



Australian Government

Australian Digital Health Agency



ANAO My Health Record Performance Audit Implementation Plan - ANAO Performance Audit of the MHR

20 February 2020 v1.0

Approved for external use



Acknowledgements

Council of Australian Governments

The Australian Digital Health Agency is jointly funded by the Australian Government and all state and territory governments.

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Product or document version history

Product or document version	Date	Release comments
1.0	20 February 2020	Draft reviewed by Board Advisory Committees, endorsed by Audit & Risk Committee 29 January 2020, approved by Board 20 February 2020.

Table of contents

1	Introduction	5
1.1	Purpose	5
1.2	Intended audience	5
1.3	Scope.....	5
2	The recommendations	6
2.1	Performance audit recommendations.....	6
2.2	Principles informing approach to implementation.....	7
2.3	Success criteria	7
2.4	Outcomes	9
3	Governance.....	12
3.1	Better practice	12
3.2	Accountability.....	12
3.3	Oversight	13
3.4	Responsibility.....	14
3.5	Quality.....	14
3.6	Independent testing.....	15
3.7	Reporting progress.....	15
4	Implementation risks	16
4.1	Lack of resources	16
4.2	Disengaged stakeholders	16
4.3	Wrong scope.....	16
4.4	Operational risk	16
5	Engagement plan	17
5.1	Engagement methodology	17
5.2	Effective stakeholder engagement	18
5.3	Engagement completed in 2019.....	19
5.4	Engagement to be undertaken in 2020	19
6	Timeframe.....	20
6.1	Gantt chart.....	20
6.2	Indicative timeline	20
7	Appendix A - Implementation scope for ANAO recommendations	21

1 Introduction

1.1 Purpose

This document sets out the Agency's plan to implement recommendations of the [ANAO Performance Audit into the Implementation of the My Health Record System](#) and sets out the planned co-production approach, timeframes and measures of success. High level actions are described for the purpose of managing scope and developing a plan, but will be refined from March - August 2020 through a co-production process.

The ANAO has advised that "Tabling of responses to recommendation formalises government or entity commitments to Parliament to implement recommendations. Entities should develop implementation plans that clearly identify intended actions, timeframes and measures of success."¹ This document performs this function and sets out the plan for the Agency to meet its commitment to Parliament.

1.2 Intended audience

This document is intended to provide advice to the groups overseeing the implementation of the ANAO recommendations. This includes the Audit and Risk Committee and Agency Board as accountable authority with responsibility for implementing the recommendations. The Executive Leadership Team and Agency staff will use this document to help guide the development of detailed implementation activities in 2020.

1.3 Scope

This document is limited to discussing the approach and timeframes for implementing the recommendations, including the engagement plan for co-producing key parts of the response. It does not cover the actual changes which the Agency and others must make to implement the recommendations; this detail will be developed in 2020 through the activities described in this plan.

¹ ANAO (2019) [Implementation of ANAO and Parliamentary Committee Recommendations](#), p.13.

2 The recommendations

2.1 Performance audit recommendations

On 25 November 2019, the ANAO tabled its performance audit report into the Implementation of the My Health Record system. It included five recommendations and the Agency's response:

Recommendation 1:

The Agency conduct an end-to-end privacy risk assessment of the operation of the My Health Record system under the opt-out model, including shared risks and mitigation controls, and incorporate the results of this assessment into the risk management framework for the My Health Record system.

Agency response:

Agreed.

The Agency will work with public and private sector healthcare providers, professional associations, consumer groups and medical indemnity insurers on an overarching privacy risk assessment, and incorporate results into the risk management plan for My Health Record.

Recommendation 2:

The Agency, with the Department of Health and in consultation with the Information Commissioner, should review the adequacy of its approach and procedures for monitoring use of the emergency access function and notifying the Information Commissioner of potential and actual contraventions.

Agency response:

Agreed.

The Agency will work with the Department of Health and OAIC on the use of the emergency access function and monitoring by the Agency, and compliance with our obligations for notifications.

Recommendation 3:

The Agency develop an assurance framework for third party software connecting to the My Health Record system – including clinical software and mobile applications – in accordance with the Information Security Manual.

Agency response:

Agreed.

An assurance framework exists for systems (including clinical software and mobile applications) connecting to the Healthcare Identifiers Service and the My Health Record system, including processes to confirm conformance.

The Agency will review the standards that apply to these systems, and alignment with the Information Security Manual. We will work with industry to update the assurance framework as required.

Recommendation 4:

The Agency develop, implement and regularly report on a strategy to monitor compliance with mandatory legislated security requirements by registered healthcare provider organisations and contracted service providers.

Agency response:

Agreed.

The Agency will develop, implement and regularly report on a compliance program that monitors adherence to security requirements.

Recommendation 5:

The Agency develop and implement a program evaluation plan for My Health Record, including forward timeframes and sequencing of measurement and evaluation activities across the coming years, and report on the outcomes for benefits evaluation.

Agency response:

Agreed.

The Agency will develop a longer term evaluation plan, and work with the Department of Health on assumptions and modelling for benefits realisation.

2.2 Principles informing approach to implementation

We have adopted the following principles in developing this implementation plan:

1. We will implement recommendations with a view ensuring the system remains safe and secure for users into the future, and supports improved health and wellbeing for the Australian community.
2. We will act on learnings from other entities implementing audit recommendations, set out in the ANAO report on [Implementation of ANAO and Parliamentary Committee Recommendations](#);
3. We will have regard to the spirit as well as the letter of the recommendations;
4. We will consider the broader context of the health sector, controls currently in place to manage risk and improve quality;
5. We will co-produce changes which will affect others; and
6. The solutions will be designed to be scalable beyond the immediate recommendations.

2.3 Success criteria

Successful implementation of the recommendations will improve the overall quality of the operation and benefits of the My Health Record system and will increase maturity across the health sector with respect to data management and use.

Recommendations are mapped into workstreams that are designed to achieve desired outcomes. Successful implementation will encompass the following characteristics:

Privacy risk assessment workstream (recommendation 1)

What does success look like?

- The Agency documents an overarching, end-to-end privacy risk assessment of the My Health Record system, including any shared risks.
- The risks identified through the privacy risk assessment and appropriate controls are incorporated into the risk management framework for the My Health Record system. Treatments will focus on reducing potential harm to individuals and the community.
- Shared risks will be identified and analysed through appropriate information exchanges between relevant government and non-government stakeholders. Responsibility for implementing controls and ongoing monitoring is agreed and documented by relevant parties through a collaborative process. Reporting mechanisms are established to identify any new privacy risk exposure.

Compliance and regulation workstream (recommendations 2 and 4)

What does success look like?

- The Agency develops compliance approaches in relation to the adoption of agreed specifications and standards relating to digital health, that gives confidence to the Parliament, Government, stakeholders and the community that required standards are being met.
- The framework provides participants in the My Health Record system, and other digital health initiatives, with a clear understanding on how the Agency monitors third party compliance with legislative obligations.
- The Agency's regulatory compliance framework will facilitate interaction with My Health Record and digital health activities whilst also mitigating risks posed to the community.
- An independent review of the compliance regime is conducted after one year of operation. This review will determine whether the compliance regime is:
 - achieving the desired objective in changing or controlling behaviours;
 - minimising the potential for harm;
 - impacting regulated entities in a way that is proportionate to the risk; and
 - addressing the risks identified by the ANAO, particularly recommendations 2 and 4.

Standards and technology workstream (recommendation 3)

What does success look like?

- Security standards are identified for health IT systems connecting to the My Health Record, which also set an appropriate standard for health IT systems that do not connect to the My Health Record.
- A national digital health standards selection, development, maintenance and management model is agreed, which takes over the function of overseeing health IT security standards.

- The existing conformance, compliance and accreditation (CCA) and conformance, compliance and declaration (CCD) schemes are evolved to assure compliance of health IT systems with security standards.

Benefits evaluation workstream (recommendation 5)

What does success look like?

- That the Agency finalises a Benefits Measurement and Management Plan to reflect a 10 year time horizon, ensuring key benefits milestones and dependencies for achieving these are clearly outlined.
- Assumptions concerning the feasibility and sequencing of dependencies for achieving benefits milestones are the subject of consultation with key collaborators internally and externally.
- Limitations to benefits modelling are shared to set expectations around the likelihood of achievement. This will inform strategies to respond incrementally where realisation of benefits milestones is sensitive to external forces.
- Progress towards benefits realisation will be data driven and reported according to agreed governance.
- Benefits milestones will be staged to support the incremental roll out of the compliance and assurance framework for third party software and monitoring of mandatory legislated security requirements.

2.4 Outcomes

The ANAO audit presents an opportunity to lift the maturity of the entire health sector with respect to security and privacy practices.

The scope of the audit was limited to the My Health Record system and healthcare providers connected to and using data from the My Health Record. However, recommendations 1-4 call out risks to the System arising from less mature data management standards and practices that exist in healthcare settings when compared to the standards and practices adopted by the core infrastructure.

Our target state by November 2021 is to see measurable improvements in security standards in priority parts of the health system, and a roadmap for improving standards and practices across the rest of the sector. This extends beyond the My Health Record; with the ANAO recommendations providing an opportunity to progress digital maturity in the workforce and technology. This aligns with outcomes in the National Digital Health Strategy.

What does 'good' look like?

When considering recommendations in combination rather than as discrete activities, the outcome of implementation will improve the health system in the following ways

- **Maintaining trust.** Healthcare providers consistently top the list of 'most trusted professionals' in Australia, reflecting the high regard Australians have for nurses, doctors, pharmacists and other healthcare providers. Maintaining this trust is paramount to patient reported outcome measures and the overall effectiveness of the health system.

Recent reports by the OAIC identify the private health service provider sector as reporting the most notifiable data breaches of any industry sector², and that around half of these were as a result of cyber attacks³.

Remaining complacent about security standards in health IT systems could risk the high levels of trust between providers and consumers.

- **Continuing digital momentum.** Managing cybersecurity threats is imperative to maintain the confidence required for governments and private healthcare providers to digitise and improve the experience of healthcare for consumers, population health outcomes, and sustainability of the system.

Any cyber attacks arising from risks that could and should have been managed will erode this confidence and reduce the community and political appetite for digital reform.

- **Sharpening expectations about benefits.** In the absence of clear expectations of the benefits that will be realised from the My Health Record and digital health, any new risks introduced by technology (such as cyber) can appear unbalanced. This can impede progress in digitisation and become a self-fulfilling prophecy by reducing provider and consumer adoption, with reduced benefits realisation.

Clarity of what benefits are expected and in what timeframe, will provide confidence to stakeholders about the future.

- **Enhancing the health sector's ability to deal with shared risk.** By recognising the contribution of the Agency to a 'system of systems', where the sum is often greater than individual parts with associated complexity, we have a lot to gain from improving our approach to shared risks across multiple system participants.

Implementing a framework for managing shared risks as they relate to the My Health Record will provide a useful mechanism that could be scaled to manage risk across boundaries in healthcare in other technical and non-technical domains.

- **Improving data quality.** More proactive monitoring of system generated data by the Agency will create an opportunity to improve data quality entering the My Health Record system and over time, improve our ability to measure compliance with legislation, foundational to confidence in our systems. It will also improve the quality of data driven decision support and population health planning.

We will use these higher order outcomes as the starting point for co-producing responses to the recommendations, as opposed to a more narrow approach to 'complete' the recommendations in line with our commitment to Parliament (although, this will also be achieved as a consequence of the broader activity).

Authorising environment

The 'authorising environment' is the formal and informal authorities for an organisation to deliver on its functions.

In this context, the formal authority is through the requirement for the Agency to implement the recommendations in the ANAO report, and within the functions of the Agency as defined in the PGPA Rule establishing the Agency.

² All healthcare providers are caught by the NDB scheme as opposed to other sectors for which turnover thresholds are in place, which contributes to the over-representation.

³ Office of the Australian Information Commissioner, Notifiable Data Breaches Quarterly Statistics Report series, <https://www.oaic.gov.au/privacy-law/privacy-act/notifiable-data-breaches-scheme/quarterly-statistics-reports/>.

In order to embark on a wider scope to work with the sector to improve security standards and privacy practices over time, we will require the explicit support and involvement of many stakeholders across governments, industry, consumer and clinical groups.

We believe we will get consensus for this broader mandate from stakeholders. Our early consultation with clinical, industry, government and indemnity insurer stakeholders in December 2019 has confirmed that all are aware of risks arising from immature security and privacy practices in some settings, and all are working to reduce these risks within their own sphere of influence. They cautiously welcomed a co-ordinated national approach to improving security standards and awareness across the sector, and more mature approaches to managing consumer information and meeting privacy expectations.

This Implementation Plan includes a substantial block of co-production in the first six months, followed by six months of refinement, then implementation and review. This approach uses some of the key themes outlined in material published by the Commonwealth, including:

- The ANAO's *Better Practice Guide to Administering Regulation 2014*, which outlines a set of five key principles to support effective regulatory practice⁴.
- The Department of Finance's *Understanding and Managing Shared Risks 2016*⁵, which outlines seven steps to consider when developing and implementing shared risks.

This approach will support us to develop a collective baseline understanding of the roles and responsibilities amongst the network of delivery and oversight organisations, who are positioned to support digital health maturity in areas that are or should be candidates for a supervisory and or risk based regulatory model.

⁴ <https://nla.gov.au/nla.obj-494731946/view> Page 7

⁵ <https://www.finance.gov.au/sites/default/files/2019-11/comcover-information-sheet-understanding-and-managing-shared-risk.pdf> Page 6

3 Governance

3.1 Better practice

The ANAO provides the following key message for entities implementing recommendations:

To ensure entity objectives are delivered upon, effective governance arrangements should include clear responsibilities, reporting arrangements and systems that provide the accountable authority with a clear line of sight of implementation and assurance that underlying risks and issues that have been identified are addressed⁶.

The suitability of governance arrangements overseeing implementations is a consistent theme in ANAO reports concerning implementation of audit recommendations. Elements relating to what the ANAO expects of governance overseeing includes:

- Differentiation between the central coordinating function for ensuring implementation and the operational areas delivering against the recommendations;
- Identification, or new development of clear policies and process. It is expected these are consistently applied to coordination of implementation delivery;
- Professional record keeping is maintained by all involved including in corporate systems;
- Internal monitoring and reporting is undertaken through appropriate committee governance structures;
- External monitoring and reporting is particularly through the functions of the Audit and Risk Committee; and
- Transparency of progress against recommendations is provided in Annual Reports.

Ultimately the performance of the Agency is subject to external scrutiny of the Senate Standing Committee Community Affairs- Legislation Committee. A set of National regulators also form to varying degrees, an important aspect of governance and of the quality and suitability of workstreams responding to implementations.

This Plan has been designed in accordance with this guidance and oversight framework.

3.2 Accountability

The Chair of the Agency Board, representing the accountable authority, responded to the s19 proposed audit report in October 2019, including agreeing with the recommendations and providing a high-level outline of how the Agency would implement changes. This response is included in the tabled report and constitutes a commitment by the accountable authority to implement the recommendations.

The Board – as accountable authority under section 12(2) of the *Public Governance, Performance and Accountability Act 2013*, has an obligation to measure and assess the performance of the Agency, and it is expected that it would ensure the recommendations are implemented.

⁶ ANAO (2019) [Implementation of ANAO and Parliamentary Committee Recommendations](#), p.13.

No timeframe is stipulated for implementation, however the ANAO report [Implementation of ANAO and Parliamentary Committee Recommendations](#) states:

... it would be expected that agreed recommendations are implemented as intended and within a reasonable timeframe. Unless otherwise stated, a reasonable timeframe for the implementation of an agreed ANAO recommendation is taken as within two calendar years of a tabled report ...

Notwithstanding the above, accountable authorities may determine shorter timeframes for the implementation of ANAO recommendations with their respective entities. Accountable authorities may also advise of other impediments to implementation, for example, the requirement to achieve legislative change in relation to a particular program.⁷

This Implementation Plan sets out the timeframes for implementing the recommendations, with regard to risk, complexity and cost for the Agency and broader health sector.

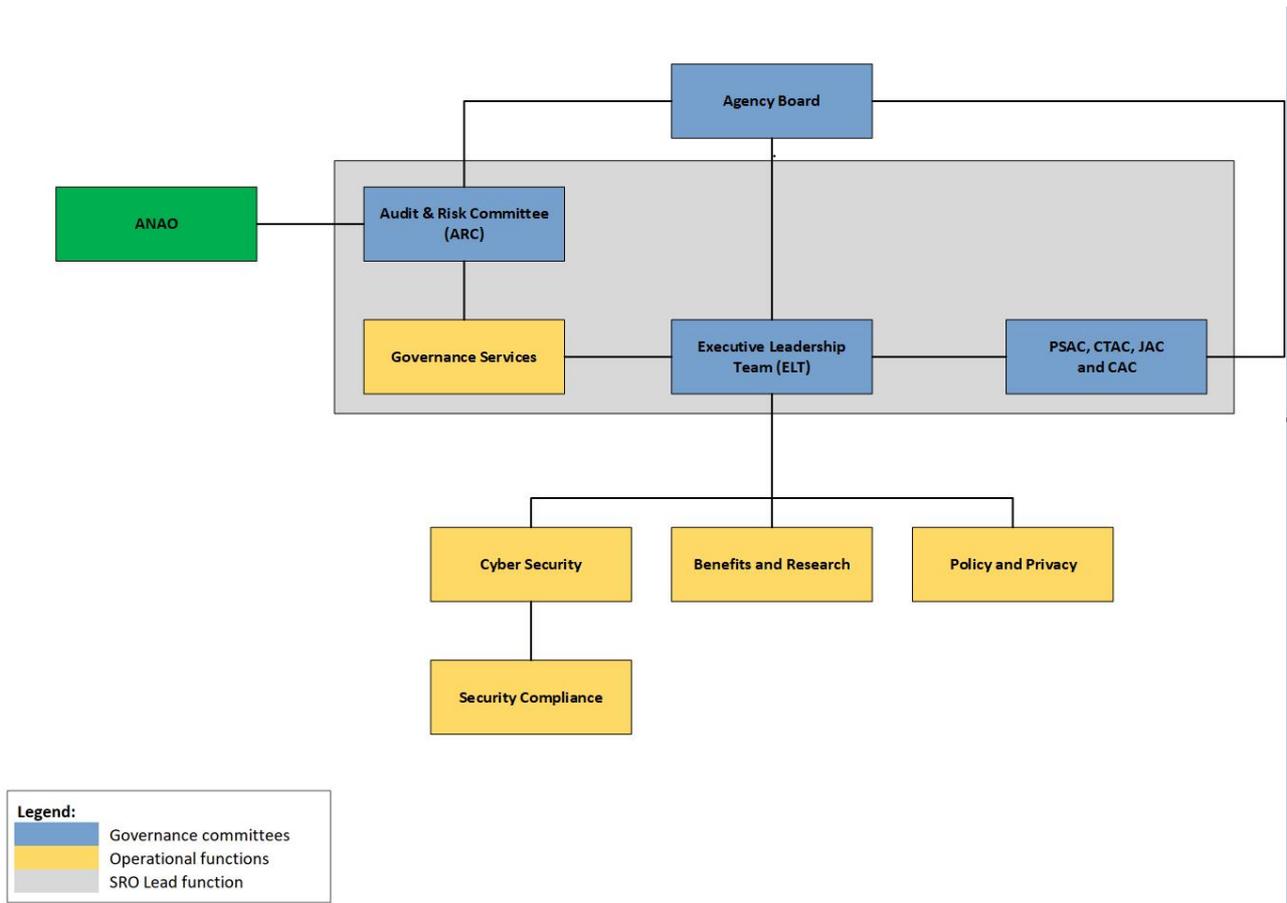
3.3 Oversight

The Board as accountable authority is responsible for ensuring that the agreed recommendations were implemented effectively and in a timely manner. It will get this assurance through management reporting and advice from its Advisory Committees:

- Management will provide reports to the Board in Board papers on progress to implement recommendations;
- The Audit and Risk Committee (ARC) will oversee and approve progress against the Implementation Plan, oversee independent testing of closed recommendations, and will meet with the same frequency as currently planned and provide advice to the Board on this through the Chair's report;
- The Privacy and Security Committee will provide technical input to management during the co-production process, and given the heavy focus on privacy and security risks raised in the report will meet more frequently in the first half of 2020 and provide advice to the Board on this through the Chair's report;
- The Jurisdictional Advisory Committee will provide input on the suitability of responses, adequacy for public health services, and alignment with broader government health policy, and will meet with the same frequency as currently planned and provide advice to the Board on this through the Chair's report; and
- The other Advisory Committees will provide technical input to management on the co-production process being undertaken with clinical, technical and consumer stakeholders, and will meet with the same frequency as currently planned.

All Advisory Committees will provide advice to the Board on the implementation of the recommendations through the regular Committee Chair reports.

⁷ ANAO (2019) [Implementation of ANAO and Parliamentary Committee Recommendations](#), p.18.



3.4 Responsibility

The Senior Responsible Officer for delivering the program of work is the CEO.

Responsibility for progressing each of the recommendations will be with the following leaders:

- Recommendation 1 Privacy Risk Assessment
 - Responsible leader: Steven Issa
- Recommendation 2 Emergency Access function
 - Responsible leader: Steven Issa
- Recommendation 3 Security standards in software and apps
 - Responsible leader: Ronan O’Connor
- Recommendation 4 Monitoring compliance of healthcare providers
 - Responsible leader: Rodney Ecclestone
- Recommendation 5 Benefits evaluation
 - Responsible executive: Steven Issa

3.5 Quality

Quality has been built into the Implementation Plan by:

- Applying better practices as described by the ANAO in their recent [Implementation of ANAO and Parliamentary Committee Recommendations](#) audit;

- Obtaining feedback from Gartner on the Implementation Plan template, with regard to international better practice;
- Review by the ARC, which includes an observer from the ANAO who will be in a position (but not under any obligation) to raise ideas or concerns; and
- Adopting a co-production process for the specific actions, which substantial evidence shows is an approach more likely to improve the quality of design.

3.6 Independent testing

The Agency's existing process for tracking and closing completed audit recommendations will be used, which involves:

- The Governance Services team maintaining the register of audit recommendations and obtaining updates from responsible staff on progress on implementing recommendations;
- Where a recommendation is to be closed as complete, obtaining evidence from business units of work performed;
- The Executive Leadership Team agreeing to close recommendations as complete; and
- Oversight by ARC of this process and recommendations closed, with the ability for ARC to reopen closed items.

This will be supplemented by an additional step, reflecting the more serious nature of reporting that an ANAO performance audit recommendation is closed as compared with an internal audit recommendation.

After the Executive Leadership Team closes an action, this will be tested by an independent party who will consider evidence that the recommendation was implemented effectively. The party will be the internal auditor or an independent expert with domain knowledge. A report will be provided to the ARC on the outcomes of this independent testing, and will support the ARC in providing advice to the Board as part of the assurance process.

3.7 Reporting progress

Responsible leaders will provide quarterly reports to the Board on progress of implementation. This will be complemented by:

- Reports to the ARC from management progress;
- Reports from ARC to the Board on its views on progress and quality at each Board meeting;
- Reports from other Advisory Committees to the Board on approach and quality, quarterly;
- A section in the Agency's annual reporting of the report on the entity; and
- Responding to any reporting request from the ANAO; which is likely to be received in November 2021 (24 months after tabling).

Records will be maintained of the co-production of solutions with partners, all interactions with the governance process, and completion of recommendations. Existing corporate systems will be used, rather than a specific tool purchased to track recommendations, as is sometimes used in larger entities and Departments.

4 Implementation risks

The Senior Responsible Officer (CEO) will identify and manage risks to implementing the recommendations, and will record these through the Agency risk register. High level risks identified at the outset of the program are listed below.

4.1 Lack of resources

Co-design activities are scheduled to run from February 2020 – July 2020. This activity is unfunded and outside the scope of the 2019/20 work program.

This will be controlled by resourcing being provided by mid-February 2020 to allow this work to proceed to plan.

Execution of the solutions (designed in early 2020) is scheduled to commence in August 2020, however, funding is not secured for the Agency beyond June 2020. Additional funding of \$1.4m is estimated in 2021/22 for support new functions that are beyond the current capabilities within the Agency, and other activities will need to be built into the 2021/22 workplan.

If resourcing is not available in the 2020/21 budget, execution on the plan would largely shift to FY 2021/22, which could put completion of all recommendations within two years at risk (particularly recommendation 4 which calls for implementation of the compliance framework).

4.2 Disengaged stakeholders

The degree to which recommendations are implemented and the principles in section 2.2 achieved, is dependent on effective engagement with internal and external stakeholders.

This will be controlled by identifying the broader outcomes to be achieved by this work, and obtaining consensus on this as a shared goal, rather than addressing this primarily as a compliance exercise.

It will also be controlled by adopting a co-production process to developing solutions.

4.3 Wrong scope

The response to recommendations will be developed through a co-production process, which could lead to incorrect scope. Too broad a scope could risk the ability for the Agency to implement the findings (creating a risk to our obligation to respond within two years), or too narrow (missing an opportunity to achieve the spirit of the recommendations to ensure the quality and security of the system).

This will be controlled by the senior leader responsible for each recommendation and the Senior Responsible Officer ensuring the co-design process is managed appropriately and expectations managed.

4.4 Operational risk

There a range of risks to successful delivery of the plan as a program of work (such as requisite expertise, internal buy in, executive engagement, effective governance). These have been considered when developing this Implementation Plan and will be tracked in the Agency's Operational Risk Register.

5 Engagement plan

5.1 Engagement methodology

The Agency will apply its Stakeholder Engagement Framework to engage with external stakeholders to co-produce the action plan to the audit recommendations and to implement them.

The Agency's vision and values inform the way we engage with all stakeholders;

- Engaging with respect to ensure we engage meaningfully, recognising stakeholder motivations, skills and diversity of opinions. Listening to and using feedback to demonstrate understanding of the needs of our stakeholders enables us to develop strong relationships.
- Collaboration and working together leverages the value of open and robust exchanges of opinions, expertise, views and ideas and allows us to gain a deep knowledge of the external digital health landscape.
- Engaging early in the process by identifying who will be affected ensures we begin the journey with the right stakeholders.
- Engaging regularly in a transparent manner, recognising and incorporating constructive criticism to develop better overall outcomes and build stronger relationships based on mutual trust. Successful engagements demonstrate how stakeholder insights have been considered and incorporated into the current and future digital health agenda.
- Co-design engagement to ensure results meet stakeholder needs, reflecting their preferences and ways of working.

The Agency's Stakeholder Engagement Framework is based on the International Association for Public Participation (IAP2) Design, Plan, Manage model. It provides a systematic and consistent approach to engagements, and when applied, ensures stakeholders are well prepared prior to consultations, that engagements are well coordinated, and stakeholders and the Agency derive value from the process. It provides Agency staff with guidance on the priority stakeholder groups, how to engage with them and which Agency staff need to participate. This Framework is supported by the Agency's Quality and Clinical Governance Frameworks to ensure quality, good governance and appropriate clinical co-design throughout the engagement lifecycle.

The diagram below illustrates the four-step engagement approach and key inputs, outputs and deliverables. Successful engagements follow all four steps and develop clear problem definition statements, requirements documentation and a comprehensive stakeholder engagement plan.



5.2 Effective stakeholder engagement

The ANAO's *Better Practice Guide to Administering Regulation*⁸ outlines several considerations to effectively manage stakeholder relationships between regulators and regulated entities:

- Identify key stakeholders, the value of engagement and how best to undertake engagement activities.
- Effective two-way engagement and communication with regulated entities is required to lead to positive regulatory outcomes.
- Regulated entities must have a clear understanding of compliance requirements to be able to and be more willing to comply.
- Regulators can gain valuable insights into the behaviour of regulated entities through effective interactions with regulated entities. This can be used to guide future compliance activity and the allocation of available resources.
- Two-way engagement also provides insights into the overall effectiveness of the regulatory regime and regulator performance.

The Better Practice Guide outlines that regulators must act as an authoritative source of information for regulated entities and other stakeholders. The Guide provides some strategies for designing stakeholder interactions, and outlines that a diversity of communication mechanisms is required to effectively reach regulated entities and other stakeholders. The capacity of the intended audience to effectively access and use the selected communication mechanisms must also be considered. Communication mechanisms may include one or more of the following:

⁸ <https://nla.gov.au/nla.obj-494731946/view>

- publishing information online
- social media
- electronic distribution of information to subscribers of information services
- formal consultative arrangements
- informal and ad hoc processes, or
- point of contact and feedback mechanisms.

5.3 Engagement completed in 2019

In developing this Implementation Plan, the Agency has undertaken steps 1, 2 and 3 of the Stakeholder Engagement Framework. This informed the scope of this plan, definition of success criteria, workstreams and timeframes.

5.4 Engagement to be undertaken in 2020

The next steps involve completing steps 4, 5 and 6 from February – July 2020, and steps 7 and 8 from August – December 2020.

6 Timeframe

6.1 Gantt chart

The Gantt chart for the Implementation Plan is in the Microsoft Teams folder for ANAO Implementation.

6.2 Indicative timeline

Timelines for each recommendation are shown at Appendix A. At a high level, this involves;

- Approval of Implementation Plan by accountable authority in February 2020;
- Context and analysis in February and March (this commenced in December 2019 and a team will be established in late February to continue this work);
- Engagement March – July 2020;
- Finalise design and commence implementation (sensitive to funding available for any new functions in 2020/21);
- Monitor and refine late 2020;
- Plan and cost ongoing operations late 2020; and
- Embed ongoing operations (sensitive to funding).

7 Appendix A - Implementation scope for ANAO recommendations