Review of Invitation Issues Following Address Update - Bowel Screening Pilot Programme

Reviewer and author:
Kate MacIntyre, Director, Kate MacIntyre Consulting Limited
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Review Process

The Ministry of Health (MoH) National Screening Unit (NSU) and Waitematā District Health Board (WDHB) asked Kate MacIntyre (Independent consultant, Kate MacIntyre Consulting Ltd. www.katemacintyreconsulting.co.nz) to complete an independent review of invitation issues related to address updates within the Bowel Screening Pilot programme (referred to as the Pilot or the BSP henceforward).

Toby Regan, Acting Manager Information Quality and Equity, MoH, and Ann Buckley, Data Manager BSP, WDHB provided technical expert support to the reviewer.

The scope of this review was to determine the circumstances surrounding concern that a group of people eligible for the Pilot had not been invited when they could have been, and when the health system had an up to date address for them.

An overview of the circumstances that led to this review and the context in which it was conducted is set out below.

- Issue for review – an overview of the issue for review, its “identification”, background and the circumstances that led to the commissioning of this review,
- Two independent reviews were commissioned
  - Clinical review overview
  - This review overview
- Response to the issue
  - Actions taken to communicate and mitigate the issue
  - Control of the issue in the National Bowel Screening Programme

Issue for review overview

MoH NSU staff identified a screening incident related to returned mail on 20/9/2017\(^1\) and completed a Screening Incident Report Form for this on 21/9/2017\(^2\). The NSU screening incident report states:

“It has become apparent that the ICC has been using the ‘withdraw’ option in BSP+ in instances that may result in people being inappropriately excluded from the programme. This was initially identified through looking at the returned mail process. When people had mail returned (address unknown) and further address searches did not identify a valid address the person was permanently withdrawn from the programme. BSP+ routinely searches for address updated in the NHI database however people who have been withdrawn from the programme do not get invited to rescreen even if there is an updated valid address in the system.”

MoH NSU staff phoned WDHB staff and asked them to stop the process (of withdrawing people) immediately. The MoH NSU then convened an ‘incident group’ made up of senior staff within the NSU to look into the incident. The BSP Leadership Group which considered adverse events routinely was informed 22/09/2017.

\(^1\) The reviewer was advised by MoH staff that the date recorded on the Screening Incident Report Form – 4/9/17 - was an error and that the incident was identified 20/9/2017.
\(^2\) See Appendices 1 and 2
The identification and reporting of this screening incident generated an analysis by NSU staff which resulted in the responses set out in this report.

MoH NSU staff involved at the time the incident was identified were not aware that this issue was known from the beginning of the Pilot. Nor were NSU staff aware that throughout the Pilot this issue had been considered, decisions as to how it would be managed had been documented, efforts to mitigate it had been put in place and IT system fixes had been repeatedly proposed but these had been declined.

At the time the incident was reported, the issue was thought to be that:

- People eligible for the Pilot for whom invitation mail was returned as “Gone. No Address” (GNA) or “returned mail”.
- And for whom an alternative/updated address was unable to be located,
- Were allocated “Withdrawn” status within the BSP register (the database of people eligible for free screening through the Pilot),
- This effectively prevented these people from being sent any further invitation.

The MoH NSU analysis of the incident concluded that:

- Some of the people withdrawn as GNA subsequently had their address details updated in the National Health Index (NHI) system,
- But this new address information did not “flow” into the BSP register and update as this functionality was not set up, and
- Of the people withdrawn as GNA, and whose address had subsequently been updated in the NHI system, eight people were identified as having been diagnosed with bowel cancer.
- For this group of eight people, their addresses were updated between 1-44 months before the cancer diagnosis.

MoH NSU concern was that:

- If the updated address in the NHI had also updated in the BSP register, and
- If an invitation had then been re-issued to the updated address, and
- If these people then chose to participate in the Pilot,
- They may have had their cancer diagnosed earlier and potentially been offered earlier treatment.

Two independent reviews were commissioned

In response to this situation the MoH and WDHB commissioned two independent reviews:

- A clinical review - “A review of the clinical impact on the participants most affected by this adverse event will be undertaken through an independent peer review process, led by Waitemata DHB.”
- This review – “A review of the systems and processes that may have lead to or contributed to the outcomes of the adverse event. Led by the NSU [National Screening Unit].”

Clinical review overview

WDHB commissioned a clinical review by Dr Maree Weston, Consultant Colorectal and General Surgeon, Counties Manakau DHB. Extracts from Dr Weston’s report are provided below:
Review of Clinical Records of Patients Who Did Not Receive an Invitation to Participate in the Bowel Screening Programme and Who Subsequently Received a Cancer Diagnosis (20/11/2017)³

“This review investigates the extent to which the failure to issue an invitation to participate for screening at the time of the updated address has impacted on the patient outcomes for each of these 8 patients...

Summary p 5

...In my opinion there has been definitely no impact for 5 of these 8 patients who did not receive repeat screening invitations when their address was updated, and it is impossible to prove any impact for the remaining 3 patients.”

For five of the eight patients Dr Weston concluded there was no impact. These patients already had bowel cancer in advance of their address being updated. There was no potential that they could have been diagnosed earlier so they were not spoken to. They were not re-invited as screening is only for asymptomatic people (people without symptoms).

For the other three of the eight patients Dr Weston concluded that it was impossible to prove any impact. Sadly one patient had died.

The reviewer acknowledges Dr Weston’s findings.

This review overview

The reviewer was asked to provide a report as follows.

1. “Ascertain, as far as practicable, the circumstances surrounding the adverse events including:
   a) Providing a chronological overview of the adverse events
   b) Provide an overview of system and process issues that lead to or contributed to the outcomes of the adverse events

2. In terms of the adverse events:
   a) Make an assessment of the most likely causative factor(s)
   b) Review and document the process put in place for the National Bowel Screening Programme (NBSP) to ensure sufficient fail safes are in place to protect the safety of participants,

3. Recommend any further actions that the NSU, WDHB and/or other providers should take as a result of this review.”

The review process included:

1. Review of clinical review.
2. Review of MoH reports, documents and data.
3. Review of WDHB reports, documents and data.
4. Interview of relevant MoH and WDHB staff.
5. Site visit to WDHB.
7. Provision of the draft report to staff interviewed for factual correction.

³ See Appendices 1 and 2
8. Provision of the final draft report to the review Steering Committee for comment.

The reviewer did not interview any patients.

The reviewer acknowledges and thanks all the staff who were interviewed for their professional and helpful responses.

Disclaimer: To complete this report the reviewer has relied on information provided by MoH and WDHB staff at interview and on documentation provided by both organisations. The reviewer accepts staff accounts of events and documented records in good faith. The report was provided in draft to all interviewed for factual correction.

The reviewer accepts no liability and will not be responsible for any omission or misrepresentation arising out of relying on this information, nor for information that was not corrected during circulation of the draft, nor for information not made available to the reviewer during the review, nor for information that would have been provided by people who were unavailable to interview.

Response to the issue

Actions taken to communicate and mitigate the issue

In the period since the issue was identified in September 2017, and to date, MoH and WDHB staff acted to understand the issue and mitigate the consequences. MoH and WDHB views about the situation were different. The MoH considered that an incident had been identified and took action accordingly.

WDHB considered that it was well understood that there were limitations with the register, and that during the Pilot this had been reported in both external and internal MoH reviews4. Further, that it was understood by all parties that not everyone in the eligible population on the register was being invited to participate in bowel screening, but most were, and that this was within the target which was to invite 95%5 of the eligible population. The NSU view is that the target of 95% is set to acknowledge that a mobile population may not be captured on the BSP register, but that 100% of the people on the BSP register should be invited. The reviewer understands that letters of invitation were sent to all on the BSP Register but the issue arose when mail was returned GNA.

The MoH NSU response was that open disclosure was indicated in line with the Health Quality and Safety Commission’s policy6 and the Health and Disability Commissioner’s guidance7.

In addition to commissioning this review and the clinical review, MoH and WDHB staff acted to identify any patient harm, to communicate the situation appropriately and to reach agreement on the most appropriate action to take. The reviewer notes the actions of the MoH and WDHB to communicate with people and patients involved, and extends her condolences to those patients who developed cancer and to their families and whānau.

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4 See Appendices 1 and 2
5 BSP Interim Quality Standards Final Version 2.0 - see Appendices 1 and 2
7 http://www.hdc.org.nz/resources-publications/search-resources/leaflets/guidance-on-open-disclosure-policies/
The MoH Clinical Director NSU sent a letter dated 8/12/2017\(^8\) to all those allocated “Withdrawn” status because their mail was returned GNA, and who had a different address in the NHI system. The letter re-invited them to take part in free screening.

The MoH’s Clinical Director NSU and Clinical Director Bowel Screening conveyed an apology to the three patients in consultation with their General Practitioner (family doctor). Where possible this apology was communicated directly to the patient.

On 13 February 2018 during the process of this review, the Minister of Health, Dr David Clark ordered an independent review of the National Bowel Screening Programme. Dr Clark noted that the MoH had taken full responsibility for this matter and as Minister of Health apologised unreservedly.

On 17 April 2018 during the process of this review, the Ministry of Health announced that more people than first thought had not received letters of invitation for free bowel screening during the Pilot. In addition to the primary contact method of invitation letters, public communications and publicity campaigns were also run. These included a focus on advising people to contact the Pilot if they had not received an invitation or had changed their address. While almost 200,000 Waitemata residents had been invited between 2011 and January 2017, and 117,000 had been successfully screened, about 15,000 may have missed out (this includes the 2,500 subject of this review). The MoH’s NSU Clinical Director stated that the Ministry takes full responsibility for the oversights, which were a result of Pilot IT issues and human error, and will continue to contact those affected to apologise and invite them for screening over the coming months.

**Control of the issue in the National Bowel Screening Programme**

The reviewer has been advised by MoH NSU staff that mitigations and controls have been put in place to prevent this issue occurring in the National Bowel Screening Programme register as follows:

- The NSU run weekly checks to identify any address updates in the National Health Index (NHI).
- A list of updated addresses from the NHI is provided to the NCC (National Coordination Centre) weekly
- These addresses are then manually updated in the national programme register.
- The National Enrolment Service online provides a live PHO data set and the national programme register is linked to this service.
- At the same time the NSU continues to look at address records to identify any further issues.

\(^8\) See Appendices 1 and 2
Executive Summary

The Ministry of Health (MoH) National Screening Unit (NSU) and Waitematā District Health Board (WDHB) agreed to commission an independent review of invitation issues related to address update within the Bowel Screening Pilot programme (referred to as the Pilot or the BSP henceforward). Kate MacIntyre (Independent consultant, Kate MacIntyre Consulting Ltd. www.katemacintyreconsulting.co.nz) was engaged to complete this review.

The review was to determine the circumstances surrounding concern that a group of people eligible for free screening through the Pilot had not been invited when they should have been, and when the health system had an up to date address for them.

Bowel cancer is one of New Zealand’s most common cancers and the second highest cause of cancer death. More than 3000 New Zealanders are diagnosed with bowel cancer each year and more than 1200 die from it. Bowel screening can detect cancer at an early stage when it can often be successfully treated. The Pilot invited almost 200,000 Waitematā residents between 2011 and 2017 and successfully screened 117,000 people. 375 people had cancer detected through this screening as at March 2017.

In September 2017, MoH NSU staff identified a screening incident relating to the management of returned mail. This was reported as “Withdrawal incident an issue with the Pilot and BSP register”. MoH NSU staff involved at the time the incident was identified were not aware that the issue was known from the beginning of the Pilot. Nor were they aware that throughout the Pilot the issue had been considered, decisions as to how it would be managed had been documented, efforts to mitigate it had been put in place and IT system fixes had been repeatedly proposed but these had been declined.

The Chronology section of the report provides a summary of the background to and context for the returned mail GNA issue. This section includes:

- A timeline detailing key documents. Table 1 sets out and provides a high level summary of key documents and actions against the timeline of the Pilot.
- A timeline detailing key system and process events including the set-up of the BSP register, the role of Information Technology, the extension of the Pilot, identification of and efforts to manage the returned mail GNA issue, planning for national bowel screening, identification of the returned mail GNA issue as an incident and risk management and control going forward.

The Findings section of the report sets out the root cause, contributing and causative factors.

The root cause of this set of circumstances arising is that the management of the returned mail GNA issue was not addressed by proposed IT functionality when the register was first set up (through the NHI linking to the BSP register). This functionality was intended and planned for but ultimately was not resourced by the MoH IT Board. When the decision not to resource this IT functionality in setting up the register was made, the consequences for people eligible for the Pilot did not appear to be explicitly explored, considered or fully understood.

Further attempts to address the issue then occurred, but did not result in solutions that resolved the issue. Key decisions were made within the context of establishing and running a pilot programme to learn and identify issues to inform the decision about a national bowel screening programme.
Manual workarounds were put in place to manage mail returned GNA but these became unsustainable as the volume of returned mail increased. Further attempts to address the issue occurred throughout the Pilot but did not result in solutions that resolved the issue. A key barrier was that there was no IT budget for the Pilot and proposed IT functionality solutions were repeatedly declined by the MoH IT Board throughout the period under review.

In summary:

- In the set-up of the Pilot the returned mail GNA issue was expected to be addressed through IT functionality, but this was not resourced.
- At the outset of the Pilot as mail returned GNA began to be received, process management decisions were agreed by the MoH and WDHB and workarounds implemented but these were not solutions and the issue was not fixed.
- The process developed to manage returned mail resulted in people’s records effectively being closed from any future re-issue of invitation.
- Manual workarounds became unsustainable.
- Repeated attempts to secure funding for resources, an IT enhancement, functionality or solution were declined.
- Around March 2017 Ticket #275 (opened in 2015 to secure an IT solution to the returned mail GNA issue) was closed (in error) without the issue being fixed.
- The clinical consequences of the situation continuing (particularly beyond the second cycle) were not necessarily clearly understood by all staff involved.
- Risk arising from the issue was understood to be mitigated through workarounds and publicity campaigns.
- Decision making was in the context of a time limited pilot and other decisions regarding “acceptable” risk i.e. that the Pilot would end after two cycles and learning from the Pilot would then inform a national programme.
- There was no formal review (e.g. at the end of each two year cycle) of risk to people allocated “Withdrawn” status.

The Recommendations section acknowledges actions taken since the returned mail GNA issue was identified as an incident. MoH and WDHB staff have worked to understand the issue, control and mitigate risk, invite people allocated “Withdrawn” status, and to apologise. The Minister of Health has ordered an independent review of the National Bowel Screening Programme and this review has commenced. Recommendations are made acknowledging this context and with consideration for actions already progressing.

The key recommendation is that full, in-depth expert review of the BSP register and the processes put in place to manage issues that arose during the Pilot should be conducted to assure the public of New Zealand that the National Bowel Screening Programme is safe.

Other recommendations relate to communication, documentation, testing, exploration of risks and issues, health and safety, follow up of recommendations from external review reports and open disclosure.
**Chronology**

This review considers a period from 2011 to the current day. Key documentation, events and information provided during staff interviews is summarised as relevant to the issue under review. This section provides a background summary, a document timeline and a key events timeline.

**Background summary**

Bowel cancer is one of New Zealand’s most common cancers and the second highest cause of cancer death in New Zealand. More than 3000 New Zealanders are diagnosed with bowel cancer each year and more than 1200 die from it. Bowel screening can detect cancer at an early stage when it can often be successfully treated. The primary objective of bowel screening is to reduce the mortality rate from bowel cancer, by diagnosing and treating bowel cancer at an earlier and more treatable (and less costly to treat) stage.

It is best practice internationally to pilot a screening programme before offering it more widely, to ensure it is safe for participants, there is capacity to provide timely diagnostic and treatment services and that all processes are working correctly.

The Ministry of Health (MoH) funded Waitematā DHB (WDHB) to plan and implement a Bowel Screening Pilot programme (referred to as the Pilot or BSP henceforward) over four years from 2012 to 2015. The Pilot was a population based programme that offered screening for bowel cancer to all people eligible for publicly funded healthcare and who resided in the WDHB area and who were between 50 -74 years of age.

The Pilot commenced in January 2012 and was intended to run for two, two year cycles concluding in December 2015. The main goal of the Pilot was to determine whether organised bowel screening could be introduced in New Zealand in a way that was; effective, safe and acceptable for participants, equitable and economically efficient.

In brief the key components of the Pilot pathway were:

- Identifying and developing a register of all eligible people (the BSP register) – using the National Health Index (NHI) and Primary Health Organisation (PHO) enrolment databases.
- Sending each person on the BSP register a pre-invitation letter and information booklet – at which point they could “Opt off” (ask to not be further contacted in this regard).
- Four weeks later (reduced to two weeks during Cycle 2) sending each eligible person on the register an invitation, test kit and consent form – they could “Opt off” at this point too.
- If continuing within the programme the person sent a sample to the laboratory.
- Results were communicated to the BSP register and the person’s GP.
- A negative (normal) result was communicated to the person and they were flagged in the register for recall in two years.

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11 The first 500 invitations were issued at the end of October 2011. This was done to check that processes worked smoothly and to identify any issues along the pathway, before much larger numbers were invited. Pre-invites were then issued during December 2011 so that people would start receiving their kits during January 2012. It was usual to refer to the first two year cycle as having begun on 1 January 2012.
A positive (abnormal) result was communicated to the person and they were offered a colonoscopy, subsequent to which they were either referred for surveillance, flagged in the register for recall in five years or they required treatment.

For the Pilot, the MoH populated and owned a database of eligible people – the BSP register. The WDHB Coordination Centre used the BSP register to invite people for screening. People were invited twice during the four year Pilot period. The MoH was responsible for accessing all the systems used for the BSP register information updating purposes e.g. the NHI, Cancer Registry and Primary Care age/sex registers.

The Pilot invited almost 200,000 Waitematā residents between 2011 and 2017 and successfully screened 117,000 people. 375 people had cancer detected through this screening as at March 2017.

The evaluation of the Pilot programme supported the implementation of a National Bowel Screening Programme. Information from the Pilot has helped to inform decisions about the national programme. Data collected during the Pilot has provided vital information on participation levels, cancer detection rates and the impact on health services.

The national programme commenced at Hutt Valley and Wairarapa District Health Boards on 17/7/2017. The Pilot concluded on 31/12/2017 and WDHB moved to the national programme on 1/1/2018.

A new organisation assumed responsibility for the national programme coordination functions.

Two other DHBs will join the National Bowel Screening Programme in 2018 and all DHBs are expected to have progressively joined by the end of the 2020/21 financial year.

**Key document timeline - Returned Mail/Gone No Address issue**

MoH NSU staff identified a screening incident related to returned mail on 20/9/2017 and completed a Screening Incident Report Form for this on 21/9/2017. The NSU screening incident report states:

“It has become apparent that the ICC has been using the ‘withdraw’ option in BSP+ in instances that may result in people being inappropriately excluded from the programme. This was initially identified through looking at the returned mail process. When people had mail returned (address unknown) and further address searches did not identify a valid address the person was permanently withdrawn from the programme. BSP+ routinely searches for address updated in the NHI database however people who have been withdrawn from the programme do not get invited to rescreen even if there is an updated valid address in the system.”

Investigations undertaken are recorded as:

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12 Litmus et al reports 2015 and 2016 – see Chronology and Appendices 1 and 2 for relevant detail.


14 The reviewer was advised by MoH staff that the date recorded on the Screening Incident Report Form – 4/9/17 - was an error and that the incident was identified 20/9/2017.

15 See Appendices 1 and 2
“Preliminary investigation of affected cohort to quantify the size and scope of the issue. Initial cohort has been cross matched with the cancer registry and mortality database and NHI.”

Immediate action to mitigate any risk is recorded as:

“On 20/09/17 ICC was instructed to cease withdrawing people from the programme unless the individual or their GP has requested it. This took effect on 21/09/17.”

MoH NSU staff contacted WDHB staff by phone and asked them to stop the process immediately. MoH NSU convened an ‘incident group’ made up of senior staff within the NSU. The BSP Leadership Group which considered adverse events routinely was informed 22/09/2017.

The identification and reporting of this screening incident generated an analysis by NSU staff which resulted in the responses set out in the Review Process section of this report.

The reviewer was advised that the issue was known from the beginning of the Pilot. MoH NSU staff involved at the time the incident was identified were not aware that the issue of how to manage mail returned GNA was known from the beginning of the Pilot. Nor were NSU staff aware that throughout the Pilot the issue had been considered, decisions as to how it would be managed had been documented and actioned, efforts to mitigate it had been put in place and IT functionality system fixes had been repeatedly proposed but these had been declined.

The earliest reference to changing the status of people on the register to “Withdrawn” sighted during the review is an email from the MoH to WDHB dated 24/1/2012 suggesting refinements to the Provider Resource Document (January 2012). The email states:

“When people are ineligible or opt out, they are NOT removed from the register, their demographic (and screening history) needs to be retained on the system. Their status is changed (generally automatically) to ineligible or withdrawn.”

The earliest document provided to the reviewer that refers to people being “Withdrawn” due to returned mail or GNA is titled “Returned Mail Management” and is dated 6/4/2012. The document author and organisation are not specified. This document appears to be a Standard Operating Procedure (SOP). This document sets out the process for managing returned mail and includes steps to find an up to date address. In the case of this not being possible it concludes “If after exhausting all possible resources and you are still unable to locate or contact the participant then Withdraw them in BSP.”

Further documentation that evidences reference to the returned mail GNA issue and/or attempts to resolve the issue is listed in Appendix 1 and summarised including relevant excerpts in Appendix 2.

The reviewer has carefully considered all documentation made available, and notes:

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16 The date is recorded on the form in error as 20/07/2017.
17 See Appendices 1 and 2
18 This instruction meant that the person’s record was changed to “Withdrawn” status. It does not mean they were removed from the register altogether.
• Documentation was provided to the reviewer that was not dated, was dated or numbered incorrectly, and/or the document owner was not identified (i.e. MoH, WDHB, other). This made contextualising the documentation within the review difficult.

• Documentation was provided to the reviewer after the initial draft of the report was provided to those interviewed for factual correction.

• There may be documentation that was not available to the reviewer that may have evidenced earlier identification of the returned mail GNA issue than as set out above.

• There may be documentation that was not available to the reviewer that may have provided additional information or perspective.
Table 1: Key documents and actions timeline*

* There may be other documentation of relevance that is not listed. This provides key documents and actions available or advised to the review. Refer to Appendix 1 and 2 for details of documentation referenced in this review.

<table>
<thead>
<tr>
<th>Year</th>
<th>Document/Action</th>
<th>High level summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011 and earlier</td>
<td>Planning for Pilot.</td>
<td>Included provision for IT functionality to manage address update issue. This was not resourced.</td>
</tr>
<tr>
<td>2012 Year 1 Cycle 1</td>
<td>Returned mail management (4/12)</td>
<td>If unable to contact after exhausting all resources “Withdraw” in BSP.</td>
</tr>
<tr>
<td>2013 Year 2 Cycle 1</td>
<td>Progress report to BSP Steering Group #33</td>
<td>Register accuracy an emerging risk due to volume of returned mail.</td>
</tr>
<tr>
<td></td>
<td>BSP Interim Quality Standards Final Version 2.0</td>
<td>“All eligible people within the Bowel Screening Pilot will be offered bowel screening every two years.”</td>
</tr>
<tr>
<td></td>
<td>Progress report to BSP Steering Group #34</td>
<td>Refers to draft letter to MoH ID requesting more resource for the BSP register.</td>
</tr>
<tr>
<td></td>
<td>Progress report to BSP Steering Group #31</td>
<td>Reports PHO enrolment data may not have been uploaded since beginning 2013 meaning that addresses may not have been updated.</td>
</tr>
<tr>
<td>2014 Year 1 Cycle 2</td>
<td>WDHB memo to BSP Steering Group</td>
<td>Recommends moving people who have mail returned GNA to two year recall. Those that don’t respond to two, two yearly invitations are moved to “Withdrawn” status. Sets out clearly that moving a GNA person to ‘withdrawn’ status means they will not be invited again unless they contact the Coordination Centre, that even though their address details may subsequently be updated via PHO uploads into the NHI, they will never be re-invited. And that as a consequence there may be people on the BSP register with a correct address who will not be given an opportunity to participate.</td>
</tr>
<tr>
<td></td>
<td>BSP Steering Group minutes</td>
<td>Show that the Steering Group approved recommendation that people whose invitation letters are returned “gone no address” are placed on two year recall, but agreed people should have three opportunities to participate. Work on the BSP register to allow the first recommendation to happen did not occur.</td>
</tr>
<tr>
<td></td>
<td>Memo MoH to Major Projects Committee</td>
<td>Seeks $30,000 to cover BSP register updates to ensure participant details are as up to date as possible. Notes updates are not working as planned and urgent work required.</td>
</tr>
<tr>
<td></td>
<td>WDHB actions</td>
<td>Recorded all returned mail GNA on a spreadsheet. Publicity campaign. Traffic light tool provided to primary providers. They could advise of a change of address via this tool. Two trips to Wellington to MoH to discuss and attempt to progress concerns related to register development.</td>
</tr>
<tr>
<td></td>
<td>Progress report to BSP Steering Group #35</td>
<td>Reports that register functionality continues to compromise operational efficiency. The register was satisfactory for go live but needs significant ongoing attention to meet all operational, audit and reporting requirements.</td>
</tr>
<tr>
<td>Year</td>
<td>Document/Action</td>
<td>High level summary</td>
</tr>
<tr>
<td>------</td>
<td>-----------------</td>
<td>-------------------</td>
</tr>
<tr>
<td></td>
<td>Letter Chair BSP Steering Group to Director of National IT Board</td>
<td>Notes that there are too may workarounds, and that this is inefficient.</td>
</tr>
<tr>
<td></td>
<td>BSP Steering Group minutes</td>
<td>Raises concern that frequency of new releases (to address issues) not keeping pace, too many workarounds which were inefficient and posed risk. Analysis of first round of screening compromised by limitations with the register. Further roll out not possible in current state. Responsibility for securing additional funding and resources is unclear and recommends a meeting of all parties.</td>
</tr>
<tr>
<td></td>
<td>Progress report to BSP Steering Group #38 &amp; 39</td>
<td>Record that letter resulted in a meeting. Good progress made. Reluctance to put too much resource into database that would end with the Pilot. Responsibilities for business case for capital expenditure on BSP register clarified</td>
</tr>
<tr>
<td></td>
<td>MoH BSP Population Register Analysis</td>
<td>Identifies issues with address quality and that overall PHO register(s) include about 13,000 people who appear to meet the requirements of the BSP register, but they have not been invited to participate</td>
</tr>
<tr>
<td>2015 Year 2 Cycle 2</td>
<td>Interim Evaluation Report of the BSP: Screening Round One</td>
<td>Notes a number of critical limitations with the BSP register are impacting adversely on the Pilot. It is estimated based on returned mail that between 5-15% of eligible participants may not have received a letter or kit in screening round one potentially due to incorrect address details on the BSP register. Recommends that the MoH comprehensively review the BSP register and implement a robust data quality assurance programme.</td>
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<tr>
<td></td>
<td>Memo Principal Advisor Bowel and Prostate Cancer Programmes MoH to SCIIMGG MoH</td>
<td>Re Enhancements to the Waitematā BSP IT system for round 3 seeks support to upgrade the current Pilot IT system (the BSP register) to support extending the Pilot for Round 3. States that in order to accommodate efficient running of Round 3 the IT system must be upgraded but there is no capital funding available in the current year. Proposed enhancements for Release 5 listed include allowing on hold (withdrawn) patients to be invited if they have previously been put on hold (withdrawn) due to returned mail but they have an updated address on the NHI, issues with eligibility due to address changes, a 'pending' state and improvements on how work tasks are resolved.¹⁹</td>
</tr>
<tr>
<td></td>
<td>MoH Risk Register for the delivery of a National Bowel Screening Programme (NBSP)</td>
<td>Includes current risks (not individually dated); insufficient IT maintenance, inadequate funding, IT resources not fully allocated to NBSP and participation.</td>
</tr>
<tr>
<td></td>
<td>Ticket #275</td>
<td>Asks developers to come up with a solution so that “Withdrawn no address”</td>
</tr>
<tr>
<td>2016 Year 1 Cycle 3</td>
<td>Returned Mail Management</td>
<td>Sets out the procedure for processing all mail returned to the coordination centre including if no address is found they are withdrawn from the programme.</td>
</tr>
<tr>
<td></td>
<td>Final Evaluation Report of the BSP:</td>
<td>Notes estimates based on returned mail that between 5-15% of eligible participants may not have received a</td>
</tr>
</tbody>
</table>

¹⁹ The reviewer was advised that the request for funding was not approved.
<table>
<thead>
<tr>
<th>Year</th>
<th>Document/Action</th>
<th>High level summary</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Screening Rounds One and Two</td>
<td>letter or kit in screening round one potentially due to incorrect address details on the BSP register. Notes there are known issues with the currency of addresses with a return to sender rate of around 6%. Concludes that the Pilot has done its job of testing a bowel screening pathway design, identifying feasible roles, and risk to translate to a national bowel screening programme and learning needs to be carried forward into a national roll out. States that for the BSP register to operationally manage a national bowel screening programme, at least in the interim, a number of enhancements and greater integration with other systems are needed. Recommends a functional review of the operation of the BSP register if used to support a national bowel screening programme.</td>
</tr>
<tr>
<td></td>
<td>Programme Business Case and Tranche 1 Business Case National Bowel Screening Programme</td>
<td>States that the IT solution established to support the pilot site was specifically developed for the Pilot, within constraints of costs and timeliness and within the context of the relatively small nature of the pilot. The assessment of the existing pilot system is that it would not be possible to successfully scale, in its current form, to meet the needs of a national rollout. This assessment is based on the knowledge gathered from the pilot system, including the identification that approximately 50 percent additional functionality is achieved manually by the pilot and would need to be automated in a national system.</td>
</tr>
<tr>
<td></td>
<td>Returned Mail Management</td>
<td>Working document: sets out procedure as above and proposes IT functionality solution to returned mail GNA issue.</td>
</tr>
<tr>
<td>2017 Year 2 Cycle 3</td>
<td>BSP Risk Management Post Implementation Risk No 2 states “The Register does not accurately reflect the eligible population within WDHB.”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MoH BSP Due Diligence Interim IT Solution Assessment</td>
<td>States “The BSP+ IT solution is not suitable as the foundation for a long term or strategic IT solution.”</td>
</tr>
<tr>
<td></td>
<td>Bowel Screening Register Standard Operating Procedure (SOP) Manual</td>
<td>Sets out manual processes to work through. Notes due to time restraints, returned mail can be partly investigated (to the step where the participant’s medical centre is contacted) and followed up later. If the investigation is delayed a work task should be created so the participant will not get any further mail. The workflow concludes with “Withdraw the participant from BSP Register” and “End” for the process where all efforts to check for an updated address have been unsuccessful.</td>
</tr>
<tr>
<td></td>
<td>Screening incident identified and reported</td>
<td></td>
</tr>
</tbody>
</table>
Key system and process events timeline

Population Register set up for the Bowel Screening Pilot

Bowel screening has been shown to be effective and save lives. In 2007/08 a report from the MoH Bowel Screening Advisory Group recommended a feasibility study to see if national bowel screening could be rolled out. Work to decide how the programme would be run was progressed and initially it was not clear that a pilot approach would be used.

The MoH Personal Health Unit was responsible for the programme and reported to the Sector Capability and Implementation (SCI) directorate within the MoH. The reviewer was advised that locating the programme within SCI allowed significant work on documenting and increasing colonoscopy capacity, workforce capability and improving equity of access, quality and timeliness for both diagnosis and treatment of bowel cancer and included the cancer team. The cancer team had strong connections with symptomatic and diagnostic endoscopy services and cancer networks.

The initial proposal was for a national bowel screening programme in place across all DHBs in one year. A feasibility study was commissioned. The objective was to decide if it was safe and appropriate to implement bowel screening in New Zealand. A bowel screening taskforce was established to progress the work.

It was determined that a pilot programme should be the approach taken to test the acceptability of bowel screening in New Zealand. There was a strong focus on clinical aspects of the pilot such as the number of colonoscopies and system capacity to provide these.

In 2011 two quite critical reports about breast and cervical screening were released and generated further impetus to get bowel screening underway (Muller 2011, Gillis 2011).

Waitematā DHB (WDHB) was selected as the Pilot site. An Information Technology (IT) solution provider was identified, however this did not progress and another solution provider was sought and engaged. A co-design was completed. For the Pilot a bare bones system was developed. The Pilot was a proof of concept approach to learn and inform the national bowel screening decision.

The MoH was responsible for national functions e.g. procurement of an Information Technology (IT) system, procurement of tests and governance. The MoH took ownership of the BSP register. WDHB was responsible for running the Pilot, BSP register processes and the BSP Coordination Centre. WDHB created the operational model and worked with the MOH to create the service model. WDHB developed policies and procedures to underpin the operations. Key policies were also approved by the MoH. The planning for the Pilot provided for evaluation of set up cost, cost benefit, service effectiveness and safety.

Bowel screening had not been done before in NZ, and the way the programme would operate was new. The challenge of creating an accurate functional pre-populated population register of eligible people was not unique to the Pilot, but for the Pilot a new approach to creating a register was taken (different to the approaches taken for breast and cervical screening registers). Breast screening is an “Opt on” register; people choose to participate in breast screening and are then listed on the register. For cervical screening, a woman’s smear results are recorded on the register.

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20 see Appendices 1 and 2
For the Pilot an eligible population was identified and a register of these people created. These people were then invited to participate in bowel screening. If people did not want to participate they could “Opt off”. If someone asked to “Opt off” this would result in their record in the Pilot register being changed to “Withdrawn” status. “Opting off” resulted (at the person’s request) in their record being closed from any future re-issue of invitation. This approach to how the BSP register was developed also meant the Pilot had a much bigger population to start with compared with other existing screening programmes.

In the planning stages the questions were around how to invite people, who to invite and what tools to use to do this. Consideration was given to the most appropriate source of population information. Options for data sources were the National Health Index (NHI) or Primary Health Organisation (PHO). Both were known to have inaccuracies. The decision was to use the NHI system to generate the Pilot register – known as the BSP register. The plan was to do two rounds of invitation over four years and data to cover this period was added.

Planning for the BSP register also included planning for real time interaction with the NHI so that changes in the NHI would be reflected in the BSP register as they occurred. Planning included that the system would generate:

- Work tasks - this was seen as a good safety valve that would flag mismatches between the BSP register and the NHI.
- Monthly uploads from the NHI to the BSP register of data that had changed.
- Three monthly updates of data from the PHO system.
- A list of people for whom mail had been returned “Gone no address” (GNA) and whose status was “Withdrawn” that would be cross referenced with the NHI data for an updated address.
- Weekend checking of some but not all records against the NHI for an update of information.
- Changes made by WDHB to a person’s record in the BSP register would generate a refresh of data from the NHI. These refresh checks were planned to be set to run nightly.

Ultimately these planned BSP register functionalities were not resourced by the MoH IT funding decision makers. The refresh checks were set to run nightly but the system was only capable of refreshing a limited number of records. The system did not have the capacity to refresh all the records changed daily.

Use of the NHI and updating from it was problematic from the start of the Pilot. The population on the BSP register was never able to be described as 100% accurate and this was not an expectation. MoH staff advised that it is recognised that it is not possible to create a 100% accurate population register for health. This was not unique to the Pilot; it is an issue for every screening programme.

It was recognised at the outset that some eligible people may have never been invited. The reviewer was advised that the National Enrolment Service online will reduce the likelihood of eligible people being missed but will not eliminate it. The service is being rolled out across the country and provides for a live PHO data set – if people move to a new GP they update the PHO system which

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21 Addresses on the NHI were not necessarily correct and current. Whilst a different address might be listed on the NHI than listed on the BSP register, there were examples of NHI addresses not being the current address i.e. a different address on the NHI did not necessarily mean an up to date current address.
informs the NHI. This service is now connected to the National Bowel Screening Programme. However there will still be eligible people not enrolled with a PHO and therefore not invited.

The target was to invite 95%\textsuperscript{22} of the eligible population. The Pilot could only invite people recorded on the BSP register. Attempts to check against e.g. NZ Statistics Census data, showed a third more people on the NHI database than the census indicated there should be. A lot of hard work was done by MoH staff to refine this data to increase accuracy for the Pilot population as inviting this number would have generated significant waste. NHI records were checked and a categorised as “Live” or “Stagnant”. People too young at the start of the Pilot but who would “age in” and become eligible, and people who moved into the area, were added. MoH staff involved stated that this was a difficult process.

The population register for the Pilot (the BSP register) was created in late 2011. The register was evaluated as part of a readiness assessment and while not perfect, was considered “good enough” and safe to support go-live, noting that further development work would need to be undertaken.

There were lots of issues with the BSP register. It was quite complex. There were constant changes, amendments and improvements. However this was in the context of a pilot programme. The BSP register was, in this context, a work in progress and a developmental tool that would change and evolve as the programme got underway and issues were identified. It was also in the context that the BSP register had been developed to only provide functionality for the period of the Pilot i.e. two cycles of two years each, four years in total.

People moving into the area were identified added to the register monthly during 2012. This update process then ceased until it was restarted in 2015. People could also ask to join the Pilot if they learned about it via their health provider or through the Pilot communication and awareness campaigns which continued throughout the Pilot.

Each quarter PHOs provided their age/sex registers as a source of information to check for GP/patient links and addresses. At the MoH, analysts checked the New Zealand Cancer Register (NZCR) for bowel cancer information and uploaded it manually into the BSP register to flag people who were ineligible because of a cancer diagnosis. The frequency of this process varied throughout the Pilot. Once the NZCR data was uploaded the register would not send out any further invites to those people.

The MoH and WDHB developed and agreed an invitation strategy. The purpose of the strategy was to smooth workloads and demand for colonoscopies. Standard Operating Procedures\textsuperscript{23} (SOPs or rules) were developed for the rollout of the first two years (Cycle 1). People with birthdays on even days were invited in the first year and people with birthdays on odd days were invited in the second year. What this meant is that someone eligible on day one of the programme might not receive an invitation until December of year two of the roll out. Around 6,000 invitations were sent out every month.

For Cycle 2 people were invited two years after they received their first invitation. They would get their second invitation on or around their birth date. People aging in i.e. turning 50 and becoming eligible, were invited as per the birthdate strategy.

\textsuperscript{22} BSP Interim Quality Standards Final Version 2.0 - see Appendices 1 and 2

\textsuperscript{23} Bowel Screening Register Standard Operating Procedure (SOP) Manual - see Appendices 1 and 2
Around the transition from Cycle 1 to Cycle 2 it was noted that because some people took a few months to return their sample, their second cycle invitation was being sent much sooner than two years later. This was because it was sent based on two years after the sample kit was sent to them. The rule was changed for when the person received their next invitation to ‘two years after the receipt of the first sample (if they had participated) or two years after the first invite (if they had not participated)’.

There were complaints from clinicians in relation to entering treatment data and the long time it took to deliver improvements to this part of the BSP register. A lot of workarounds were required to accommodate people who did not progress through the pathway stages routinely. As an example of limitations of the BSP register, histopathological data for 30-50 polyps could occasionally be received for one patient. The BSP register could only record information about the most significant polyp. Decisions had to be made as to what was the most significant polyp and then this data was manually entered. A system capable of holding all this data upon receipt of it would have been safer and more efficient.

Information Technology (IT)

It is important to note that during this review, efforts to arrange an interview with a MoH IT funding and decision making representative were not successful. The report has not been directly informed by an interview with IT decision makers involved during the Pilot.

Management of operational IT sat with the MoH IT services. While there was a budget for the Pilot, there was no specific provision and standalone budget for the IT requirements of the Pilot. MoH IT services were responsible for multiple very big projects and the Pilot competed for funding, resources and priority against all other projects under the MoH IT Board’s oversight and decision making. By comparison to other IT projects, the Pilot was small.

The MoH BSP team had to seek funding for each iteration of the IT budget for the Pilot. This involved having to write a paper to the IT Board each time an improvement was sought. Budget for IT improvements was repeatedly sought and five upgrades of the system were approved and actioned during the period. However other requests for updates including functionality that would address the returned mail GNA issue were repeatedly declined by the MoH IT Board. Sometimes these requests were repeated and still declined. The reviewer was advised that MoH IT Board decision makers did not necessarily understand the implications of the decisions they were making in terms of consequences for people.

Extension of the Pilot for Cycle 3 (years 5 and 6)

When it became clear that a national programme would not be up and running and able to absorb the Pilot before the end of Cycle 2 the Pilot was extended for a further two year cycle (i.e. Cycle 3 - 2015 and 2016).

A number of staff interviewed from both the MoH and WDHB advised the reviewer that when the decision was made to extend the Pilot for two more years, Argonaut, WDHB and the MoH came up with a list of enhancements, things to trial and things to fix considered necessary to rectify known

24 Budget 2010 committed $24 million over four years for the BSP. Budget 2015 invested a further $12.4 million to extend the Pilot to December 2017
issues and risks with the BSP register. This list of enhancements was costed and funding sought from the MoH IT Board but this was declined. The reason provided was that the BSP register was going to be scrapped within two years and a new solution may emerge with the launch of the national programme. A second attempt was made to secure funding for the enhancements, but this was again declined by the MoH IT Board. MoH staff interviewed stated that being turned down twice did not seem totally unreasonable as it was a lot of money to invest when it would end with the end of the Pilot.

**Returned Mail/Gone No Address issue – identification of, reference to and attempts to manage**

The reviewer was advised that the returned mail GNA issue was known from the beginning of the Pilot, and that as the Pilot commenced and issues became evident, those involved in establishing processes to manage issues as they arose, all understood a lot of mail was coming back. A chronology of relevant documentation is provided below.

The MoH BCP Risk Register dated 5/3/2012\(^{25}\) includes open risks related to role clarity, continuity of IT systems, and implementation of quality standards. Closed risks recorded are scope of register, lack of succession planning, possibility of not being able to use the NHI to populate the register, insufficient time or resources for information systems, funding yet to be secured, timeframe pressure, insufficient budget, and insufficient project team. The dates risks were added to this register are not recorded.

The earliest document provided to the review that refers to people being “Withdrawn” due to returned mail or GNA is titled “Returned Mail Management” and is dated 6/4/2012\(^{26}\). The document author and organisation are not specified. This document appears to be a Standard Operating Procedure (SOP). This document sets out the process for managing returned mail and includes steps to find an up to date address. In the case of this not being possible it concludes “If after exhausting all possible resources and you are still unable to locate or contact the participant then Withdraw them in BSP”\(^{27}\).

People invited to participate in the Pilot could “Opt off” and they would then be “Withdrawn”. If they changed their minds, this could be updated, their status changed and the person sent a kit. People for whom mail was returned GNA were allocated “Withdrawn” status and were not then offered a re-invite – they were held in the “Withdrawn” state permanently. If a record is changed to “Withdrawn” the BSP register ignores that person and keeps a record of their withdrawal and the reason e.g. returned mail GNA.

WDHB advised that in relation to mail returned GNA the issue was taken very seriously. WDHB put in place a manual workaround series of mitigations and efforts to address it. The MoH team at the time were aware and had input into the decision to allocate “Withdrawn” status to people for whom mail was returned GNA.

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\(^{25}\) See Appendices 1 and 2

\(^{26}\) See Appendices 1 and 2 for more detail.

\(^{27}\) This instruction meant that the person’s record was changed to “Withdrawn” status. It does not mean they were removed from the register altogether.
• Efforts were made to find a person’s new address as per the Standard Operating Procedures (SOPs). This included searching the WDHB patient system, the white pages and PHO patient systems. This had to be fitted in around existing staffing and workload and was a lot of work.
• The BSP coordination centre started recording all returned mail on a spreadsheet to facilitate regular checks with PHO age/sex registers and hospital systems for new addresses.
• There were a number of re-checks over time.
• As the number of entries on the spreadsheet grew, the ability to check all records routinely became impossible.
• While the volume of returned mail per week was relatively static, the accumulated volume was the issue.
• The manual workaround solutions needed automating.

This situation was an evolving process where the manual workarounds initially appeared effective but quickly became unsustainable. WDHB recognised that keeping spreadsheets with lists was a risk. A number of spreadsheets had been set up in response to various issues. An example of where spreadsheets were used as a workaround is that for the first year treatment data could not be entered so clinical staff kept a spreadsheet. Spreadsheets were also used to track adverse events.

The 6/4/2012 Returned Mail Management document indicates an agreed process from at least April 2012 where if a current address was not identified by a series of efforts, a person’s status would be altered to “Withdrawn”.

WDHB advised that it was known that this solution was not ideal, but it was occurring in the context of the four year time limit of the Pilot. An example of another rule within this context is that people who did not respond to invitation (but their mail was not returned GNA) were being invited twice and if they did not respond no further invites were extended.

WDHB advised that the issue was known, articulated as an issue and understood by members of the BSP Steering Group. This steering group included both MoH and WDHB staff, including up to six medical doctors including two public health physicians and a general practitioner.

A progress report to the BSP Steering Group dated 25/2/2013 reports register accuracy emerging as a risk because of the significant number of GNA returns (returned mail) and also the 45% who have not responded.

The BSP Interim Quality Standards Final Version 2.0 last updated 20/3/2013 includes Standard 2 “All eligible people within the Bowel Screening Pilot will be offered bowel screening every two years.”

WDHB advised that the target in the first version of the standards was to invite 95% of the eligible population.

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28 Report #33 see Appendices 1 and 2
29 See Appendices 1 and 2
30 BSP Interim Quality Standards Final Version 2.0 - see Appendices 1 and 2
2. Invitation to Bowel Screening

<table>
<thead>
<tr>
<th>Invitation of Bowel Screening to the Eligible Population</th>
</tr>
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<tbody>
<tr>
<td><strong>Standard 2:</strong> All eligible people within the Bowel Screening Pilot will be offered bowel screening every two years.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Definition</th>
<th>Eligible people are invited to take part in the screening programme by a mailed pre-notification letter and/or an invitation letter with an FIT kit.</th>
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</thead>
<tbody>
<tr>
<td>Rationale</td>
<td>There is evidence that the mortality rate from bowel cancer can be reduced by a high level of participation in a population-based screening programme.</td>
</tr>
<tr>
<td>Quality Indicator</td>
<td>All eligible people in the WDHB will be offered the opportunity to participate in the bowel screening pilot. The number of individuals responding to bowel screening is the proportion of those eligible for screening who are tested with a completed FIT kit.</td>
</tr>
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<table>
<thead>
<tr>
<th>Essential Criteria</th>
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</thead>
<tbody>
<tr>
<td>The Bowel Screening Pilot must ensure:</td>
</tr>
<tr>
<td>2a</td>
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<tr>
<td>2b</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Evaluation Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The information provided to participants meets the requirements of the Code of Health and Disability Services Consumers’ Rights Regulation 1996, rights 5, 6 and 7 and that these are fully met.</td>
</tr>
<tr>
<td>2. Information is collected through the IT system for the BSP which includes the BSP MDS for monitoring and evaluation purposes.</td>
</tr>
<tr>
<td>3. The internal audit process ensures that all criteria are complied with, and identified issues are addressed through a CCI process.</td>
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</tbody>
</table>

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<tr>
<th>Evaluation Targets</th>
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<tbody>
<tr>
<td>1. 100% of known eligible participants are sent an invitation for screening within two years (within 24 months) of commencement of the BSP.</td>
</tr>
<tr>
<td>2. At least 95% of eligible individuals are recalled for screening within 24 months of their previous invitation for screening.</td>
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<tr>
<td>3. All other criteria are met.</td>
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</tbody>
</table>

A progress report to the BSP Steering Group dated 25/3/2013 reports three fields on the register in relation to withdrawals; withdrawn, on hold and ineligible. Notes discussion with developer re further sub categories and that a draft letter to ID (MoH Information Directorate) requesting more resource applied to the management of the BSP register be held over to next meeting.

A progress report to the BSP Steering Group dated 21/11/2013 reports that PHO enrolment data has not been uploaded since the beginning of 2013 meaning that addresses may not have been updated.

When the Pilot extended into the second two year period (Cycle 2), WDHB identified that the issues with the BSP register were increasingly causing concern and needed to be addressed. Proposed

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31 Report #34 see Appendices 1 and 2
32 Report #31 see Appendices 1 and 2
solutions to issues had not been approved. WDHB advised that in early 2014 they started recording all returned mail on a spreadsheet to facilitate regular checks with PHO age/sex registers and hospital systems for new addresses. As the number of entries on the spreadsheet grew, the ability to check all routinely became impossible.

When efforts by WDHB to get the issue fixed through systems updates were not approved, further additional mitigation strategies were implemented by WDHB:

- Public communications and campaigns had always been run to raise awareness and encourage people to join the Pilot. These campaigns now included a focus on advising people to contact the Pilot if they had not received an invitation or had changed their address. Publicity included local newspapers, local radio and other WDHB communications.
- From Oct-Nov 2014 WDHB ran a major publicity drive, through all community newspapers including editorials and advertising.
- Primary care providers were provided with a traffic light tool whereby they could access information about their eligible patients’ participation status. Green = negative result within the last two years and nothing to do, orange = positive in the last two years and red = eligible and no result on the system. Primary care providers could request that kits be sent to those who had not yet been invited and they could advise of a change of address via the same tool.

WDHB maintained a programme of advertising for people to contact the BSP Coordination Centre if they had not received an invitation. While mail was the formal means of inviting people to participate in the Pilot, multiple other approaches as outlined above were used to increase the likelihood that eligible people would be aware of the Pilot.

A memo from WDHB to the BSP steering group dated 22/1/2014 recommends that the steering group approves that people who have mail returned ‘gone no address’ are moved to two year recall, and that people who do not respond to two, two yearly invitations including invitation letters returned GNA are moved to a pathway status of ‘withdrawn’. WDHB sets out clearly that moving a GNA person to ‘withdrawn’ status means they will not be invited again unless they contact the Coordination Centre, that even though their address details may subsequently be updated via PHO uploads into the NHI, they will never be re-invited. And that as a consequence there may be people on the BSP register with a correct address who will not be given an opportunity to participate. The memo indicates that the Pilot Service Delivery Model states that when a person has not responded including active follow up they are moved to two yearly recall, but does not state what happens when invitation mail is returned GNA.

The minutes of the BSP Steering Group dated 28/1/2014 record the above paper was tabled recommending:

- People whose invitation letters are returned “gone no address” are placed on two year recall, and
- People who do not respond to two successive two yearly invitations including the “gone no address” people are moved to the pathway status “withdrawn”

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33 See Appendices 1 and 2
34 See Appendices 1 and 2
The minutes show that the Steering Group approved the first recommendation but agreed people should have three opportunities to participate. WDHB advised the reviewer that the work on the BSP register to allow the first recommendation to happen did not occur and they were uncertain if work on the register to allow the second recommendation to happen ever proceeded.

WDHB had requested access to the NHI repeatedly so that when a team member was advised of a new address they could update it in the NHI immediately. This was not provided. From 2014 WDHB had access to the NHI via iPMS (the WDHB patient management system). WDHB staff would check the iPMS for address updates for returned mail and if a new address was provided on the consent form WDHB could update this in iPMS which would in turn update the NHI.

WDHB approved two trips by their staff to Wellington to hold face to face meetings to discuss and attempt to progress concerns related to resourcing improvements in the BSP register. WDHB made a trip to the MoH in early 2014 to convey WDHB’s frustration at the lack of progress with register development requests at a meeting attended by MoH IT staff, NHI staff and MoH BSP team members. The BSP register’s limited functionality, increasing dependence on workarounds and the lack of timely updates posed a risk. There was a sense on WDHB’s part that the MoH Cancer Team were struggling to get traction on IT prioritisation and budget for work to improve the BSP register.

A memo from the MoH to the Major Projects Committee dated 11/4/2014 recommends $30,000 in the 2013/14 financial year to cover investigation and redesign to ensure participant details are as up to date as possible. Notes that updates are not working as planned and urgent work is now required for redesign.

A progress report to the BSP Steering Group dated 24/4/2014 records that register functionality continues to compromise operational efficiency. That the register was satisfactory for go live but needs significant ongoing attention to meet all operational, audit and reporting requirements. Notes that there are too many workarounds, and that this is inefficient. The report notes that attention is required from the MoH ID, Cancer Team, WDHB BSP and the developer.

The issue was discussed at the BSP Steering Group and the Chair wrote to the Director of the National IT Board (letter dated 1/5/2014) raising concern that frequency of new releases (to address issues) was not keeping pace, that there were too many workarounds which were inefficient and posed areas of risk. The letter also states that analysis of the first round of screening is compromised by limitations with the register and that further roll out would not be possible in the current state. The letter further states that the responsibility for securing additional funding and resources is unclear and recommends a meeting of all parties.

A memo from the Manager Bowel and Prostate Programmes MoH to the BSP IT meeting dated 9/5/2014 notes being aware of the issues including the letter as above.

The minutes of the BSP Steering Group dated 27/5/2014 record the letter to ID (MoH Information Directorate) resulted in a meeting in Wellington and that good progress was made. Records that it was clear there was some reluctance to put too much resource into a database that was only going

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35 See Appendices 1 and 2
36 See Appendices 1 and 2
37 See Appendices 1 and 2
38 See Appendices 1 and 2
39 See Appendices 1 and 2
to be needed until the end of the Pilot. States this issue was largely resolved at the second meeting. Noted:

- More rigour needed to be applied to upgrade process.
- Responsibilities clarified including who was responsible for presenting the business case for capital expenditure on the BSP register.
- Additional resource would be secured for the MoH BSP team for a fixed term.
- MoH BSP Team will work with ID to determine needs for a system to support national roll out.
- Risk #1 to be placed on the Funding and Planning Register. Risk #6 reduced to low risk/low impact. Risk #8 can be removed.

WDHB advised that decisions were made at the meeting but no action to make changes to the register to support these decisions actually resulted.

The BSP Coordination Centre Operations Manual dated 12/6/2014\(^{40}\) sets out operational aspects of the Pilot, including pre invitation, invitation and two year subsequent re-invitation procedures. This includes that the re-invitation at two years letter is worded to take account that some people may not have received an invitation in the first cycle because of an incorrect address.

A progress report to the BSP Steering Group dated 25/9/2014\(^{41}\) notes little progress improving accuracy of addresses on register, dependency on MoH address updating, and a steady stream of returned mail (approximately 5% of all mail sent, most of which is successfully re-sent to correct address located via GP or iPMS [WDHB patient record system]. This is re-iterated in the following progress report to the BSP Steering Group dated 11/12 2014\(^{42}\).

A BSP Population Register Analysis dated December 2014\(^{43}\) and conducted by the MoH identifies issues with address quality and this section of the analysis concludes that overall the PHO register(s) include about 13,000 people whose characteristics appear to meet the requirements of the BSP register, but they have not been invited to participate.

A BSP Database Review dated December 2014\(^{44}\) and conducted by the MoH in response to data quality issues notes that there are records for which there was a request for withdrawal at some stage, but which later become eligible again, by either changing their mind or better details being available. Notes uncertainty regarding the issues affecting reporting in any significant way and concludes they are a non-issue.

The Interim Evaluation Report of the BSP: Screening Round One dated 24/2/2015\(^{45}\) notes a number of critical limitations with the BSP register are impacting adversely on the Pilot. It is estimated based on returned mail that between 5-15% of eligible participants may not have received a letter or kit in screening round one potentially due to incorrect address details on the BSP register. States that in the early implementation stages there was insufficient dedicated data and IT resource at WDHB and

\(^{40}\) See Appendices 1 and 2
\(^{41}\) See Appendices 1 and 2
\(^{42}\) See Appendices 1 and 2
\(^{43}\) See Appendices 1 and 2
\(^{44}\) See Appendices 1 and 2
\(^{45}\) Litmus, CPHR, Sapere see Appendices 1 and 2
the MoH which contributed to a lack of timely updates to the BSP register resulting in challenges to ensure data quality.

The report recommends that the MoH comprehensively review the BSP register and implement a robust data quality assurance programme. In terms of participation the report states that at least 1,456 of those invited did not respond because of an ‘invalid/not found’ address (i.e. there was no up to date address on the register).

The report identifies that incorrect participant addresses are due to NHI details uploaded to the BSP register being out of date. As a result around 5% of pre-invitation letters are returned as not living at this address. Planned regular updates from PHO data to update NHI information and ensure eligible people moving into WDHB are offered bowel screening have not occurred.

Concerns are noted regarding understanding of the BSP register sitting with a small number of people in WDHB and the MoH, that some underpinning assumptions are not known, that there are areas of incomplete documentation and there are not enough dedicated data and IT resources at WDHB and the MoH. Employment of a new full time data manager (at WDHB) in October 2013 and some other changes to increase FTE (at the MoH) is noted as helpful.

Key improvements required are a strategy to enhance accuracy of participant contact details and to identify eligible participants moving into WDHB, and ensuring adequate IT support at the MoH to undertake updates and refinements to the BSP register as needed.

The number of MoH quality documents for the Pilot is noted as duplication and potentially confusing.

WDHB put an issue relating to test kits being sent to incorrect or out of date addresses onto the WDHB Pilot Steering Group register in August 2015 (this would have been reviewed and discussed at the Steering Group meetings). The risk was described as:

“Test kits may be sent to incorrect/out of date addresses. Medium Likelihood. Medium impact. Mitigations: All contact from potential/actual participants with the information line involves a check on whether register contains correct information – address, GP, phone number.”

A memo from the Principal Advisor Bowel and Prostate Cancer Programmes MoH to SCIIMGG MoH re Enhancements to the Waitemata BSP IT system for round 3 dated 9/10/2015 seeks support to upgrade the current Pilot IT system (the BSP register) to support extending the Pilot for Round 3. The memo states that in order to accommodate efficient running of Round 3 the IT system must be upgraded but there is no capital funding available in the current year.

The memo listed issues including the number and inefficiency of work-arounds, backlogs, people not receiving an invitation or test kit, and the cost of this is calculated as $156,000. Enhancements are recommended and the need for more flexibility is noted. Agreement for support to upgrade the BSP register for Round 3 at a cost of $245,000 is sought.

The memo proposed enhancements for Release 5 listed include allowing on hold (withdrawn) patients to be invited if they have previously been put on hold (withdrawn) due to returned mail but

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46 The reviewer was advised these updates were attempted but did not work.
47 See Appendices 1 and 2
they have an updated address on the NHI, issues with eligibility due to address changes, a ‘pending’ state and improvements on how work tasks are resolved.48

The MoH Risk Register for the delivery of a National Bowel Screening Programme (NBSP) dated 10/11/201549 includes current risks (not individually dated); insufficient IT maintenance, inadequate funding, IT resources not fully allocated to NBSP and participation.

WDHB felt that all possible was being done to address the returned mail GNA issue, except:

- The proposed IT solution fix had not been implemented
- Access to the NHI gateway had not been obtained. This would have updated the BSP register with any address updates it registered. This would not have been a total solution as the BSP register was not set up for such an address update to then prompt a re-invitation.

WDHB advised that Argonaut developers completed some analysis in an effort to find a fix but no work on the register occurred. The developers suggested raising a “Ticket”. The process for addressing issues that require an IT solution was to raise a ticket. A ticket is a service request to the database developers for a change, fix or enhancement on the database. It records all these requests and any comments made. It prioritises these and often includes a business analysis of what is required for the fix. It is the history of requests made, tracks their progress and shows who made the request and to whom it was assigned and any outstanding tickets. Those who have access can view all and share all this information – it is like a shared space.

Ticket #27550 was raised by WDHB in the IT vendor’s “TRAC” system to progress an IT solution to the issue. The TRAC system is used to record tickets and is accessible to Argonaut, MoH and WDHB staff. The date this occurred is unclear, the document is not dated and the print date is recorded as 27/11/2017. The oldest changes to the document relate to two years previously i.e. 2015.

The ticket asked the developers to come up with a solution so that “Withdrawn no address” flagged records were checked overnight against the NHI, if there was a new address the system would identify where on the pathway the person had been withdrawn and then remove the withdrawn status and update the address. The system would also need to prompt a re-invitation. It appears the ticket was closed by Argonaut around March 2017 on the basis that it had been fixed indirectly. WDHB advised that the ticket was closed in error (a different ticket referring to automation around management of worktasks not the GNA issue was meant to be closed).

The ticket is recorded as closed enhancement: fixed indirectly. Record of activity related to Ticket #275 “Returned mail – put on pathway hold with a reason code of “Returned mail”. The description is “If an address update comes through and the person is on pathway hold with that reason code, then they are automatically taken off pathway holiday.”

- The document change history from 2015 to most recent details changes that initially provide for allocation to withdrawn status, noting there is no automatic work task closure (date presumed 2015). Pathway hold flexibility would allow the user to put the person on pathway hold instead of withdrawing them as a work around. The returned mail document

48 The reviewer was advised that the request for funding was not approved.
49 See Appendices 1 and 2
50 See Appendices 1 and 2
is attached. A request to check and see how much automation can be done to reduce workload is recorded (date presumed 2016).

- The status is recorded changed from analysis to closed, and resolution changed to fixed indirectly in 2017 by Argonaut. It is documented that “Analysis for the ticket #186 has determined that automated resolution of WT00 is complicated and will require development of new algorithms and potentially collection of additional data. To help resolve worktasks on time, BSP+ has implemented worktask notification via email notification. Refer to the following ticket for more details: #359 Worktask email notification.”
- WDHB advised that the ticket only contains comments by Argonaut and the WDHB team and that there was no full analysis or costing completed in relation to this ticket.

Weekly to fortnightly ticket meetings were held. The MoH prioritised the tickets and decided what would be actioned and what would not.

The Returned Mail Management document dated 29/1/2016\(^{51}\) is an update to an earlier version. This sets out the procedure for processing all mail returned to the coordination centre including; enter details of returned mail on a spreadsheet, check to see if the BSP register has been updated with a new address, search for new address in IPMS or the PHO file (age/sex register), check ethnicity (Community Coordinator to follow up active follow up groups). If no address is found through the above processes they are withdrawn from the programme choosing the drop down option of Address not valid or not found.

The Final Evaluation Report of the BSP: Screening Rounds One and Two dated 1/8/2016\(^{52}\) notes estimates based on returned mail that between 5-15% of eligible participants may not have received a letter or kit in screening round one potentially due to incorrect address details on the BSP register. It is noted that there are known issues with the currency of addresses with a return to sender rate of around 6%. The invitation strategy is detailed. Efforts to identify correct addresses for returned pre-invitation mail are noted. That the workforce has been relatively constant in Round 2 is noted, and the WDHB flexible student workforce response is noted.

It is noted that an issues register is maintained, issue are reviewed weekly, quality indicators are reviewed every third WDHB Steering Group meeting.

It is noted that the BSP register needs to be up-to-date, invite all those eligible to take part, inform “real time” follow-up activities and support reminder processes through interfacing with existing primary care systems. Further the BSP register needs to enable the monitoring of uptake and equity across the pathway. The reviews undertaken in response to the Interim Report are noted and that Lee (2014\(^{53}\)) found a lack of currency of participant contact details which may mean some people may not receive an invite. The report notes that in this context (6% return rate) most but not all eligible participants are being invited to participate.

The report notes that there have been five upgrades to the BSP register over the course of the Pilot, but that due to constrained IT resources at the MoH not all functional issues have been addressed. The use of manual processes in the BSP Coordination Centre and the demands this places on

\(^{51}\) See Appendices 1 and 2

\(^{52}\) Litmus, CPHR, Sapere see Appendices 1 and 2

\(^{53}\) See Appendices 1 and 2
capacity are noted. It is also noted that not having regular PHO enrolment updates means that contact details in the BSP register may be out of date or an incorrect GP may be listed.

The report concludes that no substantial environmental or clinical safety issues were identified. A systematic review of the operational functionality of the BSP register to determine whether it can work efficiently for a national bowel screening programme is needed. This will clarify further updates required, including ensuring participant and GP information on the BSP register is up to date.

The report concludes that the Pilot has done its job of testing a bowel screening pathway design, identifying feasible roles, and risk to translate to a national bowel screening programme and learning needs to be carried forward into a national roll out. The report states that for the BSP register to operationally manage a national bowel screening programme, at least in the interim, a number of enhancements and greater integration with other systems are needed and recommends a functional review of the operation of the BSP register if used to support a national bowel screening programme.

The Programme Business Case and Tranche 1 Business Case National Bowel Screening Programme dated 29/8/2016\(^\text{54}\) noted:

- “The IT solution established to support the pilot site was specifically developed for the Bowel Screening Pilot, within constraints of costs and timeliness and within the context of the relatively small nature of the pilot. Numerous enhancements to the pilot system have since been applied successfully, as new requirements and changes have been identified.”
- “A key assumption is that the business processes that are operating in the pilot site are largely representative of those that are expected in a national rollout. Going forward into the national programme, the assessment of the existing pilot system is that it would not be possible to successfully scale, in its current form, to meet the needs of a national rollout to a further 19 DHBs. This assessment is based on the knowledge gathered from the pilot system, including the identification that approximately 50 percent additional functionality is achieved manually by the pilot and would need to be automated in a national system.”
- **Information Technology to support a National Bowel Screening Programme:** There would be a single national IT solution to support the National Bowel Screening Programme, fully integrated across all DHBs... The IT solution (or some components thereof) would therefore be required to be available 24 hours x 7 days x 365 days a year and highly resilient... This would reuse existing technology components where appropriate and leverage and extend existing integration patterns, for example Ministry of Health investments in common services, such as the National Health Index (NHI), Address Services (eSAM) and Enrolment and Eligibility Services.”

The Returned Mail Management document dated 10/11/2016\(^\text{55}\) is an update to an earlier version. This sets out the procedure for processing all mail returned to the coordination centre.

WDHB advised that this is more correctly described as a working document associated with Ticket #275\(^\text{56}\). It summarises the processes as part of Ticket #275 and includes options suggested for addressing the issue. It should be read in conjunction with Ticket #275. Options up to #6 and #7

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\(^{54}\) See Appendices 1 and 2  
\(^{55}\) See Appendices 1 and 2  
\(^{56}\) See Appendices 1 and 2
were what the Pilot was doing. None of the options beyond #6 and #7 were put into practice; they were suggestions as to how returned mail might be managed.

The document demonstrates that work was done to scope out what the changes in the BSP register may have been needed to address the returned mail GNA issue but it is important to note that the work was never completed.

Ticket #275 sets out procedure including; enter details of returned mail in a diary note in the BSP register, check to see if the BSP register has been updated with a new address, search for new address in IPMS or the PHO file, contact the GP, try phoning the person. If no new postal address is found delete the incorrect address from the BSP register as this cannot be updated automatically. Check ethnicity (Community Coordinator to follow up active follow up groups). If no address is found through the above processes raise a WT024. After a WT024 is raised this will track overnight with the NHI for a new address. There is a note “This is our ideal and we would like it to be electronic”.

WDHB advised that these were suggestions that had not been analysed and therefore do not represent a discussed and approved process.

A five step process is set out as follows:

1. If a new address is found in NHI a date check is done against the BSP register address.
2. If a new address is found a check is done that the domicile code is valid.
3. If the domicile code is out of area update the record to invalid due to domicile code
4. If domicile valid check address valid.
5. If address valid carry out one of four actions to update the pathway state.

Questions are raised as to the criteria for establishing there is a new address, and it is noted there were issues with WT024 in the past.

(The reviewer was advised by WDHB that WT024 was not used for this purpose since 2013).

The BSP Risk Management Post Implementation document dated February 2017\textsuperscript{57} in the document title, includes regular reference to go live timeframes (early 2012). Risks, likelihood, impact and mitigations are recorded. Risk No 2 states “The Register does not accurately reflect the eligible population within WDHB.” and is recorded as a high likelihood, medium impact risk (Note: The dates risks were added to this register is not recorded. The reviewer was advised that Risk No 2 was added in January 2014 but did not sight evidence to this effect). Mitigations were recorded as:

- “Reconfirm the business rules which determine the Register population"
- “Establish a process of regular updates to maintain the eligible population on the register"
- “Maintain as many manual updating processes as resources permit"
- “Maintain a programme of advertising for people to contact the coordination centre if they have not received an invitation”

MoH BSP Due Diligence Interim IT Solution Assessment dated 12/5/2017\textsuperscript{58} completes an assessment of the BSP+ IT\textsuperscript{59} solution to understand whether or not the IT solution can be further enhanced and

\textsuperscript{57} See Appendices 1 and 2
\textsuperscript{58} See Appendices 1 and 2
extended in a way the functional suitability can meet short to medium operational needs, and is safe for bowel screening. This was in relation to rolling out a national programme. It details risks and makes a number of recommendations including documenting the full functional scope of the BSP+ IT solution including any outstanding change requests or defects.

“The BSP+ IT solution is not suitable as the foundation for a long term or strategic IT solution. This includes the NBSP and/or other potential future population health programmes as it would require significant rework and extension to support additional requirements. The functionality and scope of release 7 of the BSP+ IT solution should be locked down, and only change to support critical operational enhancements of defects that should be supported to ensure operational and quality risk is reduced as the IT solution is rolled out to further DHBs”.

The Bowel Screening Register Standard Operating Procedure (SOP) Manual dated July 2017\(^{60}\) includes a section “Returned Mail” which sets out manual processes to work through and which appears to be an update of previous versions. Notes that due to time restraints, returned mail can be partly investigated (to the step where the participant’s medical centre is contacted) and followed up later. If the investigation is delayed a work task should be created so the participant will not get any further mail. The workflow concludes with “Withdraw the participant from BSP Register” and “End” for the process where all efforts to check for an updated address have been unsuccessful.

MoH NSU staff identified a screening incident related to returned mail on 20/9/2017\(^{61}\) and completed a Screening Incident Report Form for this on 21/9/2017\(^{62}\). The NSU screening incident report states:

“It has become apparent that the ICC has been using the ‘withdraw’ option in BSP+ in instances that may result in people being inappropriately excluded from the programme. This was initially identified through looking at the returned mail process. When people had mail returned (address unknown) and further address searches did not identify a valid address the person was permanently withdrawn from the programme. BSP+ routinely searches for address updated in the NHI database however people who have been withdrawn from the programme do not get invited to rescreen even if there is an updated valid address in the system.”

Investigations undertaken are recorded as “Preliminary investigation of affected cohort to quantify the size and scope of the issue. Initial cohort has been cross matched with the cancer registry and mortality database and NHI.”

Immediate action to mitigate any risk is recorded as “On 20/09/17\(^{63}\) ICC was instructed to cease withdrawing people from the programme unless the individual or their GP has requested it. This took effect on 21/09/17.”

\(^{59}\) The IT solution specifically developed for the pilot, within constraints of costs and timeliness, and within the context of the relatively small, single site – WDHB – was referred to as the “BSP IT solution” or “Pilot Register”. “BSP+” was a term used to describe the solution after subsequent numerous enhancements were applied.

\(^{60}\) See Appendices 1 and 2

\(^{61}\) The reviewer was advised by MoH staff that the date recorded on the Screening Incident Report Form – 4/9/17 - was an error and that the incident was identified 20/9/2017.

\(^{62}\) See Appendices 1 and 2

\(^{63}\) The date is recorded on the form in error as 20/07/2017.
MoH NSU staff contacted WDHB staff by phone and asked them to stop the process immediately. MoH NSU convened an 'incident group' made up of senior staff within the NSU. The BSP Leadership Group which considered adverse events routinely was informed 22/09/2017.

The identification and reporting of this screening incident generated an analysis by NSU staff which resulted in the responses set out in the Review Process section of this report.

**National Bowel Screening Programme planning**

The Pilot was considered very successful against its participation objectives. 60% of the eligible population was participating which was higher than international rates (this also meant that 40% of the eligible population were not participating).

In December 2015 The Treasury Gateway Review Report (Review 0/1)\(^{64}\) stated that the Pilot had exceeded clinical expectations and that there was a high level of confidence in the screening processes and testing procedures adopted by the Pilot. The report noted that the Pilot has “given an opportunity to trial and end to end process and to make modifications to the service delivery model, system, processes and communications based on findings to improve participation and clinical results. It also provided an opportunity to test capacity and capability and to develop core collateral for a national programme.”

The report found that there is universal support and compelling international evidence for the introduction of a national bowel screening programme. The status is Amber i.e. “Successful delivery appears feasible but significant issues already exist requiring management attention. These appear resolvable at this stage and if addressed promptly, should not impact delivery or benefits realisation”.

The report identified concerns and made recommendations related to urgent need (do now) for strategic leadership, governance, improvement or development of a more appropriate IT system (noting end users described the system as “being a nightmare”). The report includes comment that while there had been investment in the IT system supporting the Pilot, there were concerns about timeliness of (MoH IT) response, adequacy of the investment and the recent decline of a capital request to fund necessary upgrades. The report stated that:

“The availability, reliability and functionality of IT systems are the highest risk to the successful implementation of the Programme”. And,

“There is a plethora of steering and advisory groups associated with the programme and more broadly the screening activities of the Ministry. It was identified that representation on all these groups was difficult to achieve but also meant that information was variably understood. The new governance structures should replace a number of these committees”.

As part of Budget 2016, Cabinet approved partial funding to commence the work required for a staged roll-out of a national bowel screening programme subject to a re-stated Programme Business Case. The Programme Business Case was approved by Cabinet in August 2016.

\(^{64}\) See Appendices 1 and 2
The Final Evaluation Report of the Pilot (Sapere, CPHR and Litmus 1/8/2016\textsuperscript{65}) concluded that the Pilot had done its job of testing a bowel screening pathway design. Overall the results of the Pilot were considered to support a national bowel screening programme. In 2016 the MoH started planning for a new national bowel screening programme.

An External IT Review for the National Bowel Screening Programme\textsuperscript{66} (Accenture 17/8/2016) identified three findings: the proposed overall IT delivery approach was sound, further work was required to validate proposed IT solutions and there was an evident lack of alignment between Business and IT with urgent need for the right structures, governance, resources, approach and delivery disciplines for a programme of this size and complexity.

In March 2016 a new executive structure was announced at the MoH. The SCI directorate was disestablished and the Service Commissioning directorate was established. Services reporting to Service Commissioning were then reviewed and Personal Health was disestablished. In November 2016 MoH responsibility for the Pilot and national programme moved to sit with the MoH National Screening Unit (NSU). The NSU reports to Service Commissioning. The MoH BSP team transitioned to the NSU as part of this change. The reviewer was advised there was resistance from some members of the team to coming to the NSU. The NSU team expected that the MoH BSP team would continue to work with WDHB and act as a conduit of information in relation to application of learning from the Pilot, to planning for the national programme.

The NSU Clinical Director and Manager were involved once the business case for the national programme was underway.

The NSU team initiated a discovery phase from March 2017 onwards. The purpose was to understand the BSP register and to understand what was happening to people in the system, lots of audit and data checking was involved. This process identified a number of issues with the Pilot and BSP register. WDHB advised that they were not involved in supporting this discovery phase and that they consider an opportunity to apply WDHB learning was lost by not including them in this process.

The business case proposed a new IT platform would be built for the national programme (i.e. the BSP register would not be used). A sticking point was getting the national programme business case through Treasury. These delays meant that timeframes extended. Treasury recommended options analysis regarding building an in-house platform and revisiting commercial options.

The options analysis was redone (Ernst Young 2017\textsuperscript{67}). Options were:

- Expand the current system
- Scrap the current system and start again
- Enhance the current system for a few DHBs and start with this (BSP+)  
  * “BSP+” was a term used to describe the solution after subsequent numerous enhancements were applied to the current system (the BSP register).

\textsuperscript{65} See Appendices 1 and 2  
\textsuperscript{66} See Appendices 1 and 2  
\textsuperscript{67} See Appendices 1 and 2
The recommendation was to go to market for a potential off the shelf system. This meant there was no IT system in place and launch of a national programme was planned for 2018. It would not be possible to roll out the National Bowel Screening Programme if there was no IT system.

Ernst Young concluded that the existing system (the BSP register) could be used in the interim for the National Bowel Screening Programme and for more DHBs than WDHB, Hutt Valley and Wairarapa DHBs. Changes to the BSP register were required to add Hutt Valley and Wairarapa DHBs. This was called the BS Interim Solution (BSP+). Ernst Young reported that the system in use for the 3 DHBs could technically support 20 DHBs but had shortcomings and limitations, could not achieve the strategic objective and could not be the long term solution.

The third option (BSP+) was selected to progress the national programme as an interim measure.

The Ernst Young report listed capabilities to be addressed including governance and risk management of the current BSP+ IT solution. The report described governance as inconsistent and not well-documented, noting that risk assessments are performed ad hoc. The report recommended that steps be taken to establish clear integrated governance and communicate policies and risk plans to all stakeholders.

In May 2017 The Treasury Gateway Review Report (Review 0/4)68 identified that:

- The national programme team had been significantly increased over the previous four months,
- The appointment of a Primary Care Clinical Lead had been received positively, and
- Placing the programme within the NSU was seen as a positive development providing access to experienced screening programme resources and alignment with population based health strategies, quality frameworks and thinking.

The report listed key risks for the national programme as:

- Overall programme management approach,
- Development of a suitable clinically safe national IT solution,
- Communication and relationships, and
- Timeframe.

The report also identified concerns with the quality of documentation, clarity of roles and the threshold for triggering change requests. The report also noted variable quality in the Risk and Issues Management Plan and that there was a plan in place to refresh the risk register and improve the escalation and monitoring of high, very high and deteriorating risks to the Governance group. A fortnightly managers meeting would manage other risks.

The change of focus onto the National Bowel Screening Programme in 2016 meant there was less focus on the Pilot from the MoH team. WDHB continued to run the Pilot as business as usual. Regular BSP Steering Group meetings with both WDHB and MoH in attendance, and regular IT teleconferences with the MoH, the developer and WDHB Pilot data manager continued.

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68 See Appendices 1 and 2
Returned Mail/Gone No Address issue – identification of the issue as an incident

A draft National Bowel Screening Programme (NBSP) Withdrawal Incident document dated 19 September 2017\(^\text{69}\) sets out analysis of the issue and recommends “An incident team be established, immediate action is taken to stop return mail people being put in withdrawal status, confirmation with NCC on the process for returned mail/participant withdrawals and case review for the three cancer cases and appropriate follow up action.”

As detailed above, MoH NSU staff identified a screening incident related to returned mail on 20/9/2017\(^\text{70}\) and completed a Screening Incident Report Form for this on 21/9/2017\(^\text{71}\).

There was concern that a very serious incident had been identified. The incident report stated “Some people who have been withdrawn but had a subsequent address identified have been diagnosed with colorectal cancer”. It was decided that MoH NSU staff would investigate the issue trying to understand and quantify it.

The MoH NSU then convened an 'incident group' made up of senior staff within the NSU to look into the incident. MoH NSU staff involved at this time were not aware that the issue was known from the beginning of the Pilot. Nor were they aware that throughout the Pilot the issue had been:

- Planned to be addressed through IT functionality in the set-up of the BSP register
- Communicated to the MoH by WDHB,
- Jointly considered, articulated and decisions on how to manage it agreed and documented,
- The subject of workarounds and mitigation efforts
- Recorded on the BSP Risk Management Post Implementation document dated Feb 2017\(^\text{72}\),
- Raised and potential solutions proposed regularly – see key document timeline.
- The subject of repeated proposals to fix the issue and that these were repeatedly declined or not progressed.

A decision was made to stop people being put into a “Withdrawn” status immediately. This could now only occur at a person’s request or at the request of their doctor.

MoH NSU staff phoned WDHB staff and asked them to stop the process (of withdrawing people) immediately. The decision was to stop people being put into a “Withdrawn” status immediately, and that this could now only occur at a person’s request or at the request of their doctor. This phone call was followed by an email from the MoH to WDHB stating that the practice of putting people for whom GNA mail was returned into “Withdrawn” status needed to cease, and advising that there was potential harm to people not invited.

The BSP Leadership Group which considered adverse events routinely was informed 22/09/2017.

MoH analysts who looked into the issue created queries that they ran on the data. This was more complex than anticipated. Queries had to be refined several times, key words searched and data “mined”. One reason for “Withdrawn” status was “Address not found or invalid”. This option in the

\(^{69}\) See Appendices 1 and 2
\(^{70}\) The reviewer was advised by MoH staff that the date recorded on the Screening Incident Report Form – 4/9/17 - was an error and that the incident was identified 20/9/2017.
\(^{71}\) See Appendices 1 and 2
\(^{72}\) See Appendices 1 and 2
drop down list implied it was an acceptable reason to withdraw someone and that it was not an error or incorrect action. Some information was free text. This investigation took about a month.

When the MoH BSP Leadership group was provided with the results of the investigation it was considered that there was sufficient concern that patient harm may have occurred. The MoH response to the incident proceeded. WDHB did not receive any further communication until as set out below, nor were they invited to participate in the work to quantify and understand the issue.

The MoH NSU leadership informed senior MoH management and sought advice from the Health Quality and Safety Commission, the Health and Disability Commissioner’s office, ACC, Public Health and ethicists. The advice from these experts included concern that it was a long bow to draw to connect people not having been invited to the Pilot with them developing cancer. The experts consulted expressed a consistent view that there was a responsibility to people, that there was a need to be open and transparent and that disclosure was important.

The results of the MoH analysis indicated:

- 12,800 had been allocated “Withdrawn” status because their mail was returned GNA.
- 2,500 of this group had had a different address in the NHI and were in WDHB region.
- 14 of this group had been diagnosed with bowel cancer.
- 8 had had an address updated prior to the diagnosis of cancer.

Six weeks passed and activity continued at the MoH in response to the incident. On 30/10/2017 WDHB emailed the MoH seeking information about what was going on and expressing strong concern at being alerted to something very serious back in September but then not receiving any further information.

A teleconference with MoH NSU and WDHB was held 3 Nov 2018. MoH NSU staff informed WDHB of a serious incident, that an audit of the BSP register had been done and cross referenced with the national Cancer Registry. The concern was that a number of people had been withdrawn from the programme as their mail had been returned GNA however their address had been updated in the NHI and that some of these people had been diagnosed with cancer.

At the teleconference it was agreed the MoH NSU would be in touch with WDHB to validate data. WDHB noted it was very important to re-invite the 2,500 group. The incident was considered a serious event by the MoH NSU and daily briefings were initiated. WDHB tabled concerns about the time it had taken from identifying the issue 6 weeks prior and the meeting. The MoH response was that they had wanted to confirm that there was an incident and that it had taken time to look into the data and quantify.

The MoH’s decision was that the 2,500 people would be re-invited immediately and that their invitation letter would include an explanation and apology for the delayed invitation. WDHB considered that most of this group could be invited without the need for an apology or explanation as they were within the two year re-invite time period. The NSU view is that eligibility started at the date of invitation.
A manual workaround was put in place matching the returned mail GNA list against the NHI list to look for any different or updated addresses. If any were found the National Coordination Centre was advised, the address was updated in the register and invitation sent.

WDHB and MoH agreed the terms of reference for a clinical review\textsuperscript{73} of the eight cases.

WDHB expressed concern that the terms “error”, and “incorrect withdrawal” were being used and that these were unfair and inaccurate representations of the issue. WDHB’s view was that the returned mail GNA SOP had been signed off by the MoH and was included in the updated Register Operating Manual provided to the MoH prior to the Hutt and Wairarapa programme launch. WDHB contested the MoH view that there was an error and maintained that a more fair and accurate description would be that an opportunity to invite people to participate in the Pilot had been missed, because of a system issue which had not been addressed, and that this type of issue was what a pilot programme could expect to uncover.

WDHB was very concerned for their reputation and that their population’s confidence in the screening programme would be eroded. WDHB was deeply unhappy about the implications of the language being used and made attempts to address this. WDHB did not feel that the agreement that the MoH and WDHB would work together through all Pilot matters was being upheld. WDHB also considered that they could have provided a valuable contribution that would have ensured a better and earlier understanding of the issue across all involved if they had been consulted sooner. WDHB considered that the issue could have been worked through together in a straightforward manner to identify what needed to be done and then to act.

WDHB was concerned that the MoH response was escalating the issue without an established understanding of the cause. WDHB noted that in the context of running the Pilot, the invitation strategy included smoothing demand by inviting people over a two year period. So a person could be invited in month one of a two year cycle or month 24 i.e. a two year period would pass before they received their invitation. For a number of the 2500 group they were within their two year cycle.

WDHB noted that the issue and response were in the context that this was a pilot programme, set up to test if it was possible to develop a population register and a successful bowel screening programme for New Zealanders. WDHB considered the MoH NSU was retrospectively applying requirements that were not part of the implementation of the Pilot. WDHB considered the appropriate response would be simply to re-issue invitations to most of this group. WDHB was also concerned that incorrect “error” terminology had been in use for 6 weeks beforehand and that it would be difficult to ever redress this.

The MoH NSU view was that people who were eligible and on the register had missed out on being invited to participate in bowel screening and that this constituted a serious incident. The MoH NSU view was that there was a duty of care from the point at which an individual is invited to join screening, to do everything possible to enable them to participate. Different information was available that could have prompted a further invitation for some people who were eligible, on the register and for whom mail had been returned GNA.

\textsuperscript{73} see Weston Report 20/11/2017 - Appendices 1 and 2
The MoH NSU response was that open disclosure was indicated in line with the Health Quality and Safety Commission’s policy\textsuperscript{74} and the Health and Disability Commissioner’s guidance\textsuperscript{75}. The response included provision for full information to be given to those affected in the spirit of open disclosure and communication as per the policy and guidance above and including open disclosure to those who were not invited and had developed bowel cancer.

The Clinical Director of the NSU sent a letter dated 8/12/2017\textsuperscript{76} to all those allocated “Withdrawn” status because their mail was returned GNA and who had a different address in the NHI system. The letter re-invited them to take part in free screening.

The MoH’s Clinical Director NSU and Clinical Director Bowel Screening conveyed an apology to the three patients in consultation with their General Practitioner (family doctor). Where possible this apology was communicated directly to the patient.

On 13 February 2018 during the process of this review, the Minister of Health, Dr David Clark ordered an independent review of the National Bowel Screening Programme. Dr Clark noted that the MoH had taken full responsibility for this matter and as Minister of Health apologised unreservedly.

MoH NSU staff acknowledged that with hindsight not including WDHB in the response from the outset was not ideal and that they should have engaged directly with WDHB instead of trying to work it through at the MOH end. MoH staff acknowledged that WDHB was deeply concerned for the people of its region. The MoH did extend an apology to WDHB for the delay in involving them. MoH staff also commented that it was not a good note on which to end the Pilot, as it overshadowed the fact that the Pilot had demonstrated a national screening programme was indicated, and had achieved really good results.

\textbf{GNA issue – going forward risk management and control}

MoH NSU staff confirm that since identifying the issue with people allocated “Withdrawn” status because their mail was returned GNA, a new process has been implemented. A list of updated addresses from the NHI is provided to the NCC (National Coordination Centre) weekly, and that while checking this against the national programme register is still currently a manual process, it is manageable as it is a small number each week.

\textsuperscript{74} https://www.hqsc.govt.nz/our-programmes/adverse-events/national-adverse-events-policy/
\textsuperscript{75} http://www.hdc.org.nz/resources-publications/search-resources/leaflets/guidance-on-open-disclosure-policies/
\textsuperscript{76} See Appendices 1 and 2
Findings

Bowel cancer is one of New Zealand’s most common cancers and the second highest cause of cancer death. More than 3000 New Zealanders are diagnosed with bowel cancer each year and more than 1200 die from it. Bowel screening can detect cancer at an early stage when it can often be successfully treated. It is best practice internationally to pilot a screening programme before offering it more widely, to ensure it is safe for participants, there is capacity to provide timely diagnostic and treatment services and that all processes are working correctly.

Information from the Waitematā DHB Bowel Screening Pilot has helped to inform decisions about the National Bowel Screening Programme. Data collected during the Pilot has provided vital information on participation levels, cancer detection rates and the impact on health services.

The Pilot invited almost 200,000 Waitematā residents between 2011 and 2017 and successfully screened 117,000 people. 375 people had cancer detected through this screening as at March 2017.

The reviewer was asked to determine the circumstances surrounding concern that a group of people eligible for free screening through the Bowel Screening Pilot (referred to as the Pilot or the BSP henceforward) had not been invited to participate when they should have been. These people’s invitation mail had been returned “Gone no address” (GNA) and the NHI had a different address for them.

The root cause of this set of circumstances arising is that the management of the returned mail GNA issue was not addressed by proposed IT functionality when the register was first set up. This functionality was intended (through linking the NHI to the BSP register) and planned for, but ultimately was not resourced by the MoH IT Board. When the decision was made not to resource this IT functionality in the set up of the BSP register, the consequences for people eligible for the Pilot did not appear to have been explicitly explored or considered. The reviewer did not sight any documentation that related to this decision being made or the consequences being considered by the Pilot’s governance structures.

Further attempts to address the issue then occurred but did not result in solutions that resolved the issue. Key decisions were made within the context of establishing and running a pilot programme to learn and identify issues to inform the decision about a national bowel screening programme.

When the decision was made to change people’s status to “Withdrawn” when their mail was returned GNA a key action that would have potentially resulted in earlier detection of the issue and its consequences, would have been to initiate at least two yearly (at the conclusion of each two year cycle) review of people “Withdrawn” on the BSP register. This would have ensured that each person’s status and address was at least re-considered within the two year period of the cycle (and therefore within the BSP Interim Quality Standards Final Version 2. Standard 2 “All eligible people within the Bowel Screening Pilot will be offered bowel screening every two years.”)

WDHB advised that Coordination Centre staff were reviewing returned mail on a weekly basis and that they consider the key issue was that there was no response to repeated requests for IT development of the BSP register. WDHB also notes that two yearly review without electronic support would have been unmanageable.

Efforts to progress a solution through IT functionality continued throughout the period under review and identified ongoing risk related to returned mail management, GNA and address accuracy.

At the end of Cycle 1/beginning of Cycle 2, the Memo (22/1/2014) from WDHB to the BSP Steering Group\(^78\) was explicit that moving a person for whom mail has been returned GNA to ‘withdrawn’ status means they will not be invited again unless they contact the Coordination Centre, that even though their address details may subsequently be updated via PHO uploads into the NHI, they will never be re-invited. And that as a consequence there may be people on the BSP register with a correct address who will not be given an opportunity to participate. This memo did not prompt a review of the risk to people “Withdrawn”.

At the end of Cycle 2/beginning of Cycle 3, there was an expectation by both MoH and WDHB staff that outstanding issues and fixes in the BSP register would be addressed however proposed improvements to the BSP register were declined by the MOH IT Board.

IT functionality solutions to resolve the issue by enhancing the BSP register were proposed numerous times through the three cycles of the Pilot. However decision makers at the MoH IT Board repeatedly declined these proposals.

Decision making and proposals for solutions were being made in the context of balancing resources and priorities across major programmes of work at the MoH including the Pilot. This was particularly relevant for IT resourcing of improvements to the BSP register as there was no provision for IT in the Pilot budget so the MoH IT Board decided on proposed solutions.

MoH and WDHB had input into and were informed of the management process, workarounds and proposed IT solutions. In particular:

- “Returned Mail Management” dated 6/4/2012\(^79\) sets out the process for managing returned mail and includes steps to find an up to date address. In the case of this not being possible it concludes “If after exhausting all possible resources and you are still unable to locate or contact the participant then Withdraw them in BSP”\(^80\). The reviewer did not sight documentation that evidenced a decision to take this action but the document indicates an agreed process from at least April 2012 where if a current address was not identified by a series of efforts, a person’s status would be altered to “Withdrawn”.

- In January 2014 in a Memorandum\(^81\) from WDHB to the BSP Steering Group which included both MoH and WDHB staff, WDHB recommends the steering group approves that people who have mail returned ‘gone no address’ are moved to two year recall, and that people who do not respond to two, two yearly invitations including invitation letters returned GNA are moved to a pathway status of ‘withdrawn’.

WDHB clearly sets out the consequences of the situation in the memo i.e. that moving a person for whom mail had been returned GNA to ‘withdrawn’ status means they will not be invited again unless they contact the Coordination Centre, that even though their address details may subsequently be updated via PHO uploads into the NHI, they will never be re-

\(^78\) See Appendices 1 and 2
\(^79\) See Appendices 1 and 2
\(^80\) This instruction meant that the person’s record was changed to “Withdrawn” status. It does not mean they were removed from the register altogether.
\(^81\) See Appendices 1 and 2.
invited. And that as a consequence there may be people on the BSP register with a correct address who will not be given an opportunity to participate.

- WDHB raised Ticket #275 in 2015 to progress an IT solution (this was closed – WDHB advised this was an error - in 2017 without the proposed solution being actioned).

When the issue of management of mail returned GNA was identified by WDHB at the outset of the Pilot manual workarounds to try to identify a different address were agreed with the MoH and implemented. A spreadsheet of people allocated “Withdrawn” status for this reason was maintained. However these manual workarounds were time consuming and became unsustainable as the volume of returned mail increased. The end result for people for whom mail was returned GNA and for whom a different address was not found was that they were allocated “Withdrawn” status. These workarounds were not a solution that fixed the issue.

When initial efforts by WDHB to get the issue fixed through an IT solution were not approved, WDHB implemented further additional mitigation strategies – publicity campaigns and a tool for primary care providers. Further efforts into 2015 by WDHB and the MoH Bowel Screening team to secure an IT system solution for the issue were still repeatedly declined by the MoH IT Directorate.

It is important to note that all these decisions in terms of changing people’s status to “Withdrawn”, workarounds, further mitigations and solutions (including decisions to decline proposed solutions) were being made in the context of a time limited pilot, set up to test both strategic and operational issues, budget constraints and priorities.

In summary:

- In the set-up of the Pilot the returned mail GNA issue was expected to be addressed through IT functionality, but this was not resourced.
- At the outset of the Pilot as mail returned GNA began to be received, process management decisions were agreed by the MoH and WDHB and workarounds implemented but these were not solutions and the issue was not fixed. Manual workarounds became unsustainable.
- The process developed to manage returned mail resulted in people’s records effectively being closed from any future re-issue of invitation.
- Repeated attempts to secure funding for resources, an IT enhancement, functionality or solution were declined.
- Around March 2017 Ticket #275 (opened in 2015 to secure an IT solution to the returned mail GNA issue) was closed (in error) without the issue being fixed.
- The clinical consequences of the situation continuing (particularly beyond the second cycle) were not necessarily clearly understood by all staff involved and particularly at MoH Executive and IT Board level.
- Risk arising from the issue was understood to be mitigated through workarounds and publicity campaigns.
- Decision making was in the context of a time limited pilot and other decisions regarding “acceptable” risk i.e. that the Pilot would end after two cycles and learning from the Pilot would then inform a national programme.

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82 See Appendices 1 and 2 for more detail
• There was no formal review (e.g. at the end of each two year cycle) of risk to people allocated “Withdrawn” status.

This situation, the root cause and series of contributing factors is a pertinent example of the much quoted “Every system is perfectly designed to get the results it gets” (Batalden, IHI). In this situation everyone was working very hard to make things work, to solve problems and to communicate, test and request solutions for more significant problems as they learned about running a bowel screening programme through the Pilot. Everyone was working hard to make the right decisions based on the information they had and the constraints within which they operated. There is clear evidence of reference to the issue, efforts to address it and to progress solutions over time in both WDHB and MoH combined documentation and communications as set out in brief in Table 1 and in more detail in Appendices 1 and 2.

Ultimately, when the issue was identified as an incident by MoH NSU staff in September 2017, NSU staff involved were not aware of the documented and communicated history of the issue over the duration of the Pilot. The MoH NSU decision to investigate the issue initially without involving WDHB meant that WDHB was not able to inform them of the issue’s history.

MoH analysis revealed that a group of about 2,500 people, eligible to be invited to participate in the Pilot and for whom the NHI had a different address, were not sent an invitation to the different address (it is important to note that the NHI address was not necessarily more current than that on the BSP Register). Of this group of 2,500 people, eight people had received a diagnosis of cancer. Clinical review identified that there was definitely no impact for five people and for the other three people it was impossible to prove any impact (Weston 201783).

While it was not possible to say whether the outcomes for any of the three people would have been different if they had received their invitations, their cancers might have been detected earlier if they had chosen to be screened.

The issue of mail returned GNA was a known longstanding issue from the outset of the Pilot. It had been identified and; manual workarounds put in place (however these had become unmanageable due to the volume of returned mail). The issue of mail returned GNA had been communicated, escalated and recorded as a risk. Solutions had been proposed and repeatedly declined. Change fixes had been explored but not actioned. Repeated efforts to secure funding for changes, solutions and enhancements were declined.

This situation was compounded by a number of contributing and causative factors discussed below.

**Contributing and causative factors**

**Set up of the population register for the Pilot was hurried**

There was pressure on the MoH to get bowel screening underway. The development of the population register in late 2011 was described as rushed through and that if more time had been taken issues such as this may have been identified and mitigated. The reviewer was advised that the normal approval channels were bypassed to a degree.

83 See Appendices 1 and 2
The register was developed using an iterative process i.e. progressively, as business rules for each component were agreed. As it was impossible to get the whole suite of business rules developed and written up prior to commencing development, decisions were still being made about some aspects of the service delivery model after launch. Testing the register was not well resourced and it was launched with a “learn as you go” approach.

**The solution to manage the volume of returned mail meant people were excluded**

People whose mail had been returned GNA had their status on the register changed to “Withdrawn” although this was not at their request (as it was for people who “Opted off”). There were ten reasons a person might be “Withdrawn”. This was an agreed and documented process between the MoH and WDHB, and was arrived at in the context of a time limited pilot of four years.

Once a person was allocated “Withdrawn” status, there was no automatic functionality to retrieve them from that status if different information became available. Therefore these people would not receive any further invitations to participate in the Pilot.

The solution to the issue was not simple. For example, had it been decided to leave people for whom mail was returned GNA on the BSP register that would have resulted in further invitation mail being continued to be sent to the wrong address which would be waste of both budget and resources.

**Potential clinical consequences were not explicit or universally understood**

It was clear to the reviewer that the problem of mail returned GNA was taken very seriously by all involved from the outset of the Pilot. WDHB advised that the issue was known, articulated as an issue and the potential clinical consequences understood by members of the BSP Steering Group. This steering group included up to six medical doctors including two public health physicians and a general practitioner.

The most explicit documented description of the consequences to people allocated “Withdrawn” status because their mail was returned GNA was in the January 2014 Memo from WDHB to the BSP Steering Group as above. Despite this clear articulation by WDHB of the issue and consequences, the level of understanding at the MoH was not universal. The reviewer was advised that senior and executive MoH staff were advised of the returned mail GNA issue when it was identified during the Pilot, and understood there were controls in place but were not aware of the potential size or impact of the issue. There was no indication that a deeper enquiry into the potential consequences of the situation or a clinical evaluation of risk was prompted. Subsequent communications did not articulate the situation as clearly as the memo had done.

It is unclear to the reviewer how much the clinical consequences of the solution were explored and understood when the returned mail GNA issue was under discussion in the various forums. While clinical oversight and input to the BSP was provided for in a number of ways:

- WDHB BSP Steering Group included public health specialists, a General Practitioner (family doctor) and surgeon.

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84 See Appendices 1 and 2
• Bowel Screening Advisory Group (BSAG) included public health physicians, a surgeon, General Practitioner, pathologist, oncologist and the Clinical Director of the National Screening Unit from late 2016.

• National Bowel Cancer Working Group included all specialists involved in the treatment of bowel cancer.

• Evaluation Advisory Group (EAG) for the BSP included public health specialist, gastroenterologist, General Practitioner.

The reviewer was advised that the issue was not discussed in these groups and that clinical staff focused on clinical issues and they expected that technical experts would focus on and resolve technical issues. The returned mail GNA issue was seen as important and a technical issue. This created a gap where clinical exploration and consideration of the consequences of changing the status of eligible people for whom mail had been returned GNA to “Withdrawn” may have identified the risk. As a result a different solution may have been proposed or higher priority and clearer articulation in requests for fixes would have been successful.

Not all MoH staff clearly understood that:

• Workarounds were not fully controlling the risk arising.
• Workarounds were becoming increasingly untenable due to the rising numbers.
• People for whom mail was returned GNA, were withdrawn permanently and even if their address updated this would never prompt a further invitation.

The impression held by some at the MoH was that if a person was invited and did not respond or their mail was returned GNA, they would be re-invited in two years’ time.

Efforts to fix the returned mail GNA issue did continue throughout the Pilot. The most apparent failure appears to be that the potential consequences for people who were allocated “Withdrawn” status because their mail was returned GNA was not clearly articulated when the issue was discussed and was not universally understood by all involved. Nor was the status of all people allocated “Withdrawn” status reviewed at the end of each two year cycle which may have alerted those involved to the potential problem developing.

Manual workarounds became unsustainable due to returned mail volume

As the Pilot got underway and progressed, the volume of returned mail increased. Reasonably quickly the manual workarounds agreed and in place to try and identify a current address became unmanageable. The accumulated volume of mail returned GNA became overwhelming and there were insufficient staff to continue the manual workarounds. One repeat check of mail returned GNA against the hospital system and PHO registers was always achieved but it became difficult to reliably do more than that.

This was identified as a problem and solutions were proposed including:

• additional resources and
• IT functionality fixes involving NHI address updates being communicated to the BSP register and prompting a re-invitation.

Meanwhile the established manual workarounds continued although efforts to identify an up to date address for each person had become unfeasible and staff were unable to keep up due to the
volume of returned mail. WDHB felt that all possible was being done to propose solutions to the returned mail GNA issue, except insisting on access to the NHI gateway which then would have updated the BSP register with any address changes it registered.

Articulating the risk and proposing fixes did not result in a solution

The Chair of the BSP Steering Group wrote to the Director of the National IT Board (May 2014) raising concern regarding frequency of new releases, number of workarounds and risk. A meeting was held at which it was indicated by MoH IT staff that it was not desirable to put too many resources into the BSP register and what was only a four year programme. The reviewer was advised that decisions were made at the meeting but no action to make changes to the BSP register to support these decisions resulted.

The MoH Risk Register for the delivery of a National Bowel Screening Programme dated 10/11/2015 included risks; IT maintenance not sufficient, inadequate funding and IT resources not fully allocated to the NBSP but this did not result in the proposed solution being approved.

The BSP Risk Management Post Implementation document dated February 2017 is an example of where the risk to people was not clearly articulated. Risk No 2 is recorded as “The Register does not accurately reflect the eligible population within WDHB.” This was recorded as a high likelihood, medium impact risk. Mitigations were recorded as:

- “Reconfirm the business rules which determine the Register population
- Establish a process of regular updates to maintain the eligible population on the register
- Maintain as many manual updating processes as resources permit
- Maintain a programme of advertising for people to contact the coordination centre if they have not received an invitation”

This statement does not convey the consequences of the risk in relation to the consequences for people. If the returned mail GNA issue had been more clearly articulated in terms of the risk and the consequence for people, it is likely it would have been more fully understood by MoH staff. It is also likely that the issue would have been discussed and either resolved or accepted but it would have been visible and not got lost.

The context of a pilot programme influenced decision making

The Pilot was established to test and learn whether national bowel screening was able to be rolled out safely and effectively. As is usual with a pilot programme it was expected that issues would arise and that a key part of the process would be learning through identifying and resolving issues.

Decisions regarding management of the issue, workarounds and solutions were made in the context of a pilot programme. It was recognised from the outset that a pilot will by its very nature evidence and manifest problems, challenges and successes from which learning can inform future endeavours.

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85 See Appendices 1 and 2.
86 See Appendices 1 and 2
87 See Appendices 1 and 2
It is very clear to the reviewer that all staff involved in every level of the Pilot; including set up, planning and establishment, operation of the Pilot and BSP register, at both WDHB and the MoH, were intent on doing the best possible for the population involved and on making the Pilot as successful as possible. People were working to make the Pilot work and to identify, communicate and seek resolution to problems as they became evident - as would be expected in a pilot programme.

When the BSP register was set up for the Pilot the decision to smooth invitation volumes was made in accordance with screening principles i.e. that the results of a positive test and the flow on impacts to colonoscopy need to be able to be managed. People were invited in the first cycle anywhere between month 1 year 1 to month 12 year 2. What this meant is that two people, both equally eligible for invitation to the Pilot could be invited up to two years apart, and this was the invitation process. Decision making regarding management of returned mail was also made in this context i.e. that a two year variation in when any one person might be invited was acceptable, and the Pilot would conclude within two cycles (four years).

When the Pilot concluded at four years there was an expectation held by both MoH and WDHB staff that unresolved issues would be addressed. When the Pilot was extended for a third two year cycle (Cycle 3), the focus particularly at the MoH, was on the business case for and establishment of a national bowel screening programme. The BSP register was designed originally for the Pilot period of four years, not for the six year timeframe it was ultimately used for.

Repeated efforts were made to raise the returned mail GNA issue, identify and progress solutions

MoH and WDHB staff involved worked hard to raise the issue and identify solutions:

- Returned mail management processes were established and agreed between WDHB and the MoH including manual workarounds to manage the problem of mail returned GNA.
- WDHB communicated the problem and proposed manual and IT solutions.
- The January 2014 memo\(^88\) provided a clear explanation of the situation.
- The issue was repeatedly raised through WDHB reports to the BSP Steering Group.
- The MoH BSP team communicated the problem and proposed solutions.
- MoH management were aware of the issue but not of the implications.
- Proposed IT solutions were repeatedly declined by MoH IT funders.
- When the Pilot was to extend for two more years (Cycle 3) it was expected that outstanding fixes and improvements to the BSP register would be progressed, however this did not occur.

Information Technology (IT)

The reviewer was advised by MoH staff at interview that because the Pilot programme was a government priority, it did not go through all the normal MoH approval channels as this would have taken too long. There was a lot of resistance from MoH IT funding decision makers to spending money on the Pilot and a view expressed that money could not be “thrown into” new IT systems. Writing capital expenditure proposals and justifications was described as a constant battle. As the

\(^{88}\) See Appendices 1 and 2
Pilot was an entirely new process it was a “learn as you go” approach. Trialling the BSP register was not resourced. MoH staff interviewed described the BSP register as a good database but noted that it was rushed through, and that if more time had been taken, issues such as the returned mail GNA issue may have been identified and mitigated. The Gateway Report 0/1 reported that end users described the system “as being a nightmare”.

The Pilot did not have a budget for IT resource. MoH funders and IT decision makers considered the proposed solutions and budgets against existing and competing demands on MoH IT budget and resource. A total of five upgrades of the electronic system (releases) to fix and improve issues were approved. However other proposed improvements and fixes were declined repeatedly on the basis that investment in what was a time limited pilot was not the best use of limited funds. The proposed solutions to the returned mail GNA issue were among those repeatedly declined.

With no allocated IT budget the MoH BSP Team were required to repeatedly seek IT funding from the MoH IT Board throughout the Pilot. From the MoH IT Board’s perspective the Pilot BSP register was one of many (and many much bigger) projects and programmes seeking funding and resources. The reviewer was advised that MoH IT Board decision makers did not necessarily understand the implications of the decisions they were making in terms of consequences for people. It appears that when the IT Board made a decision this was final, apart from a re-submission to the same Board. There does not appear to have been an arbitration process for where the BSP Team did not agree with the decision of the IT Board although the reviewer was advised that concerns could be escalated to the MoH Executive. The MoH IT Board met monthly to make decisions. Day to day issues and management rested with the MoH BSP Team and the MoH IT Team.

Lack of IT governance and budget for the Pilot is highlighted in April 2014 in a Memorandum from the MoH to the MoH Major Projects Committee. $30,000 additional funding is sought for the Bowel Screening Information System (i.e. the BSP register) in the 2013/14 financial year to cover investigation and redesign to ensure participant details are as up to date as possible.

“...Key to the success of the BSP is the Bowel Screening Information System...

The IT project is now in a 'business as usual' mode and as such there is no governance group specifically established for these enhancements...

The reviewer understands this request was declined and re-submitted and declined a second time.

A further example of frustrated efforts to address resource and BSP register issues was described at interview by a MoH staff member. A business case put forward in 2014/15 for $1 million for additional support was approved but was then subsequently reprioritised and reallocated to other programmes.

Responsiveness, communication and understanding between IT, operational, management, clinical was described to the reviewer as difficult. At times system decisions were delegated to IT staff who did not understand issues or implications when operational staff should have been telling IT what was required i.e. the specifications and requirements. A translator between IT and operational staff was lacking although some interviewed described trying to bridge this gap. One MoH staff member described attempting to act as a translator between the groups and stated how difficult this was,

89 See Appendices 1 and 2
highlighting differences in understanding. The reviewer was told that the fail safes that you would expect were not in place. The decision making process around accepting or declining requests for IT improvements, fixes and updates was not transparent to those making the requests. Approved changes took a long time to be implemented.

WDHB and MoH staff interviewed felt that concerns were escalated appropriately, and these staff expressed frustration at repeated declining of attempts to resolve issues through resources, budget and solutions. MoH staff talked about being very frustrated and that they did not feel listened to by those that made the IT approval and decline decisions. MoH staff interviewed described a climate of continual struggle (and often failure) to get resources. IT support was described as very limited.

As an example a MoH staff member reported that in trying to write a business case seeking additional resources and solutions for the BSP, the MoH IT service refused to contribute input describing it as “a waste of time” (because it was a given that it would be declined). At interview MoH staff stated that concerns were escalated and risks recorded on the register.

The message from MoH IT funding approvers was that there was little appetite to invest in the system as it was only a pilot and only temporary. WDHB noted that the MoH developers were very responsive and helpful in trying to progress tickets to improve the register, however at one point an embargo was placed on any further changes (generated by approved tickets). Around March 2017, Ticket #275\(^{90}\) was closed in error without a solution being actioned.

The MoH BSP team were expected to manage the IT system. Staff interviewed recalled a number of months of getting no reply when asking repeatedly for IT help. At interview, WDHB staff expressed the view that the urgency of their requests was not grasped by MoH IT. Further that their operational requests were not taken seriously and that they were not trusted e.g. a request to unmerge a merged NHI took 6 months and repeated requests to be actioned.

The Final Evaluation Report\(^{91}\) notes that there have been five upgrades to the BSP register over the course of the Pilot, but that due to constrained IT resources at the MoH not all functional issues have been addressed. The use of manual processes in the BSP Coordination Centre and the demands this places on capacity are noted. It is also noted that not having regular PHO enrolment updates means that contact details in the BSP register may be out of date or an incorrect GP may be listed. This did not result in an IT solution being implemented.

**Governance**

MoH oversight of the returned mail GNA issue, governance and responsibility for the Pilot was difficult to determine and seemed unclear. Gateway reports (0/1-2015, 0/4-2017) and a report by Ernst & Young (2017)\(^{92}\) indicated concerns regarding governance and executive understanding. MoH staff views related to governance of the Pilot differed. Some expressed the view that governance of the Pilot was insufficient and unclear. Others agreed that while with hindsight governance of the Pilot could have been improved, the governance in place had been thought to be sufficient at the time. The reviewer was advised that senior and executive MoH staff were advised of the returned

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90 See Appendices 1 and 2
91 Litmus, CPHR and Sapere 2015 – see Appendices 1 and 2
92 See Appendices 1 and 2
mail GNA issue when it was identified during the Pilot, and understood there were controls in place but were not aware of the potential size or impact of the issue. The reviewer was also advised that it was possible to escalate concerns to the MoH executive. It appears that the potential consequences for people were not understood by those who made these decisions at MoH Executive and IT Board level.

The Ernst & Young report\(^{93}\) listed capabilities to be addressed including governance and risk management of the current BSP+ IT solution. The report described governance as inconsistent and not well-documented, noting that risk assessments were performed ad hoc. The report recommended that steps be taken to establish clear integrated governance and communicate policies and risk plans to all stakeholders.

**Staff resource, workload and turnover**

The Pilot was a big programme of work. It kicked off very fast. While there was a budget for the Pilot\(^{94}\) it was described by MoH staff at interview as not well enough or quickly enough resourced in terms of staffing. Staff interviewed stated that pressure to get the Pilot up and running meant that routine MoH planning periods and procedures were bypassed. It was stated that issues would have been lessened if there had been proper planning.

The MoH Bowel and Prostate Cancer Screening team were repeatedly described to the reviewer as “very small” and “insufficient”. MoH staff stated that from early 2012 the MoH had what was described as a “tiny” team of 3-5 part time staff some of whom were also working on other projects. The core MoH team were described as under pressure, insufficient and under staffed. The reviewer was advised that MoH staff worked incredibly long hours to get the Pilot up and running (including being advised that some team members were at times working 80-100 hours a week) and that stress and burnout were inevitable. The reviewer was informed that consistent requests were made to increase FTE in the team, and that these were repeatedly declined.

There was a lot of turnover in the SCI directorate. The original team contracted to the MoH that had supported the design and implementation of the Pilot all left (except for the manager) as their work was complete. A key subject matter expert who project managed the Pilot also left which resulted in a big loss of knowledge and expertise. The developer and WDHB staff involved in the design and implementation remained. A larger MoH team was engaged however this was still described to the reviewer as too small. The reviewer was informed that MoH staff were working very long hours and ultimately the majority left (all staff except the Clinical Director left).

As this was a pilot the focus was on getting things done, and the priority was to get the programme live and to deal with issues as they arose once it was up and running. The transition and turnover of staff meant that some layers of understanding and organisational memory were lost. Part of the issue was the turnover of MoH staff so that staff that knew where and how documentation was filed

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\(^{93}\) See Appendices 1 and 2

\(^{94}\) Budget 2010 committed $24 million over four years for the BSP. Budget 2015 invested a further $12.4 million to extend the Pilot to December 2017

had left. WDHB staff commented that the high MOH staff turnover meant knowledge disappeared and people new to the Pilot did not understand the issues or history.

At interview there was a strong message that everyone did their best and that a lot of really good people were doing really good work, but that not all involved understood all the issues or implications. Staff interviewed described really good working relationships in this phase between the MoH BSP team, WDHB and Argonaut (contracted to deliver the IT system/BSP register).

**Audits, reports and analyses of the Pilot**

The document chronology and Appendices 1 and 2 provide clear evidence that the programme was scrutinised and that the problem arising from the returned mail GNA issue was identified, communicated and solutions proposed repeatedly.

Feedback and evaluation of the Pilot was very positive on pick up (people opting in), participation (people staying in through the process) rates and quarterly monitoring indicators. Findings from the Pilot supported the implementation of a national bowel screening programme.

A strong evaluation focus was on uptake from an equity perspective. Evaluation findings were reviewed by clinical leaders at the MoH and WDHB and presented to the Bowel Screening Advisory Group. The Interim Evaluation Report 24/2/2015\(^{95}\) identified a “number of critical limitations with the Register are impacting adversely on the BSP”. These included:

- Ensuring access – estimating between 5-15% of eligible participants many not have received a letter or kit in screening round one due to incorrect address details on the Register.
- Insufficient dedicated data and IT resource at WDHB and the MoH which contributed to a lack of timely updates to the BSP register resulting in challenges to ensure data quality.

The report also highlights that incorrect participant addresses are due to NHI details uploaded to the register being out of date; planned regular updates from PHO data have not occurred; and understanding of the register sits with a small number of people in WDHB and MoH. The report recommends that the MoH comprehensively review the BSP Register and implement a robust data quality assurance programme.

This prompted MoH led analyses of the register and the database (Lee December 2014\(^ {96}\) and Karalic, December 2014).

The Final Evaluation Report 1/8/2016 noted known issues with currency of addresses with a return to sender rate of around 6% and efforts to identify correct addresses for returned pre-invitation mail. There had been 5 upgrades to the BSP register over the course of the Pilot, but due to constrained IT resources at the MoH not all functional issues have been addressed. The use of manual processes in the BSP Coordination Centre and the demands this places on capacity are noted. It is also noted that not having regular PHO enrolment updates means that contact details in the BSP register may be out of date or an incorrect GP may be listed.

The report concluded that no substantial environmental or clinical safety issues were identified. A systematic review of the operational functionality of the BSP register to determine whether it can

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\(^{95}\) See Appendices 1 and 2

\(^{96}\) See Appendices 1 and 2
work efficiently for a national bowel screening programme was needed to clarify further updates required, including ensuring participant and GP information on the BSP register is up to date.

The conclusion was that the Pilot had done its job of testing a bowel screening pathway design, identifying feasible roles, and risk to translate to a national bowel screening programme and learning needed to be carried forward into a national roll out. The report states that for the BSP register to operationally manage a national bowel screening programme, at least in the interim, a number of enhancements and greater integration with other systems are needed and recommends a functional review of the operation of the BSP register if used to support a national bowel screening programme.

The wording in these reports relates to the percentage of people not being invited, however the consequences for people for whom mail was returned GNA is not explicitly articulated and the reports’ findings did not result in solutions to the issue being progressed.

**MoH focus changed to the National Bowel Screening Programme**

As the MoH focus and attention changed to the National Bowel Screening Programme in 2015/2016 there was less focus on the Pilot. WDHB was left managing the Pilot on the basis that all was going well and it was business as usual. The MoH team were focused on what was needed going forward for the national programme and there was little or no focus on the Pilot and what was still needed there. The reviewer was advised by MoH staff at interview that there were “not enough resources” to meet the requests to improve the BSP register and progress the national programme work.

WDHB noted that there was no formal handover or process where the learning from WDHB from the Pilot could be shared with those planning the national programme. The MoH NSU view is that there was a transition process where learning from the Pilot should have been carried forward to the national programme through the MoH BSP Team who had worked closely with WDHB through the Pilot.

While solutions to the returned mail GNA issue had been requested, they did not progress. The MoH and WDHB assumed that all logged issues would be fixed when the Pilot was extended into Cycle 3 and the BSP register was enhanced as proposed at the end of Cycle 2. The risk for people “Withdrawn” due to mail returned GNA does not appear to have been specifically re-visited as a risk (with a review of the risks, controls in place and the residual risks) at the end of Cycle 1, nor at the end of Cycle 2 when the Pilot was extended for a further two year cycle, and the National Bowel Screening Programme became the focus.

The Memorandum⁹⁷ (22/1/2014) from WDHB to the BSP Steering Group recommends that people who have mail returned ‘gone no address’ are moved to two year recall, and that people who do not respond to two, two yearly invitations including invitation letters returned GNA are moved to a pathway status of ‘withdrawn’. WDHB sets out clearly that moving a person for whom mail has been returned GNA to ‘withdrawn’ status means they will not be invited again unless they contact the Coordination Centre, that even though their address details may subsequently be updated via PHO

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⁹⁷ See Appendices 1 and 2
uploads into the NHI, they will never be re-invited. And that as a consequence there may be people on the BSP register with a correct address who will not be given an opportunity to participate.

The BSP Steering Group Minutes (28/1/2014)\(^{98}\) show the above Memo was tabled recommending:

- People whose invitation letters are returned “gone no address” are placed on two year recall, and
- People who do not respond to two successive two yearly invitations including the “gone no address” people are moved to the pathway status “withdrawn”

The minutes show that the Steering Group approved the first recommendation but agreed people should have three opportunities to participate.

The point is that there was not a two yearly review of the risks, controls and residual risk.

**MoH leadership of the Pilot and the national programme changed to the National Screening Unit**

In March 2016 a new executive structure was announced at the MoH, directorates and services were disestablished and reviewed. In November 2016 MoH responsibility for the Pilot and national programme moved to sit with the MoH National Screening Unit (NSU). The NSU reports to Service Commissioning. The MoH BSP team transitioned to the NSU as part of this change. The reviewer was advised there was resistance from some members of the team to coming to the NSU. The NSU team expected that the MoH BSP team would continue to work with WDHB and act as a conduit of information in relation to application of learning from the Pilot, to planning for the national programme.

Views on the location of the Pilot within the MoH vary, some expressed the view that the Pilot should have sat with the NSU from the outset, others stated that the NSU was not the right place for the Pilot to be run from at the time it was set up due to flux in the NSU.

In picking up the Pilot and national programme, NSU staff described difficulties tracking decision making and documentation (this was also a challenge for the reviewer). The hierarchy of decision making was described as unclear, at times ad-hoc and informal. Systems to record all decisions and archive this information in an easy to find way should have been in place. Had such systems been in place, the impact of earlier staff turnover and loss of knowledge and memory would not have been such an issue.

The Gateway Review Report (0/4-2017)\(^{99}\) identified:

- The national programme team had been significantly increased over the previous four months,
- The appointment of a Primary Care Clinical Lead had been received positively, and
- Placing the programme within the NSU was seen as a positive development providing access to experienced screening programme resources and alignment with population based health strategies, quality frameworks and thinking, and

\(^{98}\) See Appendices 1 and 2

\(^{99}\) See Appendices 1 and 2
• Concerns regarding documentation quality.

Gateway reports (2015, 2017) and a report by Ernst & Young (2017) indicated concerns regarding governance and executive understanding. The reviewer understands from MoH NSU staff that the National Bowel Screening Programme has clear and explicit governance established and that this is working well.

It does not appear that a Decision Log (or similar) was in use up until the programme moved to the NSU. IT issues were recorded in the IT vendor’s “TRAC” system which was available to MoH staff.

The reviewer was advised that the NSU team planning the national system were not aware of the returned mail GNA issue although other MoH BSP Team staff were aware. While it was well understood by most MoH and WDHB staff who worked on the Pilot that not all the eligible population were being invited, it was not well understood by the NSU team. When NSU took responsibility for national planning and oversight of the Pilot, NSU staff were not aware that the consequences for people with mail returned GNA was that they were “Withdrawn” and would not receive any further invitations.

The NSU team initiated a discovery phase from March 2017 onwards. The purpose was to understand the register and to understand what was happening to people in the system, a significant amount of audit and data checking was involved. This process identified a number of issues with the Pilot and BSP register. WDHB advised that they were not involved in supporting this discovery phase and that they consider an opportunity to apply WDHB learning was lost by not including them in this process.

In September 2017, MoH NSU staff involved in “identifying” and responding to the issue of people “Withdrawn” from the Pilot were not aware that this was a known and repeatedly raised issue that had been apparent, documented and communicated from early in the Pilot, and for which solutions had been proposed but repeatedly declined.

**A change process was explored but not actioned and Ticket #275 was closed in error**

Developers had conducted some analysis in an effort to find a fix. The proposed solution was that “Withdrawn no address” flagged records were automatically checked overnight against the NHI, if there was a new address the system would identify where on the pathway the person had been withdrawn and then remove the withdrawn status and update the address. The system would also need to prompt a re-invitation.

Ticket #275 was closed off (WDHB advised that this was an error) around March 2017 by Argonaut. It is documented that “Analysis for the ticket #186 has determined that automated resolution of WT00 is complicated and will require development of new algorithms and potentially collection of additional data. To help resolve worktasks on time, BSP+ has implemented worktask notification via email notification. Refer to the following ticket for more details: #359 Worktask email notification.”

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100 See Appendices 1 and 2
No IT functionality solution resulted from work done by the developers and proposed within Ticket #275. WDHB advised that the ticket was closed in error (a different ticket referring to automation around management of worktasks not the GNA issue was meant to be closed).
National Bowel Screening Programme process

The reviewer was asked to review and document the process put in place for the National Bowel Screening Programme (NBSP – the national programme) to ensure sufficient fail safes are in place to protect the safety of participants.

The reviewer has been advised that since identifying the issue with people allocated “Withdrawn” status because their mail was returned GNA, a new process has been implemented for the National Bowel Screening Programme register. A list of updated addresses from the NHI is provided to the NCC (National Coordination Centre) weekly, and that while checking this against the national programme register is still currently a manual process, it is manageable as it is a small number each week. In addition the National Enrolment Service online provides a live PHO data set and the national programme register is linked to this service. It is important to note that while this is potentially most helpful, there will always be eligible people who are not on either the NHI or the National Enrolment Service.

The reviewer would be more assured if IT system functionality was the solution for this issue. Whilst the reviewer is advised that the current manual process is working, it can be expected that the population numbers will grow significantly as each DHB joins the programme. Therefore there is a risk the current manual process will become unsustainable as occurred in the Pilot. If this manual workaround is to be the solution ongoing, resourcing sufficient staff to manage the process will be critical.

The reviewer was advised that the National Bowel Screening Programme is to have a new IT system, and it is expected the limitations and issues with the current system will be addressed with the new system. The reviewer notes that this same type of assurance was provided at the end of Cycle 2 but did not result in a solution to the returned mail GNA issue. The reviewer was advised that the design and approach for the National Bowel Screening Programme are very different to the Pilot. A screening context with extensive clinical input has been included in both the Request on Information (ROI) and Request for Proposal (RFP). Detailed requirements based on planned outcomes are specified. The reviewer was advised that the IT solution is currently being priced.

The reviewer considers that a full, in-depth expert review of the BSP register and the processes put in place to manage issues that arose during the Pilot should be conducted to assure the public of New Zealand that the National Bowel Screening Programme is safe. This review needs to also assure the MoH, WDHB and the people of the WDHB region that there are no other groups of people at risk from the Pilot processes or period. This review should also be informed by both WDHB and MoH staff involved in the Pilot processes and decision making. This review should not delay continued progression of the National Bowel Screening Programme but should be undertaken concurrently with any learning applied to the national programme as it arises.

The above review is recommended in the context of the following:

1. Issues identified during the NSU discovery phase from March 2017,
2. The identification of the returned mail GNA issue in September 2017 as an incident (this review),
3. The April 2018 MoH announcement that about 15,000 people (including the 2,500 people subject of this review) may have missed out, and
4. The findings of this review in terms of multiple contributing factors and the root cause of the returned mail GNA issue. These indicate that there may be other actual and potential risks within the BSP register currently in use that require investigation, solutions and controls to ensure the programme is safe.
Recommendations

The reviewer acknowledges the hard work and dedication of staff who worked to make the Pilot a success. It is clear that planning for the Pilot included an expectation that changes in the NHI would be reflected in the BSP register, but this did not happen. It is also clear that from the outset of the Pilot, the returned mail GNA issue was identified, communicated and solutions were sought. Initially, manual workarounds were put in place and when these began to fail due to the volume of returned mail, further mitigations were implemented by WDHB (public communications and campaigns, a major publicity drive and primary care dashboards) and an IT solution was sought. Efforts to get funding and approval for a solution were repeated. When the returned mail GNA issue was identified as an incident in September 2017 MoH NSU staff involved, unaware of the history of the issue, acted to quantify, understand and mitigate risk related to the issue.

The identification of the returned mail GNA issue within the Pilot also prompted a detailed review of the BSP register and national programme register for risk by NSU staff. A mitigation to address the returned mail GNA issue has been developed for the national programme register and the current solution is a weekly report and update which the reviewer understands is manageable from a volume point of view.

There is no question that all staff involved at every stage and level worked to do their best to deliver a successful programme within the constraints that existed at that time.

Whilst major efforts to address the returned mail GNA issue have been made since the incident was identified, and targeted work has focused on detecting any other problems with the register, there is further work to do.

Addressing the root cause

The reviewer considers that the root cause is that the issue of mail returned GNA was not fixed when it was identified. This occurred at multiple stages across the three cycles and six years of the Pilot. In the planning of the Pilot IT functionality was planned for but not resourced. Manual workarounds were put in place to try and locate a current address but this became unmanageable. The process to manage mail returned GNA within the context of the Pilot was to change people’s status to “Withdrawn” after two attempts to invite them. Further efforts to address the issue were proposed through IT functionality fixes, but declined by the MoH IT Board. However a recommendation such as “Issues should be fixed safely as and when they arise, and everyone should understand the consequences.” is of little use.

Apology

The MoH’s Clinical Director National Screening Unit and Clinical Director Bowel Screening conveyed an apology to these three patients in consultation with their General Practitioner (family doctor). Where possible this apology was communicated directly to the patient.

On 13 February 2018 during the process of this review, the Minister of Health, Dr David Clark ordered an independent review of the National Bowel Screening Programme. Dr Clark noted that the MoH had taken full responsibility for this matter and as Minister of Health apologised unreservedly.
On 17 April 2018 the MoH announced that more people than first thought had not received invitations for free bowel screening during the Pilot. About 15,000 may have missed out (this includes the 2,500 subject of this review). The MoH’s NSU Clinical Director stated that the Ministry takes full responsibility for the oversights, which were a result of Pilot IT issues and human error, and will continue to contact those affected to apologise and invite them for screening over the coming months.

Considerations

These recommendations are based on the assessment of the root cause, contributing and causative factors and events in the period November 2017 to date, and need to be considered alongside actions already progressing.

Risk assessment of the register and supporting processes

As set out earlier there may be other actual and potential risks within the BSP register currently in use that require investigation, solutions and controls to ensure the programme is safe.

1. A full, in-depth expert review of the BSP register and the processes put in place to manage issues that arose during the Pilot should be conducted to assure the public of New Zealand that the National Bowel Screening Programme is safe.
   - This review needs to also assure the MoH, WDHB and the people of the WDHB region that there are no other groups of people at risk from the Pilot processes or period.
   - This review should also be informed by both WDHB and MoH staff involved in the Pilot processes and decision making.
   - This review should include a detailed review of any remaining risk for people eligible for the WDHB Pilot. And for any risk emerging for people eligible for the national screening programme.
   - For any risks which have not been addressed in the migration, sufficient controls should be established to reduce risk to an agreed level or eliminate it.

2. In relation to mail returned GNA, the ideal is provision of IT functionality that addresses this issue.
   Where this is not yet addressed (although this is not ideal), at minimum:
   - The process for mail returned GNA should be explicit and agreed by all parties through the programme’s governance structure.
   - People for whom mail is returned GNA must not be changed to “Withdrawn” status, unless the system has functionality that allows their return to the appropriate pathway state if a different address is available (this avoids the waste and cost of sending the next cycle invitations to the same wrong address).
   - People for whom mail is returned GNA and who are changed to “Withdrawn” status, should be reviewed within two years as per the relevant quality standards going forward and returned into the two year re-invite pool.

3. Risk Registers need to include dates and detail of decisions related to control of risks, including dates risks are added to the register, dated updates on risk controls for open risks and dates risks are closed and on what basis. It should be clear to the reader to what party/group/programme the risk register relates.
Governance, communication and documentation

Governance: The reviewer was advised of different views regarding governance of the Pilot. Gateway reports (0/1-2015, 0/4-2017) and a report by Ernst & Young (2017)\textsuperscript{101} indicated concerns regarding governance and executive understanding.

4. Communication: Communication structures between all stakeholders should be clearly set out including robust communication processes in place to ensure appropriate, timely and collegial transfer of information and advice, raising of issues and risks, reporting and investigation of incidents between stakeholders – in particular between the MoH NSU, MoH IT, other MoH, DHBs, the National Coordination Centre and other stakeholders.

5. Documentation: Documentation standards should be established and agreed for such projects. Naming of documents should indicate which parties “own” the document e.g. in this case it was unclear to the reviewer whether documents were WDHB or MoH or both as often nothing was specified. Equally all documents should be dated. Document filing and archives should also be clearly set out in accordance with public records requirements so that it is easy to understand and locate documents as required and into the future.

Testing

6. The reviewer was advised that pressure to get the Pilot underway resulted in normal processes and planning requirements being bypassed. Testing is a critical element of all projects and programmes:

The requirements to deliver a programme will always be subject to pressures. However where a decision is made to not follow normal processes e.g. not provide for testing, the risks and consequences must be discussed and agreed, taking into consideration the possible outcomes or harm for people, documented and approved based on shared understanding by all relevant parties and in line with governance requirements.

Risks and issues – exploration and articulation

7. The returned mail GNA issue and the consequences for people were not well understood by all MoH staff. In relation to risks and issues in all projects and programmes:

There should be clear documented and agreed business requirements (describing what is required) supported by technical specifications (describing how in technical detail the business requirements will be accomplished) for such projects and programmes against which emerging issues and risks can be evaluated. These documents create shared understanding between all parties.

There should be specific consideration of the consequences for people/consumers/patients. This may require a change to risk and issue templates to specify this requirement. There are three issues:

- The exploration of the risk – What risk actual or potential is there for harm or consequences for people/consumers/patients? What controls can be put in place to

\textsuperscript{101} See Appendices 1 and 2
mitigate/control this risk? What risk remains? Is this acceptable? If not what needs to be done? Have the right people had input?

- The articulation of the risk – How is the risk to people/consumer/patient safety best articulated? What is the best way to clearly communicate this in a way that is understood by all decision makers?

8. Where the MoH IT Board are making decisions related to clinical programmes, there should be a requirement that requests for resources and funding are not decided upon without a discussion involving both those seeking and those deciding. Decision making should include:

- Input by clinical as well as technical and other relevant expertise
- Evaluation of the uncontrolled risk. Explicit and informed exploration and articulation of the actual and potential consequences if the decision is declined.
- A specified process to challenge the decision and seek resolution via arbitration through established governance processes, if it is considered that the risk is not sufficiently controlled by those seeking resolution of it.

9. Where staff turnover or change is an issue, mitigations to provide for continuity need to be developed e.g. handover plans including key issues, particularly unresolved issues and risks, documentation processes and location.

Resources

10. The Pilot was insufficiently resourced at the MoH at the outset. MoH staff were working unsustainable hours and the risk associated with manual workaround solutions was not fully considered against IT functionality solutions. There was no provision for IT enhancements in annual budgets. In relation to resourcing in all projects and programmes provision needs to be made for the right quantity of resources for the expected timeframe and quality requirements:

There needs to be regular accurate measurement and reporting of demand and capacity using agreed objective criteria that monitors actual and potential increases in demand.

- Resourcing needs to be sufficient and responsive.
- This is particularly critical in Pilot and new programme roll outs and implementations where issues and risks will manifest over time and impact on workload and overall resourcing in ways that require nimble and flexible response.
- Sufficient administration support needs to be provided for.

11. The skill mix of staff created challenges particularly in relation to shared understanding at the interface between disciplines e.g. clinical specialties, policy, analyst, technical. In relation to skill mix for all projects and programmes, provision needs to be made for the right mix of expertise. Considerations should include:

- A clinician specialist cannot necessarily represent all specialties relevant to a project or programme. Provision should be made for input from all relevant specialists.
- The communication between technical and other staff is often (as in this case) a challenge in terms of understanding and assumptions. Provision for agreed business requirements at the outset of projects and programmes provides for a shared understanding reference point from which to evaluate risks and issues.
Health and safety

12. Health and safety: During implementation of the Pilot and during work on the business case for the National Bowel Screening Programme the hours that some staff at the MoH were working as described to the reviewer were unsustainable. The reviewer was advised of stress, burnout and staff turnover. There needs to be regular accurate measurement and reporting of staff hours and indicators of stress using agreed objective criteria for such projects and programmes. Where these indicators are identifying the need for more resources or support this needs to be timely and responsive and in line with health and safety requirements.

External review reports

13. Recommendations from external review reports should be checked to ensure they have been considered and as relevant actioned. A record of actions taken to address recommendations should be documented and available.

Open disclosure – open communication

14. The MoH develop an open disclosure procedure supported by the MoH Incident Management Policy for guidance and use in future incidents. This procedure to:

- Set out the principles, management and communication processes for such incidents and provide for transparency between parties involved in incident response in future.
- Align to the Health Quality and Safety Commission policy102 and the Health and Disability Commissioner’s guidance103.
- Include appropriate and timely communication with affected providers.

103 http://www.hdc.org.nz/resources-publications/search-resources/leaflets/guidance-on-open-disclosure-policies/
Appendix 1: Document list

Relevant key documents are listed below to provide a chronology. Brief analysis and excerpts from documents listed is provided in Appendix 2.

- August 2011 - Review of the BreastScreen Aotearoa Program People and Culture in the National Screening Unit: Moving Forward August 2011 (Gillis)
- August 2011 - Review of the BreastScreen Aotearoa Program Future Directions for the National Screening Unit Working in Partnership with Lead Providers for a Sustainable Quality Program August 2011 (Muller)
- 24/1/2012 - Email MoH to WDHB re refinements to Provider Resource Document
- January 2012 - Provider Resource Document
- 22/2/2012 - Argonaut Ltd BSP Analysis
- 5/4/2012 - Email MoH to WDHB re monthly reporting and outstanding SOPs (Standard Operating Procedures)
- 5/4/2012 - Email National Programme Manager Bowel Cancer MoH to Business Analyst SCI re uptake on BSP
- 6/4/2012 - Returned Mail Management
- 16/4/2012 - BSP9 Returned Mail Management
- 25/2/2013 – BSP Project Progress Report (Report number 33)
- 30/3/2013 – BSP Interim Quality Standards Final Version 2.0
- 21/11/2013 – BSP Project Progress Report (Report number 31)
- 22/1/2014 - Memorandum WDHB to BSP Steering Group: Re-inviting non responders
- 25/1/2014 – BSP Project Progress Report (Report number 32)
- 28/1/2014 - Bowel Screening Pilot Steering Group Minutes
- 25/3/2014 - Bowel Screening Pilot Steering Group Minutes
- 11/4/2014 - Memorandum MoH to Major Projects Committee: Request for additional funding of $30,000 for the Bowel Screening Information System
- 29/4/2014 - Bowel Screening Pilot Steering Group Minutes
- 1/5/2014 – Letter Chair BSP Steering Group to Director National IT Board: Bowel Screening Pilot
- 19/5/2014 – Email Manager Bowel and Prostate Programmes MoH to BSP IT Meeting
- 27/5/2014 - Bowel Screening Pilot Steering Group Minutes
- 11/6/2014 – Email Executive Assistant to Director National IT Board to Chair BSP Steering Group
- 12/6/2014 - Bowel Screening Pilot Coordination Centre Operations Manual
- 8/7/2014 – Memo Manager Bowel and Prostate Programme MoH to National Screening IT Advisory Board
- 15/9/2014 – Notes from initial BSP analysis work
- 25/9/2014 – BSP Project Progress Report (Report number 38)
- 11/12/2014 – BSP Project Progress Report (Report number 39)
- December 2014 - Bowel Cancer Screening Pilot: Population Register analysis (Lee MoH)
- Dec 2014 - Bowel Screening Pilot: Database Review
- December 2014 - Bowel Cancer Screening Pilot: Database Review (Karalic MoH)
- 24/2/2015 - Interim Evaluation Report of the Bowel Screening Pilot: Screening Round One (Litmus, CPHR, Sapere)
- 9/10/2015 – Memo Principal Advisor Bowel and Prostate Cancer Programmes MoH to SCIIMGG MoH re Enhancements to the Waitematā BSP IT system for round 3
- 10/11/2015 – Risk Register for the delivery of a National Bowel Screening Programme – MoH
- December 2015 - Gateway Review Report 0/1 - Ministry of Health National Bowel Screening Programme - Treasury
- 29/1/ 2016 – Returned Mail
- 1/8/2016 - Final Evaluation Report of the Bowel Screening Pilot: Screening Rounds One and Two (Litmus, CPHR, Sapere)
- 17/08/2016 – External IT Review National Bowel Screening Programme (NBSP) – Accenture Consulting
- 29/08/2016 – Programme Business Case & Tranche 1 Business Case National Bowel Screening Programme
- 10/11/2016 – Returned Mail
- February 2017 Risk Register
- 12/5/2017 – Ministry of Health BSP Due Diligence Interim IT Solution Assessment (Ernst Young)
- May 2017 - Gateway Review Report 0/4 - Ministry of Health National Bowel Screening Programme - Treasury
- 21/9/2017 – Screening Incident Report Form
- 30/10/2017 – Email: WDHB to MoH NSU
- 20/11/2017 – Weston: Review of Clinical Records of Patients Who Did Not Receive an Invitation to Participate in the Bowel Screening Programme and Who Subsequently Received a Cancer Diagnosis
- 27/11/2017 – Ticket #275 (closed enhancement: fixed indirectly)
- 8/12/2017 – Letter: Clinical Director National Bowel Screening Programme to about 2,500 people
Appendix 2: Analysis and extracts from relevant timeline documents

Analysis and relevant excerpts from the key documents listed in Appendix 1 is provided as a chronology below.

If no detail beyond the document or communication title is provided this is because the reviewer considered replicating the text in this report was not essential and the full documents can be sourced as required.

Analysis and extracts document chronology

The reviewer was advised by MoH staff that the release of these two reports below (critical of the breast and cervical screening programmes) generated further impetus to get bowel screening underway.

August 2011 - Review of the BreastScreen Aotearoa Program People and Culture in the National Screening Unit: Moving Forward August 2011 (Gillis)

P 44 “It is recommended that consideration be given to incorporating the national Bowel Cancer Screening Pilot Project into the NSU to maximise the efficient use of resources in population screening knowledge and skills across the cancer screening programs…”

August 2011 - Review of the BreastScreen Aotearoa Program Future Directions for the National Screening Unit Working in Partnership with Lead Providers for a Sustainable Quality Program August 2011 (Muller)

P 22 “Recommendations... #4 ii

That the cancer screening programs strengthen their collaborative alignment and the linkage with the regional cancer networks and the development of clinical pathways for breast, bowel and cervical cancers.”

24/1/2012 - Email MoH to WDHB re refinements to Provider Resource Document

Suggests numerous refinements to the Provider Resource Document (below) including a statement that when people are ineligible or opt out they are not removed from the register, their history needs to be retained on the system. Their status is changed... to ineligible or withdrawn.

 “… Page 20 included on the BSP Register, and removed when they become ineligible or opt out. When people are ineligible or opt out, they are NOT removed from the register, their demographic (and screening history) needs to be retained on the system. Their status is changed (generally automatically) to ineligible or withdrawn.”

January 2012 - Provider Resource Document

(The version reviewed was not dated, this was subsequently checked and the date advised.)

Provides information for health practitioners about the pilot. Specifies that the Coordination Centre is responsible for ensuring that the eligible population is informed of the pilot, included on the screening register, removed when they become ineligible or opt out and followed up by reminder letter if they do not respond to the invitation to participate.
P 20 The Role of the Coordination Centre

“The overarching role of the Coordination Centre is to ensure that participants proceed safely along the screening pathway in a timely manner. To achieve this, the Coordination Centre is responsible for ensuring that the eligible population is:

• informed about the existence of the pilot, risks and benefits of participating
• included on the screening register, and removed when they become ineligible or opt out...
• .. followed up with a reminder letter if they do not respond to the invitation to participate in the BSP…”

22/2/2012 - Argonaut Ltd BSP Analysis

A report by Argonaut (contracted to deliver the IT system/BSP register) indicates attempts to investigate and resolve issues emerging as the pilot commenced.


Includes current and closed risks that relate to the planning and implementation of the BSP.

Current risks of note:

• #2. Clear boundaries of the roles of all parties involved in the pilot are not fully understood and met. Impact: a lack of clarity of roles and that relationships and reputations could be damaged by uncertainty of roles. Mitigation strategy – discuss.
• #5. Continuity of IT systems day to day operations. Impact: limited people who have a clear understanding of the IT systems and running mechanisms. This will have significant impact on continuity of the pilot if any of these staff are on leave etc. States there is nobody in post within the MoH IT department who was involved in the set (up) of the system and there is no knowledge of its functionality. Mitigation strategy – Need to train more staff within the MoH and WDHB. Recommends a deputy for the information/monitoring leads in both MoH and WDHB.
• #6. Implementation of Quality Standards. Impact: limited people who have a clear understanding of the Quality Standards and how they will be monitored. This will have significant impact on continuity of the pilot if any of these staff on leave sick etc. Mitigation strategy – Need to ensure that staff are aware of the quality standards and how they will be measured within the MoH and WDHB. Recommends a deputy for the quality leads in both MoH and WDHB.

Closed risks of note:

• The scope of the population register does not cover enough of the target population. Impact: Includes noting that the currency and accuracy of the register needs to meet the needs of the pilot. Closed 1/9/2011.
• Possibility of not being able to use the NHI to populate the BSP Register. Impact: There may be a possibility of this risk. Closed 1/9/2011. Reasons for closure: The project manager for the BSP IT development is progressing the request for use of the NHI by the pilot through the NHBBU (National Health Board Business Unit) and the NHB ITB (National Health Board IT Board) as well as gaining formal approval within the Ministry.

• Insufficient time or resources to implement robust processes around information systems development. Impact: Inability to provide an Information System/Register to collect, analyse, monitor and use the information necessary to successfully implement a population based screening programme across pilot sites. Closed date unclear, date closed recorded as Nov 09 but updated reasons for closure Nov 2010 – Dedicated PM (Project Manager), BA (Business Analyst) and IT architect are following a robust work plan according to the defined project plan by the IT PM.

• Funding has yet to be secured. Impact: Potential for BCSP not to be implemented. Closed May 2010. Reason for closure: Cabinet Paper approval gained 12 April 10 and the Minister confirmed the pilot through a media announcement on 5 May 2010.

• The timeframes allocated for the development project create pressure to develop the BCSP in a much shorter time than other countries and other NZ cancer screening programmes. Impact: Corners may be cut in the development of key components of the programme. Closed Oct 09. Reasons for closure: Options paper presented and the Minister has indicated preference for a one or two DHB based pilot and a national programme.

• Insufficient budget to meet the required costs. Impact: In view of the fact that the national BCSP is being developed without the benefits of a pilot or feasibility study to inform budget planning there are many unknown variables. Closed date Oct 09. Reasons for closure: Options paper presented and the Minister has indicated preference for a one or two DHB based pilot and a national programme.

• Insufficient project team FTE approved to enable the full completion of the core BCSP project. Impact: Inability to undertake and complete adequately the various sub project work streams. Closed date May 09. Reasons for closure: DDG (Deputy Director General) has provided assurance the 12 FTE allocated to the BCSP are guaranteed.

5/4/2012 - Email MoH to WDHB re monthly reporting and outstanding SOPs (Standard Operating Procedures)
Lists published and yet to be developed SOPs including pilot mail management of undelivered mail (published), and Suspending/withdraw (expected date of publication requested).

“... BSP IT Requirements.... BSP mail management of undelivered mail... we would like copies please... Suspending/withdraw (expected date of publication)…”

5/4/2012 - Email National Programme Manager Bowel Cancer MoH to Business Analyst SCI re uptake on BSP
Includes a table for uptake of invitations issued in January 2012 (weeks 4 & 4) that includes a withdrawn column total of 139, total invitations 2,992 and uptake less withdrawns 47%.
6/4/2012 - Returned Mail Management

Sets out the process for returned mail. This includes a number of steps to try and locate a new address. It concludes “If after exhausting all possible resources and you are still unable to locate or contact the participant then Withdraw them in BSP”*.

*This instruction meant that the person’s record was changed to “Withdrawn” status. It does not mean they were removed from the register altogether.

“Returned mail (at any stage on the pathway) is received and processed on a daily basis...

When a returned mail item is received in to the Co-ordination centre create a “Work Task – Resolve Invalid Address” which will put their pathway on hold so no further communications go out to the old address.”

A process of checks is specified

- WDHB PIMS [Patient Information Management System]
- GP [General Practitioner]
- BSWN [Breast Screening] database
- Concerto [WDHB Patient Record System]
- White pages

“Once you have obtained the current address and amended this in the database, resolve the Work Task and then you can then generate and New Letter and post it out.

If after exhausting all possible resources and you are still unable to locate or contact the participant then Withdraw them in the BSP.”

16/4/2012 - BSP9 Returned Mail Management

Sets out the detailed process for returned mail in line with the document above.

25/2/2013 – BSP Project Progress Report (Report number 33)

Reports Register accuracy as a risk. Maintenance of data on the register - specifically address - data is emerging as a risk because of

a) The significant number of GNA returns and also the 45% of people who have not responded. Notes that both the Ministry and BSP are working on actions to improve accuracy levels of addresses and other details.

In relation to register development: new release successful, outages problematic, number of data items still not able to be captured correctly, good meeting with MoH and Argonaut teams re changes for next version.

“Risks... 2.2 Register accuracy

The maintenance of data on the Register - specifically address - data is emerging as a risk because of

b) The significant number of 'gone no address' returns and also the 45% of people who have not responded – many of whom may not have received an invitation. Both the Ministry and the BSP are working on actions to improve accuracy levels of addresses and other details.”
“A number of data items still not able to be captured correctly. Good meeting with Ministry and Argonaut teams re changes needed for next version.”

30/3/2013 – BSP Interim Quality Standards Final Version 2.0

P 17 “Invitation to bowel screening…. evaluation target…

1. 100% of known eligible participants are sent an invitation for screening within two years (within 24 months) of commencement of the BSP
2. At least 95% of eligible individuals are recalled for screening within 24 months of their previous invitation for screening”

21/11/2013 – BSP Project Progress Report (Report number 31)

Reports Register issues:

- Criteria on which initial register population selection was based do not appear to have been documented
- PHO enrolment data has not been uploaded since beginning of 2013 meaning that addresses may not have been updated and people moving into the area have not been included on the register
- Waitematā PHO and Procare quarterly extracts provided have not been actioned
- Early uploads of the PHO extract were rejected because of a high data error rate however no further engagement occurred to resolve this.

In relation to register development: new release successful, outages problematic, number of data items still not able to be captured correctly, good meeting with MoH and Argonaut teams re changes for next version.

“3. Issues… Register…

- The criteria on which the initial register population selection was based do not appear to have been documented
- PHO enrolment data provided to the Ministry quarterly has not been uploaded since beginning of 2013 which means that addresses may not have been updated and people moving into the area have not been included on the register
- Waitemata PHO and Procare have been providing the quarterly data extract for the BSP to upload however it appears that no further action has been taken. This means that the doctor/patient relationship will not have been updated.
- Early uploads of the PHO extract were rejected because there was a high data error rate however no further engagement with PHOs occurred to resolve this.”

“A number of data items still not able to be captured correctly. Good meeting with Ministry and Argonaut teams re changes needed for next version.”

22/1/2014 - Memorandum WDHB to BSP Steering Group: Re-inviting non responders

WDHB recommends the steering group approves that people who have mail returned ‘gone no address’ are moved to two year recall, and that people who do not respond to two, two yearly invitations including invitation letters returned GNA are moved to a pathway status of ‘withdrawn’.
WDHB sets out clearly that moving a person for whom mail has been returned GNA to ‘withdrawn’ status means they will not be invited again unless they contact the Coordination Centre, that even though their address details may subsequently be updated via PHO uploads into the NHI, they will never be re-invited. And that as a consequence there may be people on the BSP register with a correct address who will not be given an opportunity to participate. Indicates that the pilot Service Delivery Model states that when a person has not responded including active follow up they are moved to two yearly recall. But that the model does not state what happens when invitation mail is returned GNA.

Indicates that now that Cycle 2 has started, consideration needs to be given to the possibility of subsequent cycles for WDHB or national roll out and the number of times person is given a chance to participate. States that a relatively small number ask to be withdrawn, a much larger number do not respond and it is unknown if they ever will, and that continuing to send mail without response does not make good economic sense. Notes that sending an invitation for two successive cycles also allows for the possibility that an address update may have occurred in the NHI and allows reasonable time for other influences to change someone’s mind.

“Recommendation: The BSP Steering Group approves...

a) that people who have their pre-invitation or invitation letters returned ‘gone no address’ are moved to two year recall, and

b) that people who do not respond to two successive two yearly invitations to participate in the BSP (including those whose invitation letters are returned ‘gone no address’ are moved to a pathway status of ‘withdrawn’.

Clarification is required... An indicator within the Quality Standards is ‘the number of people who have opted off’. We have recently discovered that this indicator has been used to capture not only those people who contact the Coordination Centre and requests to be withdrawn, but also those people whose invitations have been returned ‘gone no address’ (footnote The Coordination Centre makes every attempt to access the correct address before moving the person to the ‘withdrawn’ status.)

When a person is moved to the status ‘withdrawn’ (i.e. they have opted off) it means that they will not be invited again unless the contact the Coordination Centre. This means that even though the ‘gone no address’ person may subsequently have their address details updated via the PHO uploads into the NHI, they will never be re-invited. Thus there may be people on the Register with a correct address who will not be given an opportunity to participate.

The BSP Service Delivery Model states that when a person has not responded to the invitation to participate (including active follow up for priority populations), that person is moved to two year recall. The Service Delivery Model is silent on what happens when a pre-invitation or invitation letter is returned ‘gone no address’. The Service Delivery model is also silent on the number of times the Coordination Centre will issue invitations to people who do not respond.

Now that cycle two has commenced, and we need to consider the possibility of subsequent cycles for WDHB or national rollout, the number of times a person is given a chance to participate needs to be considered.
A relatively small number of people contact the Coordination Centre and ask to be withdrawn. A much larger number simply do not respond and it is unknown if they ever will—no matter how many time the invitation is sent. Continuing to send such a large number of invitations without getting a response does not make good economic sense. Sending an invitation for two successive cycles allows for the possibility that an address update may have occurred in the NHI and a reasonable time for people to be exposed to other influences... and to change their mind.”

25/1/2014 – BSP Project Progress Report (Report number 32)
WDHB confirmed that the report is incorrectly dated 2013 when it should be 2014.
In relation to BSP register development: new release successful, outages problematic, number of data items still not able to be captured correctly, good meeting with MoH and Argonaut teams re changes for next version. Revised consent form tested, changes for release 4 agreed, statement of work being prepared for MoH approval, further work with CD.
“A number of data items still not able to be captured correctly. Good meeting with Ministry and Argonaut teams re changes needed for next version. Revised consent form tested...”

28/1/2014 - Bowel Screening Pilot Steering Group Minutes
Paper tabled by WDHB recommending:
- People whose invitation letters are returned “gone no address” are placed on two year recall, and
- People who do not respond to two successive two yearly invitations including the “gone no address” people are moved to the pathway status “withdrawn”

The minutes show that the Steering Group approved the first recommendation but agreed people should have three opportunities to participate.

(WDHB advised that the work on the register to allow the first recommendation to happen did not occur and they were uncertain if work on the register to allow the second recommendation to happen ever proceeded).

“(WDHB) tabled a paper which contained the following recommendations:
- People who have their invitation letters returned “gone no address” are placed on two year recall, and
- People who do not respond to two successive two yearly invitations (including the “gone no address” people) are moved to the pathway status “withdrawn”

The SG approved the first recommendation but agreed that people should have three opportunities to participate i.e. receive 3 invitations before being withdrawn.”

Reports Register accuracy as a risk. Repeats information reported in report # 33 dated 25/2/2013.
In relation to register development: new release successful, outages problematic, number of data items still not able to be captured correctly, good meeting with MoH and Argonaut teams re changes for next version.
“Risks... 2.2 Register accuracy
The maintenance of data on the Register - specifically address - data is emerging as a risk because of

   c) The significant number of ‘gone no address’ returns and also the 45% of people who have not responded – many of whom may not have received an invitation. Both the Ministry and the BSP are working on actions to improve accuracy levels of addresses and other details.”

“A number of data items still not able to be captured correctly. Good meeting with Ministry and Argonaut teams re changes needed for next version.”

25/3/2014 - Bowel Screening Pilot Steering Group Minutes

In relation to withdrawals, notes three fields on register; withdrawn (people who have asked to be withdrawn), on hold (people not progressing at present but who will do so in future) and ineligible. There is discussion with the developer re further subcategories.

Draft letter to ID (MoH Information Directorate) requesting more resource applied to the management of the BSP Register held over to next meeting.

“There are currently 3 fields on register …”

“MoH ID letter: … held over until next meeting.”

11/4/2014 - Memorandum MoH to Major Projects Committee: Request for additional funding of $30,000 for the Bowel Screening Information System

Recommends $30,000 in the 2013/14 financial year to cover investigation and redesign to ensure participant details are as up to date as possible.

“… Key to the success of the BSP is the Bowel Screening Information System...

The IT project is now in a ‘business as usual’ mode and as such there is no governance group specifically established for these enhancements...

Additional requirements

The BSO invitation system is based on a population pool that was originally drawn from the NHI database in 2011. It was envisaged that this population pool would be regularly updated with any changes (such as address details or people moving in or out of the WDHB area which had been made to the NHI database. These updates have not been working as planned and urgent work is now required to ensure the BSP population pool remains as up-to-date as possible. Participation rates are starting to fall, and one possible explanation is that invitations are not being sent to the correct addresses because the population pool is now out-of-date (note: high participation rates in a screening programme is one of the key performance indicators...)

An additional $30,000 is now required in this financial year 2013/14 to cover a re-design/re-development of the NHI, GPT and Cancer registry loads.

This includes the following deliverables:

- The NHI load file should provide a full set of eligible people rather than a change since the last extract, and the BSP application will calculate the differences.”

In relation to register accuracy, notes process where any changes to address (from GNA or participant advice) are entered into WDHB PIMS (Patient Information Management System) which in turn updates the NHI, and then the NHI updates the BSP register.

In relation to the register; functionality continues to compromise operational efficiency. That the register was satisfactory for go live but needs significant ongoing attention to meet all operational, audit and reporting requirements. Too many workarounds, inefficient. Requires attention from MoH ID, Cancer Team, WDHB BSP and the developer.

Draft letter will be tabled at this meeting.

“Register accuracy ....”

“Register....”

29/4/2014 - Bowel Screening Pilot Steering Group Minutes

Draft letter (to MoH Information Directorate) to be circulated for approval.

“... to circulate the draft...”

1/5/2014 – Letter Chair BSP Steering Group to Director National IT Board: Bowel Screening Pilot

Raises concern that the frequency of new releases (to address issues) is not keeping pace, that there are too many work-arounds which are inefficient and pose areas of risk. Notes that the analysis of the first screening round data is compromised by limitations with the BSP register and that further roll out of the pilot would not be possible with the BSP register in its current state.

Conveys the steering group's increasing concern about the issues and the risks they pose to the pilot. States that the responsibility for securing additional funding and resources is unclear. Recommends a meeting with all parties.

“The register... now requires significant on-going attention to get it to the point where all operations, audit and reporting requirements can be met... the frequency with which new releases are delivered is not keeping pace with the many issues which emerge and which require a more timely response...

There are too many areas running on work-arounds which are inefficient and pose areas of risk. In addition the analysis of the first screening round data is being compromised by limitations of the register. Further roll out of the programme would not be possible with the register in its current state.

The Bowel Screening Pilot steering group has become increasingly concerned about these issues and the risks they pose to the pilot. It is clear that input is required from all parties to further develop the register (Information Directorate, Ministry Bowel Cancer Team, WDHB and the developer) however it is not clear who is responsible for securing the additional funding and coordinating the additional resources required to achieve a robust population database.

The steering group recommends that a meeting is convened with all parties to discuss and agree the leadership, membership and funding required for a project to support the development of the register functions through to the end of the pilot in December 2015 – in the first instance.”
19/5/2014 – Email Manager Bowel and Prostate Programmes MoH to BSP IT Meeting

Noted having spoken with a number of people and being aware of a number of issues including the letter listed above. Call for agenda items.

27/5/2014 - Bowel Screening Pilot Steering Group Minutes

Returned mail noted 1% of all mail sent is returned. Notes letter to ID resulted in a meeting in Wellington, good progress made. Records that it was clear there was some reluctance to put too much resource into a database that was only going to be needed until the end of the pilot. States this issue was largely resolved at the second meeting. Noted:

- More rigour needed to be applied to upgrade process.
- Responsibilities clarified including who was responsible for presenting the business case for capital expenditure on the register.
- Additional resource would be secured for the MoH BSP team for a fixed term.
- MoH BSP Team will work with ID to determine needs for a system to support national roll out.
- Risk #1 to be placed on the Funding and Planning Register. Risk #6 reduced to low risk/low impact. Risk #8 can be removed.

(No detail beyond the #number is provided in these minutes for each risk).

“Returned mail data was tabled…”

“The letter to the ID re resources resulted in a meeting.”

“… noted the following…”

11/6/2014 – Email Executive Assistant to Director National IT Board to Chair BSP Steering Group

Acknowledged receipt of letter and indicated agreement to meet.

12/6/2014 - Bowel Screening Pilot Coordination Centre Operations Manual

(The version reviewed was not dated. The reviewer assumes this relates to 2014 within the chronology as references are made to the first cycle that imply it is completed).

The manual sets out the operational aspects of the pilot including maintenance of an issues register, relationships with other agencies, policies including active follow up management for participants who have not responded. Pre invitation, invitation and two year subsequent re-invitation procedure are set out, including that the re-invitation at two years letter is worded to take account that some people may not have received an invitation in the first cycle because of an incorrect address. Refers to odd and even birthdate invitation process i.e. that people with an even date birthday were invited in the first year of the pilot and people with an odd date birthday were invited in the second year.

The manual also notes that in terms of evaluation there is a five year plan including how the pilot might be modified during its lifetime, and the identification of factors that are facilitating or impeding progress towards goals, and the provision of recommendations about enhancements to increase effectiveness and address emerging issues. Further, that evaluation findings will inform recommendations in relation to a national programme. Evaluation aims include safety and acceptability, consideration for programme design and fair access.
“3.4 Issues Register

The BSP maintains an Issues Register to record anything that happens which is inconsistent with BSP policies and processes…. All these events must be captured to maintain a good understanding of issues and determine what needs to be done to prevent issues occurring in future. Issues should be recorded on the Issues Register (any staff member can record an issue) so that they can be discussed at the fortnightly issues management meeting.”

“3.6 Relationships with other agencies

The Coordination Centre management team meets fortnightly by teleconference with the Ministry Bowel Cancer Team. The Ministry’s National Bowel Cancer Clinical Director and Manager are members of the WDHB BSP Steering Group. The Data Manager has a fortnightly teleconference with the Ministry BSP IT (Information Technology) team, including the BSP Register developers.”

“5.2 Policies...

Active Follow-up Management: Outlines the process to follow for participants who have not responded to the BSP invitation...

BSP-Adverse Event and Incident Management Plan: Outlines the process to follow when reporting an incident or potential risk within the BSP. Used in conjunction with the WDHB Incident Management policy.”

“7.2 Pre-invitation and invitation

Invitation

An invitation letter….is sent to every eligible person: ...

Two years after their first invitation, if they were previously invited to participate in the programme (whether or not they responded to that invitation). Their invitation letter is worded to take account of the fact that some people may not have received an invitation to participate during the first cycle because of an incorrect address.

.... In the first two years of the BSP (2012-13), people whose birthday falls on an even date were invited in the first year of the BSP and people whose birthday falls on an odd date were invited in the second year.”

“8. Evaluation of the Bowel Screening Pilot

8.1 Evaluation approach

The process for evaluating the BS is detailed in the “Evaluation Plan for the Bowel Screening Pilot 2011-2016”. This is a five year plan for the evaluation of the BSP...

8.2 Purpose of the evaluation

How the BSP might be modified during its lifetime: The evaluation will identify factors that are facilitating or impeding the BSP’s progress toward its goals, and provide Waitemata DHB and the Ministry with timely and responsive recommendations about potential enhancements to increase the programme’s effectiveness, and solutions to address emerging issues.
The ongoing process of the BSP: The evaluation will provide the Ministry and Waitemata DHB with a clear picture of the performance and progress of the BSP over time, including whether to proceed with the BSP after the first round of screening.

Feasibility of a national roll-out: The evaluation findings will be used to underpin recommendations for the Ministry in relation to a national programme, including parameters and processes that might be adopted, and refinements that might be made....

8.3 BSP evaluation goal and aims

... four key aims....

2. Safety and acceptability: Can a national bowel screening programme be delivered in a manner that is safe and acceptable?

8.4 Evaluation objectives

1. Programme design: To pilot the use of a Population Register closely linked with primary health care services to invite the target population, along with a Coordination Centre and associated information system to manage the Screening Pathway...

7. Fair access for all New Zealanders: To determine whether a bowel screening programme can be delivered in a way that provides fair access for all New Zealanders...”

8/7/2014 – Memo Manager Bowel and Prostate Programme MoH to National Screening IT Advisory Board

(Copy provided appears to be a draft – some content gaps are incomplete).

The memo provides background, details IT considerations for a potential national rollout of bowel screening and recommends noting that the pilot IT system will inform a national IT system, and that there are a number of IT issues to consider in light of a potential national rollout of bowel screening services.

“Recommendations...

1. Note that the BSP IT system will inform a national IT system
2. Note that there are a number of IT issues to consider in light of a potential national rollout of bowel screening services”

15/9/2014 – Notes from initial BSP analysis work

Sets out notes, questions, timeframe for analysis, proposed work and expected outcomes. Includes reference to questions about whether everyone was invited who should have been and to address quality data.

“... Ongoing maintenance for the register includes an NHI download which records changes in addresses (people moving into and out of the Waitemata DHB boundary)...

A PHO register match to link patient with GP is in place but is not working...

It has also been said in an evaluation report that a fifth of people who should have been invited were not...

Questions
Was everyone invited that should have been?

What is the data quality like for the addresses?

Is there anything that could have been improved?

If the pilot were rolled out nationally how would the register be built and updated?

25/9/2014 – BSP Project Progress Report (Report number 38)

In relation to register accuracy – addresses, notes little progress improving accuracy of addresses on register, dependency on MoH address updating, steady stream of returned mail (approximately 5% of all mail sent, most of which is successfully re-sent to correct address located via GP or iPMS [WDHB patient record system].

“Register accuracy – addresses...”.

11/12/2014 – BSP Project Progress Report (Report number 39)

In relation to register accuracy - addresses, reiterates content of report number 38 above.

“Register accuracy – addresses...”

December 2014 - Bowel Cancer Screening Pilot: Population Register analysis (Lee MoH)

Sets out questions including whether everyone was invited to the pilot who should have been, whether the addresses are of high quality and if there is anything that could have been improved regarding addresses and invitations.

States that records tagged “ineligibleDomicile” need more investigation. Notes that spot checking reveals issues with incorrect domiciles being assigned by the NHI’s geocoding engine, address mismatches between the PHO (age/sex) register(s) and the NHI (i.e. in some cases the NHI is more up to date than the PHO register, but that the reverse is also true in some cases). Further noting that the latest address in the NHI appears to not always reflect the ineligibility status of a participant i.e. a person may have changed address to one outside of the WDHB catchment, and then moved back again, but their status remains as “ineligible”. An example is provided.

This section concludes that overall the PHO register(s) include about 13,000 people whose characteristics appear to meet the requirements of the BSP register, but they have not been invited to participate.

The report concludes that further analysis may be of interest to identify why people on the PHO register(s) geocoded to the WDHB catchment who should meet the BSP register criteria, have not been invited to be part of the pilot. Further that the PHO register(s) are currently only used to determine medical centre/GP information for each participant, and recommends extending use of the PHO register(s) to include currency of addressing/domicile information where the last updated date on the NHI is older than the last seen/last enrolled date from the PHO register.

In relation to the question “Was everyone invited that should have been?” The analysis concludes that comparing the BSP register with the Census and PHO (age/sex) register(s) the difference would be around 2-5% that the BSP register is possibly missing. In relation to the question “Are there lessons to learn from when the BSP register was set up?” The analysis concludes that yes, the
system could have taken into account currency of data in the PHO (age/sex) register(s) versus the NHI and used both of these to determine the population.

Included the questions:

“Was everyone invited onto the BSP that should have been?"

“Are the addresses within the BSP of high quality?"

“Is there anything that could have been improved regarding the address or invitations?"

... Those records tagged ineligible with “ineligibleDomicile” need more investigations....Further the latest address in the NHI appears to not always reflect the ineligibility status of a participant – that is, a patient may have changed address to one outside of Waitemata DHB catchment, but then has moved back again, but the status remains as ineligible...

Summary

“Are there lessons to learn from when the register was set up? Yes. The system could have taken into account currency of data in the PHO (Primary Health Organisation) register versus the NHI, and used both of these to determine population."

December 2014 - Bowel Cancer Screening Pilot: Database Review (Karalic MoH)

This review was initiated to investigate issues identified in the CPHR [Centre for Public Health Research] report on round one of the pilot. This report considers data quality and database design and makes recommendations.

Appendix A lists a series of data quality issues (DQ 4, 8, 12, 13, 14, 16) that are noted as lack of logic checks in database. The descriptions for DQ 8-16 inclusive are referred to DQ4. The description for DQ 4 is EnrolmentStatusCode “Eligible” or “Participant” but Withdrawal reason “Address not valid or not found”. The assessment is that there are records for which there was a request for withdrawal at some stage but which later become eligible again, by either changing their mind or better details being available etc. The recommendation notes that the author is unsure that these issues can affect reporting in any significant way, and that for reporting a point in time eligibility history table will be provided by Argonaut which can be used for this purpose. Severity is recorded as “1 – non issue” and Action recorded as “non-issue”.

“Appendix A: Data Quality Issues Register for issue brought up by CPHR ...

ID - DQ4. Category - Lack of logic checks in database. Description - EnrolmentStatusCode “Eligible” or “Participant” but Withdrawal reason “Address not valid or not found”. 418 records affected Assessment - There are records for which there was a request for withdrawal at some stage but which later become eligible again, by either changing their mind or better details being available etc. While some of these instances may be due to a human error, there is usually a valid reason for the change in eligibility. Recommendation – I am not sure that these issues can affect reporting in any significant way. For reporting on participation and coverage rates, a point in time eligibility history table will be provided by Argonaut which can be used for this purpose. The table will also contain the state of each parameter which can affect eligibility at that point... Severity - “1 – non issue”. Action - “non issue”...


24/2/2015 - Interim Evaluation Report of the Bowel Screening Pilot: Screening Round One (Litmus, CPHR, Sapere)

An evaluation report to contribute to a decision on whether or not to roll out a national bowel screening programme. It is noted that a number of critical limitations with the BSP register are impacting adversely on the pilot. It is estimated based on returned mail that between 5-15% of eligible participants may not have received a letter or kit in screening round one potentially due to incorrect address details on the BSP register. States that in the early implementation stages there was insufficient dedicated data and IT resource at WDHB and the MoH which contributed to a lack of timely updates to the BSP register resulting in challenges to ensure data quality.

The report recommends that the MoH comprehensively review the BSP register and implement a robust data quality assurance programme. Noting that the evaluation has identified data quality issues that must be addressed as a high priority. In terms of participation the report states that at least 1,456 of those invited did not respond because of an ‘invalid/not found’ address (i.e. there was no up to date address on the register).

The report identifies that incorrect participant addresses are due to NHI details uploaded to the BSP register being out of date. As a result around 5% of pre-notification letters are returned as not living at this address. Planned regular updates from PHO data to update NHI information and ensure eligible people moving into WDHB are offered bowel screening have not occurred.¹⁰⁴

Concerns are noted regarding understanding of the BSP register sitting with a small number of people in WDHB and the MoH, that some underpinning assumptions are not known, that there are areas of incomplete documentation and not enough dedicated data and IT resources at WDHB and the MoH. Employment of a new full time data manager (at WDHB) in October 2013 and some other changes to increase FTE (at the MoH) is noted as helpful.

Key improvements required are a strategy to enhance accuracy of participant contact details and to identify eligible participants moving into WDHB, and ensuring adequate IT support at the MoH to undertake updates and refinements to the BSP register as needed.

The number of MoH quality documents for the pilot is noted as duplication and potentially confusing.

Includes the following relevant extracts:

1. Executive summary p 7

¹⁰⁴ The reviewer was advised these updates were attempted but did not work.
1.1 Background

The Ministry of Health funded

Population Register objective p11

- Ensuring access to the BSP: it is estimated, based on returned mail...that between 5-15% of eligible participants may not have received a letter or kit in screening round one potentially due to incorrect address details on the Register.
- Data and IT resource at WDHB and Ministry of Health: feedback indicates that in the early implementation stages there was insufficient dedicated data and IT resource at WDHB [From September 2013 the data resource at WDHB doubled] and the Ministry of Health which contributed to a lack of timely updates to the Register resulting in challenges to ensure data quality.

2.3 Description of the BSP p 23

Pre-invitation....

Pre-invitation letters are sent out to approximately 6,000 eligible participants per month. Incorrectly addressed letters are returned to the Coordination Centre. People who call to opt out of the GSP are recorded as such on the Register.

Table 6: List of data and information used and their quality p 37

Data sources  BSP epidemiology analysis

Quality rating  Low

Comments on quality  It is recommend[ed] that the Ministry of Health comprehensively review the BSP Register and implement a robust data quality assurance programme. The evaluation has identified data quality issues that must be addressed as a high priority for the final evaluation and to monitor a national programme. Data quality issues identified include data definition, data inconsistencies, errors and data capture.

Participation p 41

At least 1456 of those invited did not respond because of an “invalid/not found” address.

Conclusions (re-iterate above Comments on quality) p 58

3.2 Programme design p 59

Key evaluation findings (re-iterate above Population Register objective findings)

The BSP Population Register p 59

A built for purpose information system (the BSP Population Register) was developed to support the BSP.... The BSP Population Register is owned and overseen by Ministry of Health. WDHB’s work on the Register is based at the BSP Coordination Centre and managed by the BSP Data Manager.

Incorrect participant address and contact details p 60

- Incorrect participant addresses are due to NHI details uploaded to the Register being out of date. As a result around 5% of pre-invitation letters are returned to the BSP Coordination Centre as not living at this address [136,575 pre-invitations were mailed out from 1 January
2012 and 1 January 2014. For the months of May- December 2013, 1954 pre-invitation letters were returned as not at this address; an average of 61 a week which is equivalent to 6344 returned mail over two years.

- Planned regular updates from PHO data to update NHI information and ensure eligible people moving into WDHB are offered bowel screening have not occurred.

Lack of data and IT resource p 61

- Understanding of the Register sits with a small number of people in WDHB and the Ministry of Health and some of the assumptions underpinning the definition of variables are not known. There is documentation about the Register at the Ministry and WDHB, although there are incomplete areas.
- Not enough dedicated data and IT resources at WDHB and the Ministry of Health which contributed to a lack of timely updates to the Register resulting in challenges ensuring data quality.

In October 2013 a new full time data manager was employed at the BSP Coordination Centre which may help to address these issues....

Key improvements required to enhance the Register’s effectiveness are: p 62

- Developing a strategy to enhance accuracy of participant contact details and to identify eligible participants moving into WDHB...
- Ensuring adequate IT support at the Ministry of Health to undertake updates and refinements to the Register as needed.

Resource and activity overview p 85

Reallocation of resources is summarised including:

BSP Coordination Centre:

- Following resignation of the 0.5 FTE Programme Manager in 2012 the Project manager took on this role as a 1.0 FTE...
- The Data Manager FTE increased from 0.5 to 1 FTE from September 2013.

Ministry of Health

- An additional senior advisor.

3.7 Quality Monitoring p 100

... Duplication and potential confusion due to the number of Ministry of Health quality documents for the BSP.

9/10/2015 – Memo Principal Advisor Bowel and Prostate Cancer Programmes MoH to SCIIMGG MoH re Enhancements to the Waitematā BSP IT system for round 3

Note: The author of this memo advised that a second request for funding was made as this was such an important issue. The reviewer requested but did not receive a copy of the second memo requesting this.
Seeking support to upgrade the current pilot IT system to support extending the pilot for Round 3. States that in order to accommodate efficient running of Round 3 the IT system must be upgraded but there is no capital funding available in the current year.

Issues listed include the number and inefficiency of work-arounds, backlogs, people not receiving an invitation or test kit, and the cost of this is calculated as $156,000. Enhancements are recommended and the need for more flexibility is noted. Agreement for support to upgrade the pilot IT system for Round 3 at a cost of $245,000 is sought.

Proposed enhancements for Release 5 listed include allowing on hold (withdrawn) patients to be invited if they have previously been put on hold (withdrawn) due to returned mail but they have an updated address on the NHI, issues with eligibility due to address changes, a ‘pending’ state and improvements on how work tasks are resolved.¹⁰⁵

“... seeks your support to a proposal to upgrade the current bowel screening pilot IT system to support the extension of the Waitemata pilot for Round 3...

The ...pilot was due to run for four years to cover two invitation rounds of two years each. In Budget 2015 the Minister announced that a further two-year round would be funded and preparations are being made to allow Round 3 to commence in January 2016.

In order to accommodate the efficient running of Round 3 of the pilot the IT system must be upgraded although no capital funding is currently available within the 2015/16 year...

Essential enhancements to prevent a negative impact on patient safety, accurate reporting and monitoring of quality standards...

There are a number of work-around processes in place that were not rectified due to the pilot originally finishing at the end of this year. It is not appropriate to continue these work-arounds now that the pilot is extended until the end of 2017...

Essential enhancements to reduce inefficiencies that are causing delays for patients and increasing workload for Waitemata staff

There are some processes (often manual) that have created a backlog of work for staff at the co-ordination centre. These backlogs will only increase unless systems can be automated and/or simplified for staff. For example there is a huge backlog of patients who have changed their address or GP details – this will lead to more people not receiving an invite and/or test results being sent to the incorrect GP. The recent Interim Evaluation ... for Round 1, identified that as many as 15 percent of the invited population were not receiving their test kits. As each invitation pack costs $7.95 this equates to wasted expenditure of approximately $156,000. This issue also puts the Ministry at risk of criticism that too many prospective participants are not being offered an invite....

Enhancements critical to test 6-12 months before the implementation of a national roll-out...

There are requirements to test alternative ways of sourcing vital information (on GP patient links and updated addresses) through Primary Health Organisations and Central Enrolment Services data (when the latter comes online). Current systems are not working as expected.

The need for more flexibility within the pilot has been identified, to enable a more agile approach to any issues that arise. Current responsiveness to issue experienced within the service is limited by

¹⁰⁵ The reviewer was advised that the request for funding was not approved.
Ministry processes. Adding a certain level of flexibility to the system could bypass the need for lengthy delays to mitigate a low level risk or rectify simple issues.

Financial implications...

Over the last few years the capital budget has made an allowance for enhancements to the BSP IT pilot system. Release 4 (which was sought from the 2014/15 budget) was funded from the 2015/16 capital budget but no further funding is currently available due to the budget being fully allocated for 2015/16.

This memo seeks your support to the proposed enhancements in Release 5 and proposes that a memo be submitted to the Performance and Finance Committee seeking their approval to the proposal being lodged initially as a pressure against the 2015/16 budget and then if funding becomes available during the year that the proposal is funded in full or part (with the balance from 2016/17).

Recommendations...

1. Agree to support the enclosed proposal to upgrade the bowel screening pilot IT system to enable an efficient and functional extension of the pilot for Round 3 at a cost of $245,000

2. Agree that a memo .... Seeking approval to Release 5 being lodged....

3. Note the potential IT options for a possible national bowel screening programme...

Appendix 1 – Description and approximate costs for Release 5 enhancements

Release 5 milestone

5.1 Allowing a patient who is currently on hold, to be invited if they have previously been put on hold due to having returned mail, but an updated address is identified on the NHI...

5.1 Issues with eligibility due to address changes and ineligibility due to death...

5.2 Add a new recall state of ‘pending’ for the many people who refuse a colonoscopy and then change their mind...

5.3 Improvements on how work tasks are resolved to make considerable efficiencies to staff

10/11/2015 – Risk Register for the delivery of a National Bowel Screening Programme – MoH

No risks are dated on this register. Current risks of note:

- Title: IT maintenance not sufficient. Risk: If the IT support for ongoing maintenance and enhancements of the bowel screening IT system is insufficient then the programme will not be sustainable. Potential Sources: There has been inadequate resource to implement enhancements required to the Pilot system. Current likelihood: Likely. Current consequence: Major. Mitigation strategy – ensure business case recommends adequate CAPEX for maintenance over time.

- Title: Quality/Consistency/Safety. Risk: If there is poor quality along the pathway then there is an increased risk of adverse events for participants and decreases consistency of participant experience across NZ. Potential Sources: Inadequate quality systems. IT system is not designed adequately. Current likelihood: Possible. Current consequence: Major.
Mitigation strategy – There is a quality manual for the pilot which can be built on using learnings from the pilot.

- Title: Inadequate funding. Risk: If the funding allocated for the bowel screening programme is insufficient to cover all costs associated then the programme will fail as services cannot be provided. Potential Sources: Uncertainty about the level of new funding that will be allocated to the programme. Current likelihood: Possible. Current consequence: Major.
  - Mitigation strategy – Business case recommends full funding of programme.

- Title: IT resources not fully allocated to NBSP. Risk: IT screening platform development could dominate resource allocation for the NBSP, thereby under resourcing requirements for the extension of the pilot system. Potential Sources: IG (Information Group) could potentially use staff and funding allocated to NBSP for platform development. Current likelihood: Possible. Current consequence: Major.
  - Mitigation strategy – Co-location of IT resources and project team to ensure open communication and allocation of resource. IT project Manager to report to SRO and IG weekly on progress against critical pathway.

- Title: Participation. Risk: If participation is not adequate to provide population benefits then it will not be viewed as cost effective or worthwhile doing the programme. Potential Sources: Screening programmes require a minimum participation of 45% to be effective in achieving population health gains. Current likelihood: Possible. Current consequence: Moderate.

27/11/2015 – Ticket #275 (closed enhancement: fixed indirectly)

- (Uncertain of date ticket was first documented, document not dated, printed 27/11/2017 but oldest changes relate to two years previously i.e. 2015).
- Record of activity related to Ticket #275 “Returned mail – put on pathway hold with a reason code of “Returned mail”. This document notes that the ticket was opened two years ago. The description is “If an address update comes through and the person is on pathway hold with that reason code, then they are automatically taken off pathway holiday.”
- The document change history from 2015 to most recent details changes that initially provide for allocation to withdrawn status, noting there is no automatic work task closure (date presumed 2015). Pathway hold flexibility would allow the user to put the person on pathway hold instead of withdrawing them as a work around. The returned mail document is attached. A request to check and see how much automation can be done to reduce workload is recorded (date presumed 2016).
- The status is recorded changed from analysis to closed and resolution changed to fixed indirectly in 2017 by Argonaut. It is documented that “Analysis for the ticket #186 has determined that automated resolution of WT00 is complicated and will require development of new algorithms and potentially collection of additional data. To help resolve worktasks on time, BSP+ has implemented worktask notification via email notification. Refer to the following ticket for more details: #359 Worktask email notification.”
- The reviewer was advised that the ticket only contains comments by Argonaut and the WDHB team and that there was no full analysis or costing completed in relation to this ticket.
- WDHB advised that the ticket was closed in error (a different ticket referring to automation around management of worktasks not the GNA issue was meant to be closed).
“Returned mail – put on pathway hold with a reason code of “Returned mail”. Opened two years ago... Description - if an address update comes through and the person is on pathway hold with that reason code, then they are automatically taken off pathway holiday...

Change history

• Changed 2 years ago (assume 2015)

Options

1. Withdraw the person, reason = unknown address/returned mail
2. Set status to ineligible
3. On NHI lookup, they can be taken off holiday/withdrawn if updated address available
4. Define new pathway action on returned mail...

• Changed 2 years ago (assume 2015)

‘As an interim measure for managing returned mail we will withdraw the person and use as reason “address not valid or not found”. We will also record the type of letter that was returned in the comments box...

• Changed 14 months ago (assume 2016)
• ... No facility to enter a pre-defined reason code when a person goes on pathway holiday...
• No automatic worktask closure...

Options to address...:

• Pathway hold flexibility would allow the user to put the person on pathway hold (instead of withdrawing them as a work around)...
• Can you please check out the WDHB process as per the attached... and see how much automation can be done to reduce workload.
• Changed 8 months ago (assume 2017)

Status changed from analysis to closed

Resolution set to fixed indirectly.

Analysis for the ticket #106 has determined that automated resolution of WT00 is complicated and will require development of new algorithms and potentially collection of additional data. To help resolve worktasks on time, BSP+ has implemented worktask notification via email notification. Refer to the following ticket for more details: #359 Worktask email notification.”
• The (national) programme team are under significant time pressure to deliver a quality business case – more collective strategic leadership, engagement and direction from Executive Leadership Team (MoH) is required.
• The availability, reliability and functionality of IT systems are the highest risks to the successful implementation of the programme. Other key risks for the programme are programme leadership, DHB preparedness, inequitable participation in the programme, quality framework, managing expectations and communications.

The report finds that there is universal support and compelling international evidence for the introduction of a National Bowel Screening Programme. The status is Amber i.e. “Successful delivery appears feasible but significant issues already exist requiring management attention. These appear resolvable at this stage and if addressed promptly, should not impact delivery or benefits realisation.

Recommendations include:
• “Do now – That the Executive Leadership Team provide strategic leadership, engagement and direction for the Programme Team to ensure a quality business case is delivered and the timelines are met….
• Do now – That the Ministry gives priority to the immediate improvement or development of a more appropriate IT system to ensure the effectiveness of the programme.”

The report notes that the pilot has “given an opportunity to trial and end to end process and to make modifications to the service delivery model, system, processes and communications based on findings to improve participation and clinical results. It also provided an opportunity to test capacity and capability and to develop core collateral for a national programme.”

The report’s findings in relation to business case and stakeholders include p 8:
“…16. The ability of the Programme team to deliver a quality business case has been compromised by:

(a) Difficulties experienced in securing the appropriate support and expertise.
(b) The short time frames.
(c) Variable and late levels of engagement, influence and contribution from other teams across the Ministry.

17. ...it became apparent to the Review Team that the Ministry’s leadership team had variable levels of understanding and commitment to the programme. Given the priority of this Programme more collective strategic leadership, engagement and direction from the Executive Leadership Team is required.”

notes that the pilot has “given an opportunity to trial and end to end process and to make modifications to the service delivery model, system, processes and communications based on findings to improve participation and clinical results. It also provided an opportunity to test capacity and capability and to develop core collateral for a national programme.”

The report’s findings in relation to risk management include p 11:
“4.3... IT Systems
28. A centralised Data Repository is critical to the implementation of the Programme. The current Ministry of Health IT system used by the Pilot is inadequate. It already has “work arounds”, manual data entry and limited clinical audit and reporting functionality. The end users described the system as ‘being a nightmare’.

29. The Ministry has plans to upgrade the system by 2017 while developing and implementing the national bowel screening IT platform.

30. There has been investment in the IT system supporting the Pilot. Concerns were expressed about the timeliness of response and adequacy of the investment. It was also reported that a recent capital request to fund necessary upgrades had been declined. There is risk that the roll out to the next SHB will be compromised by the inadequate IT system and that a new system will not be in place by 2018 to support future DHBs.

The Business Case is seeking funds for the new IT system. The solution must offer a full population screening system and address the issues described above and unearthed in the Pilot as well as fully interfacing with other GDHBs and primary care IT systems.

32. The availability, reliability and functionality of IT systems are the highest risk to the successful implementation of the Programme.

Programme Leadership

33. The national Programme will require effective operational and clinical leadership and a clearly defined governance structure to support them with implementation and ongoing maintenance and evaluation.”

Recommendations in relation to risk management include p 14:

“…4. Do Now - That the Programme update the Risk Register.

5. Do Now - That the Ministry gives priority to the immediate improvement or development of a more appropriate IT system to ensure the effectiveness of the Programme.”

In relation to readiness for next phase p 14:

“…51. There is a plethora of steering and advisory groups associated with the programme and more broadly the screening activities of the Ministry. It was identified that representation on all these groups was difficult to achieve but also meant that information was variably understood. The new governance structures should replace a number of these committees.”

29/1/2016 – Returned Mail

(The reviewer was advised that this is an update to an earlier version.)

Procedure for processing all mail returned to the coordination centre. Sets out procedure including entering details of returned mail on a spreadsheet, check to see if the BSP register has been updated with a new address, search for new address in IPMS or the PHO file (age/sex register), check ethnicity (Community Coordinator to follow up active follow up groups). If no address is found through the above processes they are withdrawn from the programme choosing the drop down option of Address not valid or not found.
1/8/2016 - Final Evaluation Report of the Bowel Screening Pilot: Screening Rounds One and Two (Litmus, CPHR, Sapere)

A final evaluation report 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. Notes estimates based on returned mail that between 5-15% of eligible participants may not have received a letter or kit in screening round one potentially due to incorrect address details on the BSP register. It is noted that there are known issues with the currency of addresses with a return to sender rate of around 6%. The invitation strategy is detailed. Efforts to identify correct addresses for returned pre-invitation mail are noted. That the workforce has been relatively constant in Round 2 is noted, and the WDHB flexible student workforce response is noted.

It is noted that an issues register is maintained, issue are reviewed weekly, quality indicators are reviewed every third WDHB Steering Group meeting.

No fixed residence/frequent change of address is noted as a barrier to participation.

It is noted that the BSP register needs to be up-to-date, invite all those eligible to take part, inform “real time” follow-up activities and support reminder processes through interfacing with existing primary care systems. Further the BSP register needs to enable the monitoring of uptake and equity across the pathway. The reviews undertaken in response to the Interim Report are noted and that Lee 2014 found a lack of currency of participant contact details which may mean some people may not receive an invite. The report notes that in this context (6% return rate) most but not all eligible participants are being invited to participate.

The report notes that there have been 5 upgrades to the BSP register over the course of the pilot. But notes that due to constrained IT resources at the MoH not all functional issues have been addressed. The use of manual processes in the BSP Coordination Centre and the demands this places on capacity are noted. It is also noted that not having regular PHO enrolment updates means that contact details in the BSP register may be out of date or an incorrect GP may be listed.

The report concludes that no substantial environmental or clinical safety issues were identified. A systematic review of the operational functionality of the BSP register to determine whether it can work efficiently for a national bowel screening programme is needed. This will clarify further updates required, including ensuring participant and GP information on the BSP register is up to date.

The report concludes that the pilot has done its job of testing a bowel screening pathway design, identifying feasible roles, and risk to translate to a national bowel screening programme and learning needs to be carried forward into a national roll out. The report states that for the BSP register to operationally manage a national bowel screening programme, at least in the interim, a number of enhancements and greater integration with other systems are needed and recommends a functional review of the operation of the BSP register if used to support a national bowel screening programme.

Includes the following relevant extracts:

2.1 Background to BSP p 6

The BSP
The Ministry of Health funded Waitemata District Health Board (WDHB) to run a Bowel Screening Pilot programme (BSP) over four years from 2012 to 2015. The BSP began with a soft launch in late 2011 with full operation of the pilot starting in January 2012.

- Ensuring access to the BSP: it is estimated, based on returned mail...that between 5-15% of eligible participants may not have received a letter or kit in screening round one potentially due to incorrect address details on the Register.

2.3 Description of the BSP p 9

Identification

All men and women aged 50 to 74 who lived in the WDHB area .... were eligible to participate in the BSP. Most people in the eligible population were to be invited to participate in two screening rounds within the four-year BSP period....

Participation in the BSP was by invitation only. The Coordination Centre invited eligible people to participate in the BSP according to their birth date. In 2012 and 2014, invitations were sent to people with even numbered birth dates. In 2013 and 2015 invitations were sent to people with odd numbered birth dates. People who “aged in” or moved into the area in 2014 and 2015 were invited in the month following their birth date. There were no referrals into the pilot by a health professional. However, eligible people not on the BSP Register could contact the Coordination Centre to be included or their general practice could request their inclusion.

Pre-Invitation

... Pre-invitation letters were sent out to approximately 6,000 eligible participants per month. Some of the incorrectly addressed letters were returned to the Coordination Centre. Action was taken to identify correct addresses. People could opt out of the BSP at this stage by advising the Coordination Centre and their decision was recorded on the register.

2.4 Changes in Round 2 p 16

Workforce changes p 19

The BSP workforce has remained relatively constant in Round 2. Some noted changes include:

- ...The BSP Coordination Centre introduced a student panel to develop a flexible workforce to assist with the many manual activities related with the Register.

Quality monitoring

Quality indicators are reviewed in every third WDHB Steering Group meeting.

5.4 Invitation to take part p 67

A review of the Register indicates that most but not all eligible participants are being invited to participate in the BSP (Lee 2014). There are known issues with the currency of addresses which is demonstrated by a return-to-sender rate of around 6% in Round 2 (refer section 6.1)...

5.8 Multi-factor interventions in a national bowel screening roll out p 71

... Table 12: Summary of enablers and barriers to participation (from the literature) ...

System: No fixed residence/frequent change of address
5.9 Conclusion p 73 ...

p 75 Integrated Register: The Register needs to be up-to-date and invite all those eligible to take part. The Register needs to inform “real time” follow-up activities and support reminder processes through interfacing with existing primary care systems. Further the Register needs to enable the monitoring of uptake and equity across the pathway.

The ability to connect systems and talk across systems so that we can get the best efficiency out of communicating with people and follow-up systems if they are required. So that we are not having to create new systems to do this work. (Stakeholder)

6.1 Assessing safety in screening programmes p 77 ...

The National Screening Unit (2005 p.10) states that safety, defined as the extent to which harm is kept to a minimum, is one of the four dimensions of quality for a screening programme.... In this context, the screening pathway of the BSP is assessed to determine whether it is safe, and thus addresses whether a national bowel programme can be delivered in a way that is safe.

P 78 Quality standards and assurance and improvement processes ...

An issues register is maintained and issues are reviewed at the weekly staff meetings. The three risks identified for the pilot are achieving equity in the pilot, the ability to ensure that all eligible people living in WDHB are on the Register and....

p 79 Ensuring all eligible participants are invited

.... However, the interim evaluation report questioned the completeness of the Register, data and IT resource to support it, and the ability to effectively assess participation and outcomes (Litmus et al 2015). To address these concerns the Ministry undertook two reviews of the BSP Register to assess completeness of the eligible population listed in the Register, and data quality.

... However, the review also found a lack of currency of participant contact details which may means some people may not receive an invite (Lee 2014) It is estimated that in 2014 the BSP Coordination Centre received 3,528 returned items compared with 5,727 in 2015 (approximately 6% of the 146,131 people who were sent items). In this context most but not all eligible participants are being invited to participate in the BSP.

p 80 Having an operationally efficient Register

.... Over the course of the pilot there have been five upgrades to the Register; although due to constrained IT resources at the Ministry not all functional issues have been addressed.

Operationally the BSP Coordination Centre uses a number of manual processes to deliver components of the screening programme... The manual nature of the workplaces more demands on the available BSP Coordination Centre data management capacity.

Not having regular PHO enrolment updates means that contact details in the Register may be out of date or an incorrect GP may be listed.

6.3 Conclusion

Safety

.... Within the scope of the evaluation, no substantial environmental or clinical safety issues were identified.
The Register

... Feedback on the operational functionality of the Register highlights the need for a systematic review to determine whether it can work efficiently for a national bowel screening programme.

A systematic review of functionality will clarify the further updates required. Based on stakeholder feedback this may include: ensuring participant and GP information on the Register is up to date......

7. Conclusion

.... The BSP has done its job of testing a bowel screening pathway design, identifying feasible roles, and risk to translate to a national bowel screening programme.

.... Learnings from the BSP need to be carried forward into a national rollout...

The Register is both the operational driver of the bowl screening programme and its monitoring and reporting tool. Whether the current Register with its manual work-arounds and support from separate databases, can undertake the day-to-day operation of a national programme has not been determined. For the Register to operationally manage a national bowel screening programme, at least in the interim, a number of enhancements and greater integration with other systems are needed.

Areas for further study include:..... A functional review of the operation of the Register, if used to support a national bowel screening programme.

17/08/2016 – External IT Review National Bowel Screening Programme (NBS) –
Accenture Consulting

Three major findings:

- Proposed overall IT delivery approach is sound (interim solution and national development of a long term IT solution.
- Further work required to validate the proposed IT solutions. Shared understanding is needed. It makes sense to enhance the current pilot solution. Further analysis is required in terms of longer term options.
- The programme is not yet effectively mobilised. There is an evident lack of alignment between the Business and IT. There is an urgent need to put in place the right structures, governance, resources, approach and delivery disciplines for a programme of this size and complexity.

29/08/2016 – Programme Business Case & Tranche 1 Business Case National Bowel Screening Programme

Sets out the:

- Justification, proposed approach, timing and cost of procuring a national bowel screening programme (including Waitematā Transition).
- Local context, proposed approach, timing and costs for the first implementation phase of the national bowel screening programme.

P 24 Bowel Screening Pilot
The participation rate of 56.8 percent was higher than the internationally accepted minimum participation rate of 45 percent.

P 26

3.4 IT solution to support a national bowel screening programme

Good information systems are vital to ensure the optimal, safe and ethical delivery of screening activities. Comprehensive and efficient information systems are pivotal to the successful identification and invitation of eligible people to participate in screening, as well as underpinning failsafe mechanisms and adequate safety provisions for individual participants. The IT solution to support the National Bowel Screening Programme would provide the workflow checks and processes to support good business processes for ensuring follow up with quality diagnostic testing and treatment for detected bowel cancers.

The IT solution established to support the pilot site was specifically developed for the Bowel Screening Pilot, within constraints of costs and timeliness and within the context of the relatively small nature of the pilot. Numerous enhancements to the pilot system have since been applied successfully, as new requirements and changes have been identified.

A key assumption is that the business processes that are operating in the pilot site are largely representative of those that are expected in a national rollout. Going forward into the national programme, the assessment of the existing pilot system is that it would not be possible to successfully scale, in its current form, to meet the needs of a national rollout to a further 19 DHBs. This assessment is based on the knowledge gathered from the pilot system, including the identification that approximately 50 percent additional functionality is achieved manually by the Pilot and would need to be automated in a national system.

Learning from other jurisdictions indicates a strong need for flexibility within particular elements of the application such as the ability to change the test technology and associated clinical pathway. The BSP IT system lacks the flexibility in its core components to adapt as required.

P 63 Preferred way forward

People in the eligible population would be invited to participate every two years.

P 65

- **Information Technology to support a National Bowel Screening Programme**: There would be a single national IT solution to support the National Bowel Screening Programme, fully integrated across all DHBs. This system would be the primary administrative system and clinical decision support tool for the successful operation of the national bowel screening programme. The IT solution (or some components thereof) would therefore be required to be available 24 hours x 7 days x 365 days a year and highly resilient.

The National Bowel Screening IT solution would be delivered in alignment with the Ministry’s IT Strategic Vision. This would reuse existing technology components where appropriate and leverage and extend existing integration patterns, for example Ministry of Health investments in common services, such as the National Health Index (NHI), Address Services (eSAM) and Enrolment and Eligibility Services. The proposed system would integrate with the relevant operational systems at DHBs, such as ‘ProVation’ and pathology reporting platforms, to allow the end-to-end bowel screening programme processes to be implemented.
Appendix 1: Initial Findings - Bowel Screening Pilot

The Bowel Screening Pilot (BSP) commenced in late 2011 with the invitation of the ‘first 500’. These 500 participants (from a single Primary Health Organisation (PHO) in Waitemata) were invited prior to the BSP officially commencing. Lessons learnt from the ‘first 500’ were incorporated into the service delivery model for Round 1, which commenced in January 2012...

The population register is kept as up to date as possible (via linkages with the NHI database, via manual update by the team at the Waitemata co-ordination centre and through data uploads from the New Zealand Cancer Registry) which ensures demographic information is as reliable as possible.

10/11/2016 – Returned Mail

(Presume an update to Returned Mail 29/1/2016 above).

Procedure for processing all mail returned to the coordination centre. Sets out detailed procedure.

WDHB advised that this is more correctly described as a working document associated with ticket #275. It summarises the processes as part of Ticket #275 and includes options suggested for addressing the issue. It should be read in conjunction with Ticket #275. Options up to #6 and #7 were what the pilot was doing. None of the options beyond #6 and #7 were put into practice, they were suggestions as to how returned mail might be managed.

The document demonstrates that work was done to scope out what the changes in the register may be to address the withdrawn issue but that the work was never completed.)

Procedure for processing all mail returned to the coordination centre. Sets out procedure including entering details of returned mail in a diary note in the BSP register, check to see if the BSP register has been updated with a new address, search for new address in IPMS or the PHO file, contact the GP, try phoning the person. If no new postal address is found delete the incorrect address from the BSP register as this cannot be updated automatically. Check ethnicity (Community Coordinator to follow up active follow up groups). If no address is found through the above processes raise a WT024. After a WT024 is raised this will track overnight with the NHI for a new address. There is a note “This is our ideal and we would like it to be electronic”. A 5 step process is set out as follows:

1. If a new address is found in NHI a date check is done against the BSP register address
2. If a new address is found a check is done that the domicile code is valid.
3. If the domicile code is out of area update the record to invalid due to domicile code
4. If domicile valid check address valid.
5. If address valid carry out one of four actions to update the pathway state.

Questions are raised as to the criteria for establishing there is a new address, and it is noted there were issues with WT024 in the past.

(The reviewer was advised by WDHB that WT024 was not used for this purpose since 2013)

February 2017 BSP Risk Management Post Implementation

(While dated February 2017 in the document’s title the content includes regular reference to go live timeframes which was early 2012.)
Risks, likelihood, impact and mitigations are recorded. There is reference to risk that the BSP register does not accurately represent the population (reviewer advised this was added in January 2014). Rated high risk and medium impact. Mitigations:

- Re-confirm the business rules which determine the BSP register population
- Establish a process of regular updates to maintain the eligible population on the BSP register
- Maintain as many manual updating processes as resources permit
- Maintain a programme of advertising for people to contact the coordination centre if they have not received an invitation

“... the register does not accurately represent the population. Rated high risk and medium impact. Mitigations:

- Re-confirm the business rules which determine the Register population
- Establish a process of regular updates to maintain the eligible population on the register
- Maintain as many manual updating processes as resources permit
- Maintain a programme of advertising for people to contact the coordination centre if they have not received an invitation”

Closed risk (not dated)

“... Funding may not available to support the required local IT developments. Rated low risk and medium impact. Mitigations:

- Involve Primary Care and the Coordination Centre in the identification of requirements as soon as the programme business model is confirmed.
- Develop business cases for systems enhancement or development
- Develop manual processes which support the pilot, in the event electronic methods are not funded or in place for ‘go live’”

12/5/2017 – Ministry of Health BSP Due Diligence Interim IT Solution Assessment (Ernst Young)

This report completed an assessment of the BSP+ IT solution to understand whether or not the IT solution can be further enhanced and extended in a way the functional suitability can meet short to medium operational needs, and is safe for bowel screening. This was in relation to rolling out a national programme. It details risks and makes a number of recommendations including documenting the full functional scope of the BSP+ IT solution including any outstanding change requests or defects.

- P 5 “Ernst & Young (EY) was tasked to complete an assessment of the BSP+ IT solution to understand whether or not this IT solution can be further enhanced and extended in a way the functional suitability can meet short to medium operational needs, and is safe for bowel screening...

- 1.2 Conclusions

- The planned Release 7 of the BSP+ IT solution, due for completion by 1 July 2017, will meet the functional needs of the NBSP and allow for the onboarding of other DHBs. However, §Release 7

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106 The IT solution specifically developed for the pilot, within constraints of costs and timeliness, and within the context of the relatively small, single site – WDHB – was referred to as the “BSP IT solution” or “Pilot Register”. “BSP+” was a term used to describe the solution after subsequent numerous enhancements were applied.
of the BSP+ IT solution cannot safely support any DHBs currently onboarded, or onboarding to, the IT solution. A safe IT solution would be defined by, but not restricted to:

- Alignment with the National Screening Unit Quality Framework guidelines and principles.
- Compliance with Interim bowel screening quality standards.
- Meets the functional needs of the screening programme and can be operated safely for the participants across the sector.
- If remedial action is taken, the BSP+ IT solution will be able to safely support DHBs 1-6 and beyond.
- The BSP+ IT solution is not suitable as the foundation for a long term or strategic IT solution. This includes the NBSP and/or other potential future population health programmes as it would require significant rework and extension to support additional requirements. The functionality and scope of release 7 of the BSP+ IT solution should be locked down, and only change to support critical operational enhancements of defects that should be supported to ensure operational and quality risk is reduced as the IT solution is rolled out to further DHBs...

P 12 To improve the functional suitability of the BSP+ IT solution the following recommendations have been identified:

1. Document the full functional scope of the BSP+ IT solution, including any outstanding change requests or defects and re-baseline all design and operational documentation for the interim IT solution, including manual data entry, management and reporting. This may include:
   a. Using new NHI interfaces
   b. Introducing batch interfaces of participant identification invitation management.
2. Lock down the scope of the BSP+ IT solution to allow for only critical functional changes required to support the successful and safe onboarding of DHBs 2 and 3 to the bowel screening programme.
3. Lock down the functional scope of the interim IT solution and deliver no further functional enhancements to the IT solution as it is rolled out to additional DHBs.”

May 2017 - Gateway Review Report 0/4 - Ministry of Health National Bowel Screening Programme - Treasury

This report is Review 0/4 – Readiness for service. The report includes the following of relevance to this review:

- Key risks for the programme include overall programme management approach and development of a suitable clinically safe national IT solution.

P 1 “The major remaining risk is the timely upload to the BSP register of population data and the necessary changes to the current BSP register software”.

P 2 “Based on timelines it is likely that the IT system for the BP register for these DHBs will be an enhanced version of the BSP register. While some analysis is being undertaken an investment strategy and a gap analysis against the planned national system will lead to a prioritised list of changes based on clinical safety and operational efficiency”.

Recommendations include p 4:
• “R2. Do now – That the three DHBs and the Ministry jointly agree the acceptable IT operations and clinical risk profile for the current BSP register and the immediate actions necessary for remediation.

• R3. Do by Sept 2017 – That the Programme develops a comprehensive strategy for enhancing the GSP register to meet the needs of on boarding more DHBs.

• R4. Do now – That the Programme structure clearly identifies the commercial, architectural and delivery expertise to engage with the vendor to deliver the national IT solution”.

Findings and Recommendations include: p 10:

“… 2. A revised Programme Business Case was approved in August 2016. There has been a change in procurement strategy for the National IT solution away from an internal build to an externally sourced solution. The implementation of the IT solution has been extended out six months. The planned timeline for the Programme has not changed” ...

“…12. Placing the Programme within the National Screening Unit is seen as a positive development providing access to experienced screening programme resources and alignment with population based health strategies, quality frameworks and thinking”.

In relation to risk management: p 11:

“Programme Risks
15. The Programme is being led by a governance group comprising senior Ministry executives. There is intent to expand this group to incorporate independent and non-health Programme advice which should enhance the quality of governance.”

“Programme Management Approach
17. The review team and some of those involved have noted concerns with documentation related to:

• Consistent application of version control
• Provision of evidence or supporting information to clarify/validate decisions or timelines
• Inconsistencies between related documents
• Clarity of Programme team roles and responsibilities and accountabilities
• Change control and the threshold for triggering change requests

18. The Risk and Issues Management Plan was provided. The risk register has varying levels of quality in risk identification and related mitigation strategies. However there is a plan to refresh the risk register and improve the escalation of risks to the Governance group.

19. The team was advised that PWD was engaged to assist the Ministry to refresh the risk strategy. As a consequence of monitoring of very high, high and deteriorating risks will now be managed by the Governance group. Other risks will be managed in a fortnightly meeting between the SRO and the Programme/NSU managers. There is an escalation path through to governance. This approach is not yet documented in the Risk and Issues Management Plan”.

Programme is being led by a governance group comprising senior Ministry executives. There is intent to expand this group to incorporate independent and non-health Programme advice which should enhance the quality of governance.”

P 17 “60. Based on timelines it is likely that the BSP register for these DHBs will be an enhanced version of the Pilot BSP. While some analysis is being undertaken we expect that an investment
strategy and gap analysis against the planned national system will lead to a prioritised list of changes based on clinical safety and operational efficiency. We have not seen evidence that the investment in this interim BSP system is aligned with the timing and completion of the future national solution”.

Appendix E p 33 describes the actions of the MoH in response to Gateway Review Report 0/1.

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Action taken by Ministry</th>
<th>Gateway Review Team Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 That the Executive Leadership Team provide strategic leadership, engagement and direction for the Programme Team to ensure a quality business case is delivered and the timelines are met</td>
<td>Completed. The Ministry established an Interim Governance Group in 2016, and has just established a full Governance Group for the NBSP.</td>
<td>Noted</td>
</tr>
<tr>
<td>4 That the Programme update the Risk Register</td>
<td>BAU. The NBSP team meets monthly to review the management of the very high and high risks.</td>
<td>Noted. Refer Section 4.2 in this report.</td>
</tr>
<tr>
<td>5 That the Ministry gives priority to the immediate improvement or development of a more appropriate IT system to ensure the effectiveness of the programme</td>
<td>BAU. The Ministry is waiting to receive a final report from Ernst &amp; Young. A Request of Interest in the national IT solution will go live in May 2017.</td>
<td>Noted. Refer Recommendation 4 in this report.</td>
</tr>
</tbody>
</table>


Includes section “Returned mail” p 81-86. Sets out manual processes to work through. Notes due to time restraints, returned mail can be partly investigated (to the step where the participant’s medical centre is contacted) and followed up later. If the investigation is delayed a work task should be created so the participant will not get any further mail. The workflow concludes with “Withdraw the participant from BSP Register” and “End” for the process where all efforts to check for an updated address have been unsuccessful.

P 81 “Returned mail

... for this reason mail that is not able to be delivered is returned to the Coordination Centre and investigated. It is important that all returned mail is followed up regularly to ensure communications are delivered…. As these … may include invitations to participate in the program and test results....

The following quality statements apply:

- Coordination Centre staff will check all returned mail and search other sources to determine the person’s current address...

Due to time constraints, returned mail can be partly investigated ... and followed up later. If the investigation is delayed, a Worktask should be created so the participant will not get any further mail.

Stages

... 8. If a new address is not identified:

- Withdraw the participant from the programme... See How to Withdraw a Participant on page 159
Returned Mail Workflow

This workflow describes the process around returned mail.

1. Start
2. Check returned mail in ReturnedMail spreadsheet
3. Check PM for alternate address
4. Address found?
   - Yes
   - No
5. Check Witness Contacts
6. Address found?
   - Yes
   - No
7. Create a Work Task
8. GP on BSR spreadsheet?
   - Yes
   - No
   - Contact GP
   - Address found?
     - Yes
     - No
   - Search White Pages
   - Address found?
     - Yes
     - No
   - Enquire participant from BSR Register
   - End
21/9/2017 – Screening Incident Report Form

Describes incident as “ICC has been using the ‘withdraw’ option in BSP+ in instances that may result in people being inappropriately excluded from the programme”.

30/10/2017 – Email: WDHB to MoH NSU

The email notes that it almost six weeks since the MoH NSU notified WDHB of serious concerns related to possibly missing cancers. Workarounds have been required which are becoming increasingly cumbersome. Concern is raised that as the provider WDHB have not been asked for an explanation and an update is sought.

20/11/2017 – Weston: Review of Clinical Records of Patients Who Did Not Receive an Invitation to Participate in the Bowel Screening Programme and Who Subsequently Received a Cancer Diagnosis

Dr Weston reviewed the clinical records of eight patients who were invited to participate in the bowel cancer screening but their mail was returned. No alternative address was able to be located and they were withdrawn from the programme. At some point after withdrawal an updated address was recorded in the NHI for these patients. This was not able to be accessed by the programme and a further invitation was not sent. These eight patients subsequently received a cancer diagnosis.

The extent to which the failure to issue an invitation to participate in the pilot at the time of the updated address has impacted on patient outcomes is considered. Dr Weston concludes that there was definitely no impact for five of the eight patients, and that it is impossible to prove any impact for the remaining three patients.

“This review investigates the extent to which the failure to issue an invitation to participate for screening at the time of the updated address has impacted on the patient outcomes for each of these 8 patients…

Summary p 5

...In my opinion there has been definitely no impact for 5 of these 8 patients who did not receive repeat screening invitations when their address was updated, and it is impossible to prove any impact for the remaining 3 patients.”

8/12/2017 – Letter: Clinical Director National Bowel Screening Programme to about 2,500 people

The letter is to all those “Withdrawn” on the BSP register as GNA who had an updated address in the NHI system. The letter invites them to take part in the free screening and informs them of a technical address issue that may have caused a delay in sending a new invitation.

“Our records show that we sent you an invitation to take part in the free bowel screening programme but you may not have received it due to a change of address. Because of a technical issue your new address was not updated in the Ministry of Health’s bowel screening register and this may have caused a delay in sending you a new invitation. We are sorry for this delay.

You will be sent a free bowel screening test kit within the next few weeks...”