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Independent Assurance Review for the National Bowel Screening Programme and further information on the “address override” issue

To: Hon Dr David Clark, Minister of Health

Purpose

1. This Health Report provides you with the proposed structure, approach and Terms of Reference for the independent assurance review for the National Bowel Screening Programme.
2. It also provides you with further information on the “address override” issue that has been identified in the Waitemata District Health Board (DHB) bowel screening pilot (the pilot).

Key points

3. The bowel screening pilot commenced in the Waitemata DHB in 2011, screening men and women aged 50-74. The pilot ended at the completion of the third screening round in December 2017. By March 2017 the pilot had detected bowel cancer in 375 people. Data collected during the pilot provided vital information on participation levels, cancer detection rates and the impact on health services, and helped inform the National Bowel Screening Programme (NBSP).
4. The pilot confirmed that:
 - Bowel screening can be introduced safely in New Zealand
 - It provides health benefits and is cost saving
 - Enabling equal participation is essential
 - Sufficient colonoscopy workforce capacity is critical to a successful roll-out of the NBSP.
5. Implementation of the NBSP was announced by the previous Minister of Health on 25 November 2016.
6. The NBSP commenced in July 2017 with a staged roll-out starting in Hutt Valley and Wairarapa DHBs for men and women aged 60 to 74 years.
7. The staged roll-out of the NBSP will be complete by 30 June 2021.
8. The early roll out of NBSP is supported by Bowel Screening Pilot Information Technology System (BSP), whilst the procurement and build of the National Screening Solution (NSS) is completed. It is estimated that the first DHB will go live on the NSS in June 2019.
9. In November 2017 you were informed of a significant clinical incident that occurred in the Waitemata DHB Pilot where eligible people were incorrectly excluded from participating in bowel screening and as a result three people could have been harmed as their diagnosis may have been delayed. The independent review of this incident is due in March 2018.
10. A second issue has arisen with the pilot due to addresses being locked in the BSP potentially affecting 2,097 people, seven of whom have subsequently developed bowel cancer. The NSU, working with Waitemata DHB, will follow the same approach as for the previous issue.
11. The NSU takes patient safety very seriously and in light of the two issues arising out of the pilot an independent external review will be undertaken to provide assurance for the NBSP to ensure a safe

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and high quality programme is provided to New Zealanders and timelines for implementation are achievable.

12. The independent assurance review, led by s9(2)(a) who will work with the Ministry to establish the team of external clinical, technical and operational experts, will undertake:
- a. An in-depth assessment of the BSP and associated operational processes to provide advice and assurance on its functionality.
 - b. Provide assurance and evidence based recommendations about the transition from the Bowel Screening Pilot to National Bowel Screening Programme.
 - c. Identification of any issues relating to the implementation and operation of the NBSP and evidence based recommendations for improvement.
13. The independent assurance review will report back to the Minister by Monday 16 April 2018.

Background

14. A bowel screening pilot operated in Waitemata DHB from 2011 until the completion of the third screening round in December 2017. Waitemata DHB moved to the National Bowel Screening Programme on 1 January 2018.
15. The pilot invited people aged 50-74 years. By March 2017 the pilot had detected bowel cancer in 375 people. Data collected during the pilot provided vital information on participation levels, cancer detection rates and the impact on health services, and helped inform the National Bowel Screening Programme which commenced on 17 July 2017.
16. The Ministry commissioned an independent evaluation of the pilot by Litmus; the Centre for Public Health Research Massey University; and Sapere Research Group to determine whether organised bowel screening could be introduced in New Zealand in a way that is effective, safe and acceptable for participants, equitable and economically efficient.
17. The final independent evaluation report released in August 2016 found that:
- The pilot demonstrated that a national bowel screening programme could be safely introduced in New Zealand.
 - A well-managed bowel screening programme will reduce deaths from bowel cancer.
 - Bowel screening is cost saving and brings health benefits.
 - Participation in the pilot was higher in most groups than the internationally accepted minimum.
 - Enabling equal participation in a national programme is essential.
 - Colonoscopy workforce capacity was a challenge to a national programme.
18. On 24 August 2016 the Cabinet Social Policy Committee approved the Programme Business Case for the full National Bowel Screening Programme roll-out at an estimated 20-year whole of life cost of s9(2)(f) (iv) s9(2)(f)(iv) (this figure is not public knowledge and is subject to further budget approval).
19. Budget 2016 allocated \$39.3 million over four years for the establishment of the National Bowel Screening Programme with Budget 2017 providing a further \$38.5 million to continue the roll-out. A further budget bid for the cost of the NBSP roll-out will be submitted for Budget 18.
20. In December 2017 Cabinet agreed to extend the timeframe for implementation to include the 2020/21 financial year.
21. The Ministry is currently on track to implement the NBSP over the next three years:
- Hutt Valley and Wairarapa DHBs commenced screening on 17 July 2017.
 - Waitemata DHB transitioned from pilot to national programme 1 January 2018.
 - Southern and Counties Manukau DHBs commence screening by 30 June 2018.

- Nelson Marlborough, Lakes and Hawkes Bay DHBs commence screening by 30 November 2018.
 - Whanganui and Mid-Central DHBs commence screening by 30 June 2019.
 - Remaining 10 DHBs implement between 1 July 2019 and 30 June 2021.
22. Implementing bowel screening is a complex process with a number of operational, technical and clinical dependencies, such as facilities, equipment and staffing. Roll-out is reliant on the ability of each DHB to provide clinically safe and appropriate services. If a DHB is not ready, the go-live date will be altered. The dependencies and challenges associated with the implementation of NBSP are being carefully managed within the roll out timeframe.
23. The early roll out of NBSP is supported by the BSP, whilst the procurement and build of the National Screening Solution (NSS) is completed. It is estimated that the first DHB will go live on the NSS in June 2019.
24. BSP is an extension of the information system used in the pilot and provides a centralised invitation and recall system and tracks the person's journey through the screening pathway.
25. Bowel Screening is an opt-off programme in which eligible people are automatically invited. Invitation lists of new people are created through an extract from the National Health Index (NHI) based on the eligible age range and geographic location. This is loaded into the BSP which generates an invitation letter at the appropriate time.
26. Re-invitation for existing people, who are within the eligible age range and geography occurs every two years from the time their previous test was received back by the Laboratory.
27. The NHI is linked to BSP and regularly updates a person's address if there has been a change to their address details on the NHI (for example a person visited their General Practitioner (GP) and updated their address).
28. In November 2017 you were informed of a significant clinical incident that has occurred in the Waitemata DHB Pilot where eligible people were incorrectly excluded from participating in bowel screening and as a result three people could have been harmed as their diagnosis may have been delayed. The independent review of this incident is due in March 2018.
29. On 31 January 2018 your office was informed that a new issue had been identified in the pilot that may have resulted in people not receiving invitations following an address update as an address override code had been applied to their record. This may result in participants having their diagnosis of bowel cancer delayed.
30. Waitemata DHB was informed of this issue on 31 January 2018.

Issue

Summary of the address override issue

31. In the week of 24 January 2018 the data team in the National Screening Unit (NSU) discovered that an address override procedure used in the pilot may have had unintended consequences for participants. On further investigation the data team confirmed on 31 January 2018 that a group of participants appear to be affected by this issue.
32. At the start of the Pilot in 2011, Waitemata DHB Coordination Centre did not have direct access to the NHI to update addresses for participants.
33. A practice was implemented whereby the records of participants, that were more current than those available on the NHI collection, were directly updated in the BSP. The record was then locked to prevent an address override from the NHI and ensure the address remained current. This has resulted in any subsequent address updates on the NHI for that record not being activated on the BSP. Those participants may not have received further invitations for screening and may now be overdue. This could have resulted in a delayed bowel cancer diagnosis.

34. In 2014 the pilot was provided with direct access to the NHI collection to update addresses. Data indicates that the practice of updating addresses in BSP and applying the “address override” lock continued although to a much lesser degree.
35. The BSP Standard Operating Procedure required addresses to be updated in the NHI “where possible” (only the Waitemata Coordination Centre staff had access to the NHI).
36. Provisional numbers indicate that of the 15,472 records in BSP which have the address locked:
- 9,515 people are not currently affected as their addresses in BSP and the NHI are the same.
 - 5,957 people have an updated address in the NHI, of these:
 - 1,833 are no longer eligible for bowel screening
 - 2,027 have been re-screened
 - 2,097 people are overdue for screening
 - Of the 2,097 people:
 - 2,090 will be invited to re-screen
 - Seven people have been diagnosed with bowel cancer after their re-screen was due. None of these people are deceased.
37. The NSU, working with Waitemata DHB, will follow the same approach as for the previous issue which includes:
- a. Commissioning an independent clinical review of those participants with a diagnosis of bowel cancer to ascertain whether or not the delay in invitation due to the address override issue has had an adverse impact on their outcome and caused harm.
 - b. Undertaking a process of open communication with participants who have potentially been harmed through their General Practitioner.
 - c. Re-inviting participants who are overdue for screening.
 - d. Continuous monitoring of results for affected participants.
38. The initial process, including open communication and re-invitation of affected participants will be completed by the end of March 2018.

Assurance review for the National Bowel Screening Programme

39. The NSU takes patient safety very seriously and in light of the two issues arising out of the pilot, linked to the BSP the Ministry proposed that a detailed review of the BSP and related operational procedures be undertaken by external clinical, technical and operational experts to examine in detail:
- a. BSP functionality against the screening pathway and operational procedures in place.
 - b. All changes and updates to BSP since 2011 assessed against the programme requirements and operational procedures, including identification of unintended consequences.
40. You asked that this review be extended to give assurance for the NBSP to ensure a safe and high quality programme is provided to New Zealanders and timelines for implementation are achievable.
41. The Ministry proposes that an external independent team of experts is brought together, led by a clinician with the appropriate population health and screening expertise. The team would include an operational-management expert as well as information technology expertise.
42. This multi-disciplinary team will ensure the review applies the appropriate population screening context and has the expertise to provide assurance and maintain confidence in the programme.
43. Internationally screening programmes operate within a strong clinical management partnership, with Information Technology as a key enabler.
44. The purpose of the review is defined as:
- a. An in-depth assessment of the BSP and associated operational processes to provide advice and assurance on its functionality.

- b. Providing assurance and recommendations about the transition from the Bowel Screening Pilot to National Bowel Screening Programme.
 - c. Identifying any issues relating to the implementation and operation of the NBSP and evidence based recommendations for improvement.
45. s9(2)(a), Executive Director at Ernst and Young will lead the review and work with the Ministry to establish the rest of the team. s9(2)(a) has extensive population health and screening expertise and is likely to be available from Monday 19 February 2018. s9(2)(a) has not been party to any of the work or advice provided by Ernst and Young to the pilot or the NBSP, to date.
46. The review will be supported by experienced project management staff to ensure timely delivery of the findings.
47. It is anticipated that the review will take up to two-months to complete, with the final report provided to the Minister by Monday 16 April 2018. Once the review team is in place a timeline for completion will be provided.
48. The Ministry will act on the evidence based review findings and develop an action plan for implementation, as part of the on-going roll out of the NBSP.
49. The draft Terms of Reference (ToR) and draft media release are attached as Appendix A and B respectively.

Assurance activity undertaken for the NBSP

50. Assurance activity is a key part of implementing a complex clinical programme. There are a number of assurance activities in place for the NBSP that support the implementation process these include:
- a. The 2016 Accenture rapid assurance review to assess progress against the overall IT project's goals (HR 20171805 refers). This review included an assessment of the business outcomes required for the NBSP, and whether the NBSP could be successfully implemented.
 - b. The 2017 Ernst and Young assurance report focussed on the options available to the Ministry in developing a fit for purpose IT screening solution (HR 20171805 refers). This included an assessment whether the IT system developed to support the bowel screening pilot could be extended into a national system and an options analysis for IT development to support the NBSP.
 - c. The Treasury's on-going major projects quarterly monitoring and reporting.
 - d. The Treasury's Gateway process has reviewed the NBSP twice, the most recent in May 2017 rated the programme green/amber for implementation readiness. The next Gateway review is yet to be scheduled. It is likely to be in April 2018 as part of the review of the National Screening Technology Solution business case.
 - e. The Ministry appointing, in June 2017, an independent assurance person to the NBSP Governance Group with extensive expertise in managing large projects that involve significant programme and Information Technology change.
 - f. Advice provided through the National Bowel Screening Advisory Group (BSAG) and the National Screening Advisory Committee (NSAC). These two groups consist of sector clinical and operational experts in the area of screening, bowel cancer and equity.
 - g. Regular (monthly, quarterly etc) quality monitoring of the NBSP to:
 - i. identify any potential quality including safety issues as early as possible
 - ii. verify that policy and quality standards are adhered to by providers and individual clinicians.
 - h. Contractual requirements of providers to immediately report to the NSU any adverse event.

Risks

51. The Ministry considers the announcement of this assurance review to have a number of risks that need to be carefully managed:

Risk	Management / mitigation
Loss of public confidence in the NBSP, which may result in lack of participation by eligible people	Communications plan and key messages including support from DHBs undertaking bowel screening and screening experts
Loss of sector confidence in the continued roll-out of the NBSP as per the December 2017 Cabinet approved timelines	Continued engagement with DHBs providing regular information updates
Pending release of OIA to Stacey Kirk on 13 February 2018 on detrimental outcomes in the bowel screening pilot	Communications plan in place for a reactive response
Heightened media interest	Communications plan including FAQs on website and reactive responses.
Review not completed in a timely manner	Review team will be supported by senior project management and other resources as required
Adverse impact on The Treasury Major Project rating	The Ministry will continue to work closely with The Treasury and other members of the Corporate Centre, providing regular updates.

Communications Plan

Issue

52. A communications plan is being prepared for the issue, including draft letters to the affected people and will be shared with your office prior to release. This will be provided to your office the week of 19 February.

Assurance review

53. The Ministry will develop a communications plan for the assurance review, including how stakeholders are informed and regularly updated.

54. The draft media release for your announcement is attached at Appendix B.

Recommendations

The Ministry recommends that you:

- a) **approve** the independent assurance review outlined in this Health Report. **Yes/No**
- b) **approve** the draft terms of reference and associated draft media release attached as Appendix A and B respectively. **Yes/No**
- c) **note** the content of this report including the risks (and associated management) of this independent review.

Jill Lane
Director
Service Commissioning

Minister's signature:

Date:

Appendix A – Assurance Review Draft Terms of Reference

DRAFT Terms of Reference – Independent Assurance Review for National Bowel Screening Programme [confidential]

Background

The Minister of Health has sought assurance for the National Bowel Screening Programme (“the Programme”) about its operation and implementation from pilot to programme through an independent review.

Purpose

The purpose of this review is to:

- (a) Conduct an in-depth review of the Bowel Pilot Information Technology System (BSP) and associated operational processes to provide advice and assurance on its functionality.
- (b) Provide assurance and evidence based recommendations about the transition from the Bowel Screening Pilot (the Pilot) to the Programme.
- (c) Identify any issues relating to the implementation and operation of the Programme and evidence based recommendations for improvement.

Review personnel

The Ministry has appointed s9(2)(a) as the lead reviewer to carry out the review. The Ministry will work with s9(2)(a) to appoint additional team members with clinical, operational management and information technology expertise to assist s9(2)(a).

The Ministry will provide expert project management support to the review team ensure timely delivery of the findings.

Review process

The reviewers will review the documentation held by the Ministry and DHBs relating to the Pilot and the Programme, this will include information relating to the pilot operated by Waitemata DHB.

The reviewers may interview former and current Ministry and DHB staff and any other persons as required.

The reviewers will also undertake further investigation and talk with representatives of other agencies (such as the Treasury, Government Chief Digital Officer and Ministry of Business, Innovation and Employment) as necessary.

In addition to the matters set out under the Purpose, the reviewers may provide advice on any other matters arising in the course of the review.

The Ministry will act on the findings and develop an action plan for implementation, as part of the on-going roll out of the NBSP.

Deliverables

The reviewers will provide a written report to the Minister, by Monday 16 April, setting out their evidence based findings, and recommend any actions or improvements to policies, processes and practices as a result of the findings of the review. The evidence on which the findings are based will also be included in the report.

The reviewers will also include interim updates on progress as required by the Ministry.

Issues, conflicts and risk resolution

Issues and potential conflicts or risks will be identified and documented by review members and escalated to the Ministry as identified.

Travel and expenses

The Ministry will determine how remuneration, travelling allowances and expenses for review members are to be met, where these are not already addressed as part of the terms of appointment.

Released under the Official Information Act 1982

Appendix B – Independent Assurance Review Draft Media Release

DRAFT

XXX February, 2018

Health Minister to review progress on the National Bowel Screening Programme

XXXXX says he is commissioning a review to provide assurance for the National Bowel Screening Programme (NBSP) to ensure it continues to make progress toward delivering free bowel screening to all eligible New Zealanders by June 2021.

The NBSP is in the process of being rolled-out around the country with three District Health Boards already on board and the remainder to join over the next three years. A National Coordination Centre and four regional centres have been set up to coordinate the programme nationwide.

“Implementing bowel screening is a complex process with a number of operational, technical and clinical dependencies, such as facilities, equipment and staffing. Roll-out is reliant on the ability of each DHB to provide clinically safe and appropriate services,” says XXXXXX.

“To ensure the Ministry has the support it needs to continue to work through these challenges, I have asked for an independent review.

“It seems prudent, with much of the foundational work done and more and more DHBs coming on board, to commission a thorough stocktake to provide assurance that a safe and effective programme is being delivered and that timelines are achievable.”

s9(2)(a) Executive Director at Ernst and Young has been appointed to lead the review. s9(2)(a) s9(2)(a) has extensive population health and screening expertise. He will work with the Ministry to establish the rest of the team, which will include an operational-management expert as well as information technology expertise.

“I look forward to delivering this hugely significant health project and New Zealand’s first screening programme for both men and women. Once fully implemented the National Bowel Screening Programme is expected to detect 500-700 cancers a year and make inroads into one of our biggest cancer killers.”

ENDS