Australian Government
Department of Health, Disability and Ageing

Updated Population Based Screening Framework

(National Screening Framework)

PUBLIC CONSULTATION DRAFT

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1. Introduction **3**
1.1 Screening 3
Benefits and harms 4
Screening principles and contemporary considerations 5
1.2 Organised screening programs and other health tests and activities 7
1.2.1 Organised screening programs 7
1.2.2 Other health tests and activities 7
1.3 The screening pathway 7
1.4 Screening in Australia 9
2. Australian criteria for the assessment of organised screening programs **10**
3. Requirements for the implementation and management of organised screening programs **13**
4. DRAFT assessment process **16**
5. DRAFT Guidance for changes to existing programs **17**
Appendix 1: Other health tests and activities 19
Glossary 20
References 23

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1. INTRODUCTION

The National Screening Framework supports governments to assess, implement and review national screening programs. It also provides guidance to support the development of screening program proposals.

The framework provides information for consumers, advocacy organisations, researchers and health professionals on how decisions about organised screening programs are made. This includes the information and evidence required to assess screening proposals. It does not guide clinical decisions for individual patients.

This framework helps ensure decisions about screening programs are made in the best interests of the population and informed by evidence. It supports screening that delivers meaningful benefits while carefully considering potential harms.

The framework focuses on organised national screening programs, including population-based, targeted and risk-stratified screening approaches. These programs may use a range of screening tests, including biochemical, genomic and imaging tests, as well as other technologies.

The framework covers:

- screening in Australia and how it has changed over time
- criteria to introduce or modify screening programs
- guidance for program implementation and management
- the process for assessing screening proposals.

Guidance and templates to support the development of screening proposals are provided on the Department of Health, Disability and Ageing website at: (*materials under development - web address tbc*).

The Australian, state and territory governments first developed the framework in 2008. The Cancer and Population Screening Committee oversees the framework. Periodic reviews are undertaken as required to maintain alignment with emerging evidence, technology and policy developments.

1.1 SCREENING

Screening is the systematic offer of tests to defined groups of people without recognised signs or symptoms of the condition being screened for. Screening aims to identify people who may have:

- a condition
- a disease-related marker or precursor state that may lead to a condition, or
- an increased risk of developing a condition.

Screening programs are important because they can:

- reduce illness and death across the community
- improve health outcomes for individuals and their families.

Screening programs identify people who may benefit from further assessment or intervention. They do not usually diagnose a condition. Further assessment may include diagnostic testing that leads to a diagnosis.

Screening programs support timely intervention that can improve health outcomes. Interventions may include treatment, surveillance, prevention or other management approaches. Some programs may also provide information to help people make personal and reproductive choices.

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Screening programs should only proceed where there is sufficient evidence that screening and subsequent assessment and intervention improve outcomes at a population level. However, screening tests may not identify everyone who could benefit from intervention, and outcomes from interventions will vary.

Benefits and harms

Decisions about screening programs involve weighing population and individual impacts. This includes benefits and harms, and other social and ethical considerations. While population-level benefits and harms are central to screening decisions, individual impacts, including personal value of health or risk information, are also relevant.

Organised screening programs can deliver significant benefits to the population. However, screening can also cause harm. Screening is offered to people who do not have symptoms and are usually healthy. Given this, there is an ethical obligation that programs only proceed where anticipated benefits outweigh potential harms. The benefits must also justify the use of community and health system resources for both the screening itself and subsequent follow-up.

The benefits and harms are presented here as discrete concepts. However, perspectives of these concepts may differ. This is because what constitutes a benefit or harm is not always clear-cut, and can differ based on individual experience.

Benefits associated with screening, assessment and intervention may include:

- reducing the burden of disease on the community and individuals
- improving health outcomes, including reductions in mortality and morbidity
- improving quality of life
- reducing time to diagnosis and detecting conditions at an earlier stage when they may be easier to treat
- supporting informed personal or reproductive decision-making
- reducing health system costs

Some individuals may also value knowing health or risk information, even in the absence of effective health interventions. Additionally, identifying an individual through screening may allow family members to also undergo cascade testing. However, in the absence of a demonstrated health benefit at an individual and population level, the value of knowing and the possibility of cascade testing for relatives are unlikely to justify a screening program.

Harms associated with screening, assessment and intervention may include:

- False positives: where the screening test is positive but the individual does not have the condition or level of risk that the test identifies. This may lead to anxiety and other psychosocial harm, additional testing and procedures, and out-of-pocket costs. For screening tests that identify future risk, a result indicating increased risk is not always considered a false positive if the condition does not eventuate. However, such results may still lead to the harms associated with a false positive result.
- False negatives: Where the screening test is negative but the individual does have the condition or level of risk that the test is intended to identify. This may result in delayed diagnosis, delayed intervention or missed opportunities for prevention where an individual is incorrectly classified as being at lower risk.
- Inconclusive or uncertain results**:** when screening delivers a result that is not clearly positive or negative or does not provide a clear answer about an individual's future health. Such results may lead to anxiety, difficulty making decisions, additional testing or ongoing monitoring.
- Incidental findings: when the screening test identifies a finding that is not actively sought. These findings may relate to the person screened or their biological relatives and require

further clinical confirmation. Incidental findings may have clinical value in some circumstances. However, where findings are clinically insignificant, the individual may be burdened by additional testing for minimal health benefit. The scope and feasibility of reporting such findings in the context of a screening program is also important to consider.

- Burden of follow-up over time: repeated testing, follow-up investigations, and ongoing monitoring over time, which may result in financial costs, exposure to physical harms, and lost time for the person being tested. This is particularly relevant for screening programs that identify individuals at increased risk, as they may require monitoring over an extended period.
- Overdiagnosis and over-treatment: when screening identifies a cancer or other condition that may never have caused symptoms, affected quality of life, or become life-threatening in an individual's lifetime. Treatment of these findings may expose individuals to unnecessary harms without health benefit, and lead to significant health resource expenditure. Overdiagnosis is not an error or misdiagnosis.
- Other potential harms include:
    - physical harms, such as biopsy complications or adverse treatment effects
    - psychological harms, such as anxiety or distress
    - social harms, such as stigma, discrimination or changed societal perceptions
    - financial impacts for individuals or families, such as out-of-pocket costs for follow-up testing or intervention, travel and accommodation costs or lost income from time spent during testing
- impacts on family members, especially where screening reports genetic information or shared familial risk
- impacts on the health system. This includes the "opportunity cost" of screening, whereby investment in screening commits funding, workforce, infrastructure and service capacity that cannot be used elsewhere.

Some outcomes that can be considered harms of screening or follow-up may be perceived differently by individuals and in different contexts. For example, where one individual may experience or perceive a benefit, another may not, or may experience harm. For this reason, what may be a benefit at an individual level for some, may not be a clear benefit when considered at the population level. Therefore, potential benefits and harms should be considered in the context of the program, the results provided to participants, and the likely consequences for individuals and families.

Screening principles and contemporary considerations

In 1968, Wilson and Jungner developed the World Health Organisation (WHO) principles of screening.[1] These principles continue to guide screening decisions today and are outlined below. Central to these principles is the need for screening programs to deliver more benefit than harm.

In addition to the WHO principles, contemporary screening practice has identified additional considerations relevant to the assessment, implementation, governance and evaluation of screening programs in the Australian context. These considerations are included below using the same domains as the WHO principles. Together, these principles and considerations inform the assessment criteria in Section 2 and the implementation requirements in Section 3 of this framework.

WHO Principles[a]

Condition

- The condition should be an important health problem.
- There should be a recognisable pre-clinical or early symptomatic stage.
- The natural history of the condition, including development from pre-clinical to declared disease, should be adequately understood.

Test

- There should be a suitable test or examination.
- The test should be acceptable to the population.

Intervention

- There should be an accepted intervention for individuals with a recognised condition.

Screening Program

- There should be an agreed policy on whom to offer intervention.
- Facilities for diagnosis and intervention should be available.
- The cost of case-finding (including diagnosis and intervention) should be economically balanced in relation to possible expenditure on medical care costs as a whole.
- Case-finding should be a continuing process and not a 'once and for all' project.[b]

Contemporary Considerations

Intervention

- Meaningful action and follow-up - screening programs should only be implemented where effective, acceptable and feasible follow-up actions are available that improve health outcomes.

Screening Program

- Equity and ethical considerations – screening programs should promote equitable access, participation and outcomes, recognising that some population groups may require additional support to participate and benefit. Any targeted approaches should be evidence-based, ethically justified, and implemented in a way that does not stigmatise difference or perpetuate discrimination.
- First Nations partnership and collaboration – screening programs should be developed and implemented in partnership with Aboriginal and Torres Strait Islander peoples. Partnership supports cultural safety and improved health outcomes.
- Informed and voluntary participation – screening programs should provide accessible, balanced and evidence-based information about the purpose, benefits and harms, limitations and uncertainties of screening. Individuals should be supported to make informed choices about participation, subsequent testing, follow-up care or management, consistent with their values, preferences and tolerance of risk and uncertainty.
- Strong data stewardship and governance – screening programs should ensure responsible stewardship of data, supported by robust governance to enable secure, ethical and transparent use. Data should also support ongoing monitoring, evaluation and continuous improvement of screening programs.

[a] Minor wording updates have been made to reflect contemporary terminology.

[b] Ongoing screening may be required at defined intervals in some, but not all screening programs.

1.2 ORGANISED SCREENING PROGRAMS AND OTHER HEALTH TESTS AND ACTIVITIES

The framework provides guidance for assessing whether an **organised** screening program should be introduced nationally or modified. It is therefore important to distinguish organised screening programs from other related health tests and activities.

1.2.1 Organised screening programs

An organised screening program is a nationally coordinated, proactive and systematic approach to screening, which aims to improve health outcomes. Defined population groups are systematically identified, invited or engaged, tested, treated where necessary, followed up and monitored. Organised programs are implemented within a framework of agreed policy, protocols, quality management, monitoring, evaluation and review.

Organised screening programs use population-based, targeted, or risk-stratified approaches. They may use a range of screening tests, including biochemical, genomic and imaging tests, as well as other technologies.

Population-based screening is the systematic offering of screening to a group of people identified from the whole population. The specific population is defined demographically, such as by age or sex. For example, bowel cancer screening is offered to all people in an age-based target population**.**

Targeted screening is the systematic offering of screening to a defined population sub-group identified through agreed program eligibility criteria that are associated with a higher risk of a condition. Eligibility may be based on factors such as lifestyle factors, genetic variants, family history or having another health condition. For example, lung cancer screening is offered to eligible individuals based on smoking history and age.

Risk-stratified screening is an approach to screening in which the test frequency and type of test offered within an organised screening program varies according to the individual's level of risk. This can improve the balance of benefits and harms at the individual as well as population level. For example, in lung cancer screening participants are stratified based on their risk identified at the first scan and this determines the subsequent scan intervals.

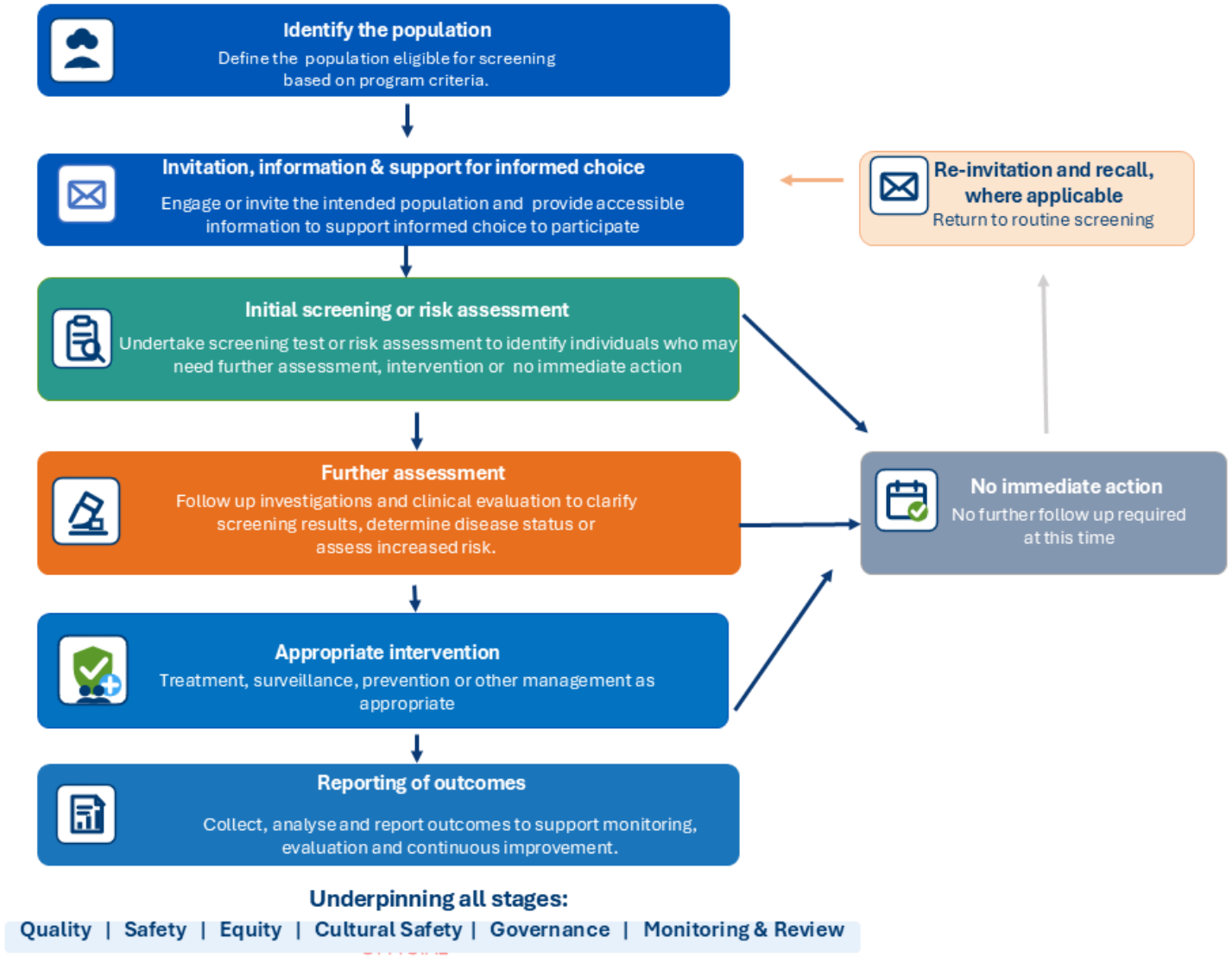
Risk-stratified approaches are typically applied within targeted and population screening programs and may include different screening intervals, screening tests or follow-up pathways according to risk category.

1.2.2 Other health tests and activities

There are a range of other health tests and activities that may involve testing but do not constitute organised screening. These activities can play an important role in clinical care and prevention, but they differ from organised screening in their purpose, structure and level of coordination. Descriptions of case-finding, opportunistic screening, routine examinations or scheduled health checks, diagnostic testing, cascade testing and clinical surveillance can be found at Appendix 1.

1.3 THE SCREENING PATHWAY

The diagram below shows a general screening pathway for an organised screening program. It starts with defining the eligible population and ends with appropriate action and reporting of outcomes. Individuals may follow different pathways, including further assessment, appropriate intervention, or no immediate action, depending on their circumstances and the screening approach. The pathway also recognises that screening may be an ongoing process, with individuals re-entering at different points over time.


Identify the population
Define the population eligible for screening based on program criteria.
Invitation, information & support for informed choice
Engage or invite the intended population and provide accessible information to support informed choice to participate
Re-invitation and recall, where applicable
Return to routine screening
Initial screening or risk assessment
Undertake screening test or risk assessment to identify individuals who may need further assessment, intervention or no immediate action
Further assessment
Follow up investigations and clinical evaluation to clarify screening results, determine disease status or assess increased risk.
No immediate action
No further follow up required at this time
Appropriate intervention
Treatment, surveillance, prevention or other management as appropriate
Reporting of outcomes
Collect, analyse and report outcomes to support monitoring, evaluation and continuous improvement.
Underpinning all stages:
Quality | Safety | Equity | Cultural Safety | Governance | Monitoring & Review

1.4 SCREENING IN AUSTRALIA

Australia has a long history of delivering high-quality screening programs that have made a significant positive impact on the population.

- Tuberculosis was Australia's first screening program, introduced in 1949 and ending in 1976 as illness and death fell substantially.
- Newborn bloodspot screening was introduced in the 1960s. It began with screening for phenylketonuria and has now expanded to include more than 35[1] conditions.
- Four national cancer screening programs, for breast, cervical, bowel and lung cancer, have been introduced and refined over time.
- Newborn hearing screening has been implemented nationally since the early 2010s.

Screening programs in Australia have evolved over time as evidence, technology and population needs have changed. The balance of benefits and harms can also change as new evidence emerges, reinforcing the importance of ongoing evaluation, transparency and program review. This includes advances in genomics and other technologies that are enabling increasingly targeted and risk-stratified approaches to screening.

Australia uses shared funding and governance for screening. The Australian Government leads national policy and plays a central role in the design, delivery and oversight of nationally coordinated screening programs.

State and territory governments support policy, design, promotion, recruitment, education, training and the delivery of screening and follow-up services through their health systems. They also contribute to data monitoring and evaluation.

For all national organised screening programs, Australian, state and territory governments collaborate, consult and communicate to deliver programs effectively.

Many other screening-related activities occur in Australia through clinical practice, commercial entities or state and territory health systems. While these activities may involve screening, they are not delivered as organised national screening programs. This framework focuses on organised approaches that involve systematic design, delivery and evaluation at the national level.

[1] Note, the number of conditions will continue to increase as agreed by Australian and state and territory governments. For the full list of conditions, visit www.health.gov.au/NBS

2. AUSTRALIAN CRITERIA FOR THE ASSESSMENT OF ORGANISED SCREENING PROGRAMS

The criteria that follow are underpinned by the principles outlined in the introduction. They support assessment of new organised screening programs and modifications to existing programs. For details on the assessment process for new screening program proposals, see Section 4. For details on how the criteria apply to existing programs, see Section 5.

Equity is a foundational consideration in the design and assessment of screening programs. Evidence should demonstrate that the screening program can be delivered safely, equitably and consistently across the intended population.

This includes consideration of priority populations, such as Aboriginal and Torres Strait Islander peoples and other groups that may experience barriers to participation, access or benefit, including those who live in regional, rural and remote areas. Potential barriers to participation, access and follow-up should be identified. Strategies should demonstrate how these barriers will be addressed through program design, implementation and ongoing evaluation.

A high level of evidence is essential when making decisions about screening programs. This is because screening is offered to people who do not have symptoms and are usually healthy. It therefore has the potential to cause harm that would not have occurred if the person had not participated in screening.

Direct evidence demonstrating that screening improves health outcomes, including reductions in morbidity or mortality, is preferred. Randomised controlled trials (RCTs) remain the preferred sources of evidence where feasible, although other high-quality evidence may be considered where RCTs are not feasible. It is recognised that RCTs are generally not available for rare conditions.

At the assessment stage, sufficient evidence is required to demonstrate that the program can be implemented safely, effectively and cost-effectively, including a credible commitment to establish any infrastructure, workforce, services or systems that are not yet available.

For programs that screen for multiple conditions, sufficient evidence should be available to demonstrate that each condition, or group of related conditions, meets the criteria and that the overall screening program is expected to deliver a net benefit. The assessment should be proportionate to the purpose and scope of the proposed screening program.

A screening program may lead to findings that are beyond the scope of the program. If this is a possibility, the design and implementation of the program should include consideration of whether and how to report them. This should take into consideration the balance of possible benefits and harms, and the feasibility of reporting them in the context of an organised screening program.

The criteria are organised into categories that reflect the components of organised screening: condition, test, assessment, intervention and screening program. When assessing a screening program, the following criteria should be considered. The criteria should be met unless there is a strong justification for an exception.

Condition

1. The condition is an important health problem with a high or increasing incidence or prevalence, and/or causes significant morbidity or mortality in Australia.
2. The condition has a detectable preclinical or early symptomatic stage; or, where relevant, screening can reliably identify an individual’s risk of developing the condition or the chance of the condition occurring in their offspring.
3. The natural history of the condition is adequately understood. This includes, where relevant:

- the relationship between the relevant marker and the manifestation of disease
- progression from the preclinical or early symptomatic stage to clinical manifestation of disease
- for genetic conditions, the genotype-phenotype relationship, penetrance and expressivity
- variation across population groups and settings.

Test

4. The test is highly sensitive and specific in the intended population.
5. The test has a relatively high positive and negative predictive value in the intended population.
6. The test is validated for the intended use and population, including risk stratification, where relevant.
7. The test is safe. Potential harms are understood and, where possible, can be appropriately mitigated.
8. The test is broadly acceptable to the intended population.
9. There are agreed criteria for interpreting test results.

Assessment

10. There is an evidence-based approach to assessment following a positive screening result. Assessment tests, procedures and referral pathways are appropriate, safe, accessible and acceptable.

Intervention

11. The intervention is effective, available, accessible and acceptable to people identified through screening. This includes where relevant, people with the condition and/or people identified as being at increased risk, and their relatives. Intervention may include treatment, surveillance, prevention or other management approaches.

Screening Program

12. There is clear evidence that early detection of a condition, carrier status or risk marker leads to better outcomes for the intended population, compared to detection at a later stage.
13. There is a recognised need for an organised screening program.
14. The intended population that is expected to benefit from screening is identified.
15. The screening program promotes equitable access to screening and follow-up for the intended population, including through culturally safe program design and delivery for priority populations.
16. Where risk assessment approaches are used, they are validated for use in the intended population.
17. The screening pathway and interval (where relevant) are clearly defined, including pathways for different risk groups where applicable.
18. There is a clearly defined and evidence-based pathway for timely follow-up assessment, diagnosis, intervention and support for individuals with a positive screening result.
19. The infrastructure, facilities and workforce required to deliver a high-quality screening program are clearly identified and available or there is a demonstrated commitment to make them available.

20. The health system requirements for delivering follow-up assessment, diagnosis, intervention and support are clearly identified and available; or there is a demonstrated commitment to make them available. This includes for people in regional, rural and remote areas and other populations that may experience barriers to access.
21. Data governance (including consideration of Indigenous Data Sovereignty requirements), information systems and screening register infrastructure are clearly identified and available or there is a demonstrated commitment to make them available. These support program delivery, invitation, recall, follow-up, monitoring, evaluation and linkage with relevant outcomes.
22. The screening program is clinically, socially, culturally, legally and ethically acceptable to health professionals, relevant researchers, consumers and the Australian public, including diverse population groups and priority populations.
23. The screening program demonstrates acceptable incremental cost-effectiveness relative to the appropriate comparator.
24. The screening program supports informed choice, confidentiality, respect for autonomy, and minimises potential stigmatisation or discrimination. This includes providing information about possible findings, uncertainty, implications for family members, and choices about receiving information and future contact.
25. The overall benefits of screening are expected to outweigh the potential harms.

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3. REQUIREMENTS FOR THE IMPLEMENTATION AND MANAGEMENT OF ORGANISED SCREENING PROGRAMS

The requirements in this section provide a practical guide to the establishment of an organised screening program. They largely apply following a decision to support implementation of an organised screening program, and as funding and implementation arrangements are established. They support the program's operation, monitoring and ongoing management. However, they are also important considerations in the early design of proposals for screening programs, to ensure that a screening program is feasible and practical.

The implementation and management requirements build on the assessment criteria. They are not additional criteria for determining whether a screening program should proceed. Rather, they support the translation of an approved and funded proposal into a safe, effective, equitable, culturally safe and sustainable screening program.

An organised screening program should operate as a coordinated and integrated system, with clear links between participant identification, information and support, screening, assessment, referral, diagnosis, intervention and support, program management, data systems, quality management and evaluation.

Where appropriate, implementation may be staged or supported by a pilot to test or refine elements of the program in the Australian context. The need for a pilot should be determined according to the nature of the program, the evidence available and the implementation risks.

National Policy and Protocols

1. Develop a detailed national policy for the proposed screening program that defines the:
    - program objectives
    - intended population and eligibility criteria
    - screening pathway, including screening interval where relevant
    - participant information needs along the pathway
    - follow-up requirements
    - clinical guidelines and information for intervention, ongoing surveillance processes, and identification and management of groups at increased risk.
2. Define a screening pathway for the program that is evidence-based, efficient and cost-effective.
3. Establish appropriate timeframes and processes for assessment, diagnosis and intervention where needed, to support timely progression through the screening pathway and minimise potential harms from delay.
4. Define the roles and responsibilities of each level of government and the operational arrangements required to coordinate and deliver the program. This includes register or information-system arrangements, participant identification or invitation processes, follow-up protocols and quality management arrangements.

Program Planning

5. Embed equity in program design, delivery, monitoring and continuous improvement. Establish structures, processes and service-delivery arrangements that identify and address avoidable barriers and inequities in access, participation, experience and outcomes for priority populations, including Aboriginal and Torres Strait Islander peoples and people in regional, rural and remote areas.
6. Undertake extensive consultation to inform program design and seek broad stakeholder support for the national approach. Identify and engage stakeholders from the conceptual stage including, but not limited to consumers, priority populations, academic researchers, health professionals involved in the diagnosis, intervention and management of the

condition, jurisdictional representatives, and Aboriginal and Torres Strait Islander representatives.

Program Design

7. Develop an implementation plan that identifies key activities, responsibilities, milestones and timeframes for establishment of the program.
8. Identify participation objectives and develop evidence-based approaches to identify and engage the intended population.
9. Develop evidence-based strategies to support awareness of, access to and participation in screening by the intended population, including priority populations, and ongoing participation where relevant.
10. Develop processes to support informed choice or informed consent. Define how and when informed choice or informed consent is sought, recorded, reconfirmed or withdrawn, as relevant to the program.
11. Develop and provide accessible, inclusive, culturally appropriate and safe information and support for participants across all aspects of the screening and referral pathways.
12. Establish processes for interpreting, communicating and managing all screening results, including negative, positive (including results indicating increased risk), uncertain or indeterminate results and incidental findings, where relevant.
13. Develop models for workforce, infrastructure and service delivery based on local circumstances and projected needs and demands as participation rates and the size or needs of the intended population change.
14. Define referral processes and management pathways for people with positive screening results, including access to appropriate assessment, diagnosis, intervention, support and follow-up services where needed. These should include processes to identify and support participants who may otherwise be at risk of being lost to follow-up.
15. Establish service-delivery arrangements that support equitable access to screening and follow-up services where needed, including through culturally safe and accessible models of delivery.
16. Establish policies for the future participation and screening status of individuals diagnosed with the condition through screening or clinical care, including whether and when they may return to, or cease participation in, the screening program.

Governance, Management and Program Sustainability

17. Clearly define and agree the program organisational structure, governance and management arrangements at national, state and territory, and service levels, including leadership, advisory mechanisms, evaluation, ongoing review, responsibilities, accountability and decision-making processes.
18. Incorporate Indigenous Data Sovereignty and Indigenous Data Governance requirements into relevant data governance, access, use, interpretation and reporting arrangements.
19. Develop data governance, retention and disclosure policies addressing, as relevant, privacy, collection, use, access, sharing, reinterpretation, secondary use, storage, destruction, future contact, future research and participant preferences.
20. Identify the resources required for establishment and ongoing operation of the screening program, including funding, workforce, infrastructure, facilities, information systems and service capacity. Determine how these resources will be developed, used efficiently, and sustained.

Quality Management

21. Develop standards, performance measures and quality assurance processes that apply to all relevant elements of the program and screening pathway.
22. Develop and maintain agreed data definitions and a data dictionary.

23. Develop accreditation processes, as required.
24. Develop a risk management plan covering implementation and ongoing operation of the program.
25. Establish processes to identify, minimise and manage physical, psychosocial, cultural and other material harms and participant burdens.
26. Support ongoing education, professional development and training to sustain the capability of the workforce across the screening pathway.

Monitoring, Evaluation and Review

27. Develop, from the outset, a formal approach to ongoing monitoring and evaluation of the screening program against the agreed objectives, including benefits, harms, equity and outcomes.
28. Identify appropriate measurable national indicators and collect the data. These should monitor program reach, participation, quality, safety, benefits, harms, resource use, equity and outcomes over time, including relevant differences between population groups.
29. Develop indicators that enable comparison over time and, where appropriate, with other programs in Australia or internationally.
30. Develop clear, nationally consistent methods for collecting and reporting data against the indicators.
31. Identify reporting milestones and recipients, including governments, governance bodies, stakeholders and the public.
32. Develop public reporting that is easily accessible and meaningful to the intended audiences, including priority populations.
33. Align monitoring and evaluation with the quality management plan and use the results of these activities to support continuous improvement.
34. Identify timeframes or circumstances that would trigger program review, modification, redesign or cessation, including material changes in evidence, technology, health-system capacity, program performance, benefits, harms or equity outcomes.

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4. DRAFT ASSESSMENT PROCESS

Please note, operation of the assessment process would be subject to approvals and government funding.

Section 2 sets out the criteria for assessing new screening program proposals. It is proposed that these criteria be considered through a staged process to support transparent, consistent and rigorous assessment. Note: for newborn bloodspot screening (NBS), the NBS National Policy Framework decision-making criteria and nationally agreed decision-making pathway would continue to apply.

DRAFT Assessment process for new screening program proposals

1 Proposal review and refinement

1. Applicant submits proposal. Department confirms availability of evidence against assessment criteria 1-12 and provides feedback to applicant on any gaps.
2. Suitable proposals progress to a new multi-disciplinary committee*(MDC) to assess availability and strength of evidence against criteria 1 – 25, including preliminary consideration of implementation feasibility through 19-21.
3. The MDC advises if ready for HTA or additional work.

GATEWAY QUESTIONS

- Is there a credible case for screening?
- Is the proposed model sufficiently defined?
- Is adequate evidence available to proceed to HTA?

YES → 2 MSAC HTA

NO → Further work required. Additional work by applicant or government, then resubmit to MDC.

*MDC includes expertise in screening, clinical practice, epidemiology, population health, public health ethics, health economics, implementation and First Nations and state and territory representation.

2 MSAC HTA

Assessment of comparative:

- Safety
- Clinical effectiveness
- Cost-effectiveness
- Total cost of screening.

GATEWAY QUESTIONS

- Does MSAC support the proposed screening program based on clinical effectiveness, safety and cost-effectiveness?

YES → 3 Program readiness review

NO → Further work required. Feedback provided to applicant on next steps

3 Program readiness review

1. Department considers the MSAC outcome and the key implementation feasibility criteria (19-21).
2. Department determines if the proposal is ready for final decision or requires further consultation or work.

GATEWAY QUESTIONS

- Is the proposed screening program sufficiently ready for implementation to support government consideration?

YES → 4 Decision

NO → Further work required. Additional work on program feasibility or delivery undertaken by government.

4 Decision

Government/s consider MSAC advice and alignment with the Framework and determine whether to implement the screening program.

5. DRAFT GUIDANCE FOR CHANGES TO EXISTING PROGRAMS

Existing programs should be responsive to significant developments in evidence and practice to ensure they continue to maximise the benefits delivered to the Australian population.

Screening programs may undergo both incremental and transformational program level change. Program level change may include modifications to the screening test, the target population, screening interval or eligibility criteria.

Whether incremental or transformational, program changes are complex, and have implications across the screening pathway and follow-up services. To support the continued delivery of high-quality screening, these changes are always driven by evidence and review.

This guidance outlines key activities for governments to guide significant changes to existing national organised screening programs. All activities should be undertaken to support change. They are interconnected and may overlap rather than follow a fixed sequence.

Engagement and consultation are essential to the activities that inform change. This includes across state and territory and Commonwealth governments, and with health care providers, consumers, including priority populations, and others.

- **Monitor evidence and engage early:** Government monitors emerging evidence, international experience and program performance. Engagement occurs between Commonwealth, state and territory governments, and other relevant stakeholders, to identify and consider the evidence-informed need for change.
- **Agree the need for change:** In line with program governance, governments determine the need for program change.

  There is no single ‘trigger for change’. However, grounds for change include where there is evidence that changes knowledge of the condition, including benefits or harms, a new condition to be included in an existing program, a new or changed test or intervention (criteria 1 – 11). In some circumstances, a change may not be warranted, or additional evidence is required before proceeding.
- **Define the change and its impact:** Define the purpose and impact of the change on the target population, technology, screening pathway and program objectives, including the cumulative effect of related changes and impacts on downstream health services. Identify the relevant assessment criteria in Section 2 of the framework that relate to the proposed change (e.g. safety, clinical effectiveness, cost-effectiveness). Depending on the change being considered, not all criteria may be relevant.
- **Confirm governance and roles:** Consider whether existing governance or bespoke governance is required. Describe the roles and responsibilities, including of Commonwealth and state and territory governments, and key stakeholders. Arrangements should be proportionate to the nature and scale of the change and draw on existing program governance where appropriate.
- **Determine the assessment approach:** Determine the most appropriate mechanism to assess the evidence for change against the relevant criteria. Assessment should establish whether there is sufficient evidence to support the proposed change and whether the anticipated benefits outweigh any potential harms.

  Depending on the nature and scale of the change, this may involve an independent review, clinical guidance review process, or another robust assessment mechanism consistent with existing program governance and approaches. For some changes, such as the introduction of a new technology or MBS item, assessment may involve a health technology assessment, through the Medical Services Advisory Committee (MSAC).

- **Undertake detailed implementation planning:** This activity should include consideration of the full range of implementation planning activities. This includes, but is not limited to project planning, including timing and sequencing of activities, risk management, change management, stakeholder engagement and public communications, workforce and training requirements, clinical guidance, protocols and information systems, and monitoring and evaluation arrangements. These plans should be adaptive and able to respond to implementation challenges as they arise.

  Consideration should be given to the implementation and management requirements in Section 3 of the framework to inform the key aspects of the program that will require updating.

- **Confirm funding arrangements:** Funding decisions would occur in line with relevant budgetary processes, informed by assessment outcomes and implementation considerations including long-term financial sustainability.

- **Implement change:** Implement the change in accordance with established governance arrangements and implementation plans. This should be undertaken collaboratively across governments and with service providers and other relevant stakeholders. Communicating change is critical, and supported by appropriate communications, stakeholder engagement and change management activities.

- **Monitor and review outcomes:** Informed by the relevant implementation and management requirements, and existing monitoring and evaluation approaches, measure impacts of the change on participation, quality, equity and outcomes, and identify any unintended consequences of the change.

DRAFT

APPENDIX 1: OTHER HEALTH TESTS AND ACTIVITIES

The health tests and activities outlined below can play an important role in clinical care and prevention, but they differ from organised screening in their purpose, structure, and level of coordination.

Case-finding is the examination of an individual suspected of having, or being at risk of, a condition when they present to a healthcare practitioner. Case-finding is initiated in response to clinical concerns rather than through a systematic population-based approach. For example, a general practitioner offering testing for type 2 diabetes to a patient with obesity and hypertension based on their individual risk factors.

Opportunistic testing or screening involves offering a screening test to an individual without symptoms of the condition when they present to a healthcare practitioner for reasons unrelated to that condition. This form of screening is initiated during routine clinical encounters rather than through a systematic, organised approach. For example, a general practitioner offering osteoporosis testing to a patient attending for a review of hormone replacement therapy, where the patient has no symptoms suggestive of osteoporosis but may have relevant risk factors that warrant consideration of testing.

Routine examinations or scheduled health checks deliver tests or assessments as part of routine care or broader services. Eligibility is generally very broad and not based on increased risk of the health condition of interest. Examples include school or workplace-based checks. These activities may identify conditions, assess development, support prevention or inform service delivery. They are not typically delivered through nationally coordinated programs with systematic population identification, invitation, monitoring and evaluation. They may also not be subject to the same governance, infrastructure and quality assurance arrangements.

Diagnostic testing occurs when a test is offered to an individual with symptoms or signs of a condition to confirm or exclude the suspected condition.

Cascade testing refers to the systematic offer of testing to biological relatives of an individual identified as having a genetic condition, pathogenic variant or other inherited risk factor. The purpose is to identify relatives who may also be at increased risk and may benefit from prevention, surveillance, reproductive planning or other management strategies. Cascade testing is not an organised screening program but may form part of broader follow-up care following screening or diagnosis of an index case or proband.

Clinical monitoring involves ongoing monitoring of individuals identified in a clinical setting as being at higher risk of a condition. Risk may arise from genetic predisposition, a predisposing condition, family history or previous test results. Monitoring aims to detect changes in health status and support timely assessment and intervention. Individuals are monitored because of a recognised clinical risk rather than a screening result.

DRAFT

GLOSSARY

Note: The following definitions have been agreed for the purposes of the Framework.

Assessment:

Follow-up investigations and clinical evaluation for people identified with a positive or uncertain screening test. Assessment may determine whether a person has a condition, disease-related marker or precursor state, or help clarify the nature, significance and implications of an identified risk.

False negative screening result:

Where the screening test is negative but the individual does have the condition or level of risk that the test identifies.

False positive screening result:

Where the screening test is positive but the individual does not have the condition or level of risk that the test identifies. For screening tests that identify future risk, a result indicating increased risk is not always considered a false positive if the condition does not eventuate.

Genes:

The basic physical and functional unit of heredity. A segment of DNA that serves as instructions for the body to function, most commonly by making proteins. Genes are passed from parents to offspring and provide the information for physical traits like eye colour, but they can also control other genes or serve other functions within a cell.

Genetics:

The study of genes and how they and the traits they produce are inherited from parents to children.

Genome:

The complete set of DNA (genetic material) in an organism. This includes all the genes, as well as other functional sequences that provide the instructions for an organism to develop, function and maintain itself throughout its life.

Genomics:

The comprehensive study of an organism's set of genetic information and how the genes work together and interact with the environment.

Genomic test:

A laboratory process used to analyse part or all of a person's genome to support screening, diagnosis, risk assessment, prognosis or treatment of a condition or other health-related decision making. It involves the collection of a biological specimen and the extraction and analysis of genetic material, sequencing, interpretation and reporting.

Incidental findings:

Findings identified through screening, assessment, or analysis that are not actively sought and are beyond the program's primary purpose or target condition.

Informed choice:

A person's voluntary and informed decision about whether to participate in screening, consistent with their values and preferences.

Informed consent:

A person with capacity's voluntary and formal agreement to a specific screening test, or related procedure or intervention, having received and understood relevant information about its purpose and possible outcomes.

Intervention:

An action, or series of actions, taken following screening and assessment that aims to improve health outcomes. Interventions may include treatment, surveillance, prevention or other management approaches.

Negative predictive value:

The extent to which individuals with a negative screening test result are free of the condition.

Negative screening result:

A result indicating the person is unlikely to have the condition, an increased risk of developing the condition, or relevant disease marker.

Organised screening program: See Section 1.2.1

Population screening: See Section 1.2.1

Positive predictive value:

The extent to which individuals with a positive screening test result, or a positive screen for increased risk, have the condition, or end up developing the condition.

Positive screening result:

A result indicating the person may have the condition, an increased risk of developing the condition, or a relevant disease marker.

Risk marker:

An anatomical, behavioural, physiological, biochemical, genetic or pathological characteristic that indicates an increased likelihood of developing a condition.

Reproductive carrier screening:

Reproductive carrier screening uses genomic testing to identify carriers of genetic conditions with an autosomal recessive inheritance or X-linked inheritance pattern. It is offered to people planning a pregnancy, or who are already pregnant.

Risk-stratified screening: See Section 1.2.1

Screening:

The systematic offer of tests to defined groups of people without recognised symptoms to identify a condition, a disease-related marker, precursor state or increased risk of developing a condition.

Screening pathway:

All activities from defining the eligible population to appropriate action and reporting of outcomes. Following the initial screening test individuals may follow different pathways, including further screening, surveillance, intervention or no immediate action, depending on their circumstances, the screening approach, and result of the screening test.

Screening test:

A test, or combination of tests, used to classify people according to their likelihood of having a particular condition, disease-related marker, precursor state, or an increased risk of developing a condition.

Screening workforce:

The multidisciplinary group of health professionals, scientists and personnel who contribute to the delivery, assessment, diagnosis, follow-up, quality assurance and management of screening programs. This may include, but is not limited to medical practitioners, nurses and midwives, Aboriginal and Torres Strait Islander health practitioners, genetic counsellors, pathologists, laboratory scientists and technicians, and radiologists and radiographers.

Sensitivity:

The performance of a test in correctly identifying individuals who have the condition, disease-related marker, precursor state or level of risk that the test is intended to identify.

Specificity:

The performance of a test in correctly identifying individuals who do not have the condition, disease-related marker, precursor state or level of risk that the test is intended to identify.

Surveillance:

Ongoing monitoring of an individual's health status over time through repeat testing, examination or review. Surveillance may occur as part of a screening pathway, particularly following a screening result indicating increased risk. It aims to detect changes in health status and inform assessment and intervention.

Targeted screening: See Section 1.2.1

DRAFT

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