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Briefing: Bowel Screening Pilot's incorrect withdrawal of eligible people

To: Hon Dr David Clark, Minister of Health

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Introduction

1. This briefing provides you with information on a serious clinical incident that has occurred in the Waitemata District Health Board (DHB) bowel screening pilot (the pilot).
2. The incident affects a group of eligible people in the pilot who were incorrectly excluded from participating in bowel screening. As a result eight people may have been harmed as their diagnosis of bowel cancer may have been delayed. Three of these people have died.
3. A detailed briefing on the roll-out of the National Bowel Screening Programme will be provided to your office the week commencing 6 November 2017.

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 in December 2017. Waitemata will move to National Bowel Screening Programme status on 1 January 2018. The pilot invited people in the 50-74 year age range. 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.
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). BSP 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.
9. 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).

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

Withdrawal from the pilot programme

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). These are the only official reasons for withdrawal. 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 results 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, the person is 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.

Issue

Summary and timeline of the pilot incident review

15. 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 at Waitamata DHB. It appeared that the pilot had permanently withdrawn people as a result of mail being returned, which prevented a new invitation being sent to a person even if their address was subsequently updated in the NHI.
16. On the same day the NSU requested Waitemata DHB immediately stop this practice and 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.
17. 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.
18. During the week of 16th October 2017 the NSU confirmed 12,834 people were incorrectly withdrawn from the programme. 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
 - Six people have bowel cancer but their address was 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.
19. The Director General of Health was advised of this issue, by the Director of Service Commissioning on 16 October, and the need for further analysis before further actions and decisions could be taken.
20. The former Minister of Health Dr Jonathan Coleman was informed by phone of the issue on 18 October 2017 following a meeting with his office.

21. 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.
22. This work 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. The impact on these eight people as a result of this delay is unknown and cannot be retrospectively quantified.
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, are reviewing this data against the clinical notes of the patients. The Clinical Director for the NSU, Dr Jane O'Hallahan will discuss with clinicians the findings from the clinical notes and next steps by 13 November 2017.
24. Waitemata DHB is also validating the numbers identified through the NSU process to ensure the data is as robust as possible. This process will be completed the week of 6 November 2017.

Next steps

25. Considering the impact of this incident on people the NSU must undertake a process of open disclosure, 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.
26. In the week of 13 November 2017 the Clinical Director of NSU and the Clinical Director of the Bowel Screening Programme plan to contact and offer to meet the eight people (and/or their families where appropriate) who were incorrectly withdrawn from the pilot and subsequently diagnosed with bowel cancer.
27. The NSU will explain what has happened and will take the opportunity to apologise. The conversations will be tailored to the circumstances of each case.
28. Following the principles of open disclosure, the NSU will also write to the 2,441 people incorrectly withdrawn from the screening programme to explain what happened and to re-invite them to participate in screening.
29. The NSU plans to write to the 2,441 people, by the end of November 2017, as some may have a bowel cancer that has not yet been detected.
30. For the 10,349 people who are not currently affected by this inappropriate withdrawal, 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 national screening programme.
31. The NSU will commission a full serious event review through an independent expert to further reduce the possibility of this occurring again.
32. Contacting these people and/or their families may attract media attention.
33. To mitigate the risk of a negative media response the NSU is proposing to take a proactive approach to inform the public of this incident, once the eight people and/or their families have been contacted.
34. A communications plan is being prepared, including draft letters to the eight affected people and will be shared with your office prior to release. This will be provided to your office the week of 6 November.

35. Dr Jane O'Hallahan, Clinical Director of the NSU will be available to answer any media questions.

Recommendations

The Ministry recommends that you:

- a) **Note** this report
- b) **Agree** to meet with officials to discuss this incident and planned actions.

Yes / No


Jill Lane
Director
Service Commissioning


Minister's signature:
Date: 4/11/17