Office of the Associate Minister of Health

Chair, Cabinet Social Wellbeing Committee

Endorse National Cervical Screening Programme Business Case

Proposal

1 The paper seeks Cabinet agreement to:

1.1 endorse the attached business case that sets out the justification for urgent investment to ensure the sustainability of the National Cervical Screening Programme (NCSP), through the implementation of human papillomavirus (HPV) primary screening, with the option for self-testing and upgrading the supporting information and communications technology.

1.2 delegate the final approval of the implementation business case to the Minister of Health and Minister of Finance (joint Ministers).

Relation to government priorities

2 This investment supports our commitment to equitable health outcomes in Aotearoa New Zealand by enabling the identification and targeting of priority groups. The priority groups are wāhine Māori and Pacific peoples, as well as those who are unscreened and underscreened. It also provides opportunities to improve access to screening services for disabled people, aligning with the Government commitment to improve health outcomes for disabled people in the New Zealand Disability Strategy.

Executive Summary

3 The NCSP is a national public health screening programme that aims to reduce the incidence of and mortality from cervical cancer through early detection of the precursors of cervical cancer.

4 Budget 2021 approved a total of up to $52.992 million over four years to ensure the sustainability of the NCSP and deliver service improvements [CAB-21-MIN-0116.14: 2021 Budget Package: Vote Health refers].

5 The NCSP will implement HPV primary screening with the option of selftesting under clinical oversight and upgrade the supporting ICT. This investment will improve the quality, safety, and effectiveness of the programme, and aid in addressing persistent equity gaps.

6 Funding of s 9(2)(i) was appropriated in Budget 2021 for the financial year 2021/22 to develop a full programme implementation business case.

7 Implementation funding of s 9(2)(i) has been set aside in the *Human*

Papillomavirus Primary Screening for the National Cervical Screening Programme – Contingency in Budget 2021. Additionally, the National Screening Unit (NSU) as part of Health New Zealand will be exploring opportunities to fund improved access and future changes to the service delivery model to improve coverage and in particular, equitable outcomes.

8 Cabinet authorised joint Ministers to draw down funding from this tagged contingency, subject to Cabinet approval of the implementation business case. The expiry date of the tagged contingency has been extended from 1 February 2022 to 1 February 2023 by joint Ministers.

9 Subject to delegation by Cabinet, the implementation business case will be presented to joint Ministers for approval in July 2022.

Background

10 The programme offers three-yearly cervical screening to people between 25 and 69 years of age. This equates to an eligible population of over 1.4 million people. Regular screening detects changes in cervical cells (cytology screening) that identify a risk for developing cervical cancer. Each year, approximately 400,000 women are screened, and 25,000 colposcopies undertaken to diagnose and treat pre-cancerous cell changes. Screening services primarily occur in a primary care setting and use a cytology screening pathway.

11 Since the NCSP began in 1990 the incidence of cervical cancer has decreased by about 50 percent. There has also been a steady decline in cervical cancer mortality of about 60 percent since the NCSP began.

12 There is continuing inequity of access and outcomes for wāhine Māori and for Pacific peoples that has not been able to be addressed within the existing programme. Over the last eight years screening coverage for all women has declined, with a greater decline for wāhine Māori, Pacific and Asian people. The total NCSP coverage in the three years ending March 2022 by ethnicity for women aged 25-69 was: Māori 55.7%, Pacific 56.7%, Asian 55.6% and Other 75.0%.

13 District Health Boards and health care providers have identified that the continuation of the current liquid-based cytology (LBC) programme which requires an invasive procedure undertaken by a clinician, is a barrier to achieving equitable health outcomes for wāhine Māori, Pacific peoples and ethnic communities.

14 Maintaining the high quality of diagnostic and early treatment pathways for people with cervical abnormalities has become increasingly difficult. Cost pressures within the existing programme are impacting on colposcopy service

delivery, and the laboratories are experiencing loss of capacity in the cytoscreener workforce.

15 The programme change seeks to address challenges that cannot be resolved within the existing LBC programme or within current budget. This is because the cytology procedure is a barrier for many people, and the current programme has not been successful in achieving equitable outcomes for priority groups.

16 The investment will:

16.1 introduce a more effective, equitable and cost-effective screening test

16.2 reduce the significant barriers to accessing screening which exist within the current programme due to the acceptability of the cytology screening test, whakamā, time and cost

16.3 reverse the declining screening coverage for all eligible people over the past eight years, with specific emphasis on the greater decline for eligible wāhine Māori and Pacific peoples. And provide opportunities to improve access to screening services for disabled people

16.4 enable the development of a fit for purpose population-based register to ensure all eligible participants are invited to cervical screening.

17 Additionally, the NSU as part of Health New Zealand will be exploring opportunities to fund improved access and future changes to the service delivery model to improve coverage and in particular, equitable outcomes. This will be informed by research into emerging options of care that will strengthen and expand on an equity first approach.

Analysis

Expected Benefits of HPV Primary Screening

18 The introduction of HPV primary screening with the option of self-testing will support the reduction of incidence and mortality from cervical cancer and improve the quality, safety, equity, and effectiveness of the NCSP.

19 Analysis has indicated a low incidence of cervical cancer at younger ages, increasing by the age of 25–29 years to reach a peak in the five-year age groups between 30-44 for all ethnicities. A general decrease following a plateauing is seen for the remaining ages until the age of 80.

20 Clinical modelling predicts that moving to HPV primary screening will see over 305 cancer cases avoided and mortality reduced. This will assist with the achievement of the World Health Organization (WHO) elimination threshold for cervical cancer by 2040 (≤ 4/100,000 women).

21 Mortality reduction from cervical cancer of more than 19% is predicted over the next 20 years, resulting in 103 fewer women dying of cervical cancer. The

programme change is estimated to have a greater relative reduction in mortality for Māori women (at least 27.6 %) compared to non-Māori women (at least 7.3 %).

22 The clinical benefits delivered by introducing HPV testing include improved effectiveness, enabling the current screening cycle to be extended from three to five years which would deliver multiple benefits to people, including reduced costs.

23 New Zealand research has shown self-testing to have greater acceptability thereby supporting increased participation in screening by significantly reducing barriers to participation for wāhine Māori and Pacific peoples. People can self-test in privacy when they visit their primary care provider or in a community health care setting.

24 The development of a population health-based register will enable identification of priority groups to ensure effective use of resources that can be directed to areas with the greatest need and greatest inequity. It will support people not registered with a general practice to access the NCSP. Underserved groups may include disabled people, people who do not speak English, prison populations, the homeless and the LGBTQI+ community.

25 HPV primary screening and development of a new register are the mitigation for existing programme risks. These include low cytoscientist workforce capacity and risk of service disruption, outdated ICT cervical screening register technology that carries unmitigated risk, and deterioration in overall programme effectiveness.

26 An overall cost saving to the programme will be realised once the project is fully implemented as a result of reduced laboratory costs and ICT support costs.

27 The programme business case modelled outcomes based on pre pandemic cervical screening coverage and HPV immunisation coverage. The ongoing impact of the COVID-19 pandemic will be addressed in the implementation business case.

Consultation on Screening Pathway

28 The introduction of HPV self-testing is a change in the screening test and therefore requires a new clinical pathway for the NCSP. Sector wide consultation has been undertaken and a new HPV primary screening clinical pathway has been endorsed and finalised.

29 The clinical requirements will provide a safety net for participants, ensuring the next appropriate step in the screening pathway occurs using a nationally consistent system of quality assurance and indicators. This is particularly important if there is an abnormal result.

Service Delivery Model for HPV Primary Screening

30 Currently the NCSP is provided predominantly through primary care and other trained cervical screening sample takers. Primary care practitioners have responsibility for the screening of eligible people when they are due for screening and this would continue during the programme transition to the screening test (and procedure).

31 The new population health register will enable notification and recall to be centralised which will release primary care clinical time from administrative tasks.

32 Self-testing will provide an option for people to either request to have an HPV sample taken by a sample taker or complete the test themselves in a primary care or community setting. Further consultation is planned with primary care and community providers to inform planning and detailed change requirement to support the transition to the new screening test.

33 A co-design process will commence in 2022 and will inform and strengthen the future service delivery approach to better meet the needs of participants, particularly for Māori and Pacific participants.

Impact of the change to HPV primary screening on the Laboratory Workforce

34 Analysis of primary screening samples will test for the presence of HPV using polymerase chain reaction (PCR) technology as the first test, instead of the current cytology test. Cytology identifies cell changes that result from HPV infection and will be used as a second test performed on samples that have already tested positive for HPV. Cytology remains a critical secondary test when an HPV positive result is confirmed as this determines the next step of the clinical pathway. Changing the primary screening test will result in a significant reduction in the volume of cytology reported.

35 As a result of the change in the primary screening test, there would be a significant reduction in the demand for the cytoscientist workforce. However, this workforce will continue to be important as secondary cytology assessment will remain as part of the pathway for participants with a positive HPV result.

36 The NCSP will undertake further consultation with laboratories to develop a workforce management plan to ensure a clinically safe transition and a stable and sustainable workforce in a low cytology volume environment.

Colposcopy capacity to manage varying demand with HPV primary screening

37 HPV is a more sensitive screening test than the current cytology screening test. This combined with the potentially higher uptake of screening due to the offer of the option of self-testing is expected, based on clinical modelling, to result in an increased referral rate to colposcopy in the first five to six years.

From year seven onwards, the clinical modelling predicts there will be a reduction in colposcopy volumes, due to a reduction in the prevalence of disease in the population, for two reasons: (1) primarily from the impact of the HPV vaccination programme; and (2) lower positivity after the first round of testing due to the use of a more accurate test.

38 Further consultation will be undertaken to inform the implementation business case and ensure that services have a transition capacity plan in place. Services will need to meet changes in demand while maintaining clinical standards and equitable access to diagnostic and treatment services.

39 The population health register will support notification and recall of eligible participants that are not enrolled on primary care.

The ICT solution with a new population-based register

40 The current ICT system that was designed to support the cytology-based programme is reaching an end-of-life state and cannot be adapted to support the changes to the test and the clinical pathway. A new population-based register will be built utilising the technology platform, the National Screening Solution (NSS), that was established as part of the National Bowel Screening Programme (NBSP) implementation. This would leverage the integration with existing systems and external parties necessary to support Primary HPV screening including DHB Colposcopy Systems (GynaePlus) and laboratories.

Implementation

Approach and timeline

41 The anticipated project go-live date is from June 2023 and includes two phases as follows.

41.1 Phase 1 - October 2021 to July 2022: design of the replacement ICT and non-ICT workstream establishment. At the end of this phase an implementation business case will be prepared to confirm final costs, implementation detail and timing.

41.2 Phase 2 - July 2022 to June 2023: Development and implementation of the ICT solution and delivery of programme change, this includes the NSS build and testing, and the training and education of the sector.

41.3 From 1 July 2023: The programme will change to HPV primary screening as the primary test which will include the option for selfscreening. Participants will be offered the option of self-testing when they are due for their next cervical screen.

Risks and mitigation

42 The NZ Treasury Risk Profile Assessment has been assessed as 'Low' and no Gateway is required. Assurance and governance mechanisms have been established to ensure the successful delivery of the project, building on the approach used for the National Bowel Screening Programme (NBSP).

Monitoring and reporting

43 The NCSP has established reporting and monitoring to assess overall programme performance, quality, safety and equity of the programme. Indicator reports are provided to the NSU, the sector and the public on a monthly, quarterly and annual basis depending on the indicators.

44 Specific benefits realisation reporting will be undertaken in accordance with the benefits realisation plan and reported to the Minister of Health. These reports will commence one year after the initiative has commenced and will run through until the full benefit of the initiative has been released in 17 years (the frequency of reporting over this period varies). These reports see key benefits monitored to ensure the programme is delivering on expectations.

45 Appendix 1 outlines the intervention logic map including when specific benefits are expected to be realised.

Financial Implications

46 The NCSP currently has a baseline funding of s 9(2)(i) , after additional funding of s 9(2)(i) was approved in Budget 21 to address cost pressures of delivering frontline services.

47 Budget 2021 approved a total of up to s 9(2)(i) over four years for the implementation of HPV primary screening with the option of self-test. The funding includes:

47.1 s 9(2)(i) appropriated for Phase 1 for the financial year 2021/22, including s 9(2)(i) in operating costs and s 9(2)(i) in capital requirements, to support sector engagement and consultation that informs the development of an implementation business case including detailed cost of the ICT build, and implementation costs.

47.2 s 9(2)(i) of implementation funding in a tagged contingency based on the indicative costs for Phase 2, including operating costs of s 9(2)(i) and estimated capital requirements cost of s 9(2)(i) million.

48 The investment in NCSP over the 20-year modelled period is s 9(2)(i) which includes the implementation funding and cost savings over time. This is comprised of a capital cost of s 9(2)(i) and an incremental operating cost of s 9(2)(i)

49 The indicative costs and the implementation funding requirement will be further refined during the development and the finalisation of the implementation business case. This will include updates following changes to CAPEX/OPEX rules.

50 The economic assessment of the shortlist options using Treasury's multi criteria analysis indicated the recommended scope for this investment for programme sustainability is Minimum. This addresses the two biggest drivers for investment (the need to move to HPV primary screening and to replace the NCSP Register). However, as this assessment and the Budget 21 funding will not fully address the challenge of achieving equitable outcomes, the NSU will be exploring opportunities to fund future changes to the service delivery model. It should be noted, however, that equity will still be improved significantly as a result of implementing HPV primary screening, as this materially reduces some of the barriers to screening presented by the current LBC approach.

Legislative Implications

51 There are no legislative implications associated with this proposal.

Impact Analysis

Regulatory Impact Statement

52 There are no regulatory impacts associated with this paper.

Climate Implications of Policy Assessment

53 There are no climate change impacts associated with the paper.

Population Implications

54 HPV primary screening with the option of self-testing is predicted to have a positive impact on cervical screening rates, especially wāhine Māori and Pacific women; ethnic communities; disabled people; people who are survivors of sexual assault; and transgender and non-binary people (Table 1).

55 The NCSP is a population health screening programme. A trend of declining screening coverage has persisted over the last eight years with a greater decline for wāhine Māori and Pacific peoples. The key barriers to accessing screening is decreasing acceptability of the current test, whakamā, time and cost. This has been further exacerbated by the impacts of the initial response to the COVID-19 pandemic.

56 The option of self-testing has been shown to have greater acceptability by participants thereby supporting increased participation in screening and

provides choices for women (and people with a cervix) who are survivors of sexual violence or who have cultural or religious beliefs which make the current test unacceptable and/or uncomfortable.

57 HPV primary screening would further reduce incidence of and mortality from cervical cancer and improve the quality, safety, equity and effectiveness of the NCSP including:

57.1 an overall reduction in cervical cancer for women. Clinical modelling suggests over 305 cancer cases will be avoided over the 17 years following implementation

57.2 an estimated 75 cases and 28 deaths avoided for wāhine Māori

57.3 the option of self-testing has been shown to have greater acceptability by women thereby supporting increased participation in screening HPV testing with the option to self-test is less invasive and, in some cases, can be administered by the persons themselves.

Table 1. HPV testing with the option of self-testing impact on population groups

Women	Reducing mortality from cervical cancer will mean that more women experience better health outcomes and live longer.
Priority populations	The development of a population health-based register will enable identification of priority groups to ensure effective use of resources that can be directed to areas with the greatest need and greatest inequity. By reducing barriers to participation for wāhine Māori and Pacific peoples, the NCSP will reduce the inequity in access. Wāhine Māori and Pacific peoples experience a greater burden of disease from cervical cancer compared to nonMāori and non-Pacific. Improving outcomes for these priority groups will have a positive impact that will extend out to the wider community.
Disabled people	HPV testing with the option to self-test is also likely to benefit some groups of disabled people as the new screening test is less invasive. The test is a vaginal swab which may be more acceptable for some people than the current speculum examination.
Transgender and non-binary people	HPV testing with the option of self-testing may also reduce barriers to screening for transgender and non-binary people with a cervix. Research suggests many transgender and non-binary people with a cervix would prefer the option of HPV self-testing.

Human Rights

58 The proposals in this paper advance New Zealand's commitments under the Convention on the Elimination of Discrimination Against Women, the Covenant on Economic, Social and Cultural Rights and the United Nations Convention on the Rights of Persons with Disabilities by advancing the accessibility of health care for women, addressing inequities in outcomes, with a focus on Māori and Pacific women.

Consultation

59 The following agencies have been consulted on this Cabinet Paper: the Treasury; Ministry of Social Development; Ministry for Women; Te Puni Kōkiri; the Ministry for Pacific Peoples; the Office for Disability Issues; and the Ministry for Ethnic Communities. The Department of the Prime Minister and Cabinet has been informed.

Communications

60 I announced government support for the implementation of HPV primary screening on 9 May 2021 at a stakeholder event held at Kōkiri Marae in Lower Hutt. A detailed communication plan is being prepared to support the next stages of communication and sector engagement.

Proactive Release

61 I intend to release the Cabinet paper proactively subject to redaction as appropriate under the Official Information Act 1982.

Recommendations

I recommend that the Committee:

1 note that while the National Cervical Screening Programme has been successful at a population level, changes are needed to ensure sustainability quality, safety, equity and effectiveness of the programme. Human papillomavirus (HPV) primary screening would further reduce incidence of and mortality from cervical cancer, with a greater relative reduction for wāhine Māori compared to non-Māori women

2 note that in Budget 2021 Cabinet approved a total of $52.992 million over four years [CAB-21MIN-0116.14: 2021 Budget Package: Vote Health refers] to implement HPV primary screening with the option of self-testing

3 note that s 9(2)(i) has been appropriated for Phase 1 to support the development of an implementation business case

4 note that s 9(2)(i) of implementation funding is set aside in *Human*

Papillomavirus Primary Screening for the National Cervical Screening Programme - Contingency based on the indicative costs for Phase 2, and that the costs will be further refined as part of the implementation business case

5 note that the Minister of Health and Minister of Finance are authorised to draw down funding from the above tagged contingency subject to Cabinet approval of the programme business case

6 endorse the attached programme business case that sets out the justification for investing in improvements within the National Cervical Screening Programme, through the implementation of HPV primary screening with the option for self-testing

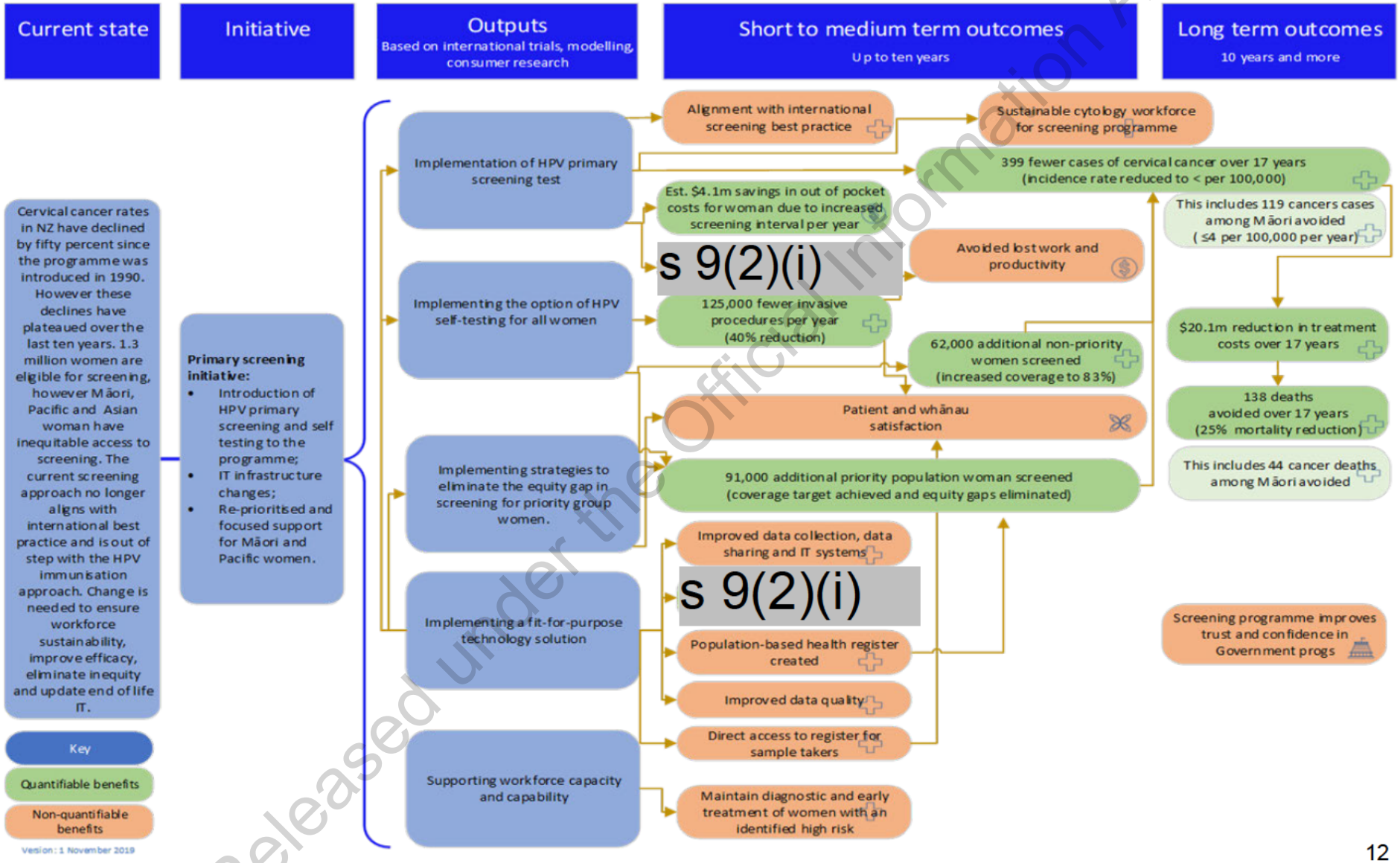
7 authorise the Minister of Health and the Minister of Finance to jointly approve the implementation business case which will be presented in July 2022.

Authorised for lodgement

Hon Dr Ayesha Verrall

Associate Minister of Health

Appendix 1 Intervention Logic Map



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