative Research Centre		✓		HTML
		The Australian Institute of Health and Welfare		✓	✓	email
		NACCHO		✓	✓	HTML
		The Australian Digital Health Agency		✓		HTML
3	Specialist advisors					
		DUSC		✓		email
		Sydney Local Health District		✓		HTML
		Australian Genomics Alliance		✓		HTML
		Data Governance Committee		✓	✓	email
		Consumer Advisory Committee		✓	✓	email
		General Practice Advisory Committee		✓		email
		Data Development Committee		✓	✓	email
		SPHERE NSW		✓		
4	Consultees					
		Australian Commission for Safety and Quality in Health Care		✓	✓	HTML
		TGA		✓		HTML
5	Departmental					
		Department of Health - Health		✓		email

	Segment	Organisation	Timing	Content		Email Format
				Consent report and privacy impact	Strategy	
		Analytics Projects and Futures Section and Digital Infrastructure Branch				
		DRAP Committee		✓		email
6	Researchers and data linkage					
		Uni of Tasmania		✓		HTML
		Uni Melbourne		✓		HTML
		Uni Adelaide		✓		HTML
		Monash University		✓		HTML
		La Trobe University		✓		HTML
		Curtin University		✓		HTML
		Australian Bureau of Statistics		✓		HTML

Explanatory notes

- Timings for the first dispatch are subject to approval of recommendations
- Key information will be uploaded to the NPS MedicineWise MedicineInsight site section
- Subsequent quarterly and biannual communications will be based on developments and relevant information being available
- Email content will be personalised as appropriate based on the relationship held

Supplementary channels and formats

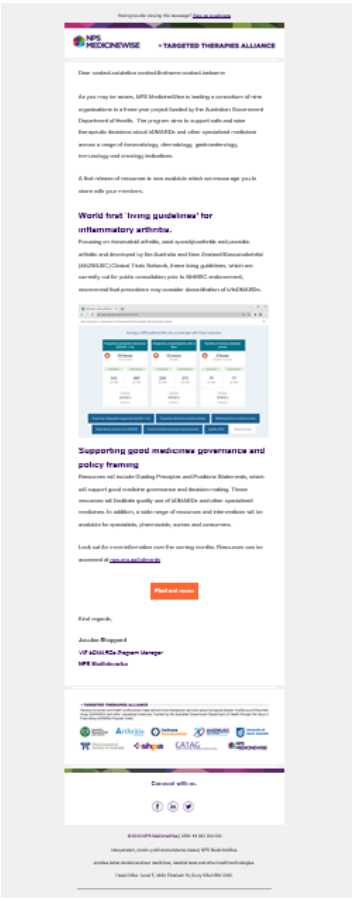
PR and social media

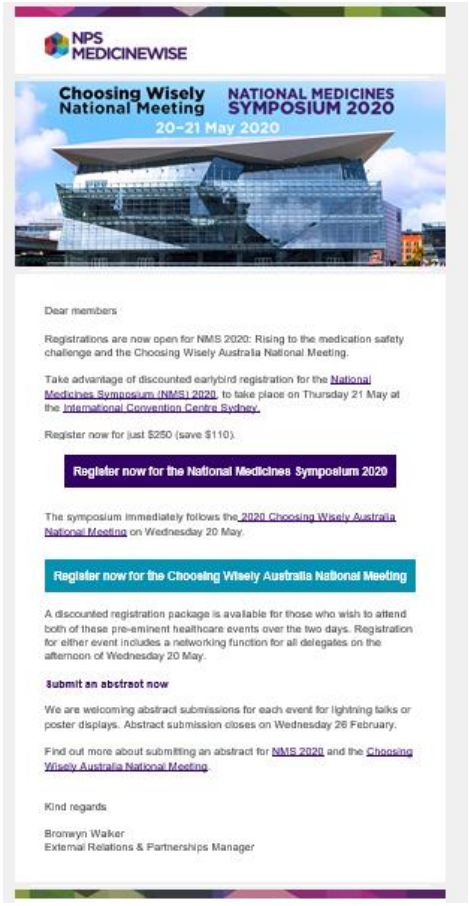
- Wider coverage and access to recommendations and examples of data utility can also be achieved through media outreach to trade and consumer press
- Organic posts via LinkedIn and tweets to NPS MedicineWise followers directing them to website content
- Supporting /additional communication assets in scope include:
    - Information graphics to illustrate MedicineInsight data utility process and governance and privacy

- Q&A style videos with Data Governance members e.g. Dr Nigel Stock; consumer representatives e.g. Anne McKenzie
- NB. These are in line with recommendations from the privacy impact and consent model reviews
- These would be uploaded to the MedicineInsight section and promoted and via social and media/PR as appropriate
- Implementation will commence Q3 FY2020/1

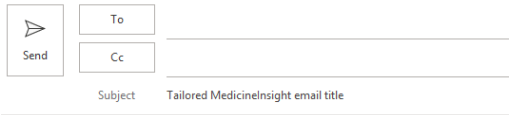
Appendix

Style reference for forwardable HTML emails





Microsoft outlook email template



Gloria Antonio
Deputy CEO
Executive Manager - Strategy, Programs and Delivery

NPS MEDICINEWISE

Level 7 / 418a Elizabeth St
Surry Hills NSW 2010
PO Box 1147
Strawberry Hills
NSW 2012

P. (02) 8217 8604
F. (02) 9211 7578
M. 0427 823 778
gantonio@nps.org.au
www.nps.org.au

Independent, not-for-profit and evidence based, NPS MedicineWise enables better decisions about medicines and medical tests.

Please consider the environment before printing this email

****