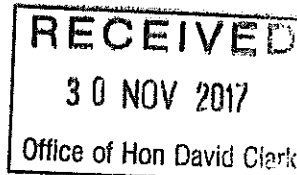


Security classification: In-Confidence



File number: AD62-14-2017
Action required by: urgent

Briefing: Withdrawal of eligible people in the Bowel Screening Pilot

To: Hon Dr David Clark, Minister of Health

Introduction

1. This briefing provides you with an update on the withdrawal of eligible participants in the bowel screening pilot (the pilot) (Health Report 20171489 refers).
2. The withdrawal of eligible participants affects three eligible people who have subsequently developed bowel cancer and may have been harmed as participation in the screening programme could have resulted in an earlier diagnosis of bowel cancer. One of these people has died.

Background

The Bowel Screening Pilot

4. A bowel screening pilot has been running in the Waitemata DHB since 2011 and is due to complete the third screening round on 31 December 2017. Waitemata DHB will move to National Bowel Screening Programme (the Programme) status on 1 January 2018. 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 Programme which commenced on 17 July 2017.
5. The pilot confirmed that:
 - Bowel screening provides health benefits and is cost saving
 - Equal participation is essential
 - Sufficient colonoscopy workforce capacity is critical to a successful roll-out
6. The pilot was supported by the Bowel Screening Pilot Information Technology System (BSP) which provides a centralised invitation and recall system and tracks the person's journey through the screening pathway.
7. 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.
8. 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 or from the date of their previous invitation if the test was not returned.
9. The NHI is linked to BSP and regularly updates a person's address if there has been an address change on the NHI (for example a person visited their General Practitioner (GP) and updated their address).

| | |
|-----------|--|
| Contacts: | Jill Lane, Director, Service Commissioning |
| | Astrid Koornneef, Group Manager, National Screening Unit |

s9(2)(a) to protect the privacy of individuals

10. This process enabled the programme to re-invite eligible people following an address update.

Withdrawal from the pilot

11. A person either directly or via their GP can opt not to take part in the pilot for either clinical or personal reasons (for example they had a colonoscopy in the last five years). They contact the Waitemata DHB Coordination Centre (the Coordination Centre) and ask to be withdrawn.
12. As part of any invitation based process there are people who no longer live at the address active in the NHI which can result in returned "gone no address" mail to the Coordination Centre.
13. The Coordination Centre makes the best effort to find a current address, if no new address can be found, it was the standard operating protocol agreed with the Ministry for the person to be assigned a withdrawn status.
14. Once a person is assigned to withdrawn status BSP no longer checks for updated addresses and excludes the person from any future invitations. A manual change is required in the BSP to change a withdrawn status.

Withdrawal from the National Bowel Screening Programme

15. In the Programme a person is only withdrawn from the programme when they either directly or via their GP can opt not to take part in the pilot for either clinical or personal reasons (for example they had a colonoscopy in the last five years).

Issue

Summary and timeline of the investigation of withdrawals from the pilot programme

16. On the 20th of September 2017, as part of a quality review of pilot records, the National Screening Unit (NSU), a business unit in the Ministry of Health, became concerned about the process of withdrawal in place in the pilot. The permanent withdrawal of people as a result of mail being returned prevented a new invitation being sent to a person even if their address was subsequently updated in the NHI.
17. On the same day the NSU requested the pilot to only assign a withdrawn status when asked directly by a person or their GP. The NSU also asked that people for whom invitations were returned to the coordination centre as "gone no address", be assigned a two year recall. This ensures the person is re-invited and not permanently withdrawn.
18. The NSU undertook a lengthy and in-depth analysis of the pilot data to ascertain whether people missed out on the opportunity to be part of the pilot programme. This data was matched against the NHI and the New Zealand Cancer Registry.
19. During the week of 16th October 2017 the NSU confirmed 12,834 people were withdrawn from the programme due to mail being returned. In analysing these withdrawals the NSU found:
 - 10,349 are not currently affected by this inappropriate withdrawal as their address in the NHI had not been updated since they were withdrawn.
 - 2,441 people had their address updated in the NHI but were not invited to participate in bowel screening because they were classed as withdrawn.
 - 30 people have died of unrelated causes.
 - Fourteen people have been diagnosed with bowel cancer, six of whom had their address updated appropriately and at the time of their diagnosis.
 - Eight people have been diagnosed with bowel cancer after their address was updated in the NHI, this includes three people who have died from bowel cancer.

20. The Director General of Health was advised of the potential issue, by the Director of Service Commissioning on 16 October, and the need for further analysis before further actions and decisions could be taken.
21. The former Minister of Health Dr Jonathan Coleman was informed by phone of the potential issue on 18 October 2017 following a meeting with his office.
22. The further analysis indicated that the delay between an address update and the bowel cancer diagnosis for the eight people with bowel cancer is between one and 41 months. Waitemata DHB also validated the numbers identified through the NSU process to ensure the data was as robust as possible.
23. On 1 November the NSU informed Waitemata DHB that this issue had been identified and shared the NHIs of the eight people with bowel cancer. The clinicians for the Waitemata Bowel Screening Pilot, reviewed this data against the clinical notes of the patients.
24. Work has been ongoing to clarify and understand the impact on people particularly for the eight people diagnosed with bowel cancer after their address was updated in the NHI both at Waitemata DHB and within the Ministry.
25. Waitemata commissioned an independent clinical review of the eight people diagnosed with bowel cancer. A clinical group with representatives from the Ministry, Waitemata DHB and the independent reviewer met on 27 November to determine if bowel screening could have had an impact on the outcome of the eight people.
26. It was agreed that an invitation to participate in bowel screening would have had no impact on five of the eight cases. For the remaining three the impact as a result of the delayed invitation to screening is unknown and cannot be retrospectively quantified. One of these three has died from bowel cancer.
27. It was agreed that the Ministry would work through the process of open disclosure for these three cases, which is an accepted principle across our health system and internationally under these circumstances. Open disclosure means being open and transparent with people and/or their family when they could be adversely affected by a clinical event.
28. The NSU has commissioned a full event review through an independent expert to further reduce the possibility of this occurring again. The report from this event review is expected in the new year.

Next steps

29. On 1 December the NSU will contact the general practitioner of the three people to arrange a time to discuss their patient.
30. It is expected this conversation will happen on Monday 4 December. The NSU will be guided by the general practitioner as to the most appropriate approach to the person, including if the person or family should be contacted.
31. Based on the discussion with the general practitioner In the week of 4 December 2017 the Clinical Director of NSU and the Clinical Director of the Bowel Screening Programme will contact and offer to meet the three people (and/or their families where appropriate) who were withdrawn from the pilot and subsequently diagnosed with bowel cancer.
32. The NSU will explain what has happened and will take the opportunity to apologise. A letter will be provided to these three people after the conversation has occurred. The conversations and letter will be tailored to the circumstances of each case.

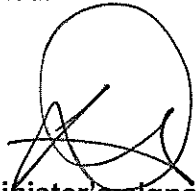
33. Following the principles of open communication, the NSU will also write to the 2,441 people withdrawn from the screening programme to apologise for the technical issue which prevented them being re-invited earlier and to invite them to participate in screening.
34. The NSU plans to write to the 2,441 people, on 8 December 2017, to re-invite them to bowel screening. It is anticipated the invitation and screening kit will be sent out to the 2,441 before Christmas.
35. For the 10,349 people who are not currently affected by this withdrawal from the programme, their status will be changed to recall in order that should their address in the NHI be updated in the future they will be re-invited to participate in the Programme.
36. Contacting these people and/or their families may attract media attention.
37. A reactive communications plan is attached, including draft letters to the 2,441 people being re-invited and a draft media holding statement for reactive use.
38. The letters to the three people are yet to be confirmed. They will be tailored based on the discussion with the general practitioner and the individual or family. A depersonalised draft of the letter will be shared with your office.
39. Dr Jane O'Hallahan, Clinical Director of the NSU will be available to answer any media questions.
40. You will receive a briefing on the recommendations and any actions to be taken resulting from the full event review.

Recommendations

The Ministry recommends that you:

- a) **Note** this report and the next steps planned.

Jill Lane
Director
Service Commissioning


Minister's signature:

Date: 2/12/17