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Executive Summary

1. The Scottish Breast Screening Programme (SBSP) invites women aged between 50 and 70 years old for a screening appointment every 3 years. In August 2015, a local breast screening service highlighted an error in the invitation process that resulted in 126 women not receiving an invitation. Through further investigation, it became evident that a total of 249 women across Scotland had not received an invitation to attend a routine screening appointment.

2. During a national meeting in December 2015, to understand how the service could learn from this incident, the IT provider (Atos) confirmed they could develop a bespoke process to identify women who had not been invited for a breast screening appointment for more than 3 years. This is known as a “failsafe” report. Since 2002, the SBSP was aware that women who moved in or out of a GP practice area would not automatically appear on the IT system that generated letters to invite women for breast screening appointments. The new IT system which had been planned since 2008 and was implemented in 2016 was intended to rectify this issue.

3. Following a technical process undertaken between January and March 2016 and a manual cross check by the SBSP centres, 3,831 women were identified as having not attended a breast screening appointment for between 3 and over 9 years. The SBSP centres sent out letters to offer these women an appointment during April and May 2016. Additional measures were introduced including extra screening sessions and appointments. National Services Division (NSD) coordinated the management of this incident through a series of teleconferences with representatives from across all NHS boards and the Scottish Government. As the management of this event progressed the Scottish Government became concerned with the way in which the process was being managed. In June 2016, the Scottish Government asked Healthcare Improvement Scotland to commence a review to look into the management of the incident in August 2015 and the incident investigated between January and May 2016.
4. The main findings of this review are as follows:
   - Local services worked hard to provide support and appointments to those women identified as having not attended a breast screening appointment for between 3 and over 9 years. This was challenging for staff as they needed to maintain routine breast screening services and were in the process of implementing a new IT system.
   - Roles, responsibilities and lines of accountability across the SBSP are not clear. While lines of accountability have been set out, these are overly complex and do not help to support the effective management of the SBSP.
   - Governance and accountability was unclear throughout the incidents and a structured and well documented incident management process was not followed. For example, it was unclear who was responsible for the overall management of the incidents. These factors had an effect on how the incidents were handled and led to a number of difficulties including ambiguity in communication and decision making and limitations with documentation. NSD should have provided clear leadership throughout the management of these incidents.
   - NHS Greater Glasgow and Clyde proactively led the West of Scotland Breast Screening Service response to the August 2015 incident which included a root cause analysis of the issues identified.
   - A breast screening programme risk register was in place but was not used routinely as a live document by NSD to help to manage and account for risks inherent in the SBSP.
   - The new IT system will help to address a number of the issues raised in this review. However, it will require ongoing monitoring to ensure any initial software problems are appropriately resolved and any future risks identified are appropriately dealt with.

5. By 30 November 2016, 2,250 (59%) of the 3,831 women had responded to the letters sent out by the centres. This included 1,907 women (50%) who had arranged an appointment with their local screening centre and 343 women (9%) who had decided to defer/decline an appointment or who were excluded for other reasons. This level of uptake is significantly lower than would be expected for breast screening in Scotland. We have asked NSD, in conjunction with the Scottish Breast Screening Centres, to urgently review whether every reasonable step has been taken to enable this group of women the opportunity to attend a screening appointment in a reasonable timeframe.
6. Healthcare Improvement Scotland will continue to monitor the arrangements to follow up this group of women.

7. This report sets out a number of recommendations to help to improve the incident management process and the wider governance arrangements for the SBSP. While the recommendations are specific to this review, they should be considered and applied where appropriate, across other Scottish screening programmes.
Recommendations

Recommendation 1

8. NSD, in conjunction with key stakeholders from the SBSP centres, should establish an adverse event management team to urgently review whether every practical step has been taken to offer the women identified in the 36-month failsafe report the opportunity to attend a breast screening appointment within a reasonable timeframe.¹ This review should:
   - follow a structured adverse event management process using the guidance set out in the NHS National Services Scotland Adverse Event Management Policy²
   - include a detailed and documented action plan with clear timescales recording any additional actions to follow up individual women. This should also include a risk assessment of any actions taken.

Recommendation 2

9. NSD, in conjunction with key stakeholders from the SBSP, should put in place effective governance arrangements to ensure roles, responsibilities and lines of accountability across the SBSP are clear. This should include:
   - a review of the existing groups and committee functions, membership, remit, how they relate and communicate to each other and the information that is presented to them
   - a definition of each function, role and the responsibilities of all stakeholders in relation to breast screening, means and methods of communication across the SBSP to facilitate an open dialogue and involvement in decision-making, and
   - a description of how stakeholders work together across the various functions they perform including leadership roles, how decisions are made and how information is shared.

¹During the process of concluding the fieldwork to this review Healthcare Improvement Scotland wrote to NSD, highlighting the issue described in Recommendation 1. The HIS letter and NSS response is provided in Appendix 2.
Recommendation 3

10. NSD, in conjunction with key stakeholders from the SBSP, should put in place a clear and structured adverse event management process, with supporting guidance for the SBSP. This should be in line with NHS National Services Scotland’s Adverse Event Management Policy and take into account the governance framework described in Recommendation 2. This process should also include:

- accountability and responsibility arrangements in the event of a screening incident
- a standard and consistent approach across NSD to documenting decisions as part of managing an adverse event (including templates and checklists). This should ensure that investigations are risk based, informed by relevant stakeholders and transparent, to allow an appropriate level of scrutiny and assurance
- a documented escalation process for NHS boards and the SBSP through to NSD and then to the Scottish Government.

Recommendation 4

11. NSD, in conjunction with key stakeholders from the SBSP, should establish a mechanism to manage ongoing IT issues. This should include a process for reporting, investigating (applying adverse event management principles where appropriate), communicating and resolving any issues across the SBSP.

Recommendation 5

12. NSD should review its current risk management arrangements to ensure they effectively manage and provide assurance about key operational risks. This should take account of the arrangements put into place under recommendations 2, 3 and 4 and specify lines of accountability, including how any shared responsibility with other organisations is assessed, agreed and communicated.
Section 1: Background to this review

13. In June 2016, Healthcare Improvement Scotland was asked by the Scottish Government to undertake a review into the incident management process used by the Scottish Breast Screening Programme (SBSP) following the identification of a number of women who had not been sent a routine invitation to be screened.

14. In August 2015, a woman contacted the West of Scotland Breast Screening Service (WoSBSS) to report that she had not been called for a breast screening appointment for over 3 years, breaching the usual screening invitation cycle. Following a detailed investigation by the local breast screening service, NSD coordinated, through a series of teleconferences, the work to extend the investigation to the other centres across Scotland. This resulted in 249 women from some of these centres who were identified as having not received an invitation for breast screening within the usual 3-year cycle.

15. In December 2015, once all the women had been invited for screening, a meeting was convened, led by the National Services Division (NSD) of NHS National Services Scotland (NSS), to discuss the circumstances of the August 2015 incident so that lessons could be learned by the service across Scotland.

16. A central IT system is used to generate the letters that invite women for screening. The system is commissioned by NSS and provided by Atos. Women are invited for breast screening based on the GP practice where they are registered. Since 2002, it was known within the SBSP that the IT system could not identify women who had moved GP practice area just before or after invitations had been sent to women registered at a specific practice. Therefore there was a recognised and long-standing known risk across the service, that these women were being missed from the screening programme. NSD understood that the number of women affected would be a small percentage, however there was no way to identify these women through the IT system that had been in place for a number of years. To help to mitigate this risk, additional efforts were made to publicise the breast screening service in GP surgeries to encourage women to make GP surgery staff aware if they had not received an appointment. This information was included in a leaflet. In 2016, a new IT system was
introduced with the functionality to identify those women who had not been sent an invitation in over 3 years.

17. At the meeting in December 2015, Atos suggested that they could use the new IT system to identify those women who had not been invited for screening in the last 36 months. This was later confirmed in early January 2016.

18. Between January and March 2016, Atos developed a process which enabled a report to be run from the IT system which identified a number of women who had been missed from screening.
   • Initially 18,080 women across Scotland were identified as not being invited within the usual 3-year cycle, however nearly 80% of this group were due to be invited for screening in the next 6 months.
   • This left 3,831 women who had not been invited and who were not due to be invited in the next 6 months. These women had not been invited for screening for between 3 to over 9 years.

19. The immediate priority for the SBSP was to ensure that the women who had not been screened within the usual timescales were identified, invited and fast tracked for a breast screening appointment. Whilst the process to identify these women was initially generated through a search on the IT system, manual checks by local SBSP staff had to be made to identify those women who were already scheduled to be invited in the near future from those who were not. Those who were not scheduled to be invited in the near future were sent letters apologising and offering screening as a matter of urgency. The generation of the list of women through the IT system was finalised between January and March 2016. The letters were sent to women in April and May 2016.

20. It was after these initial letters had been issued that Healthcare Improvement Scotland started this external review.

21. This report provides the findings, conclusions and recommendations of the review into the SBSP routine appointment process.
Methodology

22. The Scottish Government asked Healthcare Improvement Scotland to undertake a review to (a) fully understand the reasons why some women had not been invited to their routine breast screening appointment, (b) provide assurance in relation to the response by stakeholders, including the management of the incidents, the governance arrangements and that there are no further patient safety risks and to (c) identify any points of learning for the SBSP.

23. The review team gathered evidence for this review by:
   • examining key documents and data
   • meeting with screening providers, NSD as the commissioning body and key staff involved in the delivery of breast screening in Scotland, and
   • visiting two centres and speaking with staff.

24. This report includes an assessment of the quality assurance of the incidents to ensure that all possible steps have been taken to minimise risks to women. The implementation of the recommendations will support future improvements to existing services.

25. The review was carried out by a multidisciplinary team including cancer, screening and IT specialists and supported by staff in Healthcare Improvement Scotland. A list of the review team members is provided in Appendix 1 of this report.

26. During the finalisation of this report, we sought additional expert knowledge and experience to provide comment to the conclusions and recommendations. These individuals formed the assurance team and details are provided in Appendix 1.
Background to breast screening

27. The SBSP was established in 1988 and was fully implemented nationally in 1991. SBSP currently provides routine screening and assessment from six static centres as well as 20 mobile screening units across Scotland. The service is divided into six geographical areas: North East, North, South West, West, East and South East Scotland. The six screening centres are based in Aberdeen, Inverness, Irvine, Glasgow, Dundee and Edinburgh. Each centre has a static base and provides the screening service to the outlying areas by mobile units.
The purpose of breast screening

28. The purpose of breast screening is to reduce the number of women who die from breast cancer each year through early detection and prompt treatment.

29. The age range for breast screening is for women aged between 50 and 70 years and runs on a 3-year rolling cycle. Women aged 71 and over are able to attend through self referral to their local screening centre. The SBSP appointment process is triggered by the local screening centres which organise a caseload of eligible women, by GP practice, with appointments made at a local screening mobile unit or static unit. Before appointment letters go out to eligible women, the GP practice is asked by the screening centre to confirm the women who should be included in the screening process. Women who are excluded include those who are no longer eligible for screening, for example, having undergone bilateral mastectomy or those who have signed a disclaimer stating that they do not want to be screened. Women who receive a letter inviting them for routine breast screening also receive an information leaflet, *Breast Screening: Helping you decide*\(^3\), providing an overview of the screening process, benefits and risks.

30. If the outcome of the screening is normal, the woman is informed of this, and her details returned to the system to be routinely recalled after 3 years. If an abnormality is detected, the woman is referred for further diagnostic investigation. Some women may have to come back if there was a technical issue with their screen. If the woman is found not to have breast cancer, she will then be recalled for routine screening after 3 years. If cancer is found, the woman will be referred on for further treatment.

31. The screening activity in the SBSP for a typical year is provided below:
   - during the period 2014-2015\(^4\), a total of 218,073 women were invited for routine breast screening appointments
   - of this figure, 158,405 women attended appointments - an uptake rate of 72.6% against a minimum target of 70% for Scotland
   - over that same period an additional 13,316 women were screened, the majority of whom self referred

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• overall, for the period 2014-2015 a total of 171,721 women were screened for breast cancer, and
• for the 2014-2015 period, 1,362 women were found to have breast cancer. (Approximately 9 out of every 1,000 women who are screened are found to have breast cancer\textsuperscript{5}.)

The way the Scottish Breast Screening Programme is provided

32. NSD is responsible for commissioning aspects of the SBSP. The Scottish Government provides the 14 territorial NHS boards with funding each year for breast screening services. The 14 territorial NHS boards then pool this funding and transfer a proportion of the funding to NSD who use it to commission certain elements of the programme. There is one Scottish Breast Screening Programme, provided from six centres to the population served by all 14 territorial NHS boards.

33. Each of the six territorial NHS boards who host a screening centre have Service Level Agreements (SLAs) set up with the commissioning organisation, NSD. The SLAs provide a framework in which the breast screening programme is delivered through the six centres. The performance of the screening centres is monitored through regular performance meetings with NSD and culminates in the production of a publically available annual report for the service. The report provides data and information about the breast screening service and pathway, against each of the Quality Domains\textsuperscript{6} including activity numbers, finance and key performance indicators.

34. The Service Level Agreement refers to accountability arrangements and states that:

“The Chief Executive of [the NHS Board] will be accountable for the quality of the clinical service provided. NSD as the commissioner expects that robust mechanisms will be in place to support clinical governance. Exception reports to the [NHS Board] clinical governance committee should also be provided to NSD.”

35. And:

“In respect of any problems or incidents that may adversely affect the performance of service provision by the centre the provider will ensure that the escalation procedures given in [Annex F] will be adhered to.”

36. Annex F sets out the Management of adverse incidents or events – Escalation Procedures an Escalation Framework. The review team understands that, if these procedures had been applied, both the August 2015 and 36-month failsafe report incidents would have been assessed as RED incidents. A RED incident is defined as:

“A significant problem is defined as the Centre being unable to meet mandatory quality standards to such an extent that cessation of the service for a period of time is likely or necessary. It is where an incident cannot be resolved locally and there is the potential for adverse publicity. This will include major clinical incidents and/or where loss of key staff for an extended period of time is likely or necessary. The risk assessment in such circumstances will be Red.”

37. The SLA does not provide any detailed guidance on the management of such incidents.

Leadership/management – roles and responsibilities

38. There are a number of organisations involved in the delivery of the SBSP (see Exhibit 1):

**Exhibit 1: Organisations involved in the delivery of the SBSP**

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Responsibilities</th>
</tr>
</thead>
</table>
| Scottish Government | Develops policy for national screening programmes in Scotland  
Liaises across health directorates within the Scottish Government and the UK Screening Committee |
| National Services Scotland (NSS) | A national NHS board which provides strategic support services and expert advice to Scotland’s health sector  
NSD is part of NSS |
| National Services Division (NSD) | National coordination and quality assurance of the SBSP  
Commissions elements of the SBSP including performance management and has service level agreements with the six territorial NHS boards who host a screening centre  
Supports quality assurance, service change and management of adverse events in SBSP |
| NHS boards | 14 territorial NHS boards in NHS Scotland. Six of these boards host a breast screening centre who form with NSD, the Scottish Breast Screening Programme  
Responsible for delivery of screening programmes for the NHS board population through the six host territorial NHS boards |
| Healthcare Improvement Scotland | A national healthcare improvement organisation for Scotland  
Provides clinical standards, guidelines and advice and is in the process of developing a way of quality assuring the national screening programmes |
Key roles in NSD

39. Within NSD there is a director of specialist and screening services. The director is supported by the national coordinator, a senior programme manager and programme support staff, with leadership provided by the NSD medical director.

40. In addition to commissioning aspects of the SBSP, NSS also leads the commissioning of the IT provider, Atos, and Public Health and Intelligence (PHI) which is responsible for providing data management oversight for screening programmes.

Key roles in NHS boards

41. Each of the 14 NHS territorial boards has a board screening coordinator who is a senior member of staff and reports to the director of public health (generally a consultant in public health). Board screening coordinators are responsible for overseeing the delivery, quality and effectiveness of the screening programme for their NHS board area. This includes working with staff in the SBSP to provide a public health perspective, taking appropriate action when a risk to patient safety is identified and coordinating the delivery of changes to the programme at a local level.

42. All of the NHS boards are responsible for the delivery and availability of screening services for people living in that area. This is delivered through the service provided by the SBSP centres in the six NHS boards that host a screening centre, either in the static centres or through mobile units. Each breast screening centre has a clinical director, a screening centre manager and a range of health professionals, who are responsible for the day-to-day running of the screening centre. The screening centre staff work closely with the 14 NHS board screening coordinators across all areas of Scotland.

Governance and decision-making structure

43. There are a number of quality assurance groups and working groups which have been set up to support the delivery and quality assurance of the SBSP.

44. There is a quality assurance group for each of the professional groups within the SBSP. Examples include radiologists, radiographers, surgeons, pathologists, nurses and administrators groups. These groups each have a representative on the Quality
Assurance Reference Centre which is currently chaired by a clinical director of a breast screening centre and reports directly to NSD. The national co-ordinator and senior programme manager from NSD attend and provide the secretariat for this group. The purpose of this group is to provide advice and guidance to NSD on quality assurance issues, for example, the monitoring of compliance with quality assurance standards. The quality assurance groups for each of the professional groups also have links with UK national groups for example, the UK National Radiology Group.

45. The SBSP superintendent radiographers, clinical directors and breast and cervical coordinators also meet and report into both the Quality Assurance Reference Centre and NSD.

46. All of these groups reported into the National Advisory Group up until 2013 when this group disbanded. The Scottish Screening Committee was set up in summer 2016. The group has representation from some NHS boards and a range of professionals and reports to the Scottish Government. The group is responsible for providing an oversight of screening programmes based on 6-monthly reports from NSD and responds to requests from the UK National Screening Committee. It also provides advice to the Scottish Government and NHS boards on the resources required to deliver screening programmes at a national level.

47. The governance and decision-making structure is complex. This is set out in the diagram provided by NSD in Appendix 4.

Scottish Breast Screening Programme IT system

48. The SBSP uses an IT system to manage the call and recall of women for breast screening. The system was first introduced in the early 1990s, and the most recent update to the initial IT system was in the late 1990s to ensure Year 2000 compliance. A new system was proposed in 2007 following the recommendation to move to digital mammography. This also provided the opportunity to integrate the breast screening IT system and address some of the limitations of the old IT system, including:

- no daily feed from the Community Health Index (CHI) system where up-to-date patient information is held
- no way to manage cross-boundary/cross-border GP practices – a separate list had to be generated for each NHS board, and
• limited failsafe reporting with no ability to identify women who were due for screening and had moved GP practice.

49. Scoping for the new system started in 2008. An evaluation of the English National Breast Screening Programme IT system took place in 2009, and developments to the original IT system stopped in 2010. In 2010, it was decided not to use the English call/recall system as it was not in line with the Scottish Government eHealth policy. In 2012, the Scottish Government announced funding for digital mammography in screening. The eHealth Programme Board, who have responsibility for decision-making on national screening IT systems, decided that the screening system used for abdominal aortic aneurysm (AAA) screening would be adapted for use in the SBSP.

50. In 2013, design of the new IT system began with testing of the new system taking place in 2014. At this stage, it was identified that numerous changes were required to the system, and the project was running over time and budget. The Breast Screening IT Project Board decided to continue development of the new system, focusing on the clinically critical elements of the system. The new system was initially implemented in NHS Tayside in 2015, and the system was implemented in all centres in 2016. The new system can:

• link daily with the CHI system, meaning up-to-date patient information is available
• improve failsafe reporting, including the ability to run a 36-month failsafe report to identify any women who have not been invited for screening in over 3 years, and
• integrate clinical and administrative information.

51. There is an SLA between NSS as commissioner of the IT system and Atos as provider of the IT system. The SLA outlines the process for requesting changes to the system. Change requests are prioritised based on the type of change required and approved by the National Users Group, which is chaired by a clinical director from one of the centres.
Section 2: The incidents – a description of what happened

52. The review team examined the evidence provided by NSD and the NHS boards and spoke with a number of staff in relation to the two incidents which led to this review:
1. the West of Scotland Screening Breast Screening Service adverse event (August 2015), and
2. the identification of women not screened in more than 3 years (the 36-month failsafe report).

Incident 1: The West of Scotland Breast Screening Service adverse event (August 2015)

53. In August 2015, a woman living in Lanarkshire contacted her local GP to enquire about her last breast screening date. Following a local review, it transpired that the woman had not been called for a screening appointment since 2010 (the normal cycle is 3 years). The issue was reported to the West of Scotland Breast Screening Service (WoSBSS) immediately and an urgent internal investigation took place.

Process for calling women for screening

54. There were a number of stages at the time of the August 2015 event involved in calling women for their routine screening appointment.
1. When a GP practice is due for screening (every 3 years), the screening centre uses a Prior Notification List (PNL) to identify women from the GP practice who are eligible for screening.
2. The PNL is a list generated in the IT system and is requested by screening centre staff a number of weeks before the screening date.
3. The list shows all women who are eligible for screening at that point of time. Running this list moves women from a status code of “mammo ok” to “selected for screening – details to be checked by GP”.
4. The screening centre then asks the GP practice to check their own system and to advise them to exclude any ineligible women.
5. The final list is then invited for screening and invite letters are sent out from the screening centre.
The response to the incident

55. On initial investigation, the reason for women being missed from their usual screening appointment was because the PNL for the women’s GP practice was run in error on 22 February 2012 by the screening centre. The WoSBSS then contacted Atos in March 2012 to undo this action.

56. In reversing this action, some women from the GP practice were left with a “rejected” status. This resulted in 126 women remaining on the list of exclusions. This exclusion list was not verified by the centre when the PNL was run for the GP practice when it was due in 2013. Initial assessment confirmed that this was a manual error rather than an IT system error, due to failure to complete a manual check of the rejected/excluded women list for the GP practice. The primary issue was that on reversing the PNL error, the IT system allocated the women to a “rejected status” and the women were, therefore, not invited for screening.

57. On 20 August 2015, NSD asked Atos to check across the national IT system to determine if there were any other women with a “rejected status” code. The Scottish Government were also notified of the incident. The review of the national system and further investigations by the NSD and the six centres identified a total of 249 women who had not been invited for screening at the appropriate time. The reasons why these women had not been invited included 83 women residing at a nursing home who were not invited along with the rest of the GP practice and 18 women with an incorrect status code assigned to them. This meant that these women did not appear on the PNL as eligible for selection and would not have been sent an appointment letter.

58. On the 25 August 2015, NSD started the first of the weekly teleconferences with representatives from all six centres and NHS boards. A series of teleconferences took place during September 2015 to discuss the status of those women who had not been sent letters.

59. Exhibit 2 below illustrates the key milestones in the management of the August 2015 incident.
Exhibit 2: Key milestones in August 2015 incident

10 August 2015
WoSBSS notified that a woman had not been invited for routine screening since 2010

11 August 2015
WoSBSS undertake internal investigation with Atos

14 August 2015
WoSBSS escalate to NSD

17 August 2015
Scottish Government notified. NSD arrange teleconference meetings to discuss and agree next steps

20 August 2015
NSD request Atos investigation

25 August 2015
NSD start weekly teleconferences with all centres and NHS boards

3 September 2015
249 women identified as being missed from routine breast screening appointment process

17 December 2015
NSD host a lessons learned meeting to discuss incident and implement recommendations

21 December 2015
NHS Greater Glasgow and Clyde publish a root cause analysis report on the incident
The outcome of the incident

60. Following the management of the August 2015 incident, NHS Greater Glasgow and Clyde undertook a detailed root cause analysis of the incident between September and December 2015. The purpose of this was to fully understand the reasons why women were missed, to share the learning from the incident and make recommendations to reduce the likelihood of a similar incident reoccurring.

61. NHS Greater Glasgow and Clyde implemented a series of measures to reduce the likelihood of human error happening again, including adding additional checks to the running of a PNL and sending GPs an audit list of women who had attended a screening appointment 6 months after the GP practice was called for screening.

62. In addition, NHS Greater Glasgow and Clyde looked in detail at the call/recall process, from identifying those women to be invited for screening, through to what action to take for those women who decline an appointment or who are not registered. They also looked at the arrangements for women who would be screened in a different NHS board area to where they lived, and made a series of recommendations which they shared with NSD.

63. On 17 December 2015, NSD chaired a meeting which primarily focused on the review of the August 2015 incident and lessons to be learned. Some time was also allocated to identify differences between the old and new systems and to understand the safeguards required to minimise a similar event recurring. Board coordinators, clinical directors, centre managers and other key staff from within the SBSP were invited to attend this meeting. Atos and the Scottish Government also attended the meeting. A number of recommendations were made at this meeting in order to streamline procedures. The review team understands that these recommendations are being implemented and should now be considered and implemented with the recommendations set out in this report. The recommendations from the December meeting are listed in Exhibit 3 below.
Exhibit 3: Recommendations arising from December 2015 lessons learned meeting (extract from meeting note)

RECOMMENDATIONS

1. Effort needed to increase awareness of escalation procedures within SBSP
2. Timely notification of incidents to Scottish Government
3. Reporting/follow-up proforma may be helpful for incidents notified to NSD
4. NSD to review guidance on management of screening incidents
5. Better communication with Solution Stewardship within National Services Scotland
6. Requirements for when an incident management team should be established
7. Standardised operating procedures (SOPs) across the SBSP and reduction in manual safeguarding checks when the SBSS is implemented
8. Extract data on women who have not been invited for breast screening in more than 36 months

64. At the meeting in December 2015, Atos confirmed they would now be able to develop a bespoke process that would provide the 36-month failsafe report to identify those women who had not been invited for screening. The report was within the specification of the new IT system and was run earlier than planned in order to support the early identification of these women not called for screening. This was reflected in Recommendation 8 set out in Exhibit 3.

65. The arrangements to send out letters, in September 2015, to those women who had not been invited for screening were confirmed through the NSD arranged teleconferences. A follow-up letter was also sent out to those women who did not respond to the first letter. Of the 249 identified, 155 (62%) responded to the letter.

66. An additional 34 women (out with the 249 women identified in the August 2015 incident) were identified as having not been invited for screening. The centres involved followed the same process to invite these women for screening.

NHS Greater Glasgow and Clyde proactively led the West of Scotland Breast Screening Service response to the August 2015 incident which included a root cause analysis of the issues identified.
**Incident 2: The identification of women not screened in more than 3 years (the 36-month failsafe report)**

67. The technical process to generate the list of women who were not called for their routine screening appointment was developed between January and March 2016 and then subsequently run by Atos in March 2016. In correspondence between NSD and Atos in early March 2016, it was acknowledged that the new IT system would be able to provide the information by running a 36-month failsafe report to identify women not invited for screening in over 36 months using the data migrated from the old system. However, the exact release date of the new IT system and the criteria for checking why some women had not been invited still needed to be clarified to enable Atos to run this report before it was implemented on the new IT system.

68. During the management of the incident, work continued on the implementation of the new IT system and there were regular meetings with key stakeholders across the SBSP to discuss issues arising with the implementation of the new system. The implementation of the system was phased across the centres with NHS Tayside being an early implementer site for the system in July 2015 and NHS Greater Glasgow and Clyde being the last in February 2016. As with any major system change there would be a range of issues that would need to be understood and managed as the system was implemented.

69. Initially, NSD agreed with Atos and the South East of Scotland Breast Screening Centre to produce a report to manually check the process the rest of the centres would need to go through. This was undertaken on the 17 March 2016. This manual process identified that a large proportion of the women identified who were part of the routine 3-yearly recall cycle and so were scheduled to be sent an invitation within the next 6 months. It also identified the length of time since some women had not been screened. The Scotland-wide report identified 18,080 women who had not been invited for screening in over 3 years, based on data that had been migrated from the old IT system.
70. Following this exercise, Atos provided all of the other centres with the lists of women who had potentially not been invited for a routine appointment. The centres needed to check these lists manually to establish whether the women on the list were scheduled to have a screening appointment sent to them within the next 6 months and if so, it was deemed unnecessary to send a further letter before then. Additional cross-checks of this data were also required to identify whether the women had been referred for, or were currently in, treatment for symptomatic breast cancer. Exhibit 4 below illustrates the number of women who had not been invited for screening within the usual 3-year cycle.

Exhibit 4: Total number of women not invited for screening within the usual 3-year cycle

<table>
<thead>
<tr>
<th>Women's last breast screening invitation/appointment was due.</th>
<th>Invitations/letter sent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collated data for the six Scottish Breast Screening Centres</td>
<td>in the next 6 months</td>
</tr>
<tr>
<td></td>
<td>(additional invitation letter NOT required)</td>
</tr>
<tr>
<td>Total: 18,080</td>
<td>14,249</td>
</tr>
</tbody>
</table>

The response to the incident

71. The management of the 36-month failsafe report was led by NSD and included representation from all NHS boards, including the six SBSP centres. NSD initially used the weekly teleconferences that were set up to discuss the implementation of the new IT system to manage the incident and NSD senior management, breast screening centre managers, clinical leads and screening coordinators (public health professionals) from each of the NHS boards were invited to attend each meeting. The Scottish Government and Atos representatives were also invited to attend the meetings. NSD issued agendas, notes of meetings and a document entitled Situation, Background, Assessment, Recommendation (SBAR), to update staff on the management and current status of the incident.

72. The first of the meetings to manage the 36-month failsafe report was held on 24 March 2016.
73. At this meeting the centres were asked to establish the numbers of women who were due to be screened within the next 6 months, through a manual exercise, from a report they had received from Atos a few days earlier. Discussion focused on:
- inviting women earlier for their appointments would have an impact on the timings of future routine cycles of calling these women for screening, and
- waiting until the new IT system was fully implemented would be the more practical way to deal with this group of women.

74. In addition to this, issuing early invites meant that women could have been invited to attend screening at a static centre, rather than a mobile unit, which could mean that women could be inconvenienced if they had to travel further to their screening appointment. Whilst this view was considered, the decision was made to press on with the manual work in order to enable the letters to be issued at the earliest opportunity.

75. It was reported that many of the stakeholders expressed disagreement about the plans to continue with the manual process. However, the centres did confirm that they would collate this information as requested.

76. The group next met a week later on 31 March 2016. NSD asked each breast screening centre to check against the lists of women for symptomatic breast referral/breast cancer diagnosis, starting with women who had not had an appointment for the longest duration. It was noted at this meeting that there may be issues with this request due to accessibility of information and also the limited resources to be able to undertake this work. The request created an additional workload for the local staff, who had to undertake an intensive manual search/check of information on top of their existing workload as well as manage the implementation of the new IT system.

77. At the meetings on 31 March, 7 April, 14 April and 21 April 2016 the group discussed the wording of the letters that would be sent to the women who had been affected by this issue. A number of draft letters were shared with the group at these meetings.

78. The Scottish Government informed NSD that they considered letters should be sent to this group of women at the earliest opportunity. During the process of drafting the letters and seeking Central Legal Office advice, the Scottish Government determined
to take a more active role and contributed to the message, language and approval of the invitation letter.

79. NSD advised at the meeting on 21 April 2016 that the centres should be ready to send the letters out during week commencing 25 April 2016.

Local services worked hard to provide support and appointments to those women identified as having not attended a breast screening appointment for between 3 and over 9 years. This was challenging for staff as they needed to maintain routine breast screening services and were in the process of implementing a new IT system.

The outcome of the incident

80. The breast screening centres sent out the letters between 25 April and 3 May 2016. On 26 April 2016, NSD asked the NHS board screening coordinators to distribute a letter to all GPs advising them of the incident. This letter is in Appendix 3.

81. A tailored letter to those women who had been treated for breast cancer in the last year was sent out, following advice from the Central Legal Office, during week commencing 16 May 2016. This letter is in Appendix 3.

82. Exhibit 5 below illustrates the key milestones in the management of the 36-month failsafe report incident.
### Exhibit 5: Key milestones of 36-month failsafe report incident

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>17 December 2015</td>
<td>Lessons learned meeting takes place where Atos confirmed ability to generate a 36-month failsafe report on the new IT system using data from the old IT system</td>
</tr>
<tr>
<td>7 January 2016</td>
<td>Initial report provided by Atos</td>
</tr>
<tr>
<td>11 January 2016</td>
<td>Report reviewed by South East of Scotland Breast Screening Centre</td>
</tr>
<tr>
<td>25 January 2016</td>
<td>NSD met with the Scottish Government to discuss initial report provided by Atos</td>
</tr>
<tr>
<td>3 February 2016</td>
<td>Call between NSD and Atos to discuss scope changes to new IT system to allow more accurate 36 month report to be produced</td>
</tr>
<tr>
<td>23 March 2016</td>
<td>All breast screening centres receive 36+ month reports for checking which has ~ 18,000 women who had not been invited for screening</td>
</tr>
<tr>
<td>25 April 2016</td>
<td>All letters to be sent to 3,831 women for immediate screening by 3 May 2016</td>
</tr>
<tr>
<td>8 July 2016</td>
<td>1,600 women have made contact with the service and 1,100 women have been screened</td>
</tr>
</tbody>
</table>
83. Exhibit 6 lists the number of women who have been successfully contacted as at 30 November 2016.

**Exhibit 6: Uptake of screening appointment following May 2016 letter as at 30 November 2016**

<table>
<thead>
<tr>
<th>Collated data for the 6 Scottish Breast Screening Centres</th>
<th>Final number of women who were sent a letter following manual work</th>
<th>Number of women who have arranged an appointment</th>
<th>Number of women who have deferred/declined appointment</th>
<th>Number of women excluded for additional reasons (e.g. movement out of Scotland, excluded for clinical reason)</th>
<th>Number of women who have not responded</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SCOTLAND TOTAL</strong></td>
<td>3,831</td>
<td>1,907 (50%)*</td>
<td>288 (8%)</td>
<td>55 (1%)</td>
<td>1,581 (41%)</td>
</tr>
</tbody>
</table>

*Note, the minimum performance standard for uptake is 70%.

84. A total of 2,250 (59%) women responded to the appointment letters sent by the centres, of these 1,907 (50%) have arranged an appointment. As of 30 November 2016, a total of 1,581 (41%) women had not responded to the initial letter sent by the centres. The next letter these women would receive was generated by the new IT system and did not acknowledge the fact that they had already been sent the first letter. Therefore the women could already have responded to the manual letter stating that they did not want to attend. This led to a number of complaints. The 1,581 women who have not responded to the initial letter will be monitored until the end of 2016 and if they do not respond, they will be invited for screening at the next cycle when the GP practice they are registered with is called for screening. Healthcare Improvement Scotland sent out a letter to NSS on 8 November 2016 highlighting the need for further clarity around the incident management process that had been followed to ensure that women were contacted. This letter is provided in Appendix 2 with the response by NSS.
85. NSD continued to hold teleconferences from May 2016 and the breast screening centres provided updates on the number of responses received. At the teleconference on 26 May 2016, NSD advised that an updated SBAR had been presented to the first meeting of the Scottish Screening Committee outlining progress. In the NSS Clinical Governance Returns template dated 3 May 2016, the incident was described as “no known harm has resulted”.

86. From the information provided as part of the evidence for this review, of the 3,831 women who were not invited for routine screening, 13 women had been treated for cancer in the last year. These women were sent a separate letter by the SBSP. A further 167 women were known to be currently receiving breast cancer treatment or follow-up. These women were sent a letter describing information about the screening process for women who have had cancer.

87. At the teleconference on 23 June 2016, NSD advised that the first run of the 36-month failsafe report would take place during the week commencing 20 June 2016 from the new IT system. This report will be run every 3 months to identify any women who have not been invited for screening in over 3 years.

Based on the incident management records available it is not evident that every reasonable step had been taken to enable this group of women the opportunity to attend a screening appointment in a reasonable timeframe.

88. Through NSD, the SBSP have now established an adverse event management team to urgently review whether every reasonable step has been taken. Healthcare Improvement Scotland will continue to monitor through the recommendations set out in this report.
**Section 3: Key themes**

89. Based on the information provided by NSD, NHS boards and the discussions the review team had with staff, the key themes from this review are as follows.

**Leadership**

90. In the August 2015 incident, it was evident that NHS Greater Glasgow and Clyde took the lead in the identification and management of the incident, and escalated the incident appropriately. NHS Greater Glasgow and Clyde coordinated the actions required at a local level and updated NSD on the status of their investigations at regular intervals. When it was identified that the incident could be national, NSD convened a series of teleconferences with the centres to allow them to support the management of this incident.

91. NHS Greater Glasgow and Clyde also took the decision to conduct an in-depth root cause analysis following the incident. NSD conducted a national lessons learned event in December 2015.

92. At the outset of the 36-month failsafe report incident NSD did not provide terms of reference for the incident group or follow a structured and well-documented process and there was uncertainty in relation to:
   - membership
   - roles and responsibilities
   - the most appropriate approach to management of risk
   - governance and sign-off for decisions, and
   - management of communications.

93. These are all core functions required in the management of an incident. The lack of clarity around these key functions led to a number of difficulties, including ambiguity in communication and decision-making and limitations with documentation.

94. NSD used teleconference meetings to update staff in the NHS boards about the actions required. It was clear from the staff members that the review team spoke with that there was a difference of opinions about the way in which NSD led the 36-month
failsafe report incident. Leadership would normally be expected to present a clear risk assessment of the different options to the group to help reach a clear decision on how best to support the women affected.

95. As part of this review the team visited two centres. Screening centre staff described the pressures of undertaking additional work to manually check the information provided by Atos and noted that the letters could have waited for the relatively short period of time until the new IT system was up and running. This would have meant the 36-month failsafe report could have been automatically generated.

96. The Scottish Government asked NSD that women were sent invitations at the earliest opportunity. From the evidence provided and through discussions with stakeholders, it was clear that there were concerns about how the incident was being coordinated by NSD, in particular about:

- the time it took, due to the technical process undertaken by Atos, to generate the 36-month failsafe report (and therefore the ability to finalise the number of women affected)
- there being no clear communication about the date of when the new IT system would be up and running to generate the list of women who had not been invited for screening, and
- the length of time it took to agree the wording of the letter that would be sent to the women affected.

97. The lack of a formal and transparent process with supporting documentation compounded these concerns. The national element to the August 2015 incident or the 36-month failsafe report was not formally managed as an adverse event. It is unclear how this was being dealt with as it was reported in the NSS Jan-March 2016 Quarterly Clinical Adverse Event Report as if it was an adverse event. However, within the document it is stated that there was “...no adverse event as such”.

**Governance and accountability was unclear throughout the incidents and a structured and well-documented incident management process was not followed. For example, it was unclear who was responsible for the overall management of the incidents.**
These factors had an effect on how the incidents were handled and led to a number of difficulties including ambiguity in communication and decision-making and limitations with documentation. NSD should have provided leadership throughout the management of these incidents.

**Organisation**

98. Staff members working at the centres stated that the focus for the regular IT system implementation teleconference meetings became solely about the management of the women who had not been sent appointments and, therefore, there was no opportunity to discuss issues relating to the new IT system.

99. The scale of the second incident came as a surprise to NSD and NHS boards, despite it being a known risk to the programme since 2002. When the initial risk was identified in 2002, NSD believed that the number of women that this would affect would be minimal. There were no plans in place on how to manage this risk and NSD did not implement any additional measures to either monitor or identify the numbers of women affected since the initial risk was identified.

100. In addition to this, although NSD recognised the impact the management of the second incident had on staff and funded overtime payments, centre staff described significant pressure as a result of the additional work required to manage this incident.

101. The implementation of the new IT system continued while the August 2015 and 36-month failsafe report incidents were being managed. This put added pressure onto centre staff who were trying to contact those women affected, implement the new system and run the routine breast screening service.

102. The review team was told that the weekly teleconference meetings had a large number of attendees and were at times difficult to chair. Minutes were used to capture actions and were often issued late. Large and complex incidents often require additional resources and a small project team to undertake the work between
incident team teleconference meetings. Adequate resources or organisational support was not put in place throughout the management of this incident.

The management of the 36-month failsafe report was an ad hoc response to the situation rather than a managed process following an incident management methodology.

Documentation

103. Documentation that was created as a result of the routine teleconference meetings were in the form of an agenda, note of meeting and a document entitled Situation, Background, Assessment, Recommendation (SBAR). An SBAR is a report which is used to communicate key information about a particular issue or topic. The regular teleconference meetings were managed through the presentation and discussion of these documents. From the evidence the review team looked at, there was not always version control on key documents making it difficult to determine which version was the most up to date. There was no central action or risk log that was shared with the group which meant that it was difficult to track whether actions had been completed and which actions were ongoing.

104. There were not always opportunities for stakeholders to comment on the accuracy of the previous meeting’s documentation. The SBAR was used as the primary reporting document to update the progress of the work. NHS board staff stated that the meetings allowed them to be kept abreast of the situation and provided a regular forum to raise queries and questions with NSD and their colleagues from across Scotland. The SBARs were shared across numerous local and national groups and committees, however the level of detail provided in these documents did not help to encourage further examination.

The documentation used in the incidents does not demonstrate effective incident management.
Risk management

105. The review team was provided with the breast screening programme risk register. However it was apparent that this was not actively used by NSD to manage risks in the SBSP.

106. It was known from 2002, that the old IT system did not have the functionality to identify women who had moved in or out of a GP practice area and, as a result, had not been invited for screening in over 3 years. There is an acknowledgement from the screening service that a number of women could be missed due to moving to a different GP practice area, and that actions should have been in place to mitigate these risks. Information was provided through a leaflet, issued by the SBSP and NHS Health Scotland, to encourage women to update their address when they moved. The documentation provided did not identify how this risk was being managed. It was also not clear how risks identified in one screening programme could be shared or applied to other screening programmes where this was appropriate.

107. When Atos provided the first list of women who had not been invited for screening in over 3 years (approximately 40,000 women – this was subsequently narrowed down to 18,080 women), there was no formal incident management group identified. NSD and the NHS boards managed the actions required to contact the 3,831 women who were identified following several refinements of the report by Atos through a series of teleconferences attended by board screening coordinators and centre staff rather than convening an incident management team.

A breast screening programme risk register was in place but was not used routinely as a live document by NSD to help to manage and account for risks inherent in the SBSP.

There was no evidence that NSD took a strategic view of risk across the programme and the response to known risks was minimal.

NSD did not recognise the significance of this incident and did not escalate it appropriately within NSS.
Roles and responsibility

108. From the evidence provided and through the discussions the review team had with staff, it was apparent that stakeholders had differing views of which organisation was accountable and responsible for the SBSP.

109. In particular, views differed on the role of the NSD in both the coordination of the national programme and as lead commissioner. This lack of a shared view of which organisation and individuals were accountable and which organisation was responsible for taking action underpinned the failure to provide adequate leadership when the incident occurred. Further clarity on NSD’s role in coordination of the programme and as lead commissioner is required.

110. On the review visits, some staff we spoke with felt that NSD should have taken more of a lead role in the management of the incidents. It was evident from our discussions with NSD and the NHS boards that clarity is required on the role of each stakeholder in the identification and management of incidents.

111. Staff told us that when an incident is identified, they investigate locally and inform NSD of the incident. NSD and the NHS board then discuss whether the incident could affect all the breast screening services and what action is required to resolve the incident. Staff told us that if the incident is identified as national, NSD has the responsibility for coordinating the management of the incident. NHS boards have a responsibility to manage the incident locally through their own clinical governance reporting structures.

112. The review team was told that a sub group of the Scottish Screening Committee has been set up to look at roles and responsibilities and escalation. It is recognised that the current system does not distinguish adequately between the roles of ‘accountability’ (those with oversight) and ‘responsibility’ (those delegated to take action) and ‘consultation’ (those who should be asked for their view) and how the system manages the complex screening pathway which requires different organisations to work together. This lack of clarity on roles of organisations is compounded by lack of clarity around roles within organisations such as NSD programme staff, board coordinators and clinical directors.
113. NSD and the NHS boards need to work together to make sure the lines of accountability and responsibility are clear for each element of the SBSP. In particular, NSD should clearly set out how it will manage issues such as IT, governance and escalation in relation to the national programme and NHS boards should clearly set out how they will manage clinical issues. Further to this, the role of NSD programme staff, board coordinators and clinical directors should be reviewed and communicated to all key stakeholders in the SBSP.

Roles, responsibilities and lines of accountability across the Scottish Breast Screening Programme are not clear. While lines of accountability have been set out, these are overly complex and do not help to support the effective management of the programme.

Role of the Scottish Government

114. The Scottish Government was kept informed at key stages of the process, from August through to present, about progress of the management of the incidents as well as initially being observers at the teleconference meetings.

115. During resolution of this incident, the Scottish Government asked for clarity on the total number of women identified so that they could brief Scottish Ministers throughout the management of each incident. The number of women who had not been invited for screening kept changing in the early stages of both incidents for a number of reasons:
  • after the initial checks on a specific status code, Atos did a national sweep of the system which identified additional women who had not been invited for screening
  • screening centres then carried out additional checks on other status codes which identified more women who had not been invited for screening
  • when Atos provided the initial 36-month failsafe report they identified approximately 40,000 women, this was then refined and approximately 18,000 women were identified, and
  • following manual checks by the centres, the report was refined again where a total of 3,831 women were identified as not being invited for screening in over 3 years and not scheduled to be invited in the near future.
116. As a result of this technical process, it was difficult to provide a definitive number of how many women had not been invited for screening. The perceived concerns about the time taken to identify the women and to subsequently to offer appointments to the women, meant that the Scottish Government decided to take on a more active role in the management of the incident.

117. The Scottish Government asked for regular updates on how each incident was progressing. The review team was told that the time the letters took to be issued coupled with the lack of a clear and documented process created concerns about how the process was being managed. During this time, a number of breast screening service staff expressed the view that the Scottish Government was exerting pressure onto NSD to send out the letters as quickly as possible and not taking into account the views of the breast screening service.

**Governance**

118. There is no external governance group or committee that has responsibility for monitoring or challenging the management of incidents of this nature.

119. It was not clear how the Quality Assurance Reference Centre was involved throughout the management of the incidents, although members from this group were part of the local incident management team. There appears to be disconnect between the Quality Assurance Reference Centre and the SBSP. From the evidence we were provided with, the documentation relating to the role of the group is out of date. On the review visits, it was not clear from discussions with staff, how the Quality Assurance Reference Centre should have been involved in the incident management process. The group was not consulted throughout the management of the incident. Further clarity is also required on the roles of each group, how their activities are coordinated and reported across the programme and how they are kept informed about key developments within the programme.

120. The role of the breast screening coordinator is pivotal in the delivery of breast screening services. Screening coordinators are the key contact between the NHS boards and NSD. Effective communication between the screening coordinators and NSD is essential, particularly in incident management and the delivery and implementation of changes to the breast screening programme at a national level.
The screening coordinators meet three times a year, and this meeting is coordinated by NSD. During the management of both incidents, the screening coordinators were involved throughout.

**Information Technology**

121. The introduction of the new IT system is recognised by staff as necessary to improve the call/recall process and the way in which women are invited for screening. Improved functionality included the ability to report on women who had not been invited for screening in over 3 years. Staff told us of a number of issues in implementing the new IT system, in addition to maintaining the day-to-day running of the breast screening service. There were numerous delays in implementing the new IT system, and a number of issues, some of which are still ongoing. Although there are clearly benefits to the new IT system, implementation has placed a huge burden on centre staff who have been involved in designing and testing the new system, and data migration from the old to the new system.

122. Staff told us that they can request changes to the system by contacting Atos. It was unclear how NSD is informed of these changes and how the changes are coordinated and managed across all centres. There is a quality assurance admin group that has been involved in the implementation of the new system and has been developing standard operating procedures for staff to use. However, staff told us that implementing the new system has been extremely difficult.

123. NSD described the current process which allows staff to report faults directly to Atos. NSD coordinates the National User Group, chaired by a clinical director of one centre. This group reviews and prioritises any proposed IT changes. Any ongoing IT issues are managed by the National User Group.

124. However, the review team was told about ongoing issues with the new IT system including printing and sending of appointment invitations in June 2016 and a system issue that sporadically 'skips' a case and automatically transcribes the report from a preceding case. These issues were identified in three individual centres, but only one reported this centrally to allow the solution to be communicated at a national level. There does not appear to be a central plan showing how these issues will be managed and coordinated across the programme.
The new IT system will help to address a number of the issues raised in this review. However, the IT system has taken several years to develop and fully implement. It will require ongoing monitoring to ensure any initial software problems are appropriately resolved and any future risks identified are appropriately dealt with.

The new breast screening IT system now links to the NHSScotland CHI database to cross check against the names and addresses of women who should receive a breast screening appointment.

Quality assurance

125. From the discussions the review team had with staff, the status of local quality assurance of the SBSP is not clear. Although there are key performance indicators and standards that the SBSP work to, it was not clear how the internal quality assurance work programmes were used to routinely identify areas for improvement.

126. NHS Quality Improvement Scotland (now Healthcare Improvement Scotland) carried out the last external quality assurance review in 2006. Work is underway to carry out another programme of external assurance of all the screening programmes as well as revising the Scottish Breast Screening standards. This work will start in early 2017.
# Appendix 1: Review team membership

## Review Team

<table>
<thead>
<tr>
<th>NAME</th>
<th>ROLE</th>
<th>ORGANISATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professor Stephen Duffy</td>
<td>Director of the Policy Research Unit in Cancer Awareness, Screening</td>
<td>Centre for Cancer Prevention, Wolfson Institute of Preventative Medicine</td>
</tr>
<tr>
<td>(Chair)</td>
<td>and Professor of Cancer Screening</td>
<td></td>
</tr>
<tr>
<td>Linda Brownlee</td>
<td>Scottish Bowel Screening Service Manager</td>
<td>NHS Tayside</td>
</tr>
<tr>
<td>Professor David Cameron</td>
<td>Consultant Oncologist / Director of Cancer Services</td>
<td>NHS Lothian</td>
</tr>
<tr>
<td>Dr Sue Cohen</td>
<td>National Lead, Screening QA Service</td>
<td>Public Health England</td>
</tr>
<tr>
<td>Stella MacPherson</td>
<td>Public Partner</td>
<td>Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>Nikki McColgan (until October 2016)</td>
<td>Head of Service, eHealth</td>
<td>NHS Tayside</td>
</tr>
<tr>
<td>Mark McEwan</td>
<td>Service Planning Manager, Modernisation</td>
<td>NHS Grampian</td>
</tr>
<tr>
<td>Maria Murray</td>
<td>Professional Officer, Scotland</td>
<td>Society and College of Radiographers</td>
</tr>
<tr>
<td>Dr Iain Robertson</td>
<td>Consultant Radiologist</td>
<td>NHS Greater Glasgow and Clyde</td>
</tr>
<tr>
<td>Finlay Stewart</td>
<td>Head of eHealth Strategic Delivery</td>
<td>NHS Tayside</td>
</tr>
</tbody>
</table>

## Assurance Team

<table>
<thead>
<tr>
<th>NAME</th>
<th>ROLE</th>
<th>ORGANISATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Hilary Ansell</td>
<td>General Practitioner (GP)</td>
<td>NHS Lothian</td>
</tr>
<tr>
<td>Dr Charles Saunders</td>
<td>NHS Board Screening Coordinator / Consultant in Public Health Medicine</td>
<td>NHS Fife</td>
</tr>
</tbody>
</table>
Appendix 2: Healthcare Improvement Scotland request to NSD

The following letter was sent to NSD on 8 November 2016 requesting further clarity on the actions being taken to contact those women who had not been invited for screening in over 3 years.

8 November 2016

By email:
Chief Executive Officer
NHS National Services Scotland

Dear

I write in relation to the ongoing Healthcare Improvement Scotland review of the Scottish Breast Screening Programme (SBSP) routine appointment process.

As you will be aware, earlier in 2016, it was identified that 3,831 women had not been sent an appointment through the usual routine breast screening appointment process. This has resulted in some women not being offered a screening appointment for between 3 and 9 years. The immediate priority by the service was to ensure that the women were contacted in order for them to make an informed choice about whether or not they wish to attend a breast screening appointment.

The review team is in the process of concluding their fieldwork and would like to bring to your attention an important issue relating to the follow up of this cohort of women ahead of publication of the final report in December 2016.

From the most recent information we have received, and following the initial letter sent to the women in May 2016, to date, 1,834 (48%) women have arranged an appointment with their local breast screening centre. This is substantially lower than the achieved participation rates and performance standards in the programme as a whole, with a reported uptake of 72.8% across Scotland.

All enquiries to:

Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB
0131 623 4300

Delta House
50 West Nile Street
Glasgow
G1 2NP
0141 225 6999

It is the view of the review team that:

- this uptake is significantly lower than that would be expected for Scotland and
- that this group of women have been placed at a disadvantage in taking up an offer of breast screening because of a failure in the programme.

To date, no structured incident management process has been followed and the documentation that has been provided to Healthcare Improvement Scotland does not give the sufficient level of detail to be assured that all has been done to maximise the opportunities for women to be screened if they wish to take up the offer. We would therefore ask that NSD in conjunction with the Scottish Breast Screening Programme centres establish an adverse event management team to urgently review whether they consider every reasonable step has been taken to enable this cohort of women the opportunity to attend breast screening appointment.

In order to provide the necessary assurance we ask that, as a basis, this work follows a structured adverse event management process using the guidance set out in the National Services Scotland Adverse Event Management Policy and specifically includes a detailed and documented action plan with clear timescales that, where appropriate, records the agreed additional steps, decisions and methods to follow up on these individual women to allow appropriate closure of this incident.

We would be grateful if you could provide us with an update on progress to the points set out above. Due to the timescale of this review, it would be helpful if this initial update could be provided by noon on 2 December 2016.

Please let me know if you have any queries regarding this letter.

Yours sincerely,

Interim Director of Quality Assurance
The following letter is the response from NSS on 2 December 2016.

Dear

Review of the Scottish Breast Screening Programme

Thank you for your letter dated 9th November 2016.

Our overriding concern within NSS is to ensure that the Scottish Breast Screening Programme (SBSP) is effective in reducing the number of women who die from breast cancer. Thank you for bringing this important issue to my attention in a timely manner. NSS has, as a matter of urgency, considered the views of the Review Team and we have put in place additional interim measures as requested in your letter.

I note the concerns around the lack of a structured management process in dealing with the incident. We have reviewed this in detail within NSS. While the NSS Adverse Event Management Policy has been followed in general terms, it is evident that the clarity, documentation and communication of this have been insufficient. As such, we will be looking to ensure this is significantly improved.

You have requested that NSD, in conjunction with the Scottish Breast Screening Programme centres, establishes an adverse event management team to urgently review whether every reasonable step has been taken to enable this cohort of women to have the opportunity to attend breast screening. I confirm that this is now in place and that a structured adverse event management process is being followed. The Terms of Reference are attached as an appendix to this letter.

The current figure for women who have responded to the invitation for screening is a 58% response rate. This includes those who have taken up the offer of screening, and those who have indicated that they wish to wait until the next time screening is available in their local area.

NSS is fully committed to continuing to work with HIS and the broader screening community to respond to the final findings of the review.

Yours sincerely

Chief Executive
Appendix 3: Letters that were sent to women offering a screening appointment

(Screening Centre Details)

Our ref:

PRIVATE AND CONFIDENTIAL

Dear [Name]

This is a personal invitation offering a breast screening appointment at [insert name of Screening Centre]. This invitation for breast screening is being sent out with the standard screening cycle. A review of our records suggests that you may not have been invited for breast screening for more than 3 years. We therefore wish to offer you an invitation to attend for a breast screening examination at the earliest opportunity.

Please contact the Breast Screening Centre, on [insert telephone number] to arrange a date and time that is convenient to you.

A leaflet providing information about breast screening and describing what happens at your appointment is included. We hope this will help you decide whether to attend for breast screening.

We recognise that offering you an appointment at the Centre instead of a local Mobile Screening Unit may be less convenient. We will reimburse any travel costs if this makes it easier for you to come along.

Staff from the Scottish Breast Screening Programme and NHS National Services Scotland are currently reviewing why you may not have been invited for breast screening and all improvements that are identified will be acted upon. If you have received this invitation inappropriately, please accept our apologies and contact the screening centre so that our records can be amended.

Many thanks for taking the time to read this important letter. We are sorry for any anxiety or inconvenience this may cause. If you have any specific questions or concerns please do not hesitate to contact the Centre at the number listed above where they will be happy to help in any way they can.

Yours sincerely

[name of relevant Board lead]
[Title]
[name of screening centre]
(Screening Centre Details)

Our ref:

PRIVATE AND CONFIDENTIAL

Dear [Name]

A review of our records suggests that you may not have been invited for breast screening for more than 3 years. I understand that you are or have been receiving treatment for breast cancer and that being offered an opportunity to attend for breast screening would not be appropriate for you at this time.

From June 2016, the breast screening programme will send a letter to any woman who has not been invited for screening for more than 3 years. You are due to receive this letter but you do not need to respond to this.

Please note however, that you will continue to be invited to the breast screening programme when your GP practice is due for screening and you can choose whether to attend or not. If for any reason you change address or GP then please do let us know in order to maintain your 3 yearly offers of invitations to attend.

Many thanks for taking the time to read this important letter. We are sorry for any anxiety or inconvenience this may cause. If you have any specific questions or concerns please do not hesitate to contact the Centre on [insert telephone number] where they will be happy to help in any way they can.

Yours sincerely

[name of relevant Clinical lead]
[Title]
[name of screening centre]
Dear Colleague,

Breast Screening recall

This note is to advise you of work that is currently underway and to provide context if you are contacted by any members of the public.

From this week onwards, around 3,800 women in Scotland are being sent an offer (sample letter attached) to attend for breast screening having been identified as not having been sent an invitation for a routine breast screening appointment.

Women aged 50 to 70 years are typically invited for breast screening every three years. Women are invited GP practice by GP practice. Historically, those who moved out of Scotland or moved GPs may have dropped out of the invitation cycle. Although it was not previously possible to identify those involved, Scottish Government investment in a new call and recall system now enables these women to be identified and offered breast screening, therefore minimising the risk of this occurring. The new system means that measures are in place going forward to better audit a woman’s participation in breast screening. The system will identify women who move in and out of Scotland or who register with a different GP and allow a failsafe reminder to be sent to them.

Arrangements to offer breast screening to this group of women are being treated as a priority and each woman will receive a personal letter from the Scottish Breast Screening Programme offering them an opportunity to make an appointment for breast screening at her local centre.

Kind regards,

Service Agency for the Scottish Health Service.
Appendix 4: Overview of governance and decision making structure

The organisations and groups involved in governance and decision making in the Scottish Breast Screening Programme and how they relate to each other are set out in the diagram provided by NSD below.