

# The Independent Breast Screening Review 2018

December 2018

Return to an Address of the Honourable  
the House of Commons  
dated 13 December 2018 for

# The Independent Breast Screening Review 2018

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# Contents

<b>Introduction from the Chairs</b>	<b>v</b>
<b>Executive summary and recommendations</b>	<b>ix</b>
<b>Chapter 1: History of the breast screening programme in England</b>	<b>1</b>
The three-year interval between screenings	2
The Cancer Plan 2000 and expanding the age range	2
The Cancer Reform Strategy 2007	3
The Health and Social Care Act 2012 reforms and the April 2013 Service Specification	4
The November 2013 Service Specification	4
Conclusion	5
Recommendations	5
<b>Chapter 2: IT and processes</b>	<b>11</b>
How women are invited for routine breast screening and the use of ‘calendar age’	11
The IT systems	12
How the invitation system works	13
An addition to NBSS – the AgeX algorithm	14
IT design issues – margin for error	14
IT and policy – room for interpretation	16
Conclusions	17
Recommendations	17
<b>Chapter 3: Governance and accountability</b>	<b>19</b>
Governance structures and roles	19
The role of the Department of Health and Social Care (post-2013)	20
The role of NHS England (post-2013)	20
The role of Public Health England (post-2013)	21
Reporting mechanisms	21
Quality assurance	22
Conclusions	23
Recommendations	23
<b>Chapter 4: Handling the incident</b>	<b>25</b>
Discovery of an issue	25
Investigation of the declared incident	26
Escalation of the declared incident	27
Public announcement	28

Patient Notification Exercise	29
Conclusion	30
Recommendations	30
Timeline of events:	31
<b>Chapter 5: Impact on women</b>	<b>35</b>
How the incident has affected women	36
Impact of breast screening – background	37
NHS Breast Screening – evidence since the Forrest Report	38
The NHS breast screening programme – risks and benefits	38
Breast cancer screening and treatment – developments and impact over the last thirty years	40
Breast cancer screening now	42
Conclusion	42
Recommendation	43
<b>Chapter 6: The age extension trial – AgeX</b>	<b>45</b>
The pilot study	46
The AgeX trial	46
Process	47
Research Ethics Committee amendments to the AgeX protocol	48
Funding	50
Governance	50
Recommendation	50
<b>Annex A – terms of reference</b>	<b>51</b>
<b>Annex B – list of breast units visited by the Review team</b>	<b>52</b>
<b>Annex C – data analysis note</b>	<b>53</b>
<b>Annex D – glossary</b>	<b>55</b>
<b>Annex E – survey results</b>	<b>57</b>

# Introduction from the Chairs

On 2 May 2018 the then Secretary of State for Health and Social Care, the Rt Hon Jeremy Hunt, announced that there had been a serious failure in the English breast screening programme. It seemed clear at the time that a mistake had been uncovered which affected nearly half a million women. We were asked to conduct a review, independent of government, to establish what had happened and what lessons could be learned for the future.

Over the last six months we have spoken to many people involved in delivering the breast screening service, from those at the centre of leadership of the programme, through individuals at front line of delivery within the breast screening units, to experts in the field, in order to get a full understanding of what had occurred.

We have found that the Health Secretary's announcement was made following advice based on an incomplete understanding of what had happened. He was advised that women had not been invited to their final breast screenings between the ages of 70 and 71 because of a problem with a computer algorithm. In fact, the reason that the women were not invited between those ages is that the way the breast screening programme had been run since the late 1980s meant they had already received their final screening three years earlier. The misunderstanding arose because of a Specification document written in November 2013 which stated that women should be invited for screening "within 36 months of their previous screening, until they reach the age of 71". We believe this document was based on a misunderstanding of how the programme was being delivered in practice. The vast majority of women who were told earlier this year that they may have missed an invitation to screening were only affected under the definition of this document, and of them some (those eligible for final screening before the Specification was written) should not have had the document applied to them at all.

For many years, from the beginning of the breast screening programme in the late 1980s, the specific age range of women to be invited was not set out in sufficient detail, and there was variability across breast screening units. In the hand-over of responsibilities to the newly-formed Public Health England and NHS England in 2013 we have found no evidence that there was a shared understanding of how the screening programme was being delivered. A new Service Specification was written to provide specific instructions against which the programme could be commissioned and quality assured, but it included a level of specificity which did not align with the IT system then in use, and was not consistently implemented by the breast screening units. We believe this to have been written in error. It appears that no-one in the Department of Health and Social Care, Public Health England or NHS England realised that this was not consistent with past policy or understood that this change then caused a misalignment between policy, delivery, the IT system and the AgeX trial algorithm. This lack of understanding of the root cause of the confusion continued even as the incident was being investigated and announced.

It is a matter of debate as to whether the 2013 Service Specification can be said to have changed government policy. If it did change policy we believe it was accidental – there was no policy brief, no process followed, no Ministerial decision, no consultation, no implementation timetable, no changes to the IT and processes and no communication to breast screening units to implement the new policy. Furthermore, no-one checked that the IT programmes were

designed to deliver the new specification or were compatible with the AgeX trial algorithm. NHS England did not subsequently hold screening units to account for their contracts to deliver this 'new' policy. There is an argument for saying the November 2013 Specification – a publicly available document – created a reasonable expectation that women would be entitled to screening as set out in the document, even if it did not formally change government policy or align with other documents. However, we consider it more likely that women would have read the letters which were sent to them by their local breast screening units (drafted by Public Health England) which said “If you are 70 years or over in three years’ time, you will not automatically be invited for screening”. This mismatch in information for women makes it difficult to be definitive about what they could reasonably have expected from the breast screening programme.

If it is held that the 2013 Service Specification neither changed policy nor gave rise to a legitimate expectation different from the current practice, women were wrongly told they had missed a screening invitation. In short there was no incident and ministers were incorrectly advised. The advice to contact women to tell them that they may have missed a final screening, and to offer another, was based on a laudable desire to correct a mistake and ensure that women were safe. We believe the Health Secretary made the right decision, based on the advice he was given.

However, we believe that in the rush to announce and correct the issue, assumptions were made about policy and operations which were not sufficiently challenged. We have not found that any one person is to blame for this confusion, but it is unacceptable for there to be confusion about what women should expect from the breast screening programme. The advice from Public Health England was given based on a limited review of the range of documents on which women could reasonably have based their understanding of their entitlement in the breast screening programme. Furthermore, in estimating the number of women who may have missed their final invitation to screening, the 2013 Specification was applied retrospectively to women who were due for screenings from 2009 onwards. It is our view that there cannot have been a reasonable expectation for women to have been screened according to the 2013 Specification before 2013 and therefore the number of women affected included in advice to Ministers was incorrect. There was not a thorough understanding of what had happened when Health Ministers were alerted in March 2018, and the Health Secretary was not given the full information on which to base his announcement.

The breast screening programme now needs a re-set. The three organisations currently responsible for the programme – the Department of Health and Social Care, Public Health England and NHS England – should agree a clear and specific definition of the ages at which women will be invited for screening, based on the best available evidence and advice from experts in the field. Everything in the system should then flow from this decision, including the safest and most efficient way to deliver both the programme and the governance arrangements. Guidance issued by the relevant authorities should reflect national policy, and the IT systems should be aligned so that staff in the breast screening units can easily invite the right women at the right time. Training should be updated to make sure everyone delivering the programme is clear on what policy is and how they should implement it. Quality assurance needs to include checking that the right women are being invited to screening at the right time.

The algorithm which was introduced to invite some women to further screenings before 50 or after 70 as part of the AgeX trial contributed to the overall problems, but only because no-one realised or checked that the 2013 Specification was compatible with the existing IT systems. It is clear to us that the AgeX trial itself is not to blame for any of the issues we have encountered. It is essential that this trial continues to build the evidence base about breast

screening to inform further policy in England, the UK and throughout the world. It is an important piece of public health research and any new policy, specification or operational guidance that is developed should be done in conjunction with the AgeX investigators and their Trial Management Group so that the integrity of the study is not compromised and the knowledge held by the AgeX trialists is utilised.

In our analysis of the records of the women contacted by Public Health England, we have also found that around 5,000 women were not invited for a final breast screening when they should have been because of manual errors in using the unwieldy IT systems to invite women, and a misalignment between a computer algorithm and the way women were being invited to screenings.

The breast screening programme is one of the largest and longest running cancer screening programmes in the world. However, the value of breast screening is a contentious subject with arguments for (reduction in deaths from breast cancer) and against (causing unnecessary interventions and anxiety). Our role has not been to engage in this debate and give a view on the effectiveness of breast screening, rather we have investigated the policy, governance and operation of the programme to establish whether, and if so why, some women might have missed their final screening. The programme can only achieve its objective of reducing mortality from breast cancer if it is properly administered. We are pleased that Sir Mike Richards has been appointed to carry out a review of breast and other screening programmes and hope the recommendations in this report will help inform his work.

We are very grateful to the many people who made time to speak to us about their experiences and knowledge of the breast screening programme. In particular, the dedicated staff working in breast screening units across the country. We visited ten units – from Bolton to Bristol – and found that the staff working there were skilled, experienced and worked very hard to make sure the women in their care received the best possible service. When the incident was declared, they worked overtime during evenings and weekends to make sure every woman who was thought to have missed an appointment was contacted and screened quickly.

We thank all those we interviewed at Public Health England, NHS Digital, NHS England and the Department of Health and Social Care for their openness, cooperation and candour. In addition, we wish to put on record the genuine upset we came across from individuals within these organisations that an activity they were involved with and cared deeply about had apparently gone awry.

We are indebted to the small team of people seconded to work with us on this Review.

Finally, we are grateful to the many women who responded to our survey to tell us about their understanding of the breast screening programme, their experiences of the incident and the impact it had on them. The reasons behind the incident are bureaucratic and it is important that we remember that administrative mistakes have human consequences.



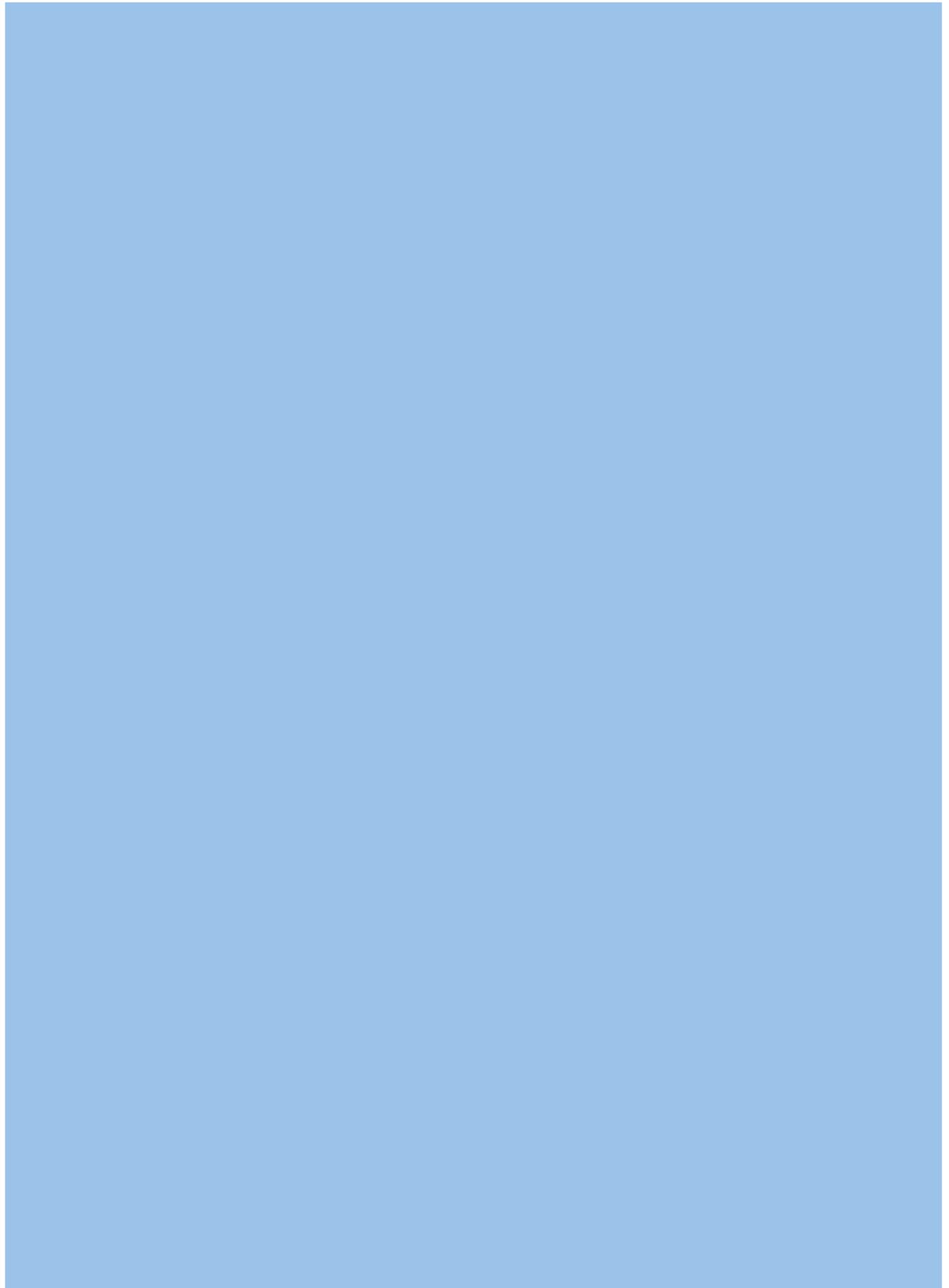
*Martin Gore*



*Lynne Athy*



*Mike Wynn*



# Executive summary and recommendations

**1 Breast screening programme policy.** From the introduction of the breast screening programme there was ambiguity in the age at which women should stop being invited for screening. This should have been clarified early in the programme, and checks carried out to ensure there was consistency across the country. When the programme was split between the Department of Health, Public Health England and NHS England in 2013 Service Specifications were written to attempt to address this ambiguity. The clarification was too late and incorrect. Those responsible for ensuring the Specification was correct did not notice and the governance structures put in place to assure the Specification did not identify the mistake.

*1.1 The Department of Health and Social Care should agree and publish a Service Specification for breast screening clarifying at what age women should stop being invited to screenings. This should take into account the advice of the UK National Screening Committee and Public Health England, based on the best available evidence. It should also take into account advice from NHS England on the implementation requirements of this Specification.*

*1.2 The new breast screening Specification should be communicated to all those involved in breast screening and used as the central document for understanding, implementing and assuring the programme.*

*1.3 Importantly, public information should be updated so that it is clear to women what they should expect from the breast screening programme, including when they are likely to receive their final screening invitation and from what age they are entitled to self-refer.*

**2 IT and processes.** The Review has found that – although dated and unwieldy – the IT systems have broadly operated as they were designed to. Around 5,000 women were not invited to their screenings when they should have been – this was caused not by a systemic IT error but by errors in using two separate and complicated systems (despite the best efforts of unit staff), and slippages in units' screenings which meant that some women might have had incremental lengthening of their screening intervals until they left the age range for core screening. The fact that an incident was called on the basis of a Service Specification which was not aligned with the IT as designed, and that women were identified as having been affected from 2009 onwards rather than when the Specification was introduced in 2014 (having been written in 2013), shows that there is a lack of understanding of how the IT was designed and how it functions as a system. The IT systems are owned and overseen by different organisations – NHAIS by Capita contracted to NHS England with technical support from NHS Digital; NBSS by Hitachi contracted to PHE; and BS-Select by NHS Digital with PHE as the product owner – with no overarching oversight of how they interact and function as a system.

*2.1 In the immediate term, a review should be conducted by Public Health England, in collaboration with NHS England to represent the users of the systems and NHS Digital as system experts, to reduce as far as possible the manual inputting and duplication involved in*

*NBSS and BS-Select and to simplify the user interface. This should abide by the principles of the recently published NHS Digital service manual,<sup>1</sup> in particular “Don’t just design your part of a service. Consider people’s entire experience, and the infrastructure and processes involved...”.*

*2.2 If the IT systems continue to be operated and overseen by different organisations in the longer-term, an overarching governance structure should be introduced with responsibility for ensuring the systems work together to deliver the breast screening programme. Thought should be given to whether this governance structure should also oversee the IT systems for the other screening programmes given they rely on some of the same IT (e.g. NHAIS). The new governance structure should take a risk-based approach to its management of the IT systems, taking into account the likely clinical harm resulting from a failure of the systems.*

*2.3 Once a decision has been taken about the specific ages at which women should be invited to breast screenings (see recommendation 1.1), the IT system/s should be reviewed to ensure they function to deliver that policy.*

*2.4 Any new systems introduced to support the screening programmes should follow the principles set out in the recent document *The Future of Healthcare: Our Vision for Digital Data and Technology in Health and Care*<sup>2</sup> (user need; privacy and security; interoperability and openness; and inclusion).*

**3 Governance.** The breast screening programme is – like many other health programmes – run by a group of organisations, with shared responsibility and accountability. In the case of the breast screening programme we have found that there is a relatively clear governance structure, but that there is no senior responsible owner to ensure the system is functioning correctly – responsibilities are shared between the Department of Health and Social Care, NHS England and Public Health England without a shared sense of how they fit together to make a cohesive and effective whole. We have also found that the main governance document – the annual section 7A agreement (see below) – included the November 2013 Service Specification and its subsequent iterations, indicating that it was accepted by the Department and NHS England as policy. It is clear that a change in policy was not intentional. It is also clear that the governance structure which was intended to ensure that there was joint responsibility for establishing and delivering policy did not function as intended. NHS England failed to hold breast screening units to account for delivering against the contracts, which were based on the Service Specifications.

*3.1 The recently announced review by Sir Mike Richards should include a consideration of the governance of all screening programmes, including giving thought to better aligning the screening programmes with the delivery of the Cancer Strategy in NHS England. It should also examine what progress has been made in implementing the recommendations of the 2017 Tailored Review<sup>3</sup> of Public Health England’s governance so far as it affects screening programmes.*

*3.2 The performance indicator in the section 7A agreement is insufficiently specific regarding the population eligible for screening. This should be clarified.*

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1 <https://beta.nhs.uk/service-manual/design-principles/>

2 <https://www.gov.uk/government/publications/the-future-of-healthcare-our-vision-for-digital-data-and-technology-in-health-and-care>

3 [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/608368/PHE\\_Tailored\\_Review.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/608368/PHE_Tailored_Review.pdf)

*3.3 The quality assurance carried out by Screening Quality Assurance Service should reflect the breast screening programme policy (see recommendation 1.1). This is likely to mean guidance and training should be updated to make sure everyone carrying out inspections is aware of what they should be assessing against.*

*3.4 NHS England should improve its contract management processes to ensure providers are delivering the service as set out in Service Specifications. The issue of contract management should be addressed for all screening programmes in Sir Mike Richards' review.*

**4 Handling of the incident.** Public Health England was slow to develop a clear understanding of the incident and the causes of the failures in the breast screening programme. As investigations into the incident response developed and revealed more information leading to the conclusion that some women had missed a screening, and why, the Review believes that the coordination group did not adequately adjust their response to the incident. This led to a public announcement which overstated the scale of the incident and many women were left anxious until they received the results of their catch-up screening appointments.

*4.1 The Department of Health and Social Care and its arm's length bodies should review their incident response protocols and ensure that they are appropriate for responding to all incidents involving the screening programmes in their different forms. The protocols should ensure all partners are included in the investigation and response, including those responsible for the supporting IT or implementation systems.*

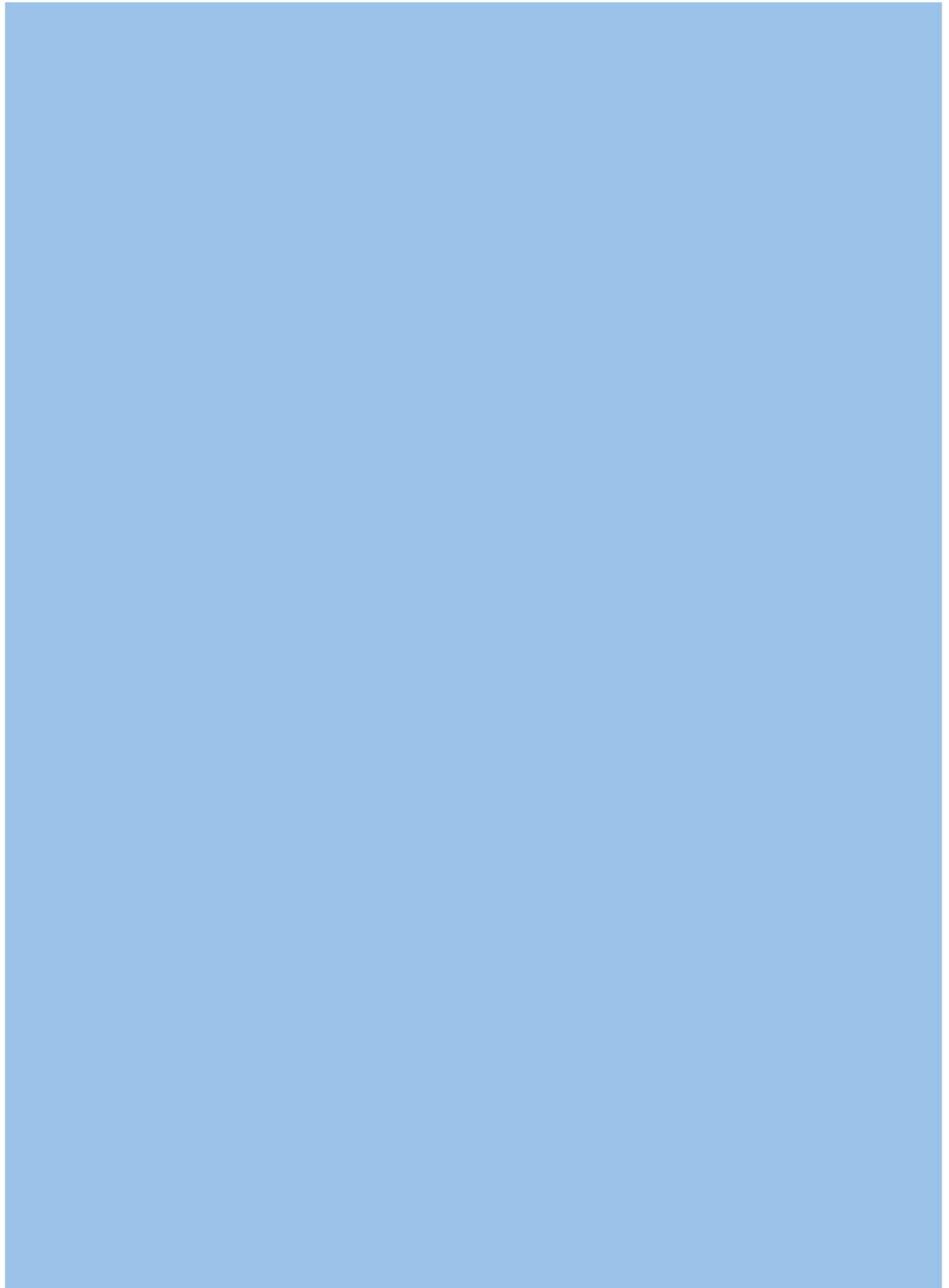
*4.2 Existing protocols should be updated to ensure those delivering the operational response – in this case breast screening units and the devolved administrations – are notified at the earliest opportunity so that they can plan and implement their response.*

**5 Impact on women.** Although most women who responded to our survey told us that their trust in the breast screening programme had not reduced as a result of the incident, those who had been diagnosed with breast cancer felt worried and wondered whether their personal situation might have been different had they received a screening invitation at the right time.

*5.1 Women who were contacted through the Patient Notification Exercise and have been diagnosed with breast cancer will be assess to try to determine whether they were caused harm by errors within the breast screening programme. Public Health England should work quickly and sensitively with these women, their families and their healthcare professionals to try to provide clarity over this and ensure the women have the support they need.*

**6 AgeX trial.** At the time of the announcement by the then Secretary of State, it was believed that an algorithm used to randomise women for the AgeX trial might have been the cause of the failure of women to be invited for their last screening. At an early stage in our inquiry, the Review team established that the algorithm was operating as designed and, in addition, that the trialists at Oxford University leading the study did not have any involvement in the randomisation process.

*6.1 The AgeX Trial should continue until its planned end date, currently 2026, to enable the most extensive analysis possible of the impacts of extending the breast screening programme both in the younger and older age groups.*



# Chapter 1: History of the breast screening programme in England

**1.1** In 1985, Professor Sir Patrick Forrest was commissioned by the then Minister of State for Health, the Rt Hon Kenneth Clarke MP, to conduct a review of the effectiveness of mammographic screening in reducing mortality from breast cancer in women, and to make recommendations to government on the costs and benefits of a screening programme. The Breast Cancer Screening Report (known as the Forrest Report), published in 1986, concluded that there was sufficient evidence to show mammographic screening had the potential to reduce mortality from breast cancer in women over 50 years of age and that there was a “convincing case” for the introduction of a screening programme for women aged 50-64.<sup>4</sup>

**1.2** The recommendations of the Forrest Report were accepted by the then Secretary of State for Social Services the Rt Hon Norman Fowler, in February 1987<sup>5</sup> and the Report’s findings were subsequently used as a guide by government for the establishment of the first national screening programme for detecting breast cancer in symptomless women.

**1.3** The roll-out of the screening programme began almost immediately, with the first women being screened in 1988. The programme was extended nationally by 1990 and all eligible women had been invited for a screening by 1993.

**1.4** The initial establishment of a national screening programme was a major undertaking and over the subsequent years it has undergone several significant changes. These included the move from film to digital mammography and an increase from one view (or image) at every screening to two. This chapter does not aim to provide a complete history of breast screening in the UK, but instead focuses on:

- key changes to intended policy on the timing, frequency and scope of the English breast screening programme;
- major changes to the IT systems used to invite women for screening; and
- how these changes were communicated and understood by all involved with the programme.

**1.5** We have found that for many years there has been a lack of clarity around the specific age range during which women should be invited to routine screening, and that this led to confusion about what should have been offered to women and what was offered in practice. This confusion continued and ultimately led to the Secretary of State declaring an incident in May 2018.

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<sup>4</sup> A working group chaired by Professor Sir Patrick Forrest, *Breast Cancer Screening: Report to the Health Ministers of England, Wales, Scotland and Northern Ireland*, (November 1986) p7;

<sup>5</sup> House of Commons Debate, *Cancer Screening and AIDS research*, 25 February 1987 vol 111 cc271-82, <https://api.parliament.uk/historic-hansard/commons/1987/feb/25/cancer-screening-and-aids-research>

## The three-year interval between screenings

**1.6** Professor Forrest's remit was not only to review the case for a breast screening programme, but also to make recommendations on the options for implementation. A key recommendation from his Report was that, while there was a lack of evidence around the optimal interval between screenings, an initial 3-year period between screenings in the new programme would be appropriate.<sup>6</sup>

**1.7** The new screening programme followed the Report's recommendation, with screening units inviting women to screenings every 36 months. To facilitate this, women were invited in 'batches' – with all eligible women within a location being invited to a screening over a set period. This 'batching' of women is a complex process, which is described in more detail in Chapter 2.

**1.8** During this period, those involved in the screening programme appear to have understood the definition of 64 as the year in which a woman turned 64. However, during this Review we have been unable to identify any document where this understanding was explained to the public, or written down in guidance.

## The Cancer Plan 2000 and expanding the age range

**1.9** The next important milestone for the breast screening programme came in September 2000, with the publication of the Cancer Plan by the then Secretary of State, the Rt Hon Alan Milburn MP. A key element of this plan was screening and particularly the breast screening programme. The programme was covered in relative detail for a strategic document and the key announcement was the Government's intention to extend breast screening to all women aged 65-70.<sup>7</sup> Helpfully, the plan also detailed the previous offer as: "Breast screening every three years is available for all women aged 50 and over. At present women receive personal invitations between the ages of 50 and 64".<sup>8</sup>

**1.10** The Cancer Plan explained the expansion of the programme only in terms of age range and with reference to the increased workload for screening staff. Similarly, the *Consolidated Guidance on Standards for the NHS Breast Screening Programme*, published in April 2005, set out that screening should take place between the ages of 50-70<sup>9</sup> and the relevant standard set for the breast screening programme was "To ensure that all women aged 50-70 are invited once every three years."<sup>10</sup>

**1.11** At this stage, the high-level policy on screening appeared in publications relatively consistently, with the number of screenings women received being based on the 36-month interval between screenings and the age range during which women were routinely screened. There was some divergence, for example *Organising a Breast Screening Programme*,<sup>11</sup> published by the NHS Cancer Screening Programme in 2002, set out that the age range was

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6 As above, p28

7 The Department of Health, *The NHS Cancer Plan*, September 2000 (p32);

8 As above;

9 NHS Cancer Screening Programmes, *Consolidated Guidance on Standards for the NHS Breast Screening Programme: NHSBSP Publication No 60 (Version 2)*, April 2005 (p4);

10 As above (p14);

11 NHS Cancer Screening Programmes, *Organising a Breast Screening Programme: NHSBSP Publication No. 52*, December 2002 (p1)

being extended “to women aged up to and including 70”, potentially suggesting (though not explicitly) that women should continue to be screened throughout the year in which they turned 70.

**1.12** However, once again this Review has been unable to find any document that sets out how 70 should be defined (i.e. when a woman turns 70 or until just before her 71st birthday). The lack of clear guidance appears to have allowed inconsistency to develop during this period, with anecdotal evidence from the interviews we have conducted suggesting that as early as 2004 there was no consistent approach to when screening should stop across units.

**1.13** The age expansion to 70 was rolled out in a similar manner to the original introduction of the screening programme, with individual screening units beginning to screen a wider range of women until all units were screening women aged 50-70. Other than expanding the age range, the design and operation of the breast screening programme remained the same and most women in scope continued to be invited in batches, based on location and year of birth.

## The Cancer Reform Strategy 2007

**1.14** At the Labour Party Conference on 24 September 2007, the then Prime Minister, the Rt Hon Gordon Brown MP, announced plans to further extend the ages for breast cancer screening by six years.

**1.15** Detail on this announcement then came in December 2007, with the publication of the Cancer Reform Strategy. This set out plans to extend breast screening to: “Nine screening rounds between 47 and 73 years, with a guarantee that women will have their first screening before the age of 50”.<sup>12</sup>

**1.16** The strategy also highlighted that currently women were invited for seven screenings at three yearly intervals.<sup>13</sup> This strategy, for the first (and only) time, explained the screening programme in terms of the number of screens a woman was due to receive, rather than simply the age range and interval of screenings.

**1.17** The intention for women to be screened seven times ensured parity in what all women should routinely receive and aligned with the design of the screening programme. However, other than the high-level Cancer Reform Strategy, there is no mention of the intention for women to receive only seven screenings, nor of how the age 70 should be defined for the purposes of the screening programme.

**1.18** The breast screening leaflet *Over 70? You are still entitled to breast screening*<sup>14</sup> was published in January 2007 and stated that women over the age of 70 were not automatically invited for breast screening, as did *Breast Screening: A Pocket Guide*,<sup>15</sup> published in April 2008.

**1.19** The *Quality Assurance Guidelines for Breast Cancer Screening Radiology*, intended for use by all screening practice administered by the NHS breast screening service, were published in March 2011 and again set out that women being screened every three years was a key

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<sup>12</sup> Department of Health, *Cancer Reform Strategy*, December 2007 (p47)

<sup>13</sup> As above;

<sup>14</sup> NHS Cancer Screening Programmes, *Over 70? You are still entitled to breast screening*, January 2007 (p3)

<sup>15</sup> NHS Breast Screening Programme, *Breast Screening: A Pocket Guide*, April 2008 (p2)

measurement for the success of the programme.<sup>16</sup> While defining the age range of routine screening as between 50-70 years, these and all other guidelines and standards assumed that screening units all understood the meaning of this age range and were applying it consistently.

## The Health and Social Care Act 2012 reforms and the April 2013 Service Specification

**1.20** Public Health England (PHE) was established in the reforms accompanying the Health and Social Care Act 2012 on 1 April 2013, and responsibility for advising on the health services provided on a population-basis (screening and immunisation) passed to them. This included developing the standards these services should meet and the performance indicators used to measure those standards.

**1.21** To agree the standard for each service with NHS England, Service Specifications for each of the screening programmes were drafted, including the breast screening programme. The first specification, prepared by the Cancer Screening Early Diagnosis and Skin Cancer Prevention Team at the Department of Health, and agreed by NHS England, was published in April 2013. Its purpose was to set out “the specific policies, recommendations, and standards services are expected to meet.”<sup>17</sup>

**1.22** Setting out the expectations for the breast screening programme in one document should have ensured a consistent offer for women across England. However, the first Service Specification for the breast screening programme was not clear in several key areas. Crucially it failed to define what the age range of 50-70 meant for the purposes of routine screening.

**1.23** Small errors were also made within the drafting of the April 2013 Specification – of possible importance is one sentence, which set out that “women aged 71 or over” should be screened on request every three years.<sup>18</sup> The implication of this being that routine screening would continue until the age of 71 – something that the Review does not believe was the original policy intention.

## The November 2013 Service Specification

**1.24** The April 2013 Service Specification was superseded by a new Service Specification, dated November 2013, again developed by the Cancer Screening, Early Diagnosis and Skin Prevention Team in the Department of Health and NHS England.

**1.25** None of the organisations involved – the Department of Health, Public Health England and NHS England – have been able to set out how this document was signed off. However, it appears from the document itself that some attempt was made to clarify key statements. The following sentence was added (and differs from the April version) “Ensure that women who have already attended for screening are offered screening again within 36 months of their previous screening, until they reach the age of 71”.<sup>19</sup>

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<sup>16</sup> NHS Screening Programmes, *Quality Assurance Guidelines for Breast Cancer Screening Radiology, Second edition: NHSBSP Publication No 59*, March 2001 (p4)

<sup>17</sup> Cancer Screening, Early Diagnosis and Skin Cancer Prevention Team, Department of Health, *Public Health Functions to be Exercised by NHS England – Service Specification No. 24: Breast Screening Programme*, April 2013 (p7)

<sup>18</sup> As above, p20

<sup>19</sup> Cancer Screening, Early Diagnosis and Skin Cancer Prevention Team, Department of Health, *Public Health Functions to be Exercised by NHS England – Service Specification No. 24: Breast Screening Programme*, November 2013 (p12)

**1.26** There are no complete records that show why this sentence was added, but the Review believes from the early drafts it has seen that the November 2013 Service Specification was not intended to change breast screening policy and there is no evidence to suggest anyone knew that it would do so. Breast screening units continued to send out invitation letters, leaflets and result letters that all stated routine screening ends at 70. No change was communicated to breast screening units, a policy change was not discussed at the UK National Screening Committee and no changes were made to procedures or processes for inviting women to their screenings.

**1.27** This policy was repeated in subsequent annual iterations including the Service Specification published in April 2017.<sup>20</sup> It is possible that some breast screening units were attempting to screen up to 71 prior to 2013 and following the release of these specifications it is likely that more have started to define the screening programme in this way. However, the Review's analysis of events suggests that this was not the original policy intention and key parts of the programme were not aligned with this specification of the breast screening service (see Chapter 2), which would mean that the November 2013 Service Specification was inaccurate when published, and subsequent iterations have remained inaccurate.

## Conclusion

**1.28** From the introduction of the breast screening programme there was ambiguity in the age at which women should stop being invited for screening. This should have been clarified early in the programme, and checks carried out to ensure there was consistency across the country. When the programme was split between the Department of Health, Public Health England and NHS England in 2013 Service Specifications were written to attempt to address this ambiguity. The clarification was too late and incorrect. Those responsible for ensuring the Specification was correct did not notice it did not align with existing policy and practice and the governance structures put in place to assure the Specification did not identify the mistake.

**1.29** It appears there was a lack of understanding of what was being delivered in breast screening units, and how this interacted with the IT systems. This meant that when Public Health England officials investigated why some women might not be being invited to their final screenings, there was confusion about what the entitlement should be. The decision to base the incident response on the policy as set out in the November 2013 Service Specification was taken on internal legal advice, but without an understanding that the Specification did not align with processes and practice in breast screening units.

## Recommendations

**1.30** *The Department of Health and Social Care should agree and publish a Service Specification for breast screening clarifying at what age women should stop being invited to screenings. This should take into account the advice of the National Screening Committee and Public Health England, based on the best available evidence. It should also take into account advice from NHS England on the implementation requirements of this Specification.*

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<sup>20</sup> Public Health England and NHS England Public Health Commissioning, *NHS Public Health Functions Agreement 2017-18 – Service Specification No. 24: Breast Screening Programme*, April 2017 (p14)

**1.31** *The new breast screening Specification should be communicated to all those involved in breast screening and used as the central document for understanding, implementing and assuring the programme.*

**1.32** *Importantly, public information should be updated so that it is clear to women what they should expect from the breast screening programme, including when they are likely to receive their final screening invitation and from what age they are entitled to self-refer.*

## Breast screening in Northern Ireland, Scotland and Wales

**1.33** The Health Secretary's announcement of May 2018 was confined to England, but had implications for the devolved administrations as some of the affected women had moved there from England and needed to be contacted and offered a further screening appointment.

**1.34** The breast screening programme was established across the United Kingdom in the late 1980s, in response to the Forrest report, and has been administered separately in each country, with devolution reinforcing the separation in processes and structures. The main features of these screening programmes are set out here in order to provide context for the English incident.

### Northern Ireland

**1.35** The Northern Ireland Breast Screening programme was established in 1989 to operate in a similar way to the English programme, following the NHS National Standards. There are five Health and Social Care Trusts and four Breast Screening Units in Northern Ireland – the Northern, Southern, Eastern and Western screening units. The Eastern Breast Screening Unit provides screening to women resident in both the Belfast and South Eastern Health and Social Care Trusts. Some of the screening is undertaken at static units within each area, but the majority of screening occurs at mobile units which move throughout the region. Women are invited for screening based on their GP surgery. The Northern Ireland Breast Screening Service aims to achieve a 36-month round length with the PHA Young Person and Adult Screening Team checking and reporting on the round length for each unit monthly, and working with Trusts to put measures in place where slippage is identified.

**1.36** The Department of Health is responsible for setting the policy. The Northern Ireland Public Health Agency commissions and quality assures the programme. Internally at the Public Health Agency there is a Young Person and Adult Screening Team which monitors Breast Screening standards and is accountable via the Chief Executive of the PHA and the PHA Board to the Department of Health. Northern Ireland does not have a service specification and would not have implemented the November 2013 specification as this would have applied to England only.

**1.37** In Northern Ireland eligible women aged 50 – 70 are invited for breast screening, by GP practice, every 3 years. Due to this three yearly round of invitations about a third of women will be invited for the first time before their 51st birthday (the year they turn 50), a third before their 52nd birthday (the year they turn 51) and the rest before their 53rd birthday (the year they turn 52). All eligible women should be invited for the first time before their 53rd birthday. As the women who are invited before their 51st birthday are invited in the year they turn 50, some women will be invited for breast screening for the first time when they are 49.

**1.38** Women invited for the first time in the year they turn 50 are invited for the last time the year they turn 68. Women invited for the first time the year they turn 51 are invited for the last time the year they turn 69, and women invited for the first time the year they turn 52 are invited for the last time the year they turn 70. Everyone receives a total of at least seven invitations. Women aged over 70 years are not automatically invited for screening, but are encouraged to continue attending every three years by phoning their local screening unit and requesting an appointment.

**1.39** Regular next test due date batches and age extension failsafe batches are specified monthly and these capture women who, for example, may have recently moved into the area, have not been invited for screening or are approaching their 53<sup>rd</sup> birthday and are eligible for screening.

**1.40** Since November 2010 Northern Ireland has used NHAIS to invite women for screening. Prior to that they would use hard copy prior notification lists to invite women for screening. There is an electronic link between NBSS and NHAIS which is managed by the Belfast Trust. The four screening units send batch specifications to the Belfast Trust to enter data onto NHAIS system and this generates batches of women to invite for screening. All units invite women by GP practice, using the parameters set up on NBSS. There is an annual NHAIS audit. As part of this, the batch specification is checked on both IT systems randomly to ensure they are correct. The individual units have their own policies and procedures and audit trails of the processes they have used to invite women for screening.

## Scotland

**1.41** The breast screening programme has been running in Scotland since February 1989. It was established at the same time as the English programme, based on the same evidence i.e. the Forrest Report. There are six units, based in Inverness, Aberdeen, Glasgow, Irvine (Ayrshire) Dundee and Edinburgh. Glasgow is the largest of the units, covering roughly half of the population of Scotland. Only the Edinburgh and Dundee Units cover solely mainland areas. Each centre has a static base and provides a service to outlying areas via mobile units on a three-yearly cycle.

**1.42** The Scottish Breast Screening Programme is part of the National Services Division and is responsible for commissioning and performance managing National Screening Programmes, Specialist Clinical Services and National Managed Clinical Networks on behalf of NHS Scotland. Scotland has a seat on the UK National Screening Committee. Policy is set by the overarching Governance Board for the Scottish Screening Committee. A national Quality Assurance Research Committee includes public health, consultants and representatives from each of the specialties on the screening programme.

**1.43** Breast screening in Scotland follows the NHS national standards (as in England), including the national performance measures which include measures such as the proportion of women eligible for screening who have had a test with a recorded result at least once in the previous 36 months.<sup>21</sup> The service uses the Scottish Breast Screening System (SBSS), which is not the same as NBSS used in England. It was introduced in February 2016.

**1.44** Women are identified for screening by using their Community Health Index (CHI). The CHI is a register of all patients in NHS Scotland. CHI contains details of all Scottish residents and ensures that patients can be correctly identified, and that relevant information relating to a patient's health is available to providers of care. The CHI number is a unique 10-character numeric identifier, allocated to each patient on first registration with the system. It is created by using an individual's date of birth and a four digit code (e.g. 010120011234).

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<sup>21</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/612739/Breast\\_screening\\_consolidated\\_standards.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/612739/Breast_screening_consolidated_standards.pdf)

**1.45** The CHI is linked to the GP practice where the woman is registered. The term used to describe the group of women being called for screening at any one time is a 'practice' as opposed to 'batch'. A practice is based on GP practices. When the practice is opened, the relevant Centre estimates the number of women in the practice and it then remains open until all the women on the list have been invited for screening. Because the CHI is a live database it means that women can enter the practice after it has opened if they reach 50 during the time the practice remains open. A woman who turns 50 the day after the practice has closed would be picked up by the failsafe programme and then screened within the next three years. The failsafe process picks up women who have not received their first screening by the age of 53, or have not been screened within 36 months or who are not registered with a GP.

**1.46** The service aims for a round length of 36 months, as in England, but they do not bring dates forward to account for potential bulges. This means that if there are delays for any reason, then the 36 month date is missed. This delay, repeated over a number of years, has been the reason why, when the Scottish Breast Screening Service conducted an audit following the announcement of the incident in England, they discovered that 1,762 women in Scotland had not received their final invitation. This has now been rectified and all women have been invited for their final screening.

## Wales

**1.47** The breast screening programme has been running in Wales since February 1989. It was established at the same time as the English programme, based on the same evidence i.e. the Forrest Report. There were originally three units, now four – in Cardiff, Swansea, Wrexham and Llandudno – across three geographical regions, and eleven mobile units which travel around Wales visiting more than 100 sites on a three-yearly cycle (maintaining the same 36 month round length as in England).

**1.48** Breast Test Wales (Bron Brawf Cymru) is part of Public Health Wales (PHW) and delivers the whole programme, including call / recall and the IT systems. This means there is no split between oversight, commissioning and operations as there is in England. Policy for Wales is set by the Welsh Government, taking account of advice from elsewhere e.g. the National Screening Committee (on which a PHW representative sits as an observer). Breast screening in Wales follows the NHS National Standards (as in England), including the national performance measures which include measures such as the proportion of women eligible for screening who have had a test with a recorded result at least once in the previous 36 months.<sup>22</sup> Monthly reports on these measures called Screening Performance Activity Reports (SPARs) are compiled at trust and programme level, and are discussed at regular Breast Test Wales programme board meetings. Any performance measures that do not meet the standard have exception reports that are escalated to the PHW Board and the Welsh Government.

<sup>22</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/612739/Breast\\_screening\\_consolidated\\_standards.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/612739/Breast_screening_consolidated_standards.pdf)

**1.49** In Wales, women are screened between the ages of 50-70. This means that women will be invited from the age of 50 (and might receive their first invitation up to the age of 53 – this is clearly stated on the Breast Test Wales website)<sup>23</sup> up to their 70<sup>th</sup> birthday. In practice, some women will be invited after their 70<sup>th</sup> birthday because of the way the invitation cycle works (as in England) but there would only be an issue if a woman had not received an invitation within the 36 months before her 70<sup>th</sup> birthday. The November 2013 specification, which was written when Public Health England was formed in 2013, was not issued in Wales. The AgeX trial does not take place in Welsh screening units, though some women living in Wales might be part of the trial if they live on the border and are screened by English units which participate in the trial.

**1.50** Breast screening units in Wales use the NBSS IT system to make appointments and for clinical records, as in England, but when Public Health England introduced BS-Select in England in 2016 Public Health Wales decided not to change and to retain NHAIS as the system for importing women's details for appointment batches. NHAIS is also the system which is used to find women's details to invite them for cervical screenings. The invitation process in Wales is broadly the same as in England (see IT and process chapter) i.e. units invite batches of women on a three-yearly cycle (set out in their roundplan). The only difference is that when the unit in Wales is inviting the next batch of women they request the details from their local cervical screening team (also part of Public Health Wales) as they are the teams with access to women's records through NHAIS. This part of the process is the equivalent of a unit in England inputting a batch ID into BS-Select and drawing down the women's details to be added to NBSS for the invitations to be generated.

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<sup>23</sup> *“Some women will be called when they are 50 but others will not have their invitation until they are 52 depending on where they live. Everyone will have their invitation by their 53rd birthday.”*  
<http://www.breasttestwales.wales.nhs.uk/general-questions>

# Chapter 2: IT and processes

**2.1** The way in which women are invited to their breast screening, and how that process is supported by IT systems, is complex and has its roots in the way the programme was introduced in the 1980s. This chapter sets out how women are invited to routine breast screenings in England and how the breast screening programme's current IT systems facilitate this, setting out their function, use and limitations. The systems are run by different organisations with no overarching 'owner' or description of the overall system or respective roles. The Review team has spoken to key members of staff with responsibility for the IT, examined the coding of the systems and reviewed the available guidance on the systems in order to draw together this description.

**2.2** The Review's analysis has found that the IT systems have broadly worked as designed. There was a misalignment of the way women were invited (by the year in which they turned a certain age, not their actual age) and the algorithm which was introduced to randomise for the AgeX trial – this affected a small number of women. However, there was no large-scale failure to invite women because of a systemic algorithm problem as announced in May 2018. The primary failing for the purposes of the incident declared in May was not the IT itself, but the absence of an appropriately specific policy to be delivered against, a lack of clarity about what the IT was designed to do and a lack of understanding of how women had been invited to screenings in practice for decades.

**2.3** The Review also found that while the IT systems have broadly worked as designed, the design is overly complex, dated and relies heavily on manual inputs. This leaves margin for error and, despite unit staff's best efforts, has in some cases meant that some women were not invited for screenings when they should have been.

## How women are invited for routine breast screening and the use of 'calendar age'

**2.4** Breast cancer screening requires the use of specialist imaging equipment, operated by trained technicians (mammographers and radiographers). To allow the use of this equipment to be maximised and to ensure women do not have to travel long distances to be screened, mobile units are used in most regions to take the equipment near the women. As breast screening should happen every 36 months (in keeping with the clinical evidence), most mobile units travel to each site on a three-yearly cycle (with some exceptions e.g. in Norfolk the units travel on a yearly cycle).

**2.5** Women are invited to these screenings in 'batches', which include all the women in that area (most commonly a GP practice) who will be within the correct age range at the time their batch is being invited to be screened. Screening eligibility is based on year of birth rather than birth date, so woman within a batch might receive her first screening invitation at age 49 (as she will turn 50 in the year in which the screening is taking place) or not until she is 52 (because her batch is not being screened until that year). For example, a batch for a screening taking

place in 2018 would include women who turn 50 in 2018 (so were born in 1968), some of whom might still be 49 by the time they are screened and others would be 50, and those who turn 52 in 2018 (so were born in 1966). Statistically, half of the women called by the system in their 50th 'calendar year' (i.e. year in which they turn 50) are only 49 at the time of screening and, on average, one sixth of all woman can expect to be called for their first screening at the age of 49.

**2.6** This method remains aligned to the evidence presented in the Forrest Report, which established that regular screening was beneficial from the age of 50, but did not specify exact ages for screening.<sup>24</sup>

**2.7** Women should be invited every 36 months and will be invited for their final screening not in accordance with age but rather at the time when the batch in which they are included falls within 36 months of the year that each woman turns 70. So, a woman who was invited to her first screening at 49 should – all things being equal (e.g. she has not moved to a different GP practice and fallen in with that invitation cycle) – receive her second screening when she is 52 and then every 36 months until her final screening when she is 67 (the year in which she turns 68). However, a woman who receives her first screening at 52 will not receive her second screening until she is 55 and – all things being equal – her final screening will take place when she is 70.

**2.8** All women, therefore, can expect their final screening in the core screening programme in the year in which they turn 68, 69, or 70, and one sixth of this group would be 67 at the time of their final screening. Unless there is a change of circumstances (for example, a woman changes GP), this would be their final invitation, despite only being 67.

**2.9** If operated as designed, this invitation system should ensure all women have received at least seven screening invitations, with intervals of 36 months, between the year in which they turn 50 and the year in which they turn 70.

## The IT systems

**2.10** To create the batches used to invite women, breast screening units use two IT systems: the National Breast Screening Services (NBSS); and Breast Screening Select (BS-Select), which was introduced in 2016. In turn, BS-Select takes information from a third system – National Health Applications and Infrastructure Services (NHAIS). The systems are owned and administered by different organisations.

**2.11** NBSS is a computer system originally designed when the breast screening programme was first introduced in the late 1980s. NBSS is used as part of the process for inviting women to their screenings, but also records clinical information about the women during that 'episode' including any treatment they might receive. NBSS is not a 'live' system – i.e. it is not connected to real-time information about women. It exists in 78 different instances in England, in each breast screening unit – holding the details of the women being screened by those individual units. The system is currently maintained by Hitachi Consulting, with Public Health England as the contract holder.

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<sup>24</sup> A working group chaired by Professor Sir Patrick Forrest, *Breast Cancer Screening: Report to the Health Ministers of England, Wales, Scotland and Northern Ireland*, (November 1986) p26-28

**2.12** NHAIS is a suite of software developed and supported by NHS Digital on behalf of the Department of Health and Social care. The system is used by Capita (contracted by NHS England) in the management of primary care services such as GP payment and pension, patient registration and cervical screening. NHAIS takes registration and demographic updates from all GP practices in England and stores these in 82 separate databases. For each different NHS Trust the details needed to produce a list of women due a screening invitation are kept in NHAIS. If patients move outside the area covered by their NHAIS database then new details are added to a different database, so the data needed for breast screening could sit across more than one of the NHAIS databases. Until 2016, NBSS requested data from NHAIS in order to invite women to breast screenings. This was slow and relied on manual processes – screening units would set out the women they wanted to invite in NBSS and then generate a paper report, which was sent to the NHAIS team to manually input and extract the correct patient details. The transfer of the data from NHAIS to NBSS could take several weeks. NHS England is the data controller for the information recorded on the NHAIS system.

**2.13** In 2016 Public Health England introduced a new system – BS-Select. This allowed NBSS to extract data from one source (BS-Select) instead of 82 separate databases (NHAIS). In reality it added another layer to the process, as BS-Select itself requests data from NHAIS. BS-Select is quicker, with data being transferred to NBSS within 24 hours, and enables a national view of the data for the first time. BS-Select was designed to replicate the functionality of NHAIS – it did not change the processes. One practical implication was that although the breast screening units could now request the data themselves (instead of requesting it from the NHAIS teams) they were still required to input the details of the women they wanted to invite to a screening both in NBSS and in BS-Select. The system was designed and maintained by NHS Digital, with Public Health England as the product owner.

## How the invitation system works

**2.14** Most units operate the Recall Interval Safety Period (RI/SP) invitation system. With the recall interval set to three years, the IT will attempt to batch women as their next local cycle approaches (without using fixed dates). The Safety Period is a rule within the code which ensures women cannot be invited to a screening within 12 months of their last screening (for safety reasons). Under this system, women are invited according to the year in which they were born. Some units operate an invitation system based on a calculation of three years from a woman's last screening – this is known as 'next test due date' (NTDD). Units using the next test due date system do not participate in the AgeX trial as the system is not compatible with the algorithm used to randomise women for the trial.

**2.15** The Recall Interval Safety Period system involves entering women's details into two separate IT systems:

- Staff in a breast screening unit set out the women to be invited to the next screening in NBSS. They manually input information, or 'batch parameters', including the GP practice/s from which the women should be invited, the years of birth of the women to be invited (e.g. 1948 – 1968) and the batch selection date. This process generates a batch ID (a 10 figure number).
- Staff in the breast screening unit input the batch ID from NBSS into BS-Select. They also re-input the batch parameters that they had entered onto NBSS. BS-Select then generates a batch based on these parameters. It might not be obvious to users of

the software, but it is only the criteria set within BS-Select which affects the women included within the batch. The fields in NBSS are a legacy from when NBSS was used to create a specification document to be used to create a batch from NHAIS.

- The batch is generated in BS-Select and transferred to NBSS (this takes 24 hours). Breast screening unit staff then manually check the batch and ‘cleanse’ the information. For example, some women with similar names, addresses or NHS numbers might be flagged by the system as potential duplicates – the staff will check each of these individual women to ensure they are due to be invited to a screening.
- Once the manual checking has been completed, the batch will be accepted and screening appointments are automatically generated for the women by NBSS.

## An addition to NBSS – the AgeX algorithm

**2.16** When the AgeX trial (see Chapter 6) was introduced in 2009, an algorithm was coded into NBSS to conduct the randomisation for this trial. Units would now input wider parameters into NBSS, requesting women who would be aged 47-73 at the time the screening took place (rather than the usual 50-70). Once the batch was delivered to NBSS an AgeX algorithm randomly allocated each batch to include either women aged 47-70 or 50-73.

**2.17** The algorithm in NBSS assigned a code to each woman in the batch. Women turning 47, 48 or 49 at the time the screening took place were assigned a ‘1’ code. Those in the standard age range of 50-70 were assigned a ‘0’ code. Women turning 71, 72 or 73 at screening were assigned a ‘2’ code. The algorithm then randomly added either the women with ‘1’ code (bottom of the age range) or those with a ‘2’ code (top of the age range) to be invited to be screened with the women with a ‘0’ code (standard age range). For batches with ‘1’ code women added, the women with a ‘2’ code had their episodes closed so they were not invited to a screening, and vice versa.

**2.18** In keeping with the design of NBSS to invite women by calendar year, some 46-year olds naturally appeared in these new batches (as they would turn 47 in the year the screening took place). Some women who were aged 73 would also not qualify for randomisation at all (because they would turn 74 in the year of screening and therefore would not have been selected by the NBSS system).

## IT design issues – margin for error

**2.19** The design and architecture of NBSS is now 30 years old and, although it has been updated during this time, is showing its age. The introduction of BS-Select in 2016 was helpful in reducing the time taken to download batch information from NHAIS and giving a national view of the data, but it did not reduce the duplication in manual entry of the details needed to extract the correct information for the batches. It has also not yet reduced the complications which could have caused some women to miss invitations (as described below).

**2.20** During visits to breast screening units (see Annex B for the full list), it was clear to the Review team that the staff work very hard to manage the unwieldy IT systems, and in some cases have designed their own additional processes to make sure no women in their area are missed. Mistakes are rare. However, the IT systems include considerable margin for error and data analysis carried out during this Review of the women included in the Patient Notification Exercise has confirmed that some women (around 5,000 over a period of nine years) were not invited to screenings when they should have been. These cases cannot be explained by IT

errors or misapplication of policy and so we have concluded that they are likely to be the result of errors in using the IT systems. These cases should be picked up by frequent audits and action taken at a local level to ensure processes are in place to prevent the same errors from happening again. The women were included in the Patient Notification Exercise so have now been contacted and invited to a further screening. Many of the women identified will have been missed because of parameters being manually inputted incorrectly, and the Review has also identified some specific causes for women not to have been invited when they should have been. These are set out below:

### **‘Failsafe’ reports**

**2.21** There are several ways in which a woman could potentially miss a screening within the existing process set out above, the most common being moving between GP practices. For example, a woman who moves address to an area recently screened, but who has not been invited for a screening for two years would wait up to five years if she were to fall in with her new area’s screening round. In order to address issues like this and ensure no woman waits more than 36 months between breast screenings, breast screening units using the Recall Interval Safety Period process are required to run monthly ‘failsafe’ reports to identify any such women.

**2.22** Failsafe reports are now run in BS-Select. Each unit can choose when to run their failsafe reports, and set parameters including the number of months to check ahead for women in danger of being overdue a screening invitation, and the minimum / maximum ages for the women. A report is generated which shows the women using those parameters who are due to become overdue for a screening within the time period set. The unit can then decide how to ensure these women are screened. If the correct action is not taken (i.e. a further screening invitation issued for all the women due to become overdue a screening) then a woman might wait longer than 36 months for her next screening.

### **Interval slippage**

**2.23** Maintaining 36-month intervals between screenings is a key standard for the breast screening programme, and the clinical evidence still supports this as an effective period for identifying cancers before they become symptomatic. However, at any given time at least one in five screening units is missing the 36-month interval, meaning the time between screenings for women in these areas is therefore extended. If a woman is due to be invited for her final screening at the age of 70 but her unit is experiencing delays she might become 71 before her screening is due and therefore not included in the batch (so would not be invited as she should). In areas participating in the AgeX trial she would have a 50/50 chance of being invited to a screening (or being randomised out) as part of the trial.

### **Identification of an error in 2017 – the year of birth issue**

**2.24** When the AgeX trial was introduced, some units which used the ‘next test due date’ invitation method (which was not compatible with the algorithm used to randomise women for the trial) were incorrectly inviting and screening women at the lower age range (47-50). When this was realised by Public Health England the units were asked to stop screening these women, and to only screen women from the core screening programme age range (50-70). Public Health England officials reviewed the national data (which had been made available by the introduction of BS-Select in 2016) to ensure the screening units were inviting women from the correct age ranges. While reviewing these data, officials in Public Health England noticed that some women aged 69 were being randomised out by the AgeX algorithm. They conducted further analysis to establish what was causing these women to be excluded from screening before the age of 70

or 71. They discovered this was as a result of NBSS using the batch selection date to calculate the birth years to be included in batches, where the batch selection date was in a different calendar year.

**2.25** As an example to illustrate this complex issue, a batch could be created on 1 November 2015 for screening to take place over two months in December 2015 and January 2016. A woman born on 15 December 1945 would be 69 on the day the batch was created, and still 69 when she was due to be screened on 1 December 2015. She would turn 70 after screening on 15 December 2015, and 71 the following year on 15 December 2016. As she was 69 when due to be screened (on 1 December 2015) and in the year in which she would turn 70 (on 15 December 2015) she was entitled to be screened under any definition of the policy. However, if the batch selection date was entered as (January) 2016 – when the screening was still taking place but not at its beginning – NBSS would have calculated the minimum year for women to be included in the core screening programme as  $2016 - 70 = 1946$ . The NBSS AgeX code specifies that women are assigned a '2' code when their year of birth is lower than the minimum year of birth (i.e. batch selection date minus 70), then if that batch is set to exclude the upper age range, those women will be excluded. As in this example NBSS would have set the minimum year as 1946, this woman (born in 1945) would be included in AgeX and at risk of being excluded from screening at age 69.

**2.26** The use of the batch selection date to determine the year of birth for the AgeX algorithm had been queried by Temenos (the company which maintained NBSS at the time) in 2009. The government product owner for NBSS at the time confirmed in an email exchange that the batch selection date should continue to be used for the algorithm, even though it was known that there was variability in the way it was being used by breast screening units.

**2.27** The issue affected a small number of women, but nevertheless constituted a problem in the way the AgeX algorithm was being applied, so merited investigation. These women have now been contacted through the Patient Notification Exercise and offered a further screening.

## IT and policy – room for interpretation

**2.28** Some women identified by Public Health England as having missed their final screening, and therefore contacted as part of the Patient Notification Exercise, appear to have been affected by errors as described above, and a further number by the AgeX algorithm being applied to 69-year-old women; however by far the largest proportion – around 117,000 of 196,000 – have been included in the list because they were not invited to be screened up until their 71<sup>st</sup> birthday as set out in the November 2013 Service Specification and subsequent iterations.

**2.29** These women all received their 'final' screening invitation at age 67 (in the year they would turn 68) and so were within tolerance for a programme which ended within three years of women being around the age of 70. The majority of the women had received at least seven screening invitations. However, they had not been screened in accordance with the November 2013 Specification.

**2.30** Even if the November 2013 Specification should have been applied, it was only published in 2014 (for financial year 2014/15), the women in the Patient Notification Exercise list date back to 2009. Therefore the Review has concluded that around half of these women can not have missed a screening under the 2013 Specification even if it is considered to represent government policy. This analysis is set out at Annex C.

## Conclusions

**2.31** The Review has found that – although dated and unwieldy – the IT systems have broadly operated as they were designed to.

**2.32** Around 5,000 women (over nine years) might not have been invited to their screenings when they should have been – this was caused not by a systemic IT error but by errors in using two separate and complicated systems (despite the best efforts of unit staff), and slippages in units' screenings which meant that some women might have had incremental lengthening of their screening intervals until they left the age range for core screening. These individual cases should have been picked up earlier. The introduction of BS-Select has meant that the data now exists to show when women were last screened, across the country, and should allow cases like these to be identified and rectified more quickly in future. There are also changes being introduced in BS-Select in response to user feedback (via the BS-Select steering group) which will reduce the margin for error – this is a helpful process.

**2.33** It appears that the design of the algorithm in NBSS to randomise women from the year in which they turned 71 (for the AgeX trial) interacted with the way in which women's ages were calculated in NBSS, and with the freedom for units to apply a later selection date, to result in a small number of women not being invited for a screening when they should have been when they were aged 69 and 70. It is to Public Health England's credit that this error was identified while carrying out checks on the new data available from the introduction of BS-Select.

**2.34** However, when this issue was being investigated in late 2017 and early 2018, confusion crept in because there was a lack of understanding of how the IT had functioned in practice, and the decision was taken that the November 2013 Service Specification should be applied as the policy and so tens of thousands more women were thought to have been affected.

**2.35** The fact that an incident was called on the basis of a Service Specification which was not aligned with the IT as designed, and that women were identified as having been affected from 2009 onwards rather than when the Specification was introduced in 2014, shows that there is a lack of understanding of how the IT was designed and how it functions as a system. The IT systems are owned and overseen by different organisations – NHAIS owned by NHS England with operational management by Capita and technical support from NHS Digital; NBSS by Hitachi contracted to Public Health England; and BS-Select by NHS Digital with Public Health England as the product owner – with no overarching oversight of how they interact and function as a system.

## Recommendations

**2.36** *In the immediate term, a review should be conducted by Public Health England, in collaboration with NHS England to represent the users of the systems and NHS Digital, to reduce as far as possible the manual inputting and duplication involved in NBSS and BS-Select and to simplify the user interface. This should abide by the principles of the recently published NHS Digital service manual,<sup>25</sup> in particular “Don't just design your part of a service. Consider people's entire experience, and the infrastructure and processes involved...”*

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<sup>25</sup> <https://beta.nhs.uk/service-manual/design-principles/>

**2.37** *If the IT systems continue to be operated and overseen by different organisations in the longer-term, an overarching governance structure should be introduced with responsibility for ensuring the systems work together to deliver the breast screening programme. Thought should be given to whether this governance structure should also oversee the IT systems for the other screening programmes given they rely on some of the same IT (e.g. NHAIS). The new governance structure should take a risk-based approach to its management of the IT systems, taking into account the likely clinical harm resulting from a failure of the systems.*

**2.38** *Once a decision has been taken about the specific ages at which women should be invited to breast screenings (see recommendation 1.1), the IT system/s should be reviewed to ensure they function to deliver that policy.*

**2.39** *Any new systems introduced to support the screening programmes should follow the principles set out in the recent document *The Future of Healthcare: Our Vision for Digital Data and Technology in Health and Care*<sup>26</sup> (user need; privacy and security; interoperability and openness; and inclusion).*

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<sup>26</sup> <https://www.gov.uk/government/publications/the-future-of-healthcare-our-vision-for-digital-data-and-technology-in-health-and-care>

# Chapter 3: Governance and accountability

**3.1** The breast screening programme is – like many other health programmes – run by a group of organisations, with shared responsibility and accountability. In the case of the breast screening programme we have found that there is a relatively clear governance structure, but that there is no senior responsible owner to ensure the system is functioning correctly – responsibilities are shared by the Department of Health and Social Care, NHS England and Public Health England but without a shared sense of how they fit together to make a cohesive and effective whole.

**3.2** We have also found that the main governance document – the annual section 7A agreement (see below) – included the November 2013 Service Specification and its subsequent iterations, indicating that it was accepted by the Department and NHS England as policy. It appears that this change and its acceptance were unintentional so the governance structure which was intended to ensure that there was joint responsibility for establishing and delivering policy did not function as intended.

## Governance structures and roles

**3.3** The governance of the breast screening programme can be divided into two distinct periods – pre- and post-2013.

**3.4** Before 2013 the programme was the responsibility of the (then) Department of Health and reported via the Cancer Programme Board to the Departmental board. Commissioning was delegated to primary care trusts, which reported to strategic health authorities and were held to account by the Department for their performance. Individual breast screening units were supported by NHS cancer screening programmes – a team hosted by Northern and Yorkshire Regional Health Authority and funded by the Department of Health.

**3.5** The 2012 Health and Social Care Act made changes to the way healthcare is delivered, setting out “clear roles and responsibilities, whilst keeping Ministers’ ultimate responsibility for the NHS”.<sup>27</sup> Public Health England and NHS England were established in the accompanying reforms. The Act also abolished primary care trusts. As a result, the way breast cancer screening was managed needed to change – it was split between the (then) Department of Health, NHS England (taking on the commissioning role formerly held by primary care trusts) and the newly-formed Public Health England (which absorbed the NHS cancer screening programme team mentioned above).

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<sup>27</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/138257/A1.-Factsheet-Overview-240412.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138257/A1.-Factsheet-Overview-240412.pdf)

**3.6** The overall governance and accountability for the NHS Breast Screening programme derives from the 2012 Act and is held within the section 7A agreement<sup>28</sup> – this is an annual agreement negotiated between the Department of Health and Social Care and NHS England, in which the Health Secretary delegates responsibility for certain health services (including breast cancer screening) to NHS England. Public Health England provides support to both parties in the agreement and develops the national specifications which form the basis of the agreement (specification number 24 for breast screening). The different organisations' roles are described below.

## The role of the Department of Health and Social Care (post-2013)

**3.7** The Health Secretary is “ultimately accountable to Parliament and the public for the system overall.”<sup>29</sup> In practice, the Department delegates responsibility for the screening programme to NHS England as outlined above, and oversees it through section 7A senior accountability meetings (see below).

**3.8** As the responsible central government department, the Department sets the strategic direction (i.e. sets the policy) for the programme, taking recommendations from the UK National Screening Committee and advice from Public Health England. It also develops the annual agreement with NHS England (the NHS public health functions agreement, known as the section 7A agreement) and secures the funding for the programme through its negotiations with HM Treasury (which is then delegated to NHS England). It sets its priorities for Public Health England through an annual remit letter.<sup>30</sup>

## The role of NHS England (post-2013)

**3.9** NHS England is responsible for negotiating the section 7A agreement with the Department of Health and Social Care, and commissioning national screening and immunisation programmes under that agreement (against national Service Specifications developed by Public Health England). The funding to deliver the screening programmes – including the breast screening programme – is devolved from the Department of Health and Social Care to NHS England through the section 7A agreement.

**3.10** NHS England has contracts with breast screening providers to deliver breast screening – against national specifications developed by Public Health England – and has responsibility for holding them account to these contracts. NHS England local teams (which include Public Health England staff) track the contracts with breast screening providers against the national specification.

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<sup>28</sup> <https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2018-to-2019>

<sup>29</sup> NHS public health functions agreement 2018-19 Public health functions to be exercised by NHSE P.11

<sup>30</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/693855/PHE\\_Remmit\\_Letter\\_-\\_March\\_2018.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/693855/PHE_Remmit_Letter_-_March_2018.pdf)

## The role of Public Health England (post-2013)

**3.11** Public Health England's main role in this context is to support the Department and NHS England with the implementation of the breast screening programme. Despite this seemingly minor support role, in practice Public Health England has responsibility for many of the elements which are essential for the running of the programme – it develops the Service Specification which forms the basis of the section 7A agreement between the Department of Health and Social Care and NHS England; it commissions and funds some of the IT infrastructure on which the programme relies (including training on how to use it); it provides the literature for units to use (e.g. leaflets and standard letters); administers government funding for the AgeX trial (see chapter 6) and ensures the trial can be delivered alongside the core screening programme; and it provides quality assurance against the Service Specification. Public Health England also provides the secretariat to the Advisory Committee on Breast Cancer Screening, which provides scientific and clinical advice to Public Health England on the day-to-day running of the breast screening programme. This Committee feeds advice to the UK National Screening Committee, which in turn advises Ministers on national policy.

## Reporting mechanisms

**3.12** There is no shortage of reporting mechanisms for the breast screening programme. The three organisations have structured reports and meetings which cover a variety of measures, but failed to recognise that the Service Specification for breast screening was not being delivered from 2014 onwards.

**3.13** Overall responsibility for the breast screening programme rests with the Department of Health and Social Care – both pre- and post-2013. The Department is the ultimate escalation route if there are problems, and it has responsibility for holding NHS England and Public Health England to account. It does this through formal routes:

- NHS England:
  - Quarterly section 7A senior accountability review meetings. These meetings are chaired by the Director General for Global and Public Health (on behalf of ministers) and attended by senior officials from the Department, NHS England and Public Health England.
- Public Health England:
  - Quarterly accountability review meetings, chaired by the Director General for Global and Public Health, and including feedback from NHS England.
  - Annual meetings with the Minister with responsibility for public health to review its performance, discuss its annual report and inform the next set of objectives for the organisation.

**3.14** There is also a less formal monthly meeting between senior officials from the Department of Health and Social Care, Public Health England and NHS England known as the NHS public health section 7A tripartite Directors' meeting.

**3.15** The mechanisms above cover everything in the section 7A agreement (NHS England) or everything Public Health England does, there is only one meeting of these organisations at a national level which looks exclusively at screening – the Policy Officials' Tripartite Group (which replaced the Screening Programme Board).

**3.16** The section 7A agreement (or NHS public health functions agreement) is the central document for measuring the performance of the breast screening programme. The Department of Health and Social Care holds NHS England to account (through the quarterly senior accountability meetings) for 32 indicators, of which there is one for breast screening: “Breast cancer screening coverage [50-70]: The proportion of women in a population eligible for breast screening who were screened adequately within the previous three years”. NHS England produces a ‘public health S7A accountability report’ and works with Public Health England to produce a joint report for the senior accountability meetings. These include information on performance, risk and spending as well as delivery issues with plans as to how to address them.

**3.17** Individual breast screening providers are held to account (through their contracts with NHS England) for five key performance indicators (minimum standards), which are set out in the Service Specification within the section 7A agreement:

- To maximise the number of eligible women who attend for screening;
- To minimise the number of women screened who are referred for further tests;
- To ensure that women are recalled for screening at appropriate intervals;
- To minimise anxiety for women who are awaiting the results of screening; and
- To minimise the delay between referral for investigation and first breast cancer treatment.

**3.18** The two measures relating to who should have been invited to / attended screenings are not specific enough to have drawn attention to the fact that some women aged between 70-71 were not being invited. For example, the performance indicator for breast screening units specified “This standard is needed to ensure that the eligible population previously invited aged 53 to 70 has been adequately identified and invited by the screening programme”.<sup>31</sup> This does not specify what is meant by “53 to 70” i.e. up to a woman’s 70<sup>th</sup> birthday, or until the day before her 71<sup>st</sup>.

**3.19** The numbers of women between 70-71 not being invited were very low as a proportion of the total women being screened so were unlikely to have been highlighted by the annual figures and therefore the reporting mechanisms which were in place would not have identified a problem.

## Quality assurance

**3.20** Public Health England holds a dual role regarding quality assurance – it both develops the Service Specifications and provides assurance against them through its Screening Quality Assurance Service (known as SQAS) for all NHS screening programmes. NHS England is responsible for holding individual breast screening units to account for delivery against their contracts.

**3.21** The Screening Quality Assurance Service visits breast screening units roughly every three years. If any problems are found on the visit, a report will be produced for both the commissioners (i.e. NHS England local offices) and the screening units themselves – the report will set out what the problems are, whether this needs to be escalated and any recommendations. The commissioner and unit are responsible for deciding what action to take.

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<sup>31</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/612739/Breast\\_screening\\_consolidated\\_standards.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/612739/Breast_screening_consolidated_standards.pdf)

**3.22** When providers do not achieve their performance measures (as set out above), they will receive advice from Public Health England to improve along a continuum ending with contract penalties imposed by NHS England.

## Conclusions

**3.23** There is no strategic oversight to ensure the separate strands of the breast screening programme are functioning as a whole – there is no senior responsible owner. The quarterly section 7A agreement meetings are too large in scope to address individual issues in a robust way.

**3.24** The November 2013 Service Specification (and its yearly updates) is central to the incident, but none of the tripartite organisations have been able to confirm how it was signed off. What is clear is that it was not implemented properly. This was a failure of governance.

**3.25** NHS England failed to hold breast screening units to account for delivering against the contracts, which were based on the Service Specifications.

## Recommendations

**3.26** *The recently announced review by Sir Mike Richards should include a consideration of the governance of all screening programmes, including giving thought to better aligning the screening programmes with the delivery of the Cancer Strategy in NHS England. It should also examine what progress has been made in implementing the recommendations of the 2017 Tailored Review<sup>32</sup> of Public Health England's governance so far as it affects screening programmes.*

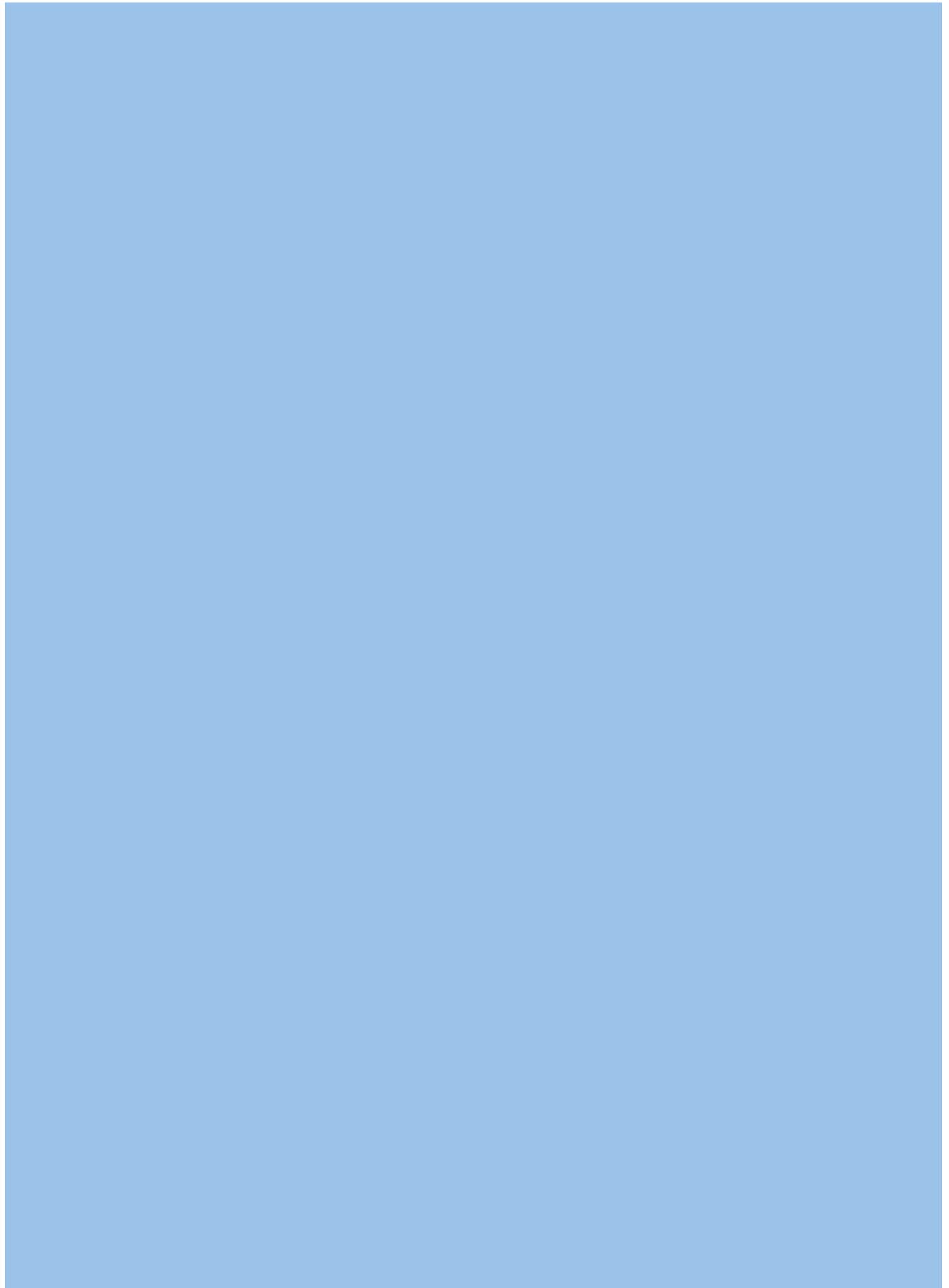
**3.27** *The performance indicator in the section 7A agreement is insufficiently specific regarding the population eligible for screening. This should be clarified.*

**3.28** *The quality assurance carried out by Screening Quality Assurance Service should reflect the breast screening programme policy (see recommendation 1.1). This is likely to mean guidance and training should be updated to make sure everyone carrying out inspections is aware of what they should be assessing against.*

**3.29** *NHS England should improve its contract management processes to ensure providers are delivering the service as set out in Service Specifications. The issue of contract management should be addressed for all screening programmes in Sir Mike Richards' review.*

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<sup>32</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/608368/PHE\\_Tailored\\_Review.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/608368/PHE_Tailored_Review.pdf)



# Chapter 4: Handling the incident

**4.1** This chapter looks at how the incident was discovered, investigated and escalated – leading to the public announcement in May 2018 and in women being told they may have not been invited to the breast screening appointment that they should have had between their 68th and 71st birthdays.

**4.2** The Review has found that the initial handling of the incident was not sufficiently gripped within Public Health England, which resulted in delays in fully understanding the nature of the incident and ultimately led to a response that did not reflect the precise failings in the service. In particular, we would have expected the most senior management to have been involved in the initial handling to provide overall direction to the response and to ensure those responding to the incident had the necessary resources available to complete a thorough review at pace. We did not find evidence that such an approach was adopted. Public Health England has an excellent track record of responding to public health incidents but the approach adopted for this incident meant that some three months elapsed between the initial realisation that an incident had occurred and the Secretary of State being advised to make a statement to Parliament. Not only is this arguably too long a period of investigation but, worse, the failure to fully understand what had occurred led to the Secretary of State being advised to make a statement that we now know to have lacked the complete evidence and analysis. This was due to assumptions being made that the November 2013 Service Specification amounted to policy, and a lack of understanding of what was being delivered by the breast screening programme in practice.

**4.3** The Review has also found that there were failings in the handling of the data which resulted in the severity of the incident being exaggerated publicly and in thousands of women being warned unnecessarily that they may have been affected by a failure in the IT system.

**4.4** The Review believes that the way in which the public was alerted to the incident and the lack of communication with screening units and the devolved administrations placed an avoidable strain on resources. Following the public announcement, the Review team has been impressed with the fast response of the service and the speed at which all women were offered a screening, either through the Patient Notification Exercise or on request. The professionalism and pace with which the breast screening units in particular have operated has fulfilled the commitment for all women who might have missed a screening to be offered another – this is to be commended.

## Discovery of an issue

**4.5** Following the introduction of the new IT system Breast Screening Select (BS-Select) in 2016, Public Health England were able for the first time to see information about women's screening across the country. Using this information, they began a number of service improvements to the breast screening programme. In 2016 Public Health England made the decision that those units using 'next test due date' (see Chapter 2) to invite women for screening should be prevented from participating in the AgeX trial, as they had identified that

these units were inviting all women aged 47-49 for screening due to their inability to randomise within the cohort. Following the decommissioning of the units from participating in the trial, Public Health England Quality Assurance teams requested the data from these units to check they were now correctly inviting women. An anomaly was found with the ages at which some women were being withdrawn from screening (as described in Chapter 2). While Public Health England were investigating this issue, the National Health Service Breast Screening Programme team informed members of the Research Advisory Committee at a January 2018 meeting of the anomaly. The Chair of the Research Advisory Committee informed the Public Health England Director of Screening, and they declared an incident.

**4.6** On declaring the incident, Public Health England argued that the systemic variation in the breast screening programme constituted a Serious Incident in the terms of the document *Managing Safety Incidents in NHS Screening Programmes*<sup>33</sup> and required a heightened response and formal governance. They stated the following reasons:

- a. “the ‘standard’ national offer, from 2014 was clearly set out in the National Service Specification which was disseminated to the service for implementation;
- b. some women may have been harmed as a result of this offer not having been made to them;
- c. the IT anomaly underlying the impact of the AgeX trial which systematically removed women before they reached the age of 70y11month is a clear systemic failure as this was not intended to happen.”

**4.7** Ministers were informed of the incident on 15 March 2018. The Review believes that the process in understanding the issues had taken too long and by this stage Public Health England should have understood what was causing women to miss their screenings. It is unclear what caused this process to be so delayed.

## Investigation of the declared incident

**4.8** Once the incident was declared, Public Health England sought to understand the cause. Their investigation during the incident response revealed their belief that the incident was caused by:

- a. “IT with limited functionality;
- b. lack of clarity amongst staff in local screening services who were inviting women for screening about the correct ages for invitation;
- c. manual entry of complex age parameters at batch selection (the process of selecting which women were to be invited for screening) which is subject to human error;
- d. a specific effect of the AgeX trial IT algorithm removing women on and around their 70<sup>th</sup> birthday into the control arm of the AgeX trial but before they reached 70y11m”.

**4.9** The Review understands that Public Health England took the November 2013 Service Specification as the standard definition of what the breast screening programme should be delivering. As part of their investigations into the incident, the Review believes that there was not a full understanding of how women were invited using the IT systems. Had there been

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<sup>33</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/672737/Managing\\_safety\\_incidents\\_in\\_National\\_screening\\_programmes.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/672737/Managing_safety_incidents_in_National_screening_programmes.pdf)

greater understanding that invitations for screening were generated by calendar year, there would have been earlier recognition that the system had been set up to exclude women in the year they turned 70 who had previously received a screening in the year in which they turned 68.

**4.10** During the incident response process the Review has found that Public Health England did not reconcile the November 2013 Service Specification with what was happening in practice in breast screening units. This would have alerted them to the misalignment between operating procedures and the Specification. The lack of basic understanding on how the units were operating has meant that assumptions were made which were not grounded in practice.

**4.11** Public Health England were informed by the AgeX trial team that the AgeX trial algorithm was not excluding people from screenings, but was aligned to how the programme had been set up. The Public Health England Screening Quality Assurance Service National Portfolio Lead for Breast Screening and Quality Assurance Programme also provided early advice that that the programme had historically not defined the age parameters of the breast screening programme (years and months) and that women aged 69 or 70 will have been excluded from a final screen due to a historic decision made on basing the algorithm on year of birth. Despite this, based on their internal legal advice, Public Health England chose to follow the definition of screening women ‘until they reach the age of 71’ as written in the November 2013 Service Specification and the subsequent specifications. The failure to understand the design of the service from inception and that different units operated the policy with regional differences, which was tolerated, resulted in a narrow understanding of the offer and limited the accuracy of the incident response and subsequent advice to the Department of Health and Social Care. There was a lack of rigorous questioning of the policy, practice and systems in place and how there were or were not aligned.

**4.12** The Review team is surprised that an incident was declared before the full extent of the problem had been understood or uncovered. The impact of this appears to have changed the focus of Public Health England to addressing the problem they thought they had discovered. So, despite the lack of understanding of the issue, work shifted in this period to how to respond operationally to the perceived problem.

**4.13** Advice from the AgeX trial team and Public Health England’s own quality assurance team was not fully considered, and key individuals with historical knowledge of the breast screening programme were not consulted during the course of Public Health England’s investigation. Had the information provided by these parties been taken account of during the course of the investigation, the Review believes that a more complete understanding of what the breast screening programme was delivering would have been developed at an earlier stage. While the Review recognises that Public Health England sought advice from their lawyers to support their approach, the Review believes that there was not a coherent view as to how the screening programme was operating, and that the practice in screening units differed from the November 2013 Service Specification. Therefore the information given to lawyers was not informed by all the facts.

## Escalation of the declared incident

**4.14** Public Health England formally advised the Department of Health and Social Care of the incident on 15 March 2018 with a submission to Ministers advising that a proportion of women at the upper end of the national routine screening programme had not been invited for their final screening and, at the younger end, had been invited for a screening earlier than they should have. Public Health England advised that their investigations had highlighted that a number of

computer programming and infrastructure issues, some of which related to the routine wider screening programme and some of which related to the interaction of the age-extension trial algorithm with this underlying system, had caused the incident. The Parliamentary Under-Secretary of State for Public Health and Primary Care requested further information on the advice provided by the Breast Screening Incident Clinical Advisory Group, which had been set up to provide clinical advice on the incident. Shortly afterwards, a group consisting of Public Health England, NHS England, NHS Digital and the Department of Health and Social Care was set up, meeting for the first time on 4 April 2018, almost three months after the incident was declared within Public Health England.

**4.15** We have found no evidence that the Breast Screening Incident Clinical Advisory Group discussed the misalignment between the algorithm and the operating procedures, or that the AgeX algorithm was operating as intended. As such, the Review believes that the decisions made by the group were based on incorrect assumptions about the impact on women and as a result the cause and severity of the incident was incorrectly shared with the public. Input from the Breast Screening Incident Clinical Advisory Group formed the communication strategy to the incident, and a different outcome might have surfaced with a different understanding of the circumstances had they been clear about the details behind the incident.

## Public announcement

**4.16** Public Health England had initially (in the March 2018 submission) estimated there to be c206,000 women who were not sent their final invitation to screening in the 36 months before their 71st birthday. This figure was based on data from approximately 30% of screening centres as NHS Digital had not yet completed the migration of all historical data from the legacy IT systems. Public Health England requested up to date figures from NHS Digital but there were delays in providing this figure both because of the legacy data issue (the data transferred to BS-Select did not cover the full time period needed) and because NHS Digital were working to understand the data to achieve greater clarity. The Review has found that analysis of the data was not made jointly between Public Health England and NHS Digital and there was a separation between the policy and IT/data expertise which could have contributed to delays in understanding the declared incident. The Review believes that organisations could have worked more closely together to analyse the data.

**4.17** The then Secretary of State had been advised that a proportion of women at the upper end of the national routine screening programme had not been invited for their final screen and he was keen to ensure that the House was informed of the incident at the earliest opportunity. However, at the time of the announcement definitive numbers of affected women were not available as NHS Digital were still working on the data and the Secretary of State was provided estimated figures. The Secretary of State opted to use the largest possible number of women aged between 68 and 71 who may have been affected by the incident. The figure of 450,000 which was announced in the House reflected a precautionary approach to ensure no women were missed and was the highest possible number of women who may have missed a screening.

**4.18** The formal notification of the incident to the Department of Health and Social Care and Ministers on 15 March 2018 changed the pace and focus of the investigation process and the Review believes that Public Health England should have been more certain regarding the number of affected women when formally informing Ministers. The figure of 450,000 was based on early data provided by NHS Digital, however it is now understood that the figure of affected women could not have been that high as it included women who had moved or had died.

Following the announcement, and once the latest data had been received from NHS Digital, the figure of affected women was initially revised down to 195,565 which the Secretary of State announced in the House on 4 June 2018. Upon further investigation the figure was further revised down to around 122,000 who were then offered an additional screening.

**4.19** The Review team believes that, based on the information provided to him, the Secretary of State made the right decision in announcing the incident to the House. However, the Review believes that the Secretary of State received incomplete advice regarding both the cause of the incident and the number of women affected and as a result the scale of the incident was overstated. The lack of timeliness and accuracy in confirming the numbers resulted in unnecessary concern to the public about the scale of the incident, causing additional distress to the women who might have been affected, and their families.

**4.20** The public announcement also does not reflect the scale of the impact and the Review believes that had the co-ordination group better understood the services being delivered by units, the response to the incident might have differed.

## Patient Notification Exercise

**4.21** On 2 May 2018 the Health Secretary informed the House of an IT-related failure that had come to light in the NHS breast screening programme. A Patient Notification Exercise to contact women who were understood to have been affected by the incident was then launched, and women were sent a letter advising them they may not have been invited to their final screening.

**4.22** On the day of the public announcement, Public Health England sent a letter to screening units formally notifying them of an issue with the NHS breast screening programme leading to some women not being invited for a final screen between their 68th and 71st birthday. The letter also explained that NHS England, Public Health England and the Department of Health and Social Care had taken the decision together to offer an additional screening to women who had been affected, and set out the main steps that units would need to take to ensure that the women affected receive the screening in a timely fashion. Units were not informed of the incident announcement ahead of the public announcement and they were not able to prepare for the public reaction in advance, placing additional administrative strain on units. The devolved administrations were also not given advance notice.

**4.23** When the incident was announced, units were asked to ensure that they had capacity in place to deal with the additional screenings that would be required as part of the Patient Notification Exercise. However, this was done without confirmation of how many women were affected and how many additional screenings would be required. Units received the list of women in their area at different times, over a period of at least two weeks.

**4.24** Public Health England provided interim updates to units with daily update calls also put in place by regional leads. Public Health England and NHS England also provided units with 'frequently asked question' briefings which were updated as the position progressed. Although NHS England and Public Health England provided units with the information they needed to respond appropriately to the Patient Notification Exercise, the timing of the information to units meant that at times they were operating with little advice and did not have the information needed to respond to queries from women. The Review's survey of women shows that the announcement made some women anxious and as a result they contacted local screening units

to alleviate their fears, however front-line staff were overwhelmed by the announcement and the resource pressures associated with putting in place the subsequent arrangements for screening additional women.

**4.25** The Patient Notification Exercise separated women into two cohorts – women under 72 and those over the age of 72. Women younger than 72 received an invitation to screening automatically whereas those older than 72 were offered the choice of a screening and were invited to call the national helpline to request self-referral. Public Health England set up a helpline that was available from the point of the public announcement, and the provision of this helpline was a useful addition as it provided a point of contact for women. However, the advice that the helpline was providing to women was not always correct which may have been due to the lack of clarity surrounding the incident.

**4.26** The Review recognises that Public Health England and NHS England worked extremely hard and put significant resource into understanding and coordinating the Patient Notification Exercise. The establishment of the national helpline supported the incident response and of the women who responded to the Review's survey, 57% of women who contacted the helpline found it useful, with most respondents who called the helpline also reporting a positive experience with the call handlers. Seventy per cent of women who responded to the Review's survey found the information was communicated well and the accompanying leaflet answered their questions.

**4.27** The Review believes that the Patient Notification Exercise could have been improved with a better understanding of the numbers of affected women, and earlier communication to units and the devolved administrations would have allowed them to be better prepared.

## Conclusion

**4.28** Public Health England was slow to develop a clear understanding of the incident and the causes of the failures in the breast screening programme. As investigations into the incident response developed and revealed more information leading to the conclusion that some women had missed a screening, and why, the Review believes that the coordination group did not adequately adjust their response to the incident. This led to a public announcement which not only overstated the scale of the incident and the possible implications, but inaccurately reported its cause.

**4.29** The Review acknowledges that once the public announcement was made and the patient notification exercise was underway, Public Health England, NHS England, breast screening units and the devolved administrations worked at pace to respond to queries from the public and offer women an additional screening.

## Recommendations

**4.30** *The Department of Health and Social Care and its arm's length bodies should review their incident response protocols and ensure that they are appropriate for responding to all incidents involving the screening programmes in their different forms. The protocols should ensure all partners are included in the investigation and response, including those responsible for the supporting IT systems.*

**4.31** Existing protocols should be updated to ensure those delivering the operational response – in this case breast screening units and the devolved administrations – are notified at the earliest opportunity so that they can plan and implement their response.

## Timeline of events:

### Discovery:

**2016:** During 2016 Public Health England noted concerns about the inability of units using the 'next test due date' process to randomise and their failsafe methods which could have resulted in younger women not being picked up for screening until they were 53 years old, and therefore missing a screen when they were 50. To prevent women being missed for screening, Public Health England decommissioned the nine breast screening units using 'next test due date' from participating in the AgeX trial and told them to stop screening women under 50 years of age.

**March 2017:** A breast screening unit (City, Sandwell and Walsall) noticed that when they were creating batches in BS-Select the algorithm was only taking account of the year and not the month of birth. The unit identified that the batches were inviting some women before their 50<sup>th</sup> birthday and randomising some women out before their 71<sup>st</sup> birthday. The unit contacted Hitachi and asked for the algorithm to be updated to take the full date of birth into account. Hitachi investigated and confirmed that the algorithm was inviting women in accordance with the Year of Birth algorithm the programme had been set up with.

**December 2017:** The Screening Quality Assurance Service National Portfolio Lead for Breast Screening and Quality Assurance Programme Manager at Public Health England requested a data extract from NHS Digital for the nine services that were decommissioned in 2016 to ensure the units were correctly specifying routine and failsafe parameters.

**22 December 2017:** The datasets returned suggested various anomalies and Public Health England expanded their data query to cover all breast screening unit parameters.

**4 January 2018:** The data return from NHS Digital highlighted issues around age parameters in batching for older women and potential link to AgeX trial.

**10 January 2018:** A routine Research Advisory Committee meeting took place attended by the AgeX trial team as part of a discussion to extend the AgeX trial age range. At the meeting, the National Health Service Breast Screening Programme team informed members of the Research Advisory Committee that there appeared to be an anomaly with the AgeX trial resulting in women possibly being randomised out from the routine programme into the control arm of the trial. The number discussed in the Research Advisory Committee but not attributed to the anomaly was c200,000. Committee members requested for the issue to be escalated and trial sponsors and ethics committee to be informed. Following the Research Advisory Committee meeting the Chair informed the Public Health England Director of Screening who subsequently informed the Executive Director of Health Improvement.

### Investigation of incident:

**11 January 2018:** The Public Health England Screening Quality Assurance Service National Portfolio Lead for Breast Screening and Quality Assurance Programme Manager sent a report to the Director of Screening outlining the potential issues with age parameters. Public Health England also requested a further data download from NHS Digital to investigate the problem.

The Director of Screening and National Lead for Screening Quality Assurance Service agreed that the scale of the incident (the number of women potentially affected) constituted a serious incident.

**12 January 2018:** The National lead for Screening Quality Assurance Service sought advice from the Regional Director regarding managing the issue as a serious incident as part of Public Health England incident structure.

**13 January 2018:** Public Health England organised a meeting with the Regional Director, Chief Operating Officer, Director of Health Improvement, Director of Screening and National Lead for Screening Quality Assurance Service and they agreed to call a national incident and invoke the Public Health England National Incident & Emergency Response Plan (NIERP) which provided the operational framework of how Public Health England responded to the incident.

**15 January 2018:** The Strategic Response Group was established and Public Health England notified the NHS England section 7A team and Chief Medical Officer setting out the understanding of the incident that the Age X trial might have affected the main NHS breast screening programme.

**17 January 2018:** Public Health England received the further data from NHS Digital and began further analysis on the data.

**19 January 2018:** National Lead for Screening Quality Assurance Service and the Head of Implementation and Training met the AgeX trialists to review the numbers.

**22 January 2018:** Public Health England Regional Director met the AgeX trial team and agreed that Trial Sponsors and ethics committee should be informed.

**28 January 2018:** The AgeX trial team wrote to the ethics committee, trial sponsors and data monitoring group informing of their findings.

### **Escalation of the incident:**

**15 March 2018:** Public Health England sent a submission to Ministers advising them that a proportion of women at the upper end of the national routine screening programme had not been invited for their final screening or, at the younger end, had been invited for a screening earlier than they should have. Public Health England advised that their investigations had highlighted that a number of computer programming and infrastructure issues, some of which related to the routine wider screening programme and some of which related to the interaction of the age-extension trial algorithm with this underlying system, had caused the incident.

**27 March 2018:** A Ministerial meeting with the Parliamentary Under-Secretary of State for Public Health and Primary Care took place. Attendees included Chief Medical Officer, Chief Scientific Adviser and the Medical Directors from NHS England and Public Health England, supported by the Department of Health and Social Care and Public Health England communications teams. The meeting was an opportunity to update Ministers on the incident following the latest Breast Screening Incident Clinical Advisory Group meeting.

**29 March 2018:** The Breast Screening Incident Clinical Advisory Group met to generate advice for submission for Ministers. It reviewed the available evidence and provided initial recommendations for consideration at the first tripartite group meeting.

**4 April 2018:** Almost three months after the incident was declared, the first meeting of the Tripartite Incident Group took place. The attendees agreed that this incident should be declared a Serious Untoward Incident. They also agreed that Public Health England should lead the tripartite response and for that NHS England should establish its own internal incident. The meeting focused on failsafe arrangements implemented to prevent women being missed for invitations and numbers of women affected, potential Patient Notification Exercise, timelines and communications plan.

**13 April 2018:** The second meeting of the Tripartite Incident Group took place with NHS Digital joining for the first time. The meeting focused on fixes, numbers and communication to women affected. Department of Health and Social Care officials from the cancer screening team first became involved with the incident from this date.

**16 April 2018:** The second Breast Screening Incident Clinical Advisory Group meeting took place where the group considered their recommendations in light of questions from the tripartite group and additional evidence from the AgeX trialists.

**19 April 2018:** The third meeting of the Tripartite Incident Group took place and attendees were presented with a plan for the running of a Patient Notification Exercise and communications plan to support it based on recommendations from Breast Screening Incident Clinical Advisory Group.

**20 April 2018:** The Public Health England Medical Director sent a letter to NHS England Chief Executives and the Director General of Health and Public Protection at the Department of Health and Social Care, copied to Ministerial private offices, with an update on the incident and summary of Breast Screening Incident Clinical Advisory Group recommendations to date.

**23 April 2018:** A meeting with the Secretary of State and Public Health England, NHS England, Department of Health and Social Care senior staff took place. They agreed that the next steps would be a submission to Ministers by Friday 27 April.

**From Mon 23 April 2018 to public announcement:** A daily Incident Management Team meeting between members of the tripartite group took place.

### Public announcement:

**27 April 2018:** A submission was sent to Ministers outlining the mitigation in place, the recommended approach to informing the women affected and communications plan.

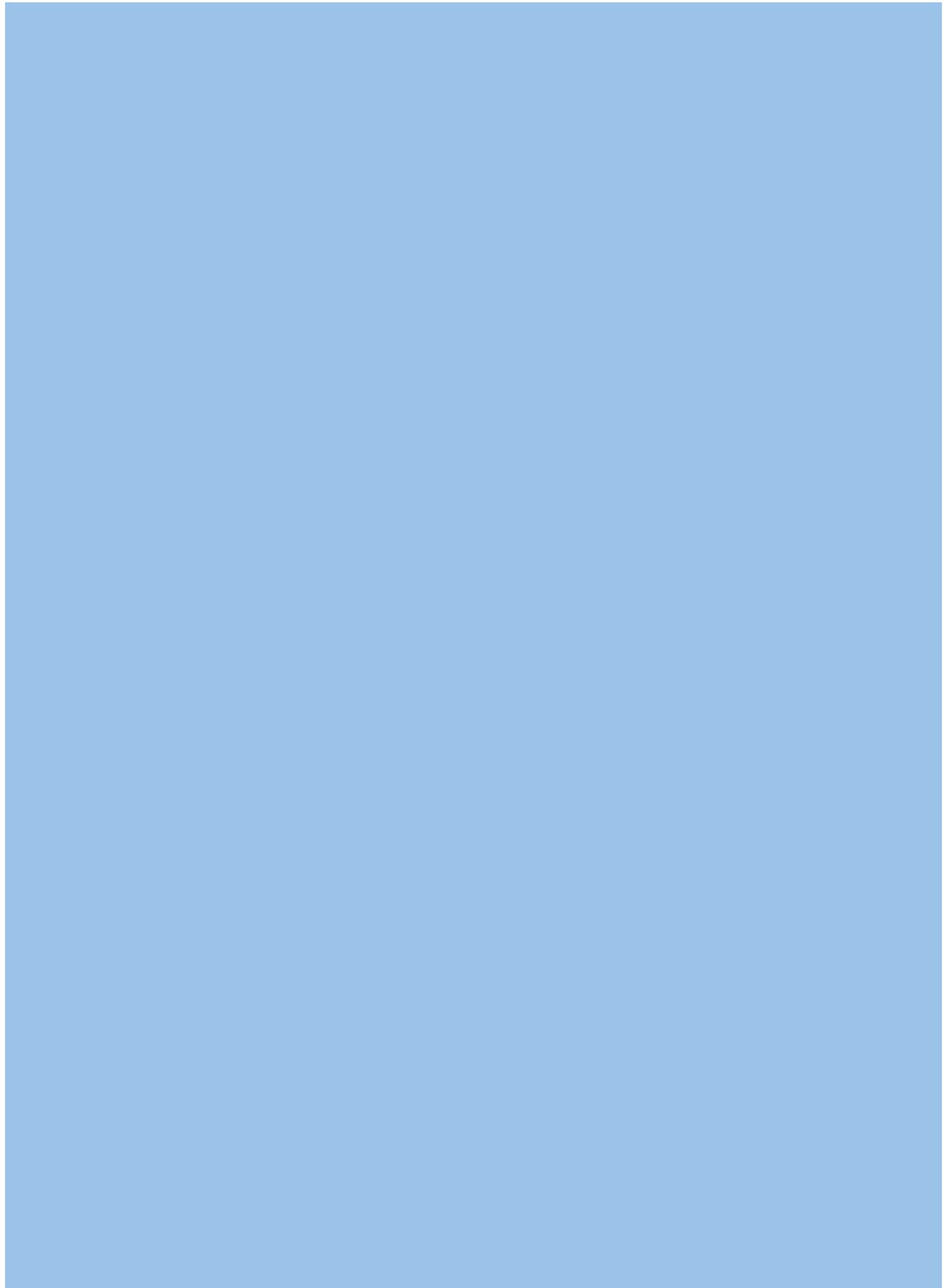
**2 May 2018:** The then Secretary of State for Health announced the incident to Parliament.<sup>34</sup> Breast screening units were informed of the incident the same day and a helpline was put in place for women to contact.

**18 May 2018:** By this date Public Health England had contacted 195,565 women registered with a GP in England who were affected by the incident.

**1 June 2018:** All the affected women known to have moved to Scotland, Wales or Northern Ireland had been written to.

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<sup>34</sup> <https://www.parliament.uk/business/news/2018/may/statement-breast-cancer-screening-2-may-2018/>



# Chapter 5: Impact on women

**5.1** The purpose of this Review is not to opine on the effectiveness or cost efficiency of the breast screening programme – that is for government, taking the advice of the UK National Screening Committee. Rather, this chapter sets out an overview of the established evidence for and against breast screening, to provide context for why the service is in place and the implications for women of missing a screening invitation.

**5.2** Evidence behind the introduction of the breast screening programme in England was persuasive but not without contention. Thirty years on, there is for example a lack of evidence about the effectiveness of screening for women over 70. That is why we believe it is important the AgeX trial continues and reports in a timely manner so that these and other data can be used to inform policy decisions, in England and elsewhere.

**5.3** For individual women found not to have been invited to their final screening mammogram who later developed breast cancer, Public Health England will run a process to establish whether harm was caused as a result. Our Review has been consulted on the approach and supports this important work. The medical concept of ‘clinical harm’ is well documented and has been described in a review published by NHS England.<sup>35</sup> When considering this issue, an assessment is required to clarify if the harm could have been avoided. This is established by identifying patients at risk and if they have come to harm. When there is evidence to suggest harm has been caused, the level should then be described. Clinical harm on the cancer pathway is categorised into: ‘severe’ (if a diagnosis is delayed), ‘moderate’ (if a treatment or medication is increased) or ‘low’ (if symptoms are prolonged). Psychological distress caused is also an important factor to be considered.<sup>36</sup>

**5.4** Clinical harm is not the only impact to consider relating to this incident. The announcement in May 2018 that an estimated 450,000 women could have been affected generated media coverage at the time which may have been distressing for women and their families, who did not know whether they had been affected. The feelings of the women who received a letter from Public Health England to tell them that they might have missed a screening should also be considered.

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<sup>35</sup> <http://www.londonsebate.nhs.uk/wp-content/uploads/2016/01/External-Clinical-Review-Handbook.pdf>

<sup>36</sup> As above

## How the incident has affected women

**5.5** On 2 May 2018 the then Health Secretary announced a “serious failure” that, “between 2009 and the start of 2018 an estimated 450,000 women aged between 68 and 71 were not invited to their final breast screening”.<sup>37</sup> This was widely reported by the media. On 4 June 2018 a further announcement was made, clarifying that “up to 174,000 women were affected by this issue, of which up to 130,000 are still alive.”<sup>38</sup>

**5.6** In order to understand how these women were affected, the Review team worked with the charity Breast Cancer Now to commission a YouGov survey. The survey was sent – via Public Health England as they held the women’s contact information – to around 122,000 women thought to be affected. The survey ran during from 24 September to 15 October and it should be noted that at this time women might not have received the results of their ‘catch-up’ screening. 2,496 women responded to the survey, and YouGov conducted face-to-face interviews with 16 women. The full results can be found at Annex E.

**5.7** The survey showed that a fifth of the women who responded were not concerned when they realised they hadn’t been invited, but a substantial number felt let down, anxious and angry.

**5.8** Many of those who were told they had missed a screening experienced anxiety and worry either about the possibility of having cancer, or that their cancer could have been picked up earlier. For those worried about having cancer, this anxiety was often intensified if they had family or friends who had been diagnosed, or they experienced delays in being given a catch-up screening. For some the anxiety and worry caused by finding out that they had missed a routine breast cancer screening was severe.

*“At first I wasn’t terribly worried, but when my friend and neighbour fell ill and had to be operated on, I got more and more anxious, I thought it could happen to me... what are they doing?”*

Madeline, 74 years old, Norfolk

**5.9** The majority of the respondents who had been diagnosed with breast cancer were concerned that the error might have delayed their cancer diagnosis and resulted in more invasive and traumatic treatment. Many of these women felt let down by the system and angry that a mistake had been made.

*“It has altered my life. I wonder ‘why me?’ and it has upset me. If I’d had the screening, would [the cancer] have been noticed earlier? Would I have been saved from harsh treatment? I relied on the system to call me in and to work. The impact on my general health would have been less.”*

Sonya, 71 years old, Middlesex

**5.10** While most women who responded to the survey stated that the experience had not negatively affected their trust in the breast screening programme and many believed that the incident had been responded to well, reports of this incident clearly had a negative emotional impact on some, particularly those whose lives had already been affected by cancer. While

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<sup>37</sup> <https://hansard.parliament.uk/Commons/2018-05-02/debates/BE9DB48A-C9FF-401B-AC54-FF53BC5BD83E/BreastCancerScreening>

<sup>38</sup> <https://www.parliament.uk/business/publications/written-questions-answers-statements/written-statement/Commons/2018-06-04/HCWS731/>

many women surveyed recognised that the anxiety created by this contact was necessary in addressing the issue, those who were written to unnecessarily could have suffered from worry and anxiety for no clear reason.

## Impact of breast screening – background

**5.11** The clinical impact of the incident is dependent on how the incident is defined. This section sets out the evidence underpinning the breast screening programme to provide context.

**5.12** The Forrest Report<sup>39</sup> published in 1986, considered data from 70 national and international papers (including 11 randomised trials), to determine whether government should offer population breast screening in Great Britain.

**5.13** Key studies available at that time were mostly from overseas (New York HIP, Malmö I and II, Swedish Two County (Kopparberg and Östergötland), Canada I and II, Stockholm, Göteborg,) and recruited women in age ranges 40-75 years.

**5.14** All trials described in the Forrest Report compared women invited to screening against a control group not invited, but different trials varied widely in their research methodology. Despite these inconsistencies in methodology, there was consensus that “deaths from breast cancer in women aged 50-64 years who are offered screening by mammography can be reduced by one third or more”. The 2012 Marmot review<sup>40</sup> which included longer follow-up and more trials, suggested a 20% reduction. The authors of the Forrest report advised that research that was still outstanding in 1986 would require appraisal when considering the evolution of the breast screening service and quality assurance mechanisms should be in place for all aspects of the service. Areas requiring scrutiny included: the optimum time between screening mammograms, the influence of age, acceptability, natural history and screening methods.<sup>41</sup>

**5.15** It is important to note that the trials described in the Forrest Report were performed decades ago, when treatments for breast cancer were less effective than they are today.<sup>42</sup> Less was known about the causes of breast cancer, although increasing age was recognised to be an associated factor. Breast cancer was, and remains, the most common cancer affecting British women, with one third of breast cancers at that time not identified until they were large and advanced and therefore often more difficult to treat successfully; 20% of breast cancers at the time were acknowledged to be too small to feel on examination. The Forrest committee subsequently suggested screening could help identify breast cancers at earlier stages, reducing the development of later stage breast cancers and lowering mortality.<sup>43</sup>

39 [webarchive.nationalarchives.gov.uk/20081112123556/http://www.cancerscreening.nhs.uk/breastscreen/publications/history.html](http://webarchive.nationalarchives.gov.uk/20081112123556/http://www.cancerscreening.nhs.uk/breastscreen/publications/history.html)

40 [http://www.cancerresearchuk.org/prod\\_consump/groups/cr\\_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf](http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf)

41 [webarchive.nationalarchives.gov.uk/20081112123556/http://www.cancerscreening.nhs.uk/breastscreen/publications/history.html](http://webarchive.nationalarchives.gov.uk/20081112123556/http://www.cancerscreening.nhs.uk/breastscreen/publications/history.html)

42 <https://www.uptodate.com/contents/screening-for-breast-cancer-strategies-and-recommendations>

43 [webarchive.nationalarchives.gov.uk/20081112123556/http://www.cancerscreening.nhs.uk/breastscreen/publications/history.html](http://webarchive.nationalarchives.gov.uk/20081112123556/http://www.cancerscreening.nhs.uk/breastscreen/publications/history.html)

## NHS Breast Screening – evidence since the Forrest Report

**5.16** In 2012, Professor Sir Michael Marmot was commissioned to review both the earlier and the more recent research studies.<sup>44</sup> The Marmot Report highlighted that since 1986, treatment and management of breast cancer had improved and there had been changes in breast cancer incidence and mammographic techniques. The periods in which the past trials had been conducted and therefore the relevance of those trials was considered, in addition to any potential internal biases that might influence the data. The studies that had been reviewed by Forrest and colleagues in 1986 were again reviewed but with longer follow-up. Further studies were added and the Panel considered the published concerns about the randomisation process in some trials. The trials reviewed in 2012 had recruited participants in various parts of the age range 39-75 years and the duration of breast screening evaluated in them varied from 4-12 years. Different trials suggested different mortality benefits and some suggested no benefit. Some studies also highlighted risks associated with breast screening, particularly the risk of over-diagnosis. Marmot and colleagues concluded that despite these inconsistencies in the data and the risks associated with breast screening, the proportional reduction in breast cancer mortality in the groups invited to screening was about 20%. This differed quantitatively but not qualitatively from the earlier findings of the Forrest Report (1986). Some uncertainty surrounded the precise number in the Marmot panel's estimate however, this reduction was considered to correspond to one breast cancer death prevented for every 235 women of age 50 years who are invited to screening for the next 20 years. The report recommended "the UK breast screening programmes confer significant benefit and should continue."<sup>45</sup> It also recommended "use of randomised trials to investigate the balance of benefit to harm of breast cancer screening to women younger than 50 years and those older than 70 years".

**5.17** More recently, another systematic review produced similar findings.<sup>46</sup> There have been many further studies on breast cancer screening since 2012: one has reported that mammography reduces breast cancer mortality in women aged 50-64<sup>47</sup> and another that screening may be beneficial in reducing mortality in women aged 40-49 years.<sup>48</sup> There has also been a position from the European Society of Breast Imaging<sup>49</sup> and recently published European Recommendations from European Breast Guidelines,<sup>50</sup> both of which support screening for breast cancer.

## The NHS breast screening programme – risks and benefits

**5.18** The NHS breast screening programme has been the subject of debate regarding risks and benefits since its introduction. The major benefit was seen to be a reduction in mortality from breast cancer with evidence suggesting a significant reduction for women invited to participate in a 20-year screening programme.<sup>51</sup> Critics of the screening programme argue that uncertainty

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44 [http://www.cancerresearchuk.org/prod\\_consump/groups/cr\\_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf](http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf)

45 As above

46 <https://jamanetwork.com/journals/jama/article-abstract/2463261>

47 <https://www.bmj.com/content/bmj/359/bmj.j5932.full.pdf>

48 [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(15\)00128-X/fulltext?code=lanacet-site](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(15)00128-X/fulltext?code=lanacet-site)

49 <https://link.springer.com/content/pdf/10.1007%2Fs00330-016-4612-z.pdf>

50 <https://ecibc.jrc.ec.europa.eu/recommendations/details/5bbf000e9a8bbc17c919c053>

51 [webarchive.nationalarchives.gov.uk/20081112123556/http://www.cancerscreening.nhs.uk/breastscreen/publications/history.html](http://www.webarchive.nationalarchives.gov.uk/20081112123556/http://www.cancerscreening.nhs.uk/breastscreen/publications/history.html)

surrounded this estimate, largely due to inconsistencies in research methodologies and data.<sup>52 53</sup> However, Marmot and colleagues assert these inconsistencies were not sufficient to undermine the mortality benefit demonstrated.

**5.19** Age is also an important consideration with NHS breast screening which is currently routinely offered to women aged 50-70 years of age, although the policy underlying this age range has formed part of our review. There remains a paucity of evidence to support screening women over 70 years<sup>54</sup> and research is ongoing to evaluate this.

**5.20** An important problem with breast screening – as with other screening programmes – is overdiagnosis of cancer. The main adverse consequences of this are overtreatment and adverse psychological impact. Overdiagnosis is described by Duffy (2005) as “the diagnosis of disease that, if left undetected and therefore untreated, would not become symptomatic”<sup>55</sup> or the definition used by the Marmot report, “detection of cancers that would never have been found were it not for the screening”.<sup>56</sup>

**5.21** Overdiagnosis is indicated if cancers identified in the screening group of a study exceed those seen in the control group over a long period. This is because these two otherwise similar groups would be expected to develop similar numbers of cancers over time, although the cancers in the screening group would be expected to be detected sooner and at an earlier stage.<sup>57</sup>

**5.22** Another potential harm of screening is ‘false-positive’ mammograms which can lead to unnecessary further investigations.<sup>58</sup> False-positive mammograms have been described as those whose result prompts a recommendation for additional work-up including further imaging or tissue sampling, in a woman who has no finding of breast cancer within one year of that mammogram.<sup>59</sup> False-positive findings are more common in younger women because the tests are less specific due to increased breast density and because breast cancer in younger women is less common.<sup>60</sup> It is considered that about 4% of women attending for screening are recalled for repeat assessment and of those receiving a biopsy, 20% will be diagnosed with cancer and 80% will not.<sup>61</sup>

**5.23** A further consideration relates to the diagnosis of ductal carcinoma in situ (DCIS) and concerns have been raised that the identification of DCIS following a mammogram may lead to overdiagnosis.<sup>62</sup> DCIS is found more frequently in screen detected breast cancers than in sporadic breast cancer. Significant numbers of women diagnosed with DCIS can develop an invasive cancer but there is controversy as to how likely this is to happen in the lifetime of the individual. There is a balance to be struck between the potential benefits and risks for some women in identifying and treating a possibly precancerous lesion such as some cases of DCIS

52 [http://www.cancerresearchuk.org/prod\\_consump/groups/cr\\_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf](http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf)

53 As above

54 <https://jamanetwork.com/journals/jama/article-abstract/2463261>

55 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1410738/pdf/bcr1354.pdf>

56 [http://www.cancerresearchuk.org/prod\\_consump/groups/cr\\_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf](http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf)

57 <https://www.uptodate.com/contents/screening-for-breast-cancer-strategies-and-recommendations>

58 [http://www.cancerresearchuk.org/prod\\_consump/groups/cr\\_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf](http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf)

59 <https://www.nejm.org/doi/full/10.1056/NEJM199804163381601>

60 <https://www.uptodate.com/contents/screening-for-breast-cancer-strategies-and-recommendations>

61 [http://www.cancerresearchuk.org/prod\\_consump/groups/cr\\_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf](http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf)

62 <https://www.uptodate.com/contents/screening-for-breast-cancer-strategies-and-recommendations>

following screening mammography.<sup>63</sup> In essence, the debate is centred on the likelihood of preventing a clinically significant invasive cancer during the lifetime of the individual and the risks of treating something that may never affected that person.<sup>64</sup>

**5.24** Other potential harms are associated with ‘false-negative’ results, false reassurance given due to missed cancers and incorrect diagnoses,<sup>65</sup> and the risks of radiation. The latter is a low risk<sup>66</sup> when compared to the potential overall benefit for women receiving breast screening.<sup>67</sup>

**5.25** The Marmot report concluded that for every woman whose death was prevented by screening, around three women treated for a breast cancer would not have had their life threatened by the ‘condition’.<sup>68</sup> They estimated that in women invited to screening, about 11% of the cancers diagnosed in their lifetime and 19% of the cancers diagnosed during the period of active screening, would constitute overdiagnosis.<sup>69</sup> These findings have been challenged by other specialists including Professor Michael Baum (2013), who argue the data used by the Marmot committee to be outdated.<sup>70</sup> Others have criticised the ways in which the evidence supporting the introduction of breast screening surveillance has been interpreted.<sup>71</sup>

**5.26** Concern also relates to pain and discomfort caused by mammography and psychological distress such as anxiety or uncertainty occurring during the breast screening process.<sup>72 73</sup>

**5.27** Although 3-yearly mammographic screening will detect many breast cancers, some will be detected between 3-yearly mammograms; these tumours are known as ‘interval cancers’. Raising awareness of cancer symptoms and achieving earlier diagnosis is highlighted in the Department of Health document *Improving Outcomes*<sup>74</sup> which specifically mentions the need for women to be breast aware and report any changes to their GP even if they had a ‘normal’ mammogram recently.<sup>75</sup>

## Breast cancer screening and treatment – developments and impact over the last thirty years

**5.28** In 1988 the NHS breast screening programme began offering women a one-image (view) X-ray mammogram of each breast. This mammogram ‘picture’ was placed on a light-box to illuminate the image and assessed or ‘read’ by a radiologist. Screening was offered from local

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63 [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(15\)00446-5/fulltext?code=lancet-site](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(15)00446-5/fulltext?code=lancet-site)

64 [http://www.cancerresearchuk.org/prod\\_consump/groups/cr\\_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf](http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf)

65 As above [http://www.cancerresearchuk.org/prod\\_consump/groups/cr\\_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf](http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf)

66 <https://www.breastcancercare.org.uk/information-support/have-i-got-breast-cancer/referral-to-a-breast-clinic/routine-breast-screening/benefits-risks-breast-screening>

67 <https://pubs.rsna.org/doi/10.1148/radiol.10100655>

68 [http://www.cancerresearchuk.org/prod\\_consump/groups/cr\\_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf](http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf)

69 As above

70 <https://www.bmj.com/content/346/bmj.f385>

71 doi: <https://doi.org/10.1136/bmj.d6894>

72 <https://www.breastcancercare.org.uk/information-support/have-i-got-breast-cancer/referral-to-a-breast-clinic/routine-breast-screening/benefits-risks-breast-screening>

73 [http://www.cancerresearchuk.org/prod\\_consump/groups/cr\\_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf](http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/breast-screening-review-exec.pdf)

74 [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/213785/dh\\_123394.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/213785/dh_123394.pdf)

75 <https://www.breastcancercare.org.uk/information-support/have-i-got-breast-cancer/referral-to-a-breast-clinic/routine-breast-screening/benefits-risks-breast-screening>

and mobile units to make it easier for women to attend. Plans to change over to mammogram images taken from two views were subsequently announced by the Department of Health in 1995, creating a new standard for breast screening. This followed a randomised controlled trial of over 40,000 women in England aged 50–64 years, which showed two views to be more accurate than the original one-view technique.<sup>76</sup>

**5.29** Partly because of the additional cancers detected by screening, breast cancer incidence appeared to be rising. In addition, disparities across England were emerging in standards of cancer care.<sup>77</sup> These inconsistencies in care were addressed in the Calman Hein Report (1995), which proposed the creation of cancer networks based around cancer centres, with local cancer units in district general hospitals having the explicit objective of providing all patients with “access to a uniformly high quality of care in the community or hospital wherever they may live to ensure maximum possible cure rates and best quality of life.”<sup>78</sup>

**5.30** By 1990 a hormone blocking drug called Tamoxifen was in common use to treat women with breast cancer diagnosis. A reduction in breast cancer mortality seen during this time was considered too early to reflect the benefits of the NHS Breast Screening Programme and more likely to be associated with such Tamoxifen use.<sup>79</sup> Later, research demonstrated an 80% 10-year survival for postmenopausal women with early breast cancer taking hormone blocking medications such as Tamoxifen.<sup>80</sup> In more recent years, some specialists have suggested that benefits of mammographic screening should be weighed against the harms associated with overdiagnosis and unnecessary treatment and that the benefits of adjuvant therapy for breast cancer have been significant.<sup>81 82 83</sup> Other specialists have suggested that early detection of breast cancer remains a vital aspect in improving outcomes for breast cancer and that it is the combination of screening, local and systemic treatments and other factors such as public health awareness that have revolutionised and improved breast cancer care.<sup>84 85</sup>

**5.31** In 2000 Blanks and colleagues suggested that “both screening and other factors including improvements in treatment, had resulted in substantial reductions in mortality from breast cancer”<sup>86</sup> and by 2004 the NHS breast screening programme increased the upper age limit for screening from 64 to 70 years.<sup>87</sup>

**5.32** The Cancer Reform Strategy (2007) then announced a plan to extend breast screening surveillance and offer women their first screen by age 50.<sup>88</sup> It also planned that direct digital mammography would eventually replace analogue mammography, resulting in improved

76 <https://www.bmj.com/content/311/7014/1189>

77 [http://webarchive.nationalarchives.gov.uk/20080817211349/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4071083](http://webarchive.nationalarchives.gov.uk/20080817211349/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4071083)

78 As above

79 doi: <https://doi.org/10.1136/bmj.321.7262.665>

80 <https://www.ncbi.nlm.nih.gov/pubmed/18083636/>

81 <https://link.springer.com/article/10.1007/s10549-011-1794-6>

82 <https://www.uptodate.com/contents/screening-for-breast-cancer-strategies-and-recommendations>

83 doi: <https://doi.org/10.1136/bmj.d6894>

84 doi: <https://doi.org/10.1001/jama.2017.19130>

85 doi: <https://doi.org/10.1136/bmj.h273>

86 doi: <https://doi.org/10.1136/bmj.321.7262.665>

87 [http://webarchive.nationalarchives.gov.uk/+http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4002960](http://webarchive.nationalarchives.gov.uk/+http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4002960)

88 <https://www.nhs.uk/NHSEngland/NSF/Documents/Cancer%20Reform%20Strategy.pdf>

specificity (fewer false positive findings)<sup>89</sup> and improved sensitivity (fewer false negative findings).<sup>90 91</sup> These factors in addition to increasing radiologist expertise, were all expected to enhance the benefit of breast screening surveillance.<sup>92</sup>

**5.33** Also in 2007, improving public awareness of cancer was linked to earlier diagnosis and treatment.<sup>93</sup> A new 'National Awareness and Early Diagnosis Initiative' was launched to measure symptom awareness, develop key messages and test, evaluate and roll out interventions to improve awareness of cancer.<sup>94</sup>

**5.34** Over the last 20 years advances in genetics and genomics have increasingly been translated into the development of new targeted drugs which have been responsible for improved outcomes in specific patient groups.<sup>95</sup>

**5.35** In 2014 The Five Year Forward View was published, further reinforcing the importance of health prevention through patient empowerment and education.<sup>96</sup>

## Breast cancer screening now

**5.36** There has been a steady increase in the number of women invited for screening each year, in part due to the contribution of the AgeX trial. In 2016/17 the number of women aged 45 and over invited for NHS Breast Screening in England annual screening was 2.96 million, 2.2 million attended, with 18,402 cancers detected (8.4 per 1000) of which 41% were invasive but small (<15mm in diameter), a size usually considered to be too small to be detect by clinical examination.

**5.37** As treatments have improved considerably since many of the screening trials were conducted, it is possible that the absolute magnitude of any benefit from breast screening may subsequently be reduced,<sup>97</sup> even if the proportional risk reduction remains the same. Women offered breast screening should be provided with accurate information to help them make informed decisions and receive screening if this is their choice.<sup>98</sup>

## Conclusion

**5.38** Fear and anxiety are among the factors which may influence a woman's decision to access breast screening.<sup>99</sup> This incident may enhance such feelings. Women should be supported to make informed decisions about accessing breast cancer screening with empathic and knowledgeable specialist support available when needed.

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89 <https://www.dictionary.com/browse/specificity>

90 <https://medical-dictionary.thefreedictionary.com/sensitivity>

91 <https://www.nhs.uk/NHSEngland/NSF/Documents/Cancer%20Reform%20Strategy.pdf>

92 doi: <https://doi.org/10.1136/bmj.321.7262.665>

93 <https://www.nhs.uk/NHSEngland/NSF/Documents/Cancer%20Reform%20Strategy.pdf>

94 As above <https://www.nhs.uk/NHSEngland/NSF/Documents/Cancer%20Reform%20Strategy.pdf>

95 [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/213785/dh\\_123394.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/213785/dh_123394.pdf)

96 <https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf>

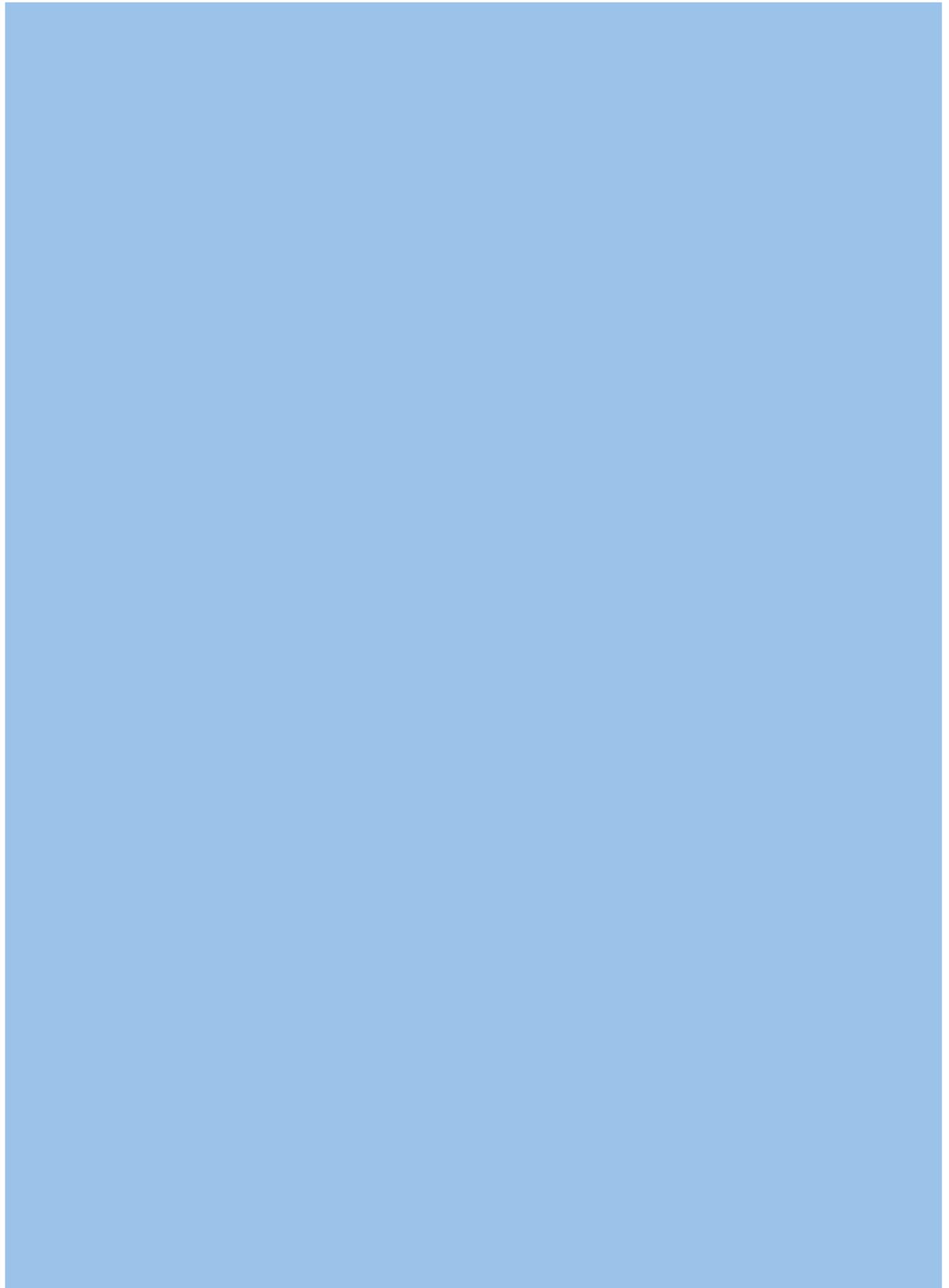
97 <https://www.uptodate.com/contents/screening-for-breast-cancer-strategies-and-recommendations>

98 <https://link.springer.com/article/10.1007/s10549-015-3373-8>

99 <http://cebp.aacrjournals.org/content/13/4/501>

## Recommendation

**5.39** *Women who were contacted through the Patient Notification Exercise and have been diagnosed with breast cancer will be assessed to try to determine whether they were caused harm by errors within the breast screening programme. Public Health England should work quickly and sensitively with these women, their families and their healthcare professionals to try and provide clarity over this and ensure the women have the support they need.*



# Chapter 6: The age extension trial – AgeX

**6.1** At the time of the announcement by the then Secretary of State, it was believed that an algorithm used to randomise women for the AgeX trial might have been the cause of the failure of women to be invited for their last screening. At an early stage in our inquiry, the Review team established that the algorithm was operating as designed and, in addition, that the trialists at Oxford University leading the study did not have any involvement in the randomisation process. However, by way of ensuring a complete picture for the breast screening programme, the history of the AgeX trial is included as part of this report.

**6.2** Chapter 1 sets out the history of the breast screening programme in England. In 2007 the Cancer Reform Strategy proposed extending breast screening to nine screening rounds between 47 and 73 years, with a guarantee that women would have their first screening before the age of 50, facilitated by the roll out of digital mammography.<sup>100</sup> The intention in the Cancer Reform Strategy was to implement this extended screening between 2008 and 2012, stating: “The necessary phasing in of this expansion will be carefully considered to ensure that the most useful epidemiological data can be gathered to inform future decisions about the programme. Full implementation is expected by the end of 2012”.

**6.3** At a meeting on 11 February 2008, a meeting was held within the Department of Health where the challenges of implementing the new policy were discussed. It was proposed that randomising batches of women (so that some batches would be invited for screening and some would not) would generate the most useful data to inform future decisions about the screening programme. The impact of extending screening on workforce and the need for consistent messaging was also highlighted. It was agreed that:

- Full implementation of nine screening rounds would happen across England by 2012;
- Limited resources and finances meant that only half the eligible population could be invited for screening in the first three years. Randomisation by batch was as fair as any other method of selecting which half of the eligible population were invited;
- Only screening units which met certain criteria (36 month round length, appropriate screen to assessment times and direct digital mammography) would be allowed to expand; and
- If a younger woman who had been selected not to be invited (randomised out) requested screening, then she should be screened, although there would be no specific encouragement as there was currently for older women.<sup>101</sup>

**6.4** This led directly to establishing a pilot age extension trial in 2009 to assess deliverability of a trial, and the following year to the full AgeX trial.

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<sup>100</sup> <https://www.nhs.uk/NHSEngland/NSF/Documents/Cancer%20Reform%20Strategy.pdf>

<sup>101</sup> Notes from a meeting to discuss options for expanding the NHS Breast Screening Programme 11 February 2008

**6.5** In 2011, the Coalition Government published its own strategy *Improving Outcomes: A Strategy for Cancer*.<sup>102</sup> It confirmed the objective of the AgeX trial, to “give directly comparable mortality data on the effectiveness of screening including the benefits and harms in these populations.” The Strategy also set out the intention to run the randomisation of the breast screening age extension over two three-year screening rounds (i.e. up to 2016) rather than one, to allow world class data on the effectiveness of screening these age groups to be gathered.

## The pilot study

**6.6** A pilot study was set up in 2009 to test the feasibility (e.g. impact on workload) and acceptability of adding an additional screening before the age of 50 and after the age of 70. The pilot study preceding the full AgeX trial involved five breast screening units: Bolton, Warwickshire Solihull and Coventry, Jarvis (Guildford, Surrey), South East London and Manchester. Cambridge was also originally included but was not pursued when it became apparent that the method they used to invite women (next test due date) was not compatible with the batch randomisation method used by the other pilot sites. Screening invitation batches from the five pilot units were created that included women from 47-73 years old. For each screening batch women aged 47-49 and 71-73 were either randomised to be invited or not invited i.e. the batch included either 47-49-year-olds or 71-73-year-olds as additions to the usual batch of 50-70-year-olds (those not invited served as controls). The software was written by the IT suppliers at the time, Temenos, with guidance provided by the then product owner for NBSS. All screening batches created and randomised by the five units between 1 June 2009 and 31 May 2010 were included in the pilot study. Data was downloaded from each unit in March 2011, to allow time for complete follow up data on each Centre’s IT system (NBSS). Information on self-referrals was obtained from the data. Results showed that the proposed extension was both feasible and acceptable.<sup>103</sup>

## The AgeX trial

**6.7** Research Ethics approval was sought for the main trial (later known as AgeX) from the Ealing and West London Research Ethics Committee. The application stated:

*“The purpose of this study is to evaluate the net effects of extending the age range for breast screening in the NHSBSP in England from 50-70 years to 47-73 years. To date there is limited evidence on the net benefit of extending the age range for breast screening, nor on whether an extra screen at younger or older ages is more worthwhile. Randomising the phasing-in would provide unbiased evidence on this.”*

**6.8** Approval was granted by the Research Ethics Committee on 22 January 2010. On 22 January 2010 approval was also granted by the National Information Governance Board for Health and Social Care (NIGB, now known as the Confidentiality Advisory Group or CAG) to “gain access to and process identifiable data under Section 60 of the Health and Social Care Act 2001 (now Section 251 of the NHS Act 2006)”<sup>104</sup>

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102 [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/213785/dh\\_123394.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/213785/dh_123394.pdf)

103 <http://journals.sagepub.com/doi/pdf/10.1258/jms.2011.011065>

104 ECC 1-04(b)/2010

**6.9** In November 2013, the Public Health England National Executive meeting confirmed that the trial should be refined to allow women to continue to be screened throughout their 70s and not just up to the age of 73. It also noted that a handling plan be drawn up in the event of any controversy regarding this decision.

**6.10** Of the 78 Breast Screening Units in England, 65 participate in the trial.<sup>105</sup> Units in the East of England and Gateshead use a different system for calling women for screening, known as the ‘next test due date’ (NTDD); this is discussed in more detail in Chapter 2. The randomisation process for AgeX is not compatible with the NTDD system. The trial is currently scheduled to continue until December 2026.<sup>106</sup>

## Process

**6.11** The review team heard about the process by which data is collected and transferred to the trial investigators. Women in the relevant cohort ages are randomised into or out of the trial. Randomisation is by cluster, not by individual. The IT that gathers information on women in the breast screening programme is discussed in more detail in chapter 2.

**6.12** Until July 2016 batches of eligible women were generated using the National Health Application and Infrastructure Services (NHAIS). These batches were sent directly to the National Breast Screening System (NBSS) IT software at individual screening units, and a computer programme at each unit randomised the batches, as required for AgeX. After July 2016 Breast Screening Select (BS-Select) was introduced as discussed in chapter 2. Prior to the AgeX trial batches consisted of around 1,000 women each on average, and the trial adds approximately a further 200 women. Each batch is randomly allocated to invite either the 47-70 group or the 50-73 group. Those not invited aged 47-49 or 71-73 become the controls. The data for women aged 47-49 and 71-73 from each batch held on local NBSS databases are then downloaded and transferred to the AgeX investigators. Women over the age of 70 are not invited for routine screening, but may request to be screened every three years. If randomised into AgeX such women are included in the analysis undertaken by the trialists in the category to which they were randomised.

**6.13** Information transferred includes patient identifiable data to enable women to be linked to various databases to collect follow-up and other information, including clinical information on screening, assessment procedures, outcomes and treatments and cancer registrations and deaths. The data are encrypted and transferred electronically from each screening centre to the Cancer Epidemiology Unit (CEU) at Oxford University and stored securely in accordance with the General Data Protection Regulation and CEU procedures and policies. Study participants are followed up via the NHS Digital for breast cancer incidence and mortality and data subsequently transferred to CEU.

**6.14** Although the study links individual patient records it has no interest in individual identities. Data are used only for medical research, and anonymised once data linkage has been completed. All data is analysed only in anonymised form and publications will not identify any individuals.

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<sup>105</sup> List of participating centres can be found here: <http://www.agex.uk/centres/>

<sup>106</sup> <https://clinicaltrials.gov/ct2/show/NCT01081288>

## Research Ethics Committee amendments to the AgeX protocol

**6.15** Since original approval was granted in January 2010, and prior to the announcement of the incident in May 2018, there were six applications to the Research Ethics Committee for amendments to the trial protocol which are discussed below. None of the amendments have affected the way the trial is run in relation to how women are batched for randomisation and invited or not for screening. The amendments have reflected changes in government policy about the time-scale of the trial and have also included expanded descriptions of the trial and linkages to additional datasets, as well as modifications to the participant information sheets. However, as described below, as a result of the incident, a further small change has now been made and approved to the protocol to align the age at randomisation with new Public Health England definitions of age in their IT software. Where amendments were considered to be “minor” these were approved by the Chair without reference to the full Ethics Committee.

**6.16** In December 2010 two minor amendments were approved to the trial:<sup>107</sup>

- To incorporate the pilot study data into the main trial; and
- Extend the end date for the trial from 2012 and to continue randomisation until 2016.

**6.17** In August 2011 further minor amendments were approved:<sup>108</sup>

- For Quality Assurance Reference Centres (QARCs) to collect the data downloads from NBSS for the Breast Screening Units in their region and then pass them on to the Cancer Epidemiology Unit (CEU) at Oxford. Data downloads were split into two downloads per year, the first giving study population data, and the second screening outcome data.
- To link the breast screening records from the trial to other records (in addition to the cancer and death registration records already included).

**6.18** In February 2013 three amendments were proposed:

- Updating the protocol, including provisions of details of the datasets to which linkages were to be made. Offering women additional screening throughout their 70s, not just one additional screening. It was proposed to pilot this in the first instance.
- Revisions to the trial information leaflet to incorporate these amendments and to add clarity.

The application to the Harrow Research Ethics Committee (previously the Ealing and West London Research Ethics Committee) was refused.<sup>109</sup> The Committee cited ethical concerns, consent and information provided to women in the trial and those who were randomised out.

**6.19** In May 2014 a further application to the Harrow Research Ethics Committee for substantial amendments was refused on the basis that it was similar to the earlier amendment in February 2013.<sup>110</sup> The application sought to:

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107 National Research Ethics Committee – North London Research Ethics Committee letter dated 16 December 2010

108 National Research Ethics Committee London – Harrow letter dated 8 August 2011

109 Health Research Authority – National Research Ethics Committee London – Harrow letter dated 25 February 2013

110 Health Research Authority National Research Ethics Committee London – Harrow letter dated 29 May 2014

- update the protocol;
- update the trial participant information sheet; and
- amend the title of the trial.

**6.20** In November 2014 an application was approved by the Harrow Research Ethics Committee for substantial amendments to the trial protocol.<sup>111</sup> Some of these amendments directly addressed the earlier amendments for which approval was not given.

The amendments included:

- An amendment to the trial protocol to include an expanded discussion on the political context of the trial;
- Further details of the scientific rationale for the trial;
- A detailed analysis plan along with calculations of statistical power;
- Clarification that randomisation is by cluster and not by individual;
- Clarification why it is not feasible to obtain individual consent given the cluster randomised design;
- Further details of the trial supervision procedures through the Trial Management Group and the Data Monitoring and Ethics Committee;
- Specification of additional electronic linkages required (e.g. to NHS Cancer Screening Records); and
- Changes to the trial participation information sheet and inclusion of a poster to display in general practices.

**6.21** In September 2016 a further application was approved for substantial amendments.<sup>112</sup> These included:

- Extending the upper age for screening so that women could be offered up to three triennial invitations (the first at ages 71-73, and where feasible others at ages 74-76 and at 77-79); the actual number of extra screens after age 73 would depend on the resources currently available at each clinic;
- Changes to the participant information sheet; and
- Updates to the trial protocol (now v4).

**6.22** As a result of the incident announced in May 2018, Public Health England made changes to the software used to randomise women into or out of the AgeX trial. In the software, which went online on 27 September 2018, age is now defined by exact date of birth as opposed to birth year. As a result, some small alterations in the AgeX protocol were proposed to the protocol and patient information sheet.

**6.23** The extra invitations offered by Public Health England and the changes in their definitions after May 2018 have necessitated a small change in the protocol. The primary analysis was re-specified to exclude women entered into AgeX since mid-2016 who were eligible according to the previous but not according to the revised Public Health England definitions of age (most of whom had been between their 70<sup>th</sup> and 71<sup>st</sup> birthday when randomised). An application for

111 Health Research Authority National Research Ethics Committee London – Harrow letter dated 4 November 2014

112 Health Research Authority National Research Ethics Committee London – Harrow letter dated 1 September 2016

changes to the protocol and Trial Participant Information Sheet was approved by the Harrow Research Ethics Committee in October 2018.<sup>113</sup> The current version of the trial protocol (5.1) can be found on the AgeX Trial website.<sup>114</sup>

## Funding

**6.24** Extending the age range for screening women incurs a cost to units for the additional screenings that they undertake. Including women in the AgeX Trial increases the number of women being screened in each batch by around 20%. This requires additional resource in terms of staff to set up, administer and then analyse each screen. When the trial was first established, the then Department of Health allocated additional funding for the purpose, initially given to the cancer screening budget. There is now an annual grant from the Department of Health and Social Care which is passed to Public Health England via the screening programme budget. This is allocated to individual units to cover their additional costs. At present the funds equate to £12/head of eligible population per annum, based on the size of the younger cohort, ie. those aged 47-49. The original baseline of funding was from 2014 population estimates supplied by NHS Digital. A further small amount of funding to support an administrator is also paid to the AgeX trialists. The funding is currently assumed to continue until completion of the trial.

## Governance

**6.25** Governance of the AgeX Trial is by its Trial Management Group (TMG) and independent Data Monitoring and Ethics Committee (DMEC) both meet annually and their terms of reference are described in the trial protocol. The Review team have seen the minutes of these meetings, dating back to 2011. Membership of the two groups is separate, and since 2015 the chair and other members of the DMEC have been in attendance at the TMG meetings.

**6.26** In 2017 Public Health England commissioned an external evaluation of the AgeX trial. Three external academics were invited to review the revised AgeX protocol in relation to its scientific merit and to provide constructive critical feedback. The three anonymous reviewers supported the trial methodology gave the trial an average score of 9.3 out of 10.<sup>115</sup>

## Recommendation

**6.27** *The AgeX Trial should continue until its planned end date, currently 2026, to enable the most extensive analysis possible of the impacts of extending the breast screening programme both in the younger and older age groups.*

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113 Health Research Authority National Research Ethics Committee London – Harrow letter dated 19 October 2018

114 <http://www.agex.uk/links/>

115 Public Health England External Review of the AgeX Trial February 2017

# Annex A – terms of reference

- 1 To investigate and report on the circumstances of the breast screening failure including:
  - The reason/s why certain cohorts of women were not called for a final screen;
  - Establishing the timeline of relevant events from 2009 to 2018 of the Age X trial and the national programme, including their administration and governance;
  - Identifying why the problems were not detected earlier, including whether there were missed opportunities to identify and rectify the failure earlier;
  - Assessing the governance, assurance and accountability processes;
  - The clinical implications for the affected population as a whole; and
  - How the issue came to light, and the handling and escalation process in 2018.
- 2 To make any appropriate recommendations based on the findings of point 1 both on breast screening, and any wider organisational or other issues that arise to ensure that such failures are not repeated.
- 3 To make any recommendations for any further reviews / analysis / investigation of the breast (and potentially other) screening programmes based on information gathered during this review.
- 4 To report by November 2018.
- 5 Secretariat to be provided by DHSC.

## Role of the secretariat

The Chairs were supported in their work by a small secretariat who assisted in research for the review, including the collation of relevant documentation and facilitated the work of the Chairs. None of the secretariat had previously worked at the organisations involved in the incident. The Review was funded by the Department of Health and Social Care.

The secretariat:

- Elin Jones
- Shona Johnstone
- Philip Horswill
- Fatima Ahmed
- Spencer Meldrum

The Chairs are grateful for specialist advice from:

- Suzy Halliday (Advanced Nurse Practitioner)
- Frankie Roberto (IT expert)

# Annex B – list of breast units visited by the Review team

The Review team spoke to ten breast screening units across the country (in addition to the screening programmes in Northern Ireland, Scotland and Wales). The staff in the units gave a great deal of their time and expertise to talk to us about their understanding of what had happened, as well as helping us to navigate the complex systems and guidance they use in their everyday work. Their help made a substantial contribution to this report, and we are grateful to them.

- Avon Breast Screening Unit, Bristol
- Bolton Breast Screening Unit, Bolton
- Epping Breast Unit, Epping
- Jarvis Breast Centre, Surrey
- Leeds and Wakefield Breast Screening Seacroft Hospital, Leeds
- Nottingham Breast Institute, Nottingham
- Norwich Breast Screening Service, Norwich
- West Midlands Breast Screening Programme, Birmingham
- Royal Free Breast Screening Service, London
- Warwickshire, Solihull and Coventry Breast Screening Service

# Annex C – data analysis note

An anonymised version of the Patient Notification Exercise dataset was provided by Public Health England for analysis by the Review team. Access to these data was strictly controlled using a Public Health England laptop and only on Public Health England premises. Subject matter experts from Public Health England with access to the same data were made available to the Review team to support the analysis process.

The Patient Notification Exercise list was compiled by NHS Digital during April and May 2018, and included women who matched criteria set out by Public Health England:

- Women aged from 68y0m0d to 70y11m31d with a WS episode (i.e. were randomised out by the AgeX algorithm) and no subsequent invited episode of any type (i.e. had not been invited for a further screening).
- Women aged 71 who were registered on BS-Select before their 71st birthday and have no episodes of any type since they were aged 68y0m0d.
- Women aged 71 who were registered on BS-Select before their 71st birthday who have a WS episode (i.e. were randomised out by the AgeX algorithm) before their 71st birthday and no subsequent invited episode of any type (i.e. had not been invited for a further screening).
- Women aged 72, 73 or 74 who were registered on BS-Select before their 71st birthday (or included in initial migration) and have no episodes of any type since they were aged 68y0m0d (i.e. had not been invited for or had a screening).
- Women aged 72, 73 or 74 who were registered on BS-Select before their 71st birthday (or included in initial migration) who have a WS episode (i.e. were randomised out by the AgeX algorithm) before their 71st birthday and no subsequent invited episode of any type (i.e. had not been invited for a further screening).
- Women aged 75, 76, 77, 78 or 79 with no episodes of any type aged 68y0m0d but with a previous episode between the ages of 65-67.
- Women aged 75, 76, 77, 78 or 79 with a WS episode (i.e. were randomised out by the AgeX algorithm) before their 71st birthday and no subsequent invited episode of any type (i.e. had not been invited for a further screening).

The criteria were set based on Public Health England's understanding at that time of what had caused the incident, and had a start point of 2009.

Around 196,000 women were contacted via the Patient Notification Exercise. Of these, it was later found by Public Health England that c74,000 had been wrongly included (and therefore wrongly contacted).

After the c74,000 women wrongly included in the Patient Notification Exercise had been removed, around 122,000 women were left in the final list of women believed by Public Health England to have been affected. This is the list which was made available to the Review team.

The Review team's detailed analysis has found that:

**Around 5,000 of these women did not receive invitations when they should have done** – they were eligible for a further invitation to screening before they turned 70 (so were correctly included in the Patient Notification Exercise). It is likely these women missed a screening invitation because of errors in using the IT system, round length slippage, 'fail safe' action not being taken or other reasons. This is described in Chapter 2 of this report.

The remaining **c117,000 women received their final invitation for screening in the year in which they turned 68** (though their age might have been 67). This was in keeping with the way the IT systems had been designed to deliver the breast screening programme. However, they could be interpreted as having missed their final invitation under the definition of the November 2013 Service Specification (and subsequent iterations) as they did not receive an invitation within 36 months of their 71st birthday.

Of these c117,000 women, some were due to be invited (under the definition of the November 2013 Service Specification) prior to the Specification's publication. The Review does not believe there can have been a legitimate expectation for these women to have been invited according to the Specification. As the Service Specification was written without an implementation period or start date it is difficult to define the number of women thought by the Review to be unaffected. For illustration purposes, the date of November 2013 (when the Specification was written) could be applied and it could be assumed that the Service Specification would not have been applied to women who had their final screening invitation before November 2010 (so they would not have been put through a further invitation cycle after the publication of the Specification). In this case, in the Review's opinion **around 55,000 of the remaining 117,000 women (just under half – 47%) should not have been included in the Patient Notification Exercise.**

This means that (using the cut-off point set out above), **in the Review's opinion 129,000 of the 196,000 women (c65%) contacted through the Patient Notification Exercise were incorrectly told they may have missed their final screening.**

# Annex D – glossary

**AgeX (age extension) trial:** established in 2009 to test the benefits of extending the breast screening programme to women from age 47 to 73.

**Batch:** women in a particular area (usually based on GP practice) who are eligible for screening and who will be invited to attend screening at a particular time.

**BS-Select (Breast Screening Select):** A new software application Introduced in 2016, it allows units to select the data required to create a batch of women for screening. It does not completely replace NHAIS (see below), but sits between NHAIS, which is still the source of demographic data, and NBSS.

**Episode:** all the events in a woman's invitation to screening, from identification to results being transmitted to the woman.

**Failsafe:** an alternative method of creating a batch, which aims to ensure all women within the specified age range will be invited within 36 months of their previous screening, regardless of their GP or postcode. These are needed primarily as women may have moved GP or address. Failsafe batches should be created by local breast screening units at monthly intervals.

**NBSS (National Breast Screening Services computer system):** the local system in each breast screening unit which holds clinical details of the women being screened by those units.

**Next Test Due Date (NTDD):** the batching method used in some units (including East Anglia and Gateshead) to identify women for screening, based on adding thirty-six months to the date of their last invitation to screening

**NHAIS (National Health Application and Infrastructure Services):** a database and suite of software implemented across primary care, which manages patient registrations, demographic details and some clinical information for England, Wales and Northern Ireland.

**NHS Digital:** supplies information and data to the health service, provides vital technological infrastructure, and helps different parts of health and care work together.

**NHS England:** leads the National Health Service (NHS) in England. It sets the priorities and direction of the NHS and encourage and inform the national debate to improve health and care.

**Patient Notification Exercise:** An exercise to identify those who may have been exposed to the risk and detect any people who may have been affected in order to offer them the necessary care.

**Public Health England:** is an executive agency of the Department of Health and Social Care; its responsibilities include supporting local authorities and the NHS to plan and provide health and social care services such as immunisation and screening programmes, and to develop the public health system and its specialist workforce.

**Recall Interval/Safety Period (RISP):** the most commonly used batching method to invite women for their next screening, based on a woman's year of birth being within a set range, whilst making sure that their previous screening wasn't within the last 24 months (the safety period).

**Round length:** a screening round length is the interval between the date of a woman's previous screening mammogram and the date of her next first offered appointment. This should be thirty-six months.

**Section 7a:** sets out for commissioners and healthcare providers notice of NHS England's commissioning intentions for certain Public Health services, commissioned as part of the NHS Public Health Functions Agreement under s.7A of the NHS Act 2006. This is an annual agreement between the Department of Health and Social Care and NHS England.

**Service Specification 24:** the document that sets out the approach to the provision and monitoring of breast screening across England and ensures that it is both consistent and equitable. It is designed to outline the service and quality indicators expected by NHS England to ensure that a high standard of service is provided to NHS England's responsible population. It therefore sets out the specific policies, recommendations, and standards that services are expected to meet.

# Annex E – survey results

The YouGov logo, with 'You' in red and 'Gov' in grey.The 'breast cancer now' logo, with 'breast cancer' in a small black font above 'now' in a large, bold black font. The letter 'o' in 'now' is replaced by a pink heart.

## Breast Cancer Now: Screening Review

Prepared by YouGov:  
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Briony Gunstone  
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Jessica Orbell

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 November 30,  
2018

# Background, objectives and method



## — Background and objectives

Breast Cancer Now commissioned YouGov in 2018 to conduct research with women who had not been invited to their final breast screening appointment between 2009 - 2018, to feed into the Government's independent review of the screening programme to investigate and understand the incident.

The key objectives of the research are as follows:

- Determine whether women raised concerns that they had missed their final screening and understand if/how they were acted upon;
- Understand whether the response to the incident was sufficient;
- Understand the impact on those affected.

Secondary objectives include:

- Explore their knowledge of screening;
- Explore their experiences of breast cancer (where relevant).



## Quantitative method and sample

- A quantitative survey was conducted online by YouGov. Contacts for women who were affected by the screening error were accessed via Public Health England's records. Rather than drawing a survey sample, all women believed to have been affected by the error were invited to take part.
- A postal letter was sent out by Breast Cancer Now and Public Health England to the relevant contacts. The letter explained the survey and contained an easy-to-remember survey link - [www.yougov.com/screeningsurvey](http://www.yougov.com/screeningsurvey). This was an open link, meaning that respondents did not need to log into the system before taking part.
- A telephone helpline was also provided by Breast Cancer Now alongside the survey link to assist anyone having any issues with completing the survey
- The survey was open from 24<sup>th</sup> September to 15<sup>th</sup> October
- 2,496 women completed the survey
- It is important to note that the sample is not representative of all those affected by the error, but just of those who responded to the survey



# Qualitative method and sample



16 x qualitative telephone-depth interviews were conducted (between 27<sup>th</sup> September - 9<sup>th</sup> October 2018) with women who had completed the quantitative survey and who had called a helpline when they received the error letter from PHE.

## Overarching Criteria

- All had not received their final breast screening invitation letter
- All recalled receiving the letter from PHE telling them they'd not been sent an appointment
- All called one of the helplines (PHE, BCC or Macmillan)
- Mix of when they realised they hadn't been sent the invitation
- Inc. some who raised concerns when they realised they hadn't been invited
- Mix of region
- Mix of ages within the age range

### 6 x Unaffected

- All suffered no long term consequences of the error - i.e. missed their final screening appointment, but subsequently attended catch up screening and had a good experience

### 5 x Mildly Affected

- All experienced worry and distress as a result of the error
- However, have received reassurance through info / helpline / catch up screening

### 5 x Severely Affected

- All missed their final screening appointment and were subsequently diagnosed with breast cancer
- All experienced worry and distress



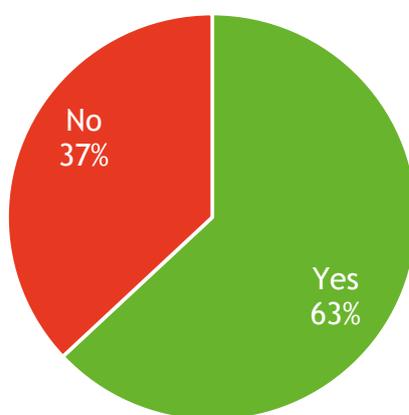
# General NHS Breast Screening programme knowledge



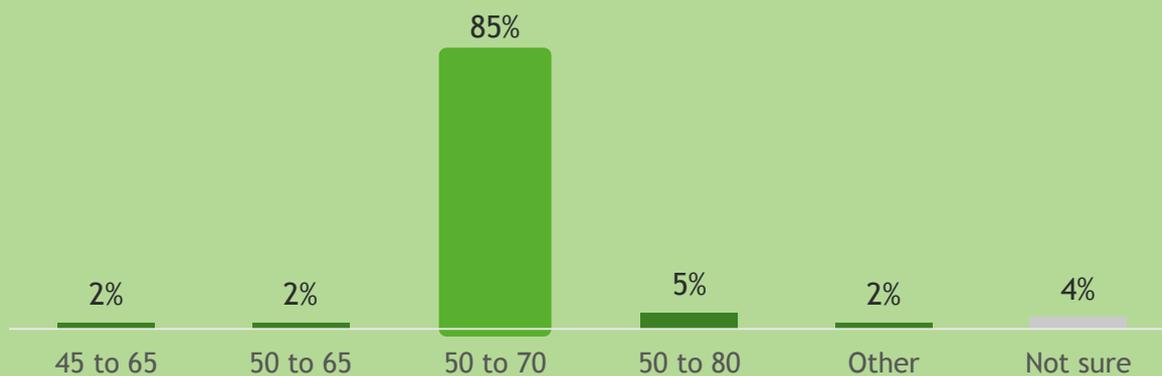
63% percent report knowing the age range for screening before the error was announced, but when asked to specify only 85% of these knew the correct answer - equating to 54% of all women surveyed

KNOW WHAT AGE RANGE WOMEN SHOULD BE INVITED FOR A SCREENING

*Equates to 54% who knew the right age range among all women surveyed*



AGE RANGE BELIEVE WOMEN SHOULD BE INVITED TO BREAST SCREENING



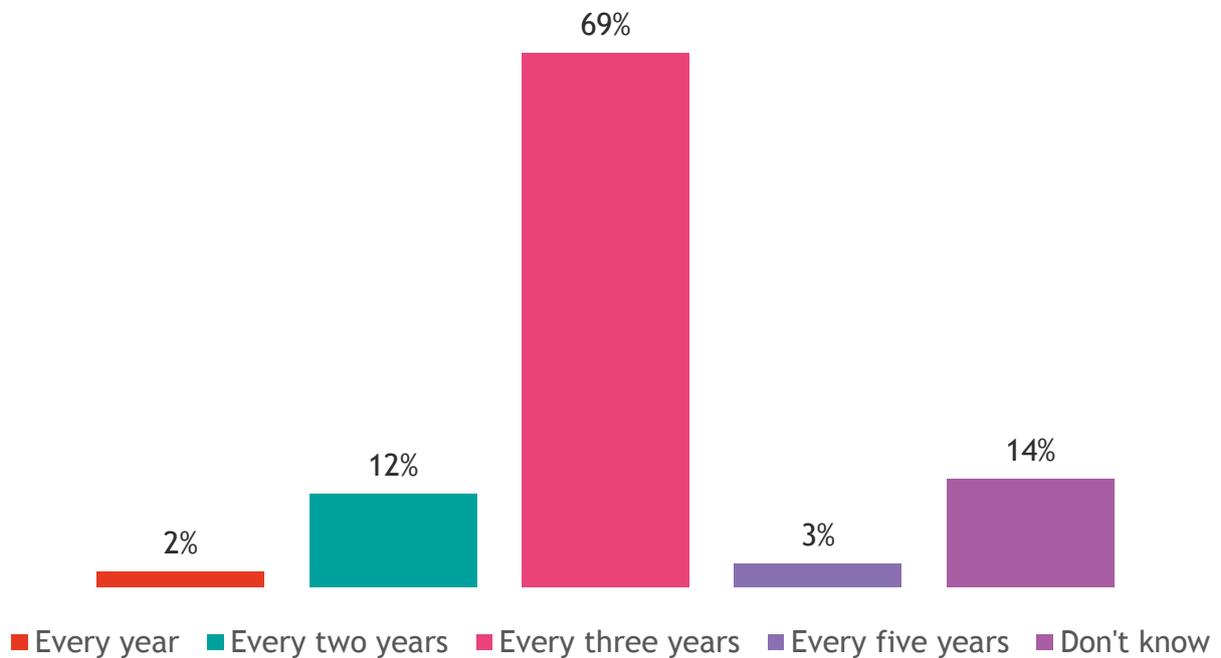
Q1. Before the error in breast screening invitations was publicised earlier this year, did you know the age range that women should be invited to breast screening? Base: all (n=2496)

Q1a. what was the age range that women should be invited to breast screening? Base: all (n=2496)



# Nearly seven in ten knew that women should receive an invitation to a screening every three years

HOW FREQUENTLY WOMEN SHOULD RECEIVE AN INVITATION



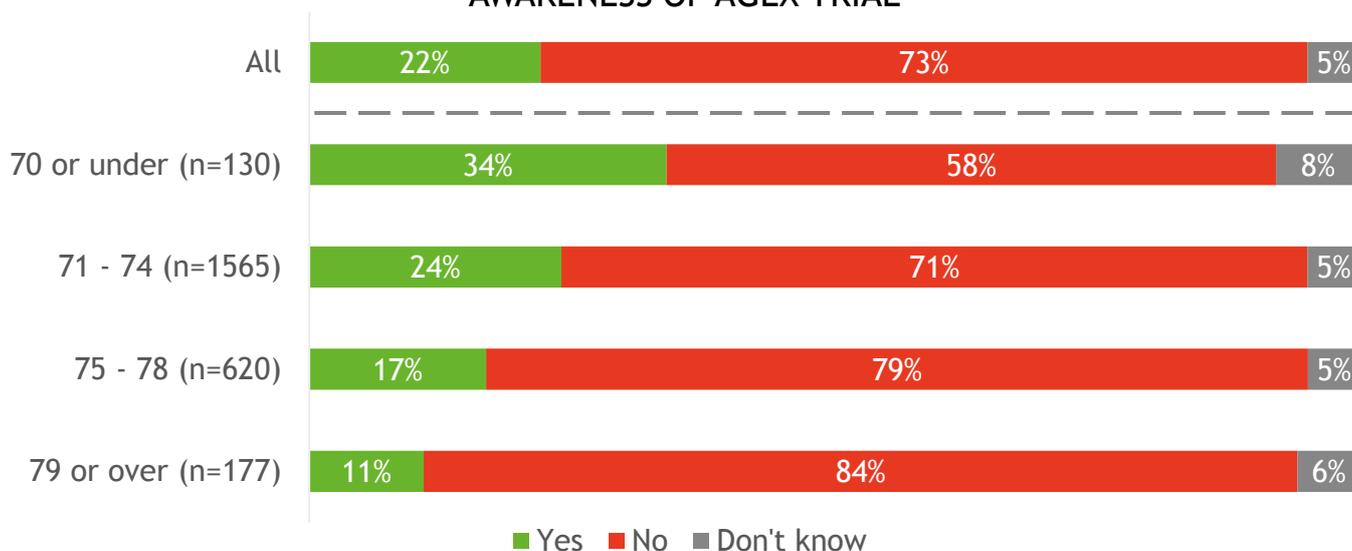
Younger women were more likely to select the right answer

Q2. Do you know how frequently women within this age range should receive an invitation to screening?  
Base: all (n=2496)

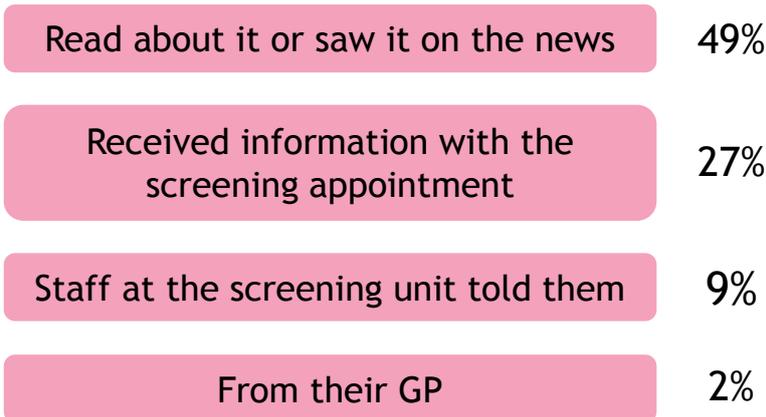


# Less than one quarter were aware of the AgeX trial, with younger women once again more likely to have heard of it

AWARENESS OF AGE X TRIAL



## How women were made aware of the trial



Q3. The AgeX trial is currently inviting women in some areas to breast screening from 47 and up to 73, to test whether screening is effective in these age groups. Before taking this survey, had you heard of this trial? Base: all (n=2496)

Q4 How were you made aware of the AgeX Trial? Base: all aware of the trial (549)

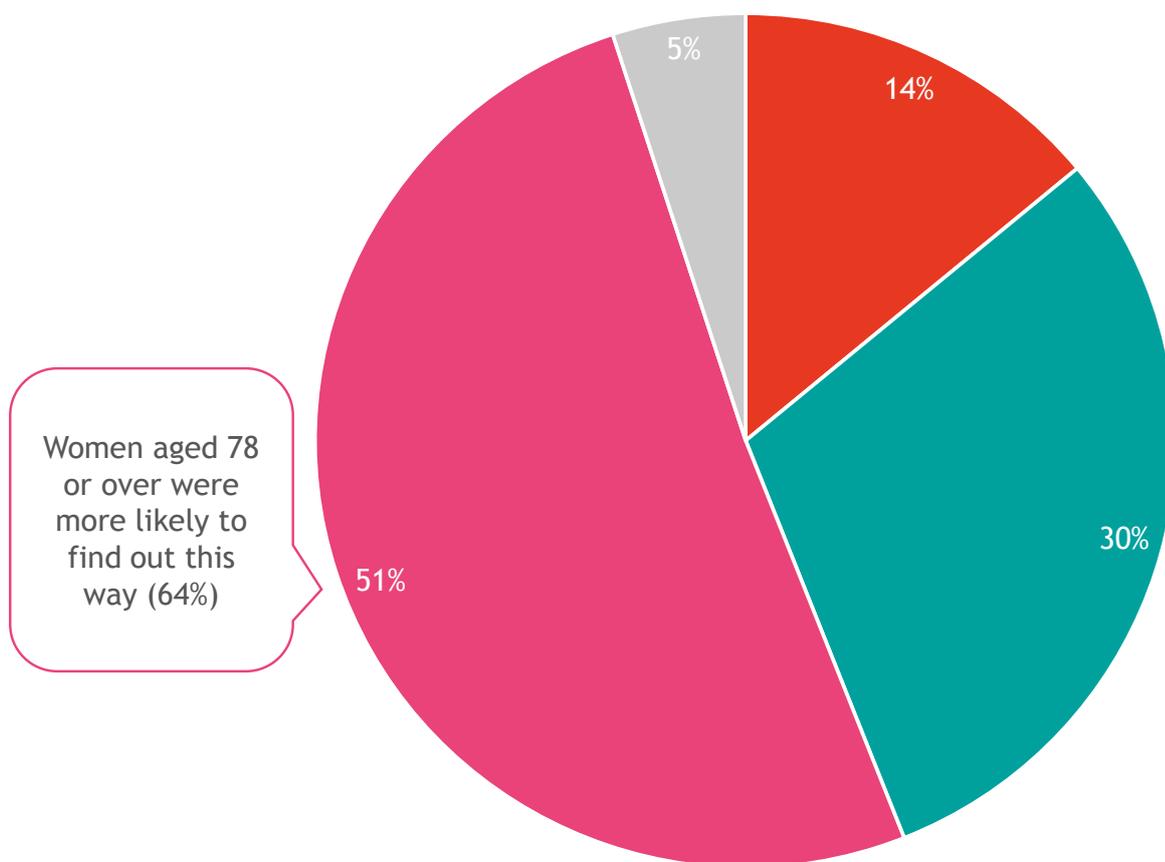


# Finding out about the screening error



# Half of the women found out about the missed appointment when they received the letter

HOW WOMEN BECAME AWARE OF THE ERROR



- Before the issue was publicised
- When the issue was announced by the Government and publicised in the media
- When I received a letter telling me I had not been sent an appointment

Q7. When did you realise you had not been sent an invitation to your final breast screening appointment?  
Base: All (2496)



## Few realised that they had missed the invite; of those that had realised, only a minority raised concerns

### When did they realise?

- Many didn't realise that they had missed the invitation due to confusion and a lack of understanding surrounding the age at which they were meant to receive their final invitation;
- Some had even heard about the error in the media, but didn't connect that it affected them personally due to this confusion;
- As a result, many only realised that they were affected by the error upon receiving the letter from PHE.
- However, there were some who did realise that they were affected upon hearing about the error in the media; and a minority who realised as they had been keeping track of their screening appointment dates and when they were due.

*"I didn't actually [realise] until it came out in the paper... I was absolutely furious - if I had gone to that screening it could well have been picked up at an earlier [stage]"*

Severely Affected, 77, Midlands

*"I didn't realise that I hadn't. I thought that I was too old to have it. Although I read about it I didn't think it covered me. Only realised on the letter"*

Mildly Affected, 75, South East

*"It went through my mind at the time but I thought I was over the age limit. . . I thought I wasn't due it. Didn't think I would receive an invite"*

Unaffected, 79, Yorkshire

*"Spoke to a friend and she said I won't get another one as I'm over 70yrs. I thought I needed to be invited so only realised when I got the letter"*

Severely Affected, 72, Hampshire

*"At last appointment the nurse said I wouldn't be invited [anymore] as I'd be too old but I can apply if want one. I didn't apply as heard about the error"*

Mildly Affected, 72, Staffordshire

*"I realised when I received the letter. I'd seen it in the media, but couldn't keep track of how long ago it was since I had my last one. Didn't know if it affected me personally"*

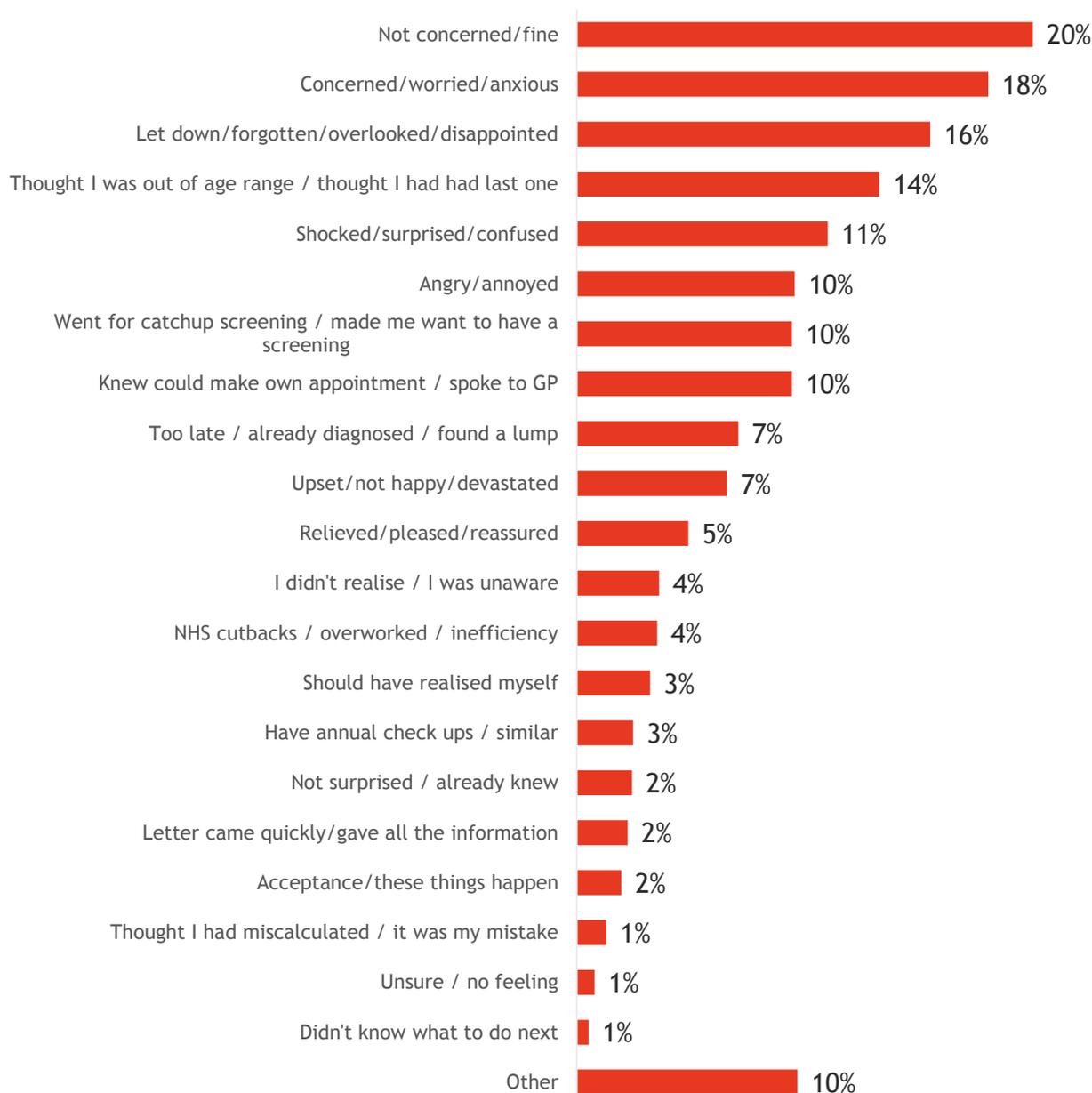
Unaffected, 72, Kent

### Did they raise concerns?

- Of the minority that did realise they had missed their final screening, not all raised concerns - this was for various reasons, such as being preoccupied with other things such as moving house or ill health.
- Some, who had realised prior to the letter arriving, planned on raising their concerns, but either didn't know how, or the letter arrived so soon after realising that they did not need to.
- One did try to raise concerns by contacting her local breast screening unit - they took her details and said they would call, but she never heard back from them.



## A fifth said they were not concerned when they realised they hadn't been invited, but a substantial number felt let down, anxious, and angry



Q8. How did you feel when you realised that you hadn't received an invitation to your final breast screening appointment? Base: all

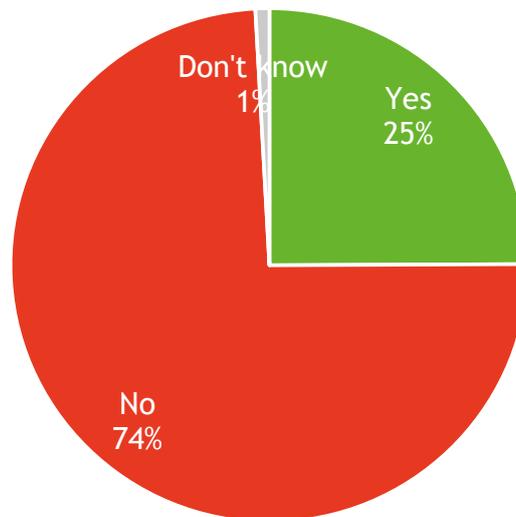
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Note: this question has been coded from an open-ended question

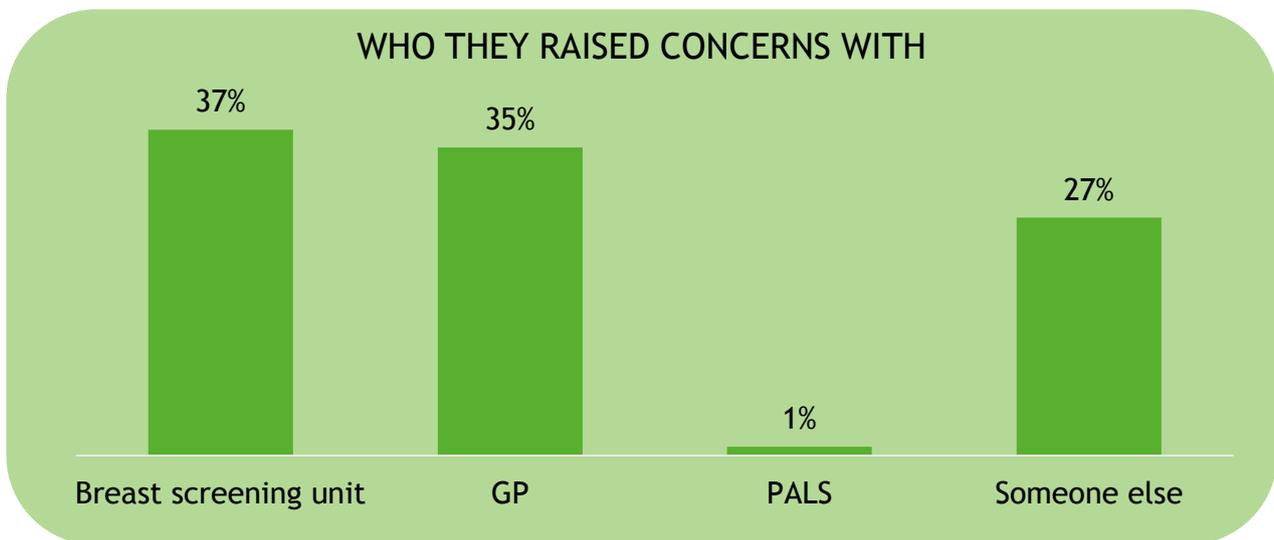
YouGov

## Only a quarter of those who became aware of the missed appointment prior to the letter raised their concerns, predominantly with their GP or breast screening unit

WHETHER THEY RAISED CONCERNS ABOUT LACK OF INVITATION TO FINAL SCREENING



WHO THEY RAISED CONCERNS WITH

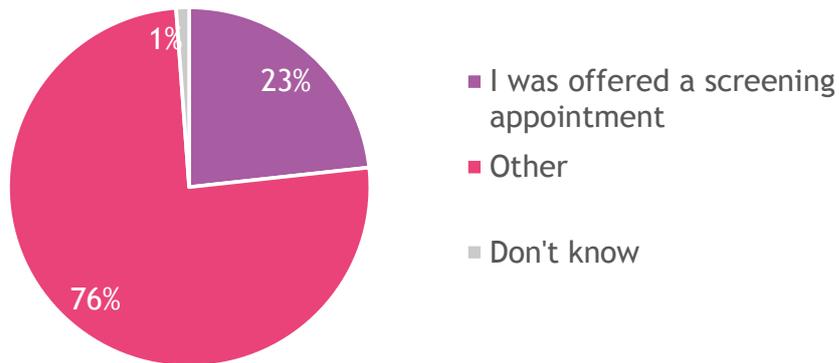


Q9. Did you raise concerns that you had not received an invitation to your final breast screening appointment when you realised? Base: all who realised before the issue was made public (345)

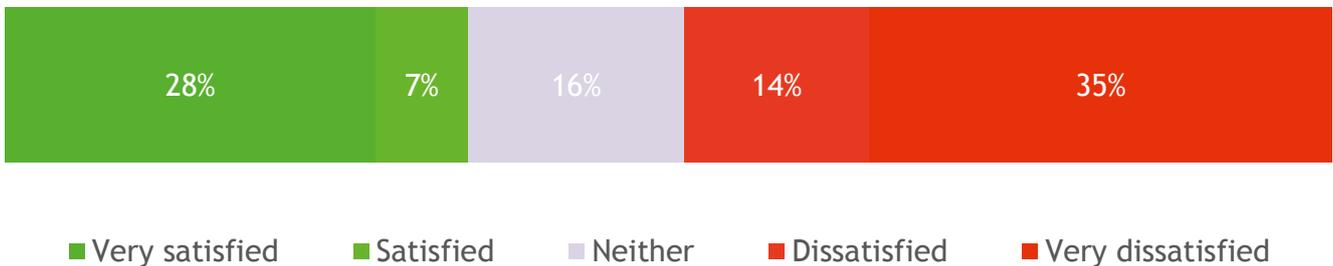
Q10. Who did you raise concerns with? Base: all who raised concerns (86)

# Half of those who raised concerns about not receiving their final screening letter were dissatisfied with the response they received

HOW CONCERNS WERE DEALT WITH



SATISFACTION WITH RESPONSE



Those who said their concerns were dealt with through something other than being offered a screening appointment said a range of things, including:

- Being given a phone number to call or someone else to talk to
- Being told they were over 70 or too old
- Being told to wait
- Receiving no response

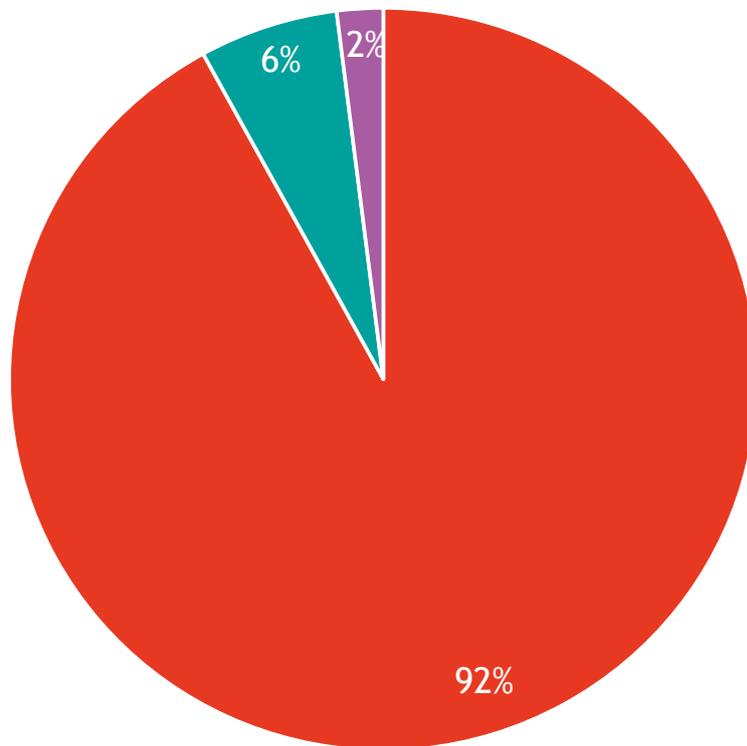
Q11. How were these concerns dealt with? Base: all who raised concerns (86)

Q12. On a scale of 1 to 5, how satisfied were you with this response? Base: all who raised concerns (86)



# Only 6% said they did not receive a letter informing them that they had not been invited to their final appointment

WHETHER RECEIVED A LETTER FROM PUBLIC HEALTH ENGLAND



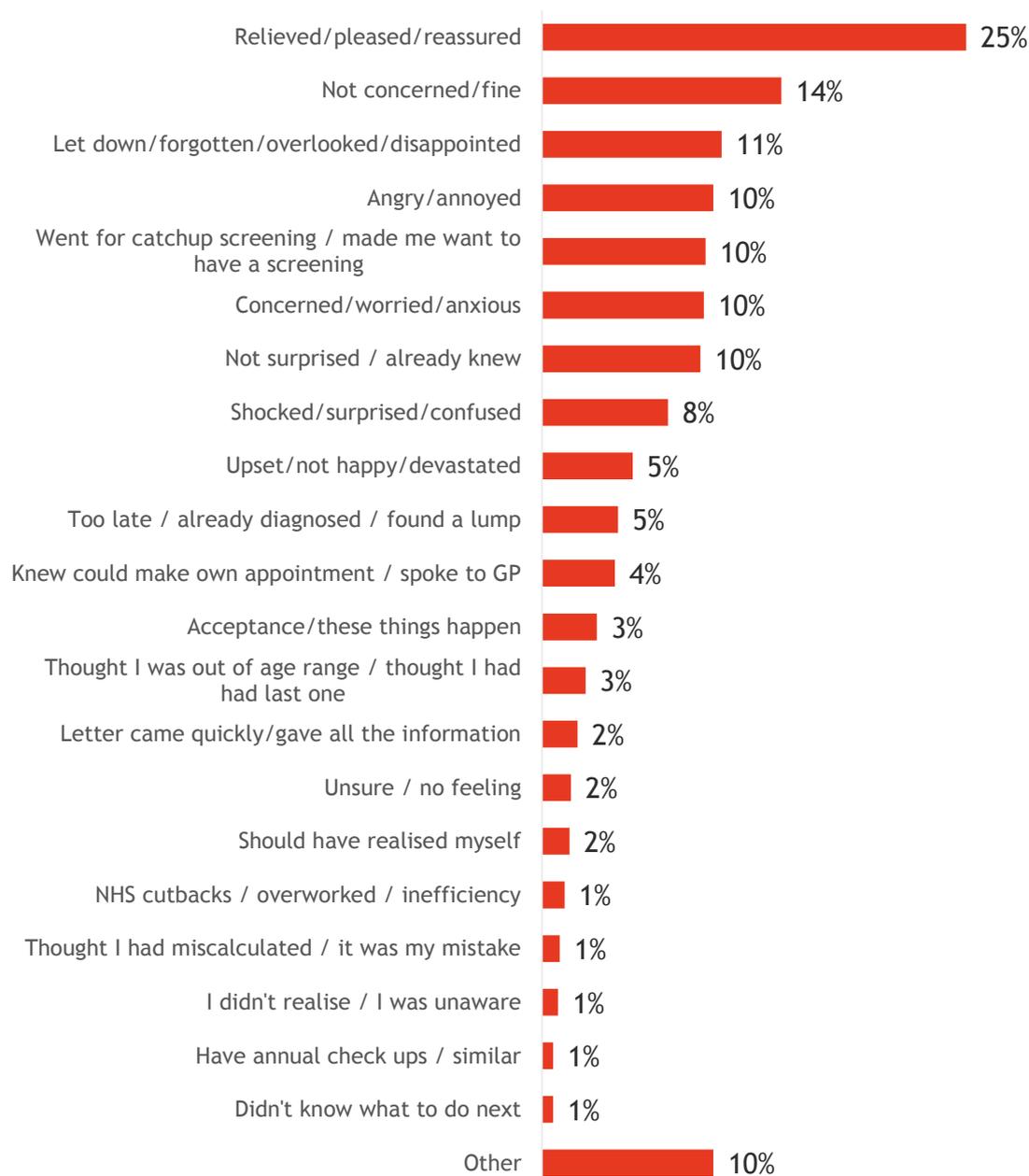
■ Yes ■ No ■ Don't know

Q14. Did you receive a letter from Public Health England earlier this year informing you that you had not been invited to your final screening appointment? Base: all (2496)

*Note - this question was seen only by those who hadn't previously told us that they had found out about the error through the letter from PHE. We have included those people in the 'yes' option in order to rebase the question to all respondents.*



## A quarter said the letter made them feel relieved or reassured, the most common reaction



Q15. How did you feel when you received the letter from Public Health England informing you that you had not been invited to your final screening appointment?

1  
7

Note: this question has been coded from an open-ended question

YouGov

Qual findings

# Reactions to the letter were mixed, depending on how personally affected by the error people felt



## Unaffected women

- Unaffected respondents were mainly pleased with the letter; They found it reassuring that the error was being addressed and something was being done about it. On the whole, they were not upset or concerned upon receiving the letter.

*“It was perfectly clear in my view as to what your options were and where you could go - it was informative. Made the risks and benefits of screening clear. The options were there”*  
Unaffected, 72, Kent

## Mildly Affected women

- Mildly affected respondents felt a lot more worried and concerned about the letter but were pleased that a letter was sent out; Some felt angry about the error, and the majority felt anxious right up until they received the results of their catch up screening appointments.

*“Put leaflet aside and thought here we go again - the NHS are letting me down. Very annoyed they got it wrong... people can still get cancer. [I] felt let down”*  
Mildly Affected, 72, Staffordshire

## Severely Affected women

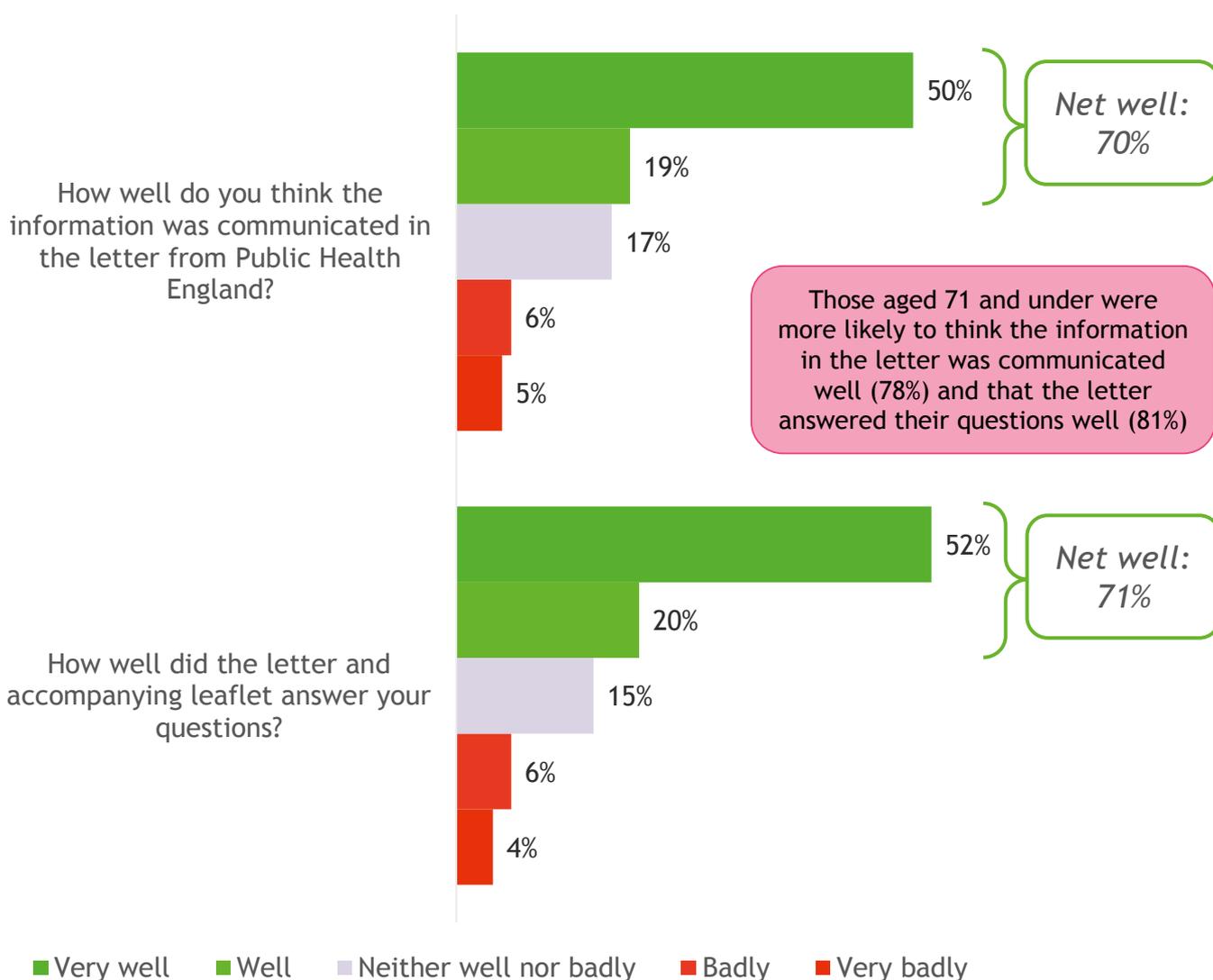
- Severely affected respondents had more mixed reactions to the letter; Some, who had already been diagnosed with breast cancer were very upset / offended that they had been sent the letter - they found it careless and impersonal that it wasn't tailored for those who had been diagnosed.
- Others, who hadn't been diagnosed at that time, felt surprised upon receiving the letter - they felt that they should do something about it and organise their catch up screening.

*“I felt rather upset [when I received the letter] as I had just had surgery to remove my breast, as I had cancer”*  
Severely Affected, 72, Manchester



YouGov

# Those who received a letter thought the information was communicated well and that the leaflet answered their questions



Q16 On a scale of 1 to 5, how well do you think the information was communicated in the letter from Public Health England? Base: all who received a letter (2308)

Q17 On a scale of 1 to 5, how well did the letter and accompanying leaflet answer your questions? Base: all who received a letter (2308)

# The letter was clear and informative for most, however it was felt to be inappropriate and upsetting for those with breast cancer



## Strengths

- For nearly all, the letter was felt to be clear and informative, providing all the information people wanted and details of where to go for more information;
- It was easy to understand and didn't use any confusing medical language;
- The majority felt that it was very clear about the risks and benefits of breast screening.
- The leaflet was also clear and well received



## Areas for improvement

- One was concerned that the letter said her appointment "may" have been missed - so she wasn't sure whether or not she was affected, which she found upsetting;
- The letter was not appropriately worded for those who had already been diagnosed with breast cancer - they feel that it should have been specifically tailored for them, as inviting those who are undergoing treatment or have already had mastectomies, to schedule catch-up appointments was felt to be thoughtless and offensive.

*"I thought it was very clear, understood completely what it was on about - it was very informative, had everything I needed to know"*  
Unaffected, 76, Peterborough

*"[I was] completely confused - because I tried my best to get an appointment, but I couldn't do so. Now I get a letter telling me that I wasn't silly and that it was an error. I blame the staff at local hospital"*  
Mildly Affected, 74, Norfolk

*"I was shocked when I got it! I didn't think I would have been invited. If I hadn't got cancer at time I would have just gone for catch-up appointment. But I was in treatment - so it was a bag of mixed feelings"*  
Severely Affected, 72, Hampshire

## Suggestions for how the letter could have been improved included...

*By offering some reassurance that the matter would be addressed and within a nominated timescale - how do I know if I am still missed off the screening list?*

*The letter made it sound as though I had been picked to attend the trial rather than having been missed. It should have been plainer and an apology would have been nice.*

*I felt that the letter greatly under stressed the gravity of the situation.*

*It set out clearly the need for screening and its advantages. What could have been indicated was some idea of how such a mistake could have been made, one which inevitably led to cancers remaining undetected and the possible results of this.*

*I think that it should have been an apology, and I should have been given a final breast screening appointment.*

*It gave too many reasons why it may be better to not have the test. Could have been less ambiguous.*

*It could have explained the cause of the error in more depth and detail.*

*By being more personalised. It felt like a generic letter to everyone in the same position. It made me worry again as it was such a long time since my initial recall to be re-scanned.*

*I got the feeling that although we were invited to book an appointment the advice was not very strongly worded and rather encouraged one to do nothing ... many negatives were stressed - discomfort, lack of clarity of the breast tissue in older women, and therefore difficulty in interpreting the result etc.*



Q18 How could the letter and leaflet have been improved?  
Base: all who received a letter

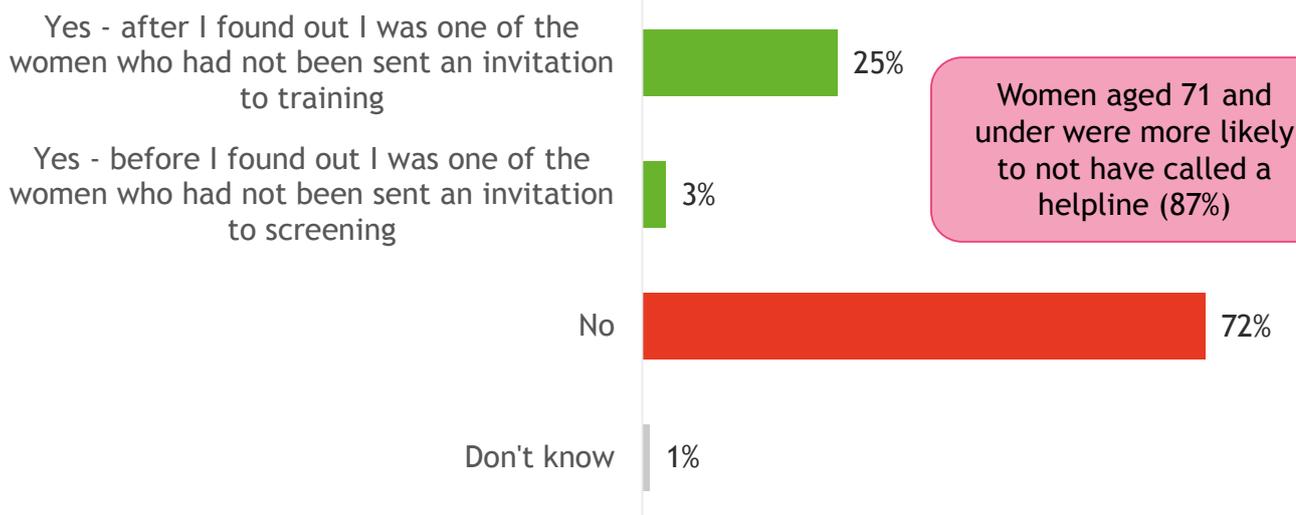
**YouGov**

# Perceptions of the helplines

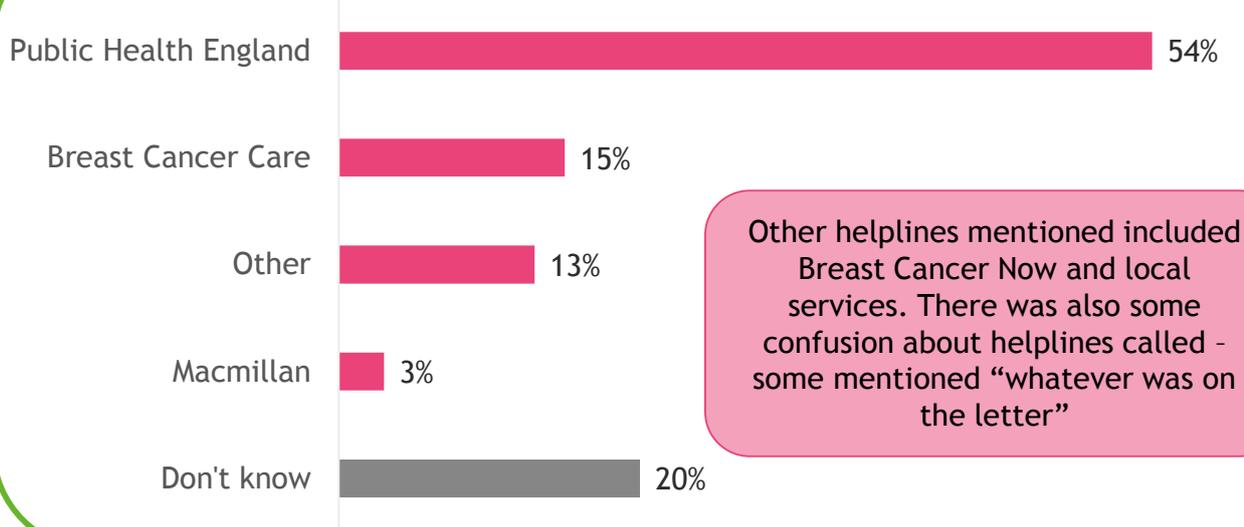


# Just over a quarter of women called a helpline for help and assistance regarding the invitation error

## WHETHER HELPLINE WAS CALLED



## WHAT HELPLINE WAS CALLED



Q19. Did you call a helpline regarding the invitation error? Base: all (2496)

Q20. Which helpline(s) did you call? Base: all who called a helpline (689)





# A number would have liked for the helplines to have been more proactive in helping them book their catch-up screening



## Strengths

- Many felt that the helpline was as good as it could be expected to be in regards to information given and the overall experience on the call;
- The majority felt that the call handlers were very 'polite, patient, friendly and helpful';
- Some said that the call handlers were able to answer their questions very effectively;
- Most felt their calls were answered very promptly - unlike many helplines, they appreciated that they weren't left on hold for a long time, waiting for someone to pick up;
- Those who were recommended to call Macmillan appreciated the offer - but not all felt the need to talk to a nurse, especially if they had not been diagnosed.



## Areas for improvement

- However, some found it frustrating that the helplines weren't able to book catch-up appointments for them there and then - they felt it would have made sense and saved time if they were able to do this;
- Others thought it would have been useful if the helplines could have provided them with details of their local units and who to contact to arrange their catch-up appointments;
- Some complained that the call handlers were unable to give them medical advice - which was one of the main reasons they were calling.
- A minority felt that the call handlers didn't treat them as individuals and didn't seem to care about their individual situations and concerns.

*"I rung it to make sure my new address had been recorded and see how long it may take to get a catch up app. Unhurried response... was clear and straight forward which gave me confidence"*

Unaffected, 72, Shropshire

*"They should have access and be able to give you an appointment there and then. That would show real care. There hasn't been any real care for me"*

Mildly Affected, 75, South East

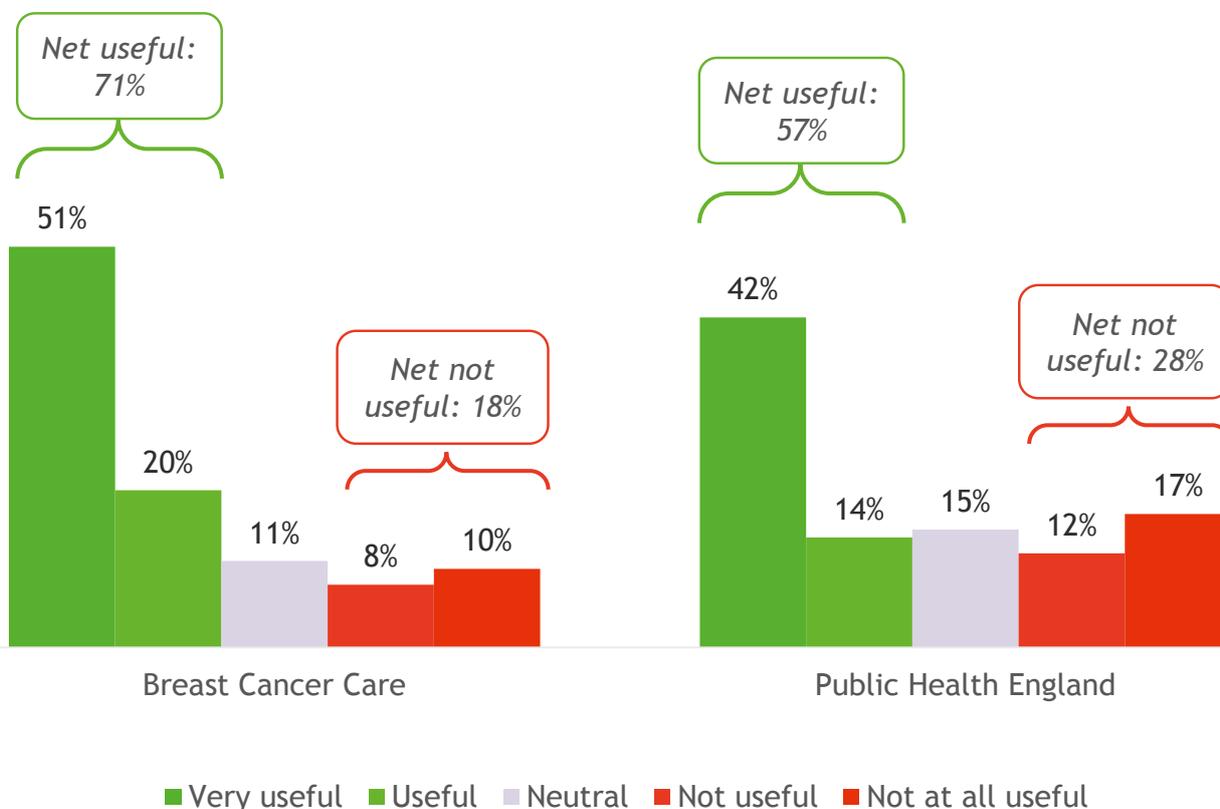
*"PHE didn't react when I said I had breast cancer - just told me that I didn't need a follow up then. They said they would investigate my case months ago - still no reply!"*

Severely Affected, 72, Manchester

**Important to note:** When discussing their experiences with the helpline, a number of respondents were unsure which specific helpline they had called - many just said they called the number on the letter. We believe that the majority called PHE first.

# Most respondents found contacting the helplines useful, with Breast Cancer Care providing the best support

HOW USEFUL WAS THE INFORMATION PROVIDED BY HELPLINE



Q21. On a scale of 1-5, how useful was the information provided by the helpline(s) you called?

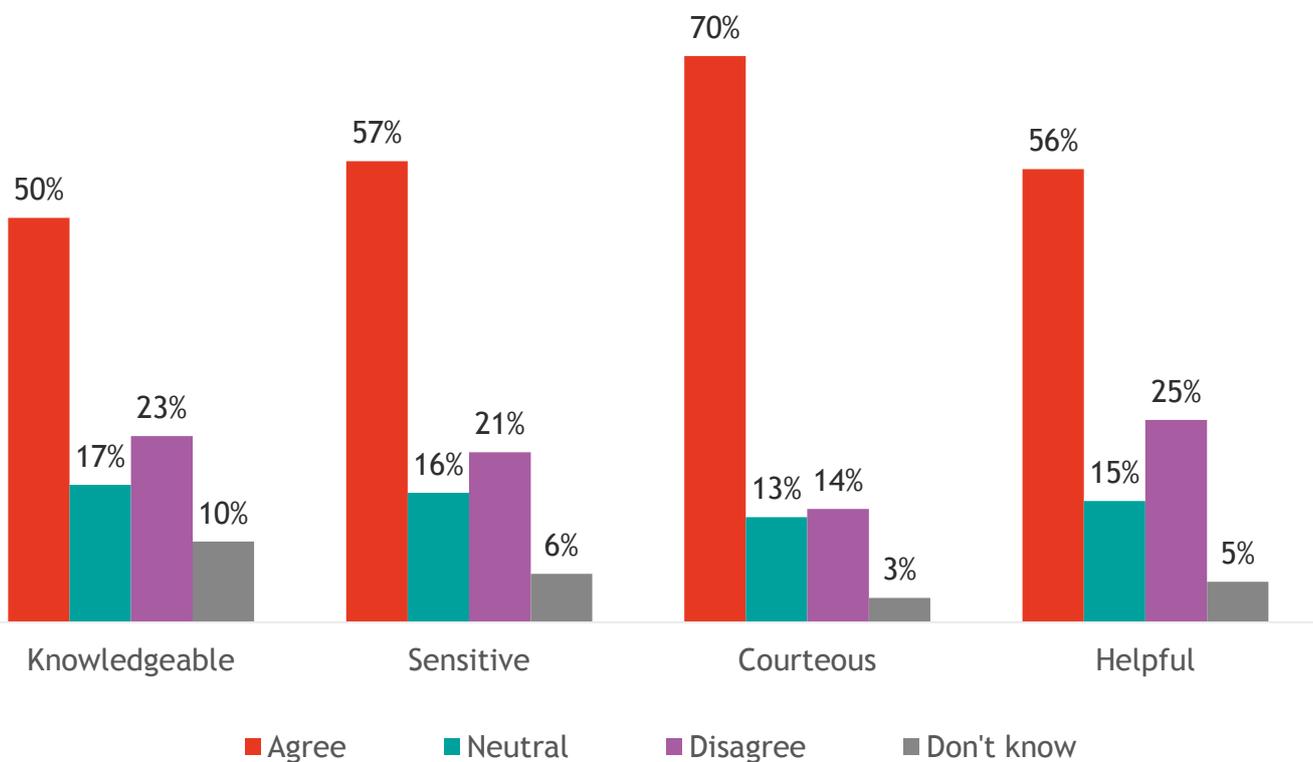
Base: all who called a helpline (689); Breast Cancer Care (106), Public Health England (373)

Note: Macmillan base size too low to look at



# Most respondents who called the PHE helpline had a positive experience with the call handlers

OPINIONS ON PHE HELPLINE CALL HANDLERS



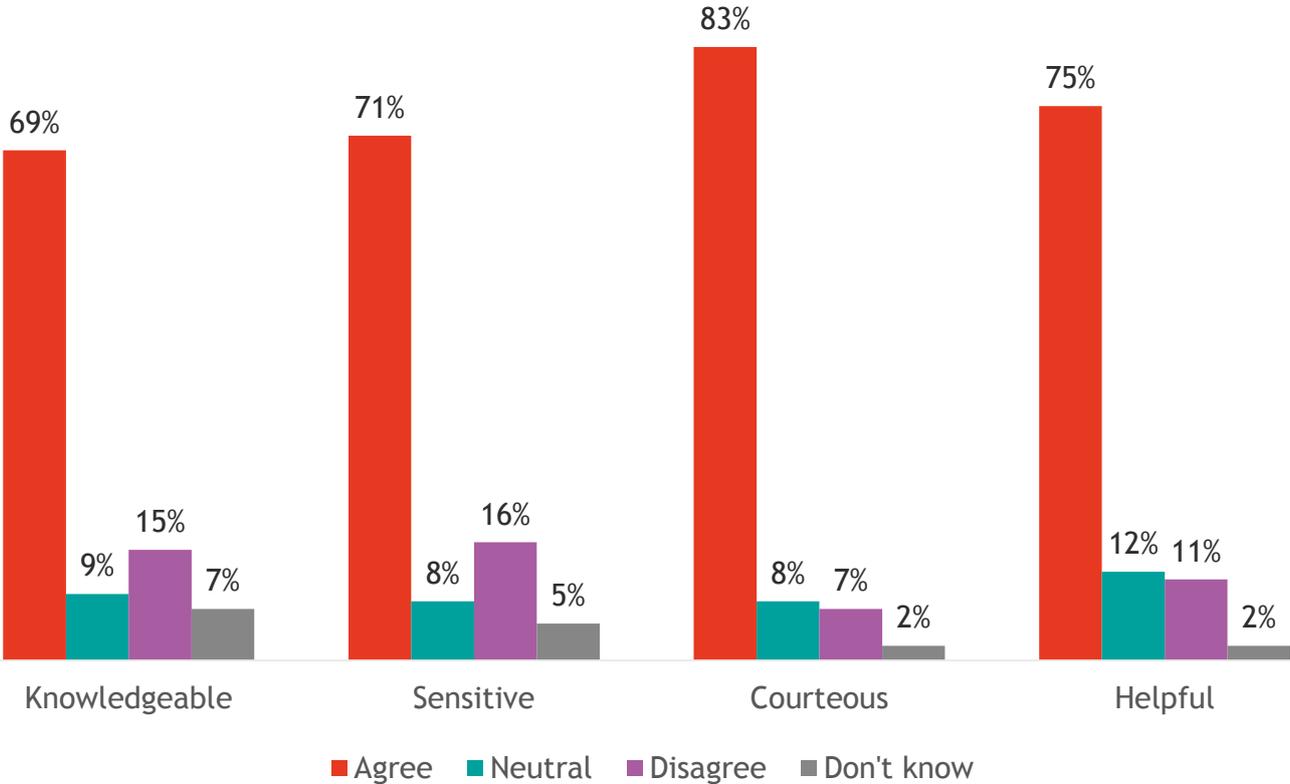
Q23a. When you called the Public Health England helpline, to what extent do you agree that the call handler was:  
Base: all who called PHE helpline (375)

2  
6



# Results were stronger for the Breast Cancer Care helpline handlers

OPINIONS ON BCC HELPLINE CALL HANDLERS



Q23a. When you called the Breast Cancer Care helpline, to what extent do you agree that the call handler was:  
Base: all who called Breast Cancer Care helpline (106)

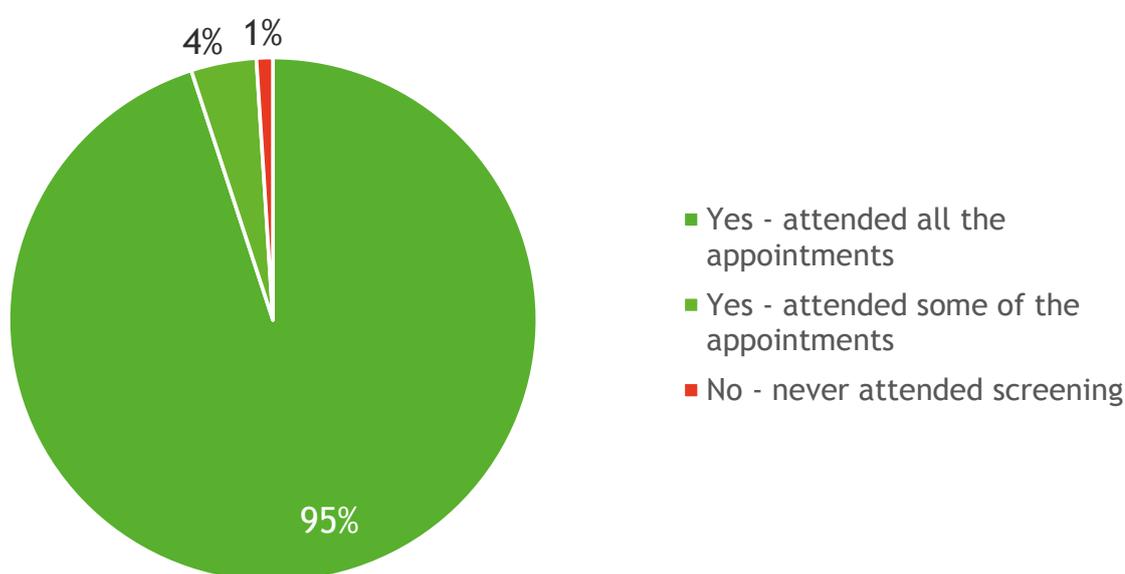


# Appointments for catch-up screening



# Nearly all women who responded to the survey attended all of their screening appointments prior to May 2018

SCREENING ATTENDANCE BEFORE MAY 2018



Those more likely to have attended all screening appointments include:

- Those aged 70 or under (97%)
- Those who knew they had not been invited to the final appointment before it was publicised (98%)
- Those who called a helpline (97%)
- Those who attended a catch-up screening appointment (98%)

Q6. Prior to May 2018, had you attended routine screening appointments for breast cancer? Base: All (2496)

2  
9

YouGov

## Prior to the error, most report attending all previous screening appointments; they would have attended the missed appointment if invited

- The majority of respondents interviewed reported attending all screening appointments to which they were invited prior to the screening error;
- There were a minority of cases where respondents had missed an appointment; this was due to either having already arranged screening separately, or in one case, due to living abroad at the time.
- Reasons for attending their screening appointments varied - some simply thought it was a sensible thing to do and that they should make the most of the free service; whereas others had more serious concerns, based on a personal / familial history of breast issues, call-backs in the past or other cancer scares.
- The common thinking by the majority of respondents is that attending screening is vital in order to detect cancer as early as possible and avoid more serious consequences down the line.
- Were it not for the error, all respondents stated that they would have attended the missed screening appointment if they were invited.

*"I always went. I thought if I can avoid cancer, so much the better"*  
Mildly Affected, 72, Staffordshire

*"[I attended] each time I was called... I just feel the tests are there and we should take advantage of them and get early diagnosis if possible"*  
Unaffected, 79, Yorkshire

*"Before the error I always went, as I felt it was necessary to detect any problems early."*  
Severely Affected, 72, Manchester

*"[I attended] every time I was called . . . A while ago a screening showed a mark and I had a cyst. I saw this as a warning"*  
Mildly Affected, 74, Norfolk

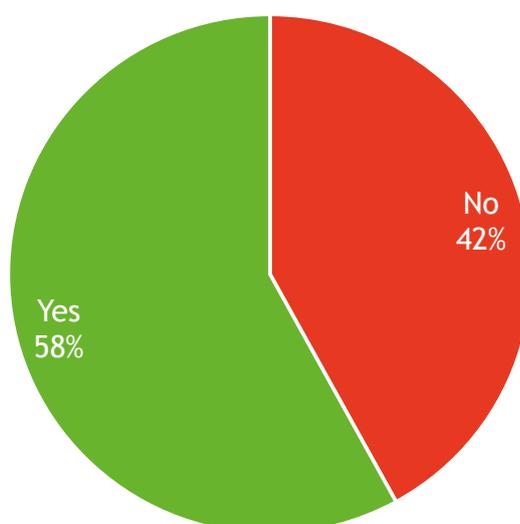
*"I went whenever I was invited because I lost my mother through breast cancer"*  
Unaffected, 73, Oxfordshire

*"I always went to every invitation. I felt it was important as there's cancer in my family. Cancer is a big thing for me. I strongly believe in the screening"*  
Severely Affected, 72, Hampshire



# Nearly six in ten had attended a catch-up screening appointment since May 2018

## WHETHER ATTENDED A CATCH UP SCREENING APPOINTMENT



Respondents were *more* likely to have attended a catch-up if:

- They were under the age of 73 (79%) (*note, those under 73 were given an appointment, while those 73+ were told they could make one if they wanted*)
- They found out about the error through the media and government announcement (64%)
- They had received a letter from Public Health England (60%)
- They had called a helpline (68%)

Respondents were *less* likely to have attended a catch-up if they were disabled (58%)

In the telephone interviews a few reported not attending as they were already part of regular screening as they had / have breast cancer.

A couple also spoke of the appointment not being a priority due to other health concerns / treatments, or being too hard to get to

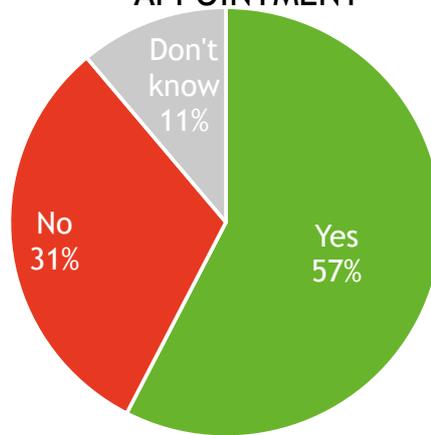
Q24. Have you attended a catch-up screening appointment since May 2018? Base: All (2496)



YouGov

Of those who did not attend a catch-up screening, 57% were told they could choose to book one if they wanted to, but less than a fifth did so

WHETHER INFORMED THEY COULD BOOK A CATCH UP SCREENING APPOINTMENT



WHETHER PROCEEDED TO MAKE A BOOKING



Q24a. Were you told you could choose to book a catch-up screening appointment if you wished? Base: All (1037)

Q24b. Did you choose to book a catch-up screening appointment?  
Base: All those told they could book a catch-up appointment (597)



## Qual findings

Some were able to arrange their catch-up appointments easily, whereas others have found it harder - a minority still haven't received their invites



## Strengths

- Most expected to received their letter within 3 weeks. Many had good experiences, and received their catch-up appointment invitation letters within this timeframe or even shortly after calling the helpline (some received this as little as a week after).
- Others were able to schedule their catch-up appointments easily by calling their local breast screening units.



## Areas for improvement

- Many received invitations for their catch-up appointments, however, due to their age, circumstances or illness, were unable to attend the scheduled time; because of this, some missed their catch-up screening, and others struggled to rearrange it for a convenient time / location.
  - A number were disappointed with how long it took them to receive a catch-up screening invitation - it took months for some
  - Some still haven't received their catch-up invitations, despite trying to contact their local units to arrange it or emailing PHE
- Some, who already had cancer, were upset that they were wrongly invited to catch-up appointments - they felt like they weren't important and weren't being treated as individuals. This also meant they had to go to the effort of cancelling the appointments.

*"I didn't go. Made an appointment but cancelled as I had a few other things going on. In that same week I had 3 different procedures in hospital so I wanted to cancel one of them"*

Unaffected, 72, Kent

*"Not very [satisfied] because the helpline didn't actually move the problem on at all, it didn't seem like it contributed to the resolution of the situation... I've had to ring again and again"*

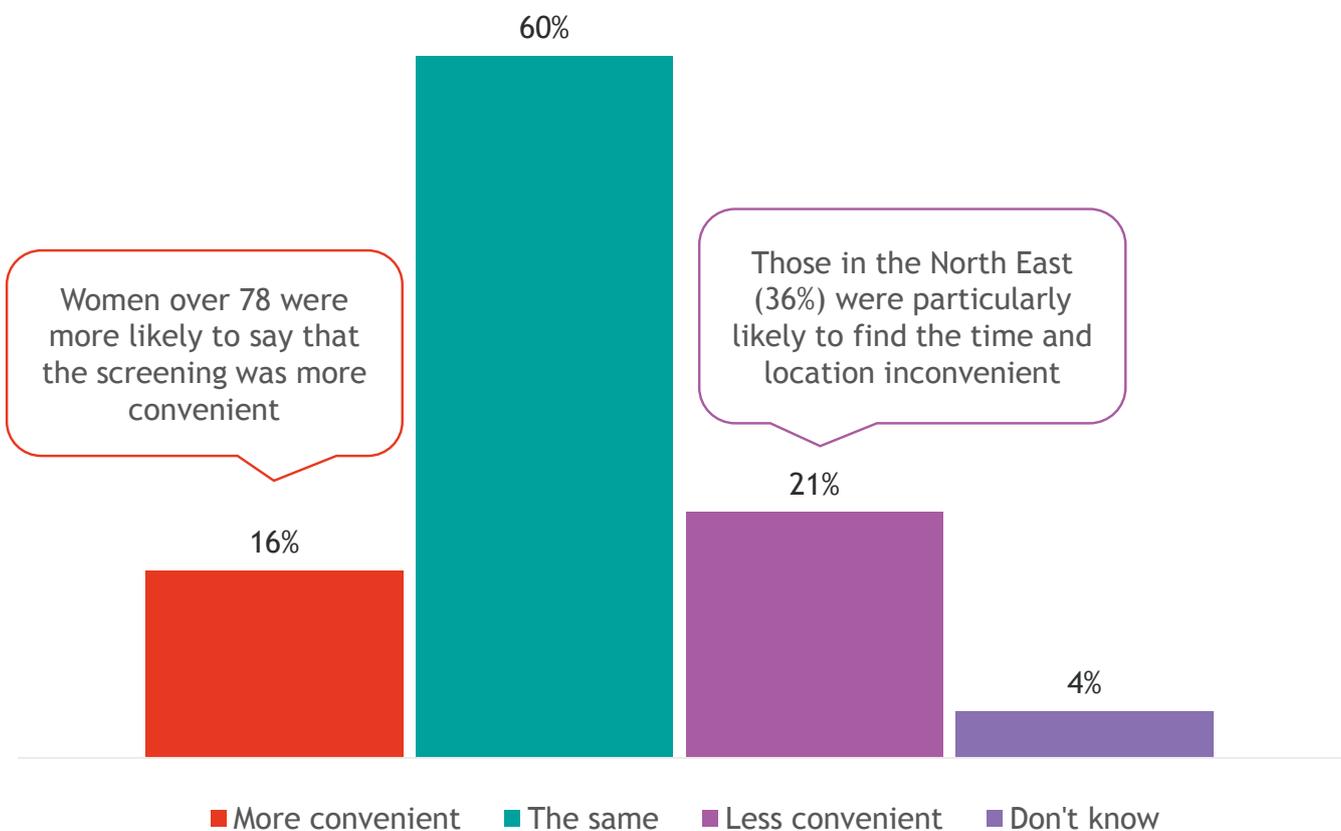
Mildly Affected, 74, Norfolk

*"Got an appointment for catch up screening. They didn't know I had cancer - wasn't their concern. I felt like a number - not important. Lack of communication. Upset and angry"*

Severely Affected, 72, Manchester

# Most women found the time and location of the catch-up screening about as convenient as a normal screening

WHETHER TIME AND LOCATION WAS CONVENIENT



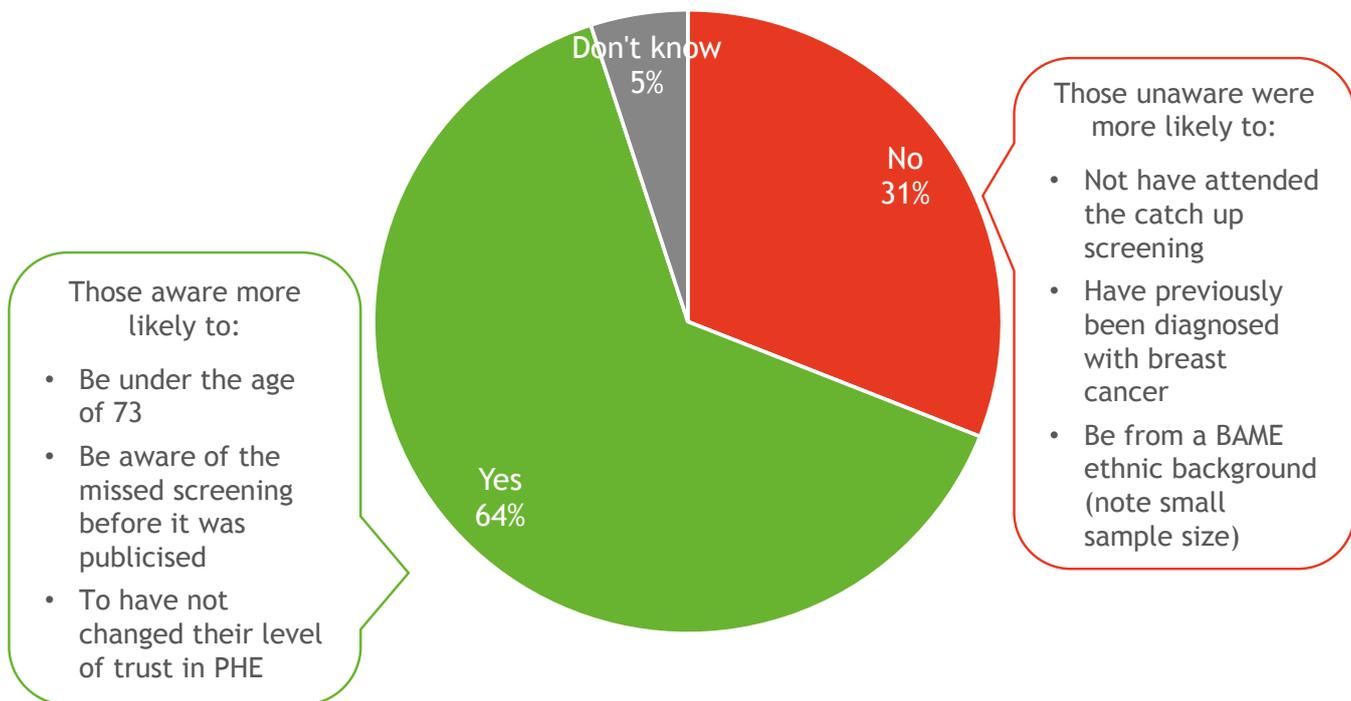
Q25. Was the catch-up screening appointment more or less convenient (in terms of time and location) than a normal breast screening appointment?

Base: those who booked a catch-up appointment (1549)



# Nearly two-thirds of women knew that they could request breast screening every three years after they turned 70

AWARENESS OF SCREENING REQUESTS



**Insight from the interviews**

Awareness was mixed - some claimed to be fully aware and already plan to do so in the future, whereas others were surprised to learn about this and think that it should be better publicised, so that women to not miss out on this opportunity.

Q5 Did you know that women over the age of 70 can request breast screening every three years, even though they are not invited automatically?

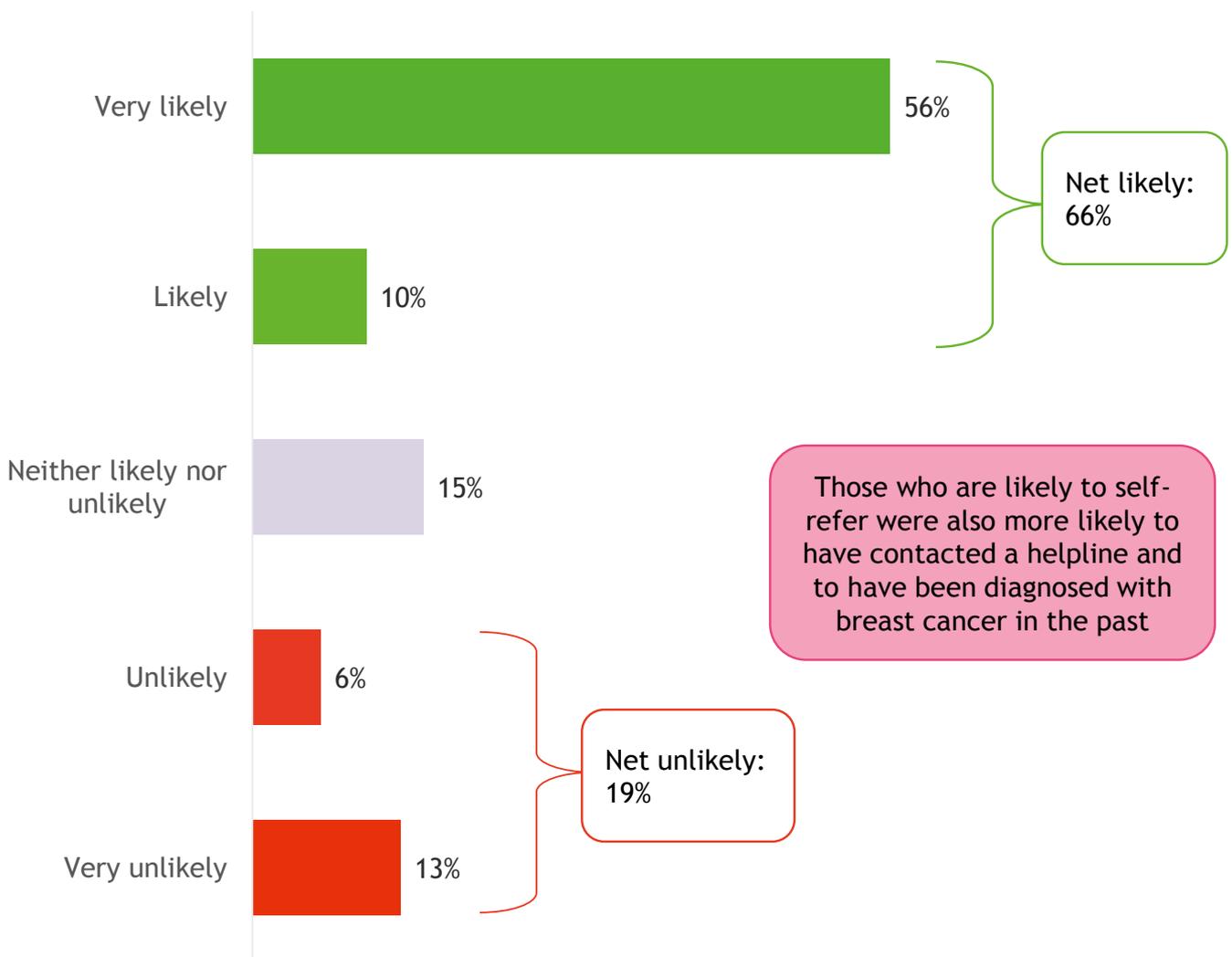
Base: all (2496)

3  
5



# Two-thirds felt they were likely to self-refer for breast screening in the future (over the age of 70), with younger women more likely than older

HOW LIKELY TO SELF-REFER FOR SCREENING



Q30. How likely are you to self-refer for breast screening in the future?  
Base: all over 70 (2632)



# — Impact of the error

# Almost a third said their level of trust in the screening programme had changed

## LEVEL OF TRUST CHANGED

■ Yes ■ No ■ Don't know



Those who called a helpline and who have been diagnosed with breast cancer were more likely to report that their level of trust had changed

Whilst women aged 71 and under and those who attended a catch-up screening were more likely to say it had not changed

## REASONS FOR CHANGED TRUST

*"I'm concerned by having no letter, and I've had no contact from PHE. I've had nothing".*

*"It's increased it because I've got the letter about the survey and I'm speaking to somebody from Breast Cancer Now. Screening would take a worry off my mind."*

*"We have not been explained to how this happened especially when I had had a lump found quite recently."*

*"I know I can contact help if I feel I might need to".*

Q32 Has this experience changed your level of trust in the breast screening programme?

Base: all (2496)



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## For most who were interviewed, their trust in the screening programme had not been negatively impacted

- On the whole, the error has not had a lasting impact on people’s trust in the breast screening programme
- Most report that the error has not affected their levels of trust; many were disappointed in it, but accept that *“these things happen”*, and don’t blame anyone in particular. They still think that the screening programme is a good thing and beneficial in helping to diagnose cancer early.
- For a few, the error led to them having greater trust in the programme; they were impressed by how much work has gone into rectifying the error and feel that there is no risk of it happening again, as those who run the programme have now *“smartened their act up”*
- However, there are some (particularly the more severely affected), whose level of trust has been negatively impacted; this is due to the harm they feel that the error caused them. Nevertheless most still think the programme is better than having no screening on offer at all.

*“They’ve smartened their act up now, because of the error. My treatment in the last month or so has been excellent, I can’t complain”*

Severely Affected, 76, Moray

*“They treated me excellently - I was delighted with the way they dealt with it . I still trust the programme - it was just a mistake”*

Unaffected, 79, Devon

*“Well if anything I’m more confident in it - I have more understanding of how it works now if anything”*

Unaffected, 76, Peterborough

*“Level of trust affected - so many affected by error and worried others have not told for sure or got their catch up appointments. So I can’t trust them fully. Bit haphazard. Who trusts someone who forgets they exist?”*

Mildly Affected, 75, Norfolk

*“Trust probably hasn’t changed. I feel like after the test has been done you probably get the right result, as long as the results are correct that all you need”*

Mildly Affected, 72, Essex

*“Info on why it happened would have been good. Level of trust - not changed. I will have screening every year now. Hope technical issue has been fixed; I think it would have been”*

Severely Affected, 71, Middlesex

## Personal impact from the error ranges from none at all, to those who feel like their lives have been significantly affected

### Unaffected women

- Unaffected respondents unsurprisingly do not feel that the error has had a significant impact on their lives;
- Apart from some feeling slightly nervous and apprehensive ahead of their catch-up screening / results, the error was not felt to have a negative impact on them;
- A minority even felt that the error (or, the response to the error) had a positive impact on them - as the letter encouraged them to go and get screening over the age of 70, whereas they wouldn't have done so otherwise.

*"I don't think it really has at all, I wouldn't even have known about it to be honest. It hasn't made me think 'oh I could have had cancer if it wasn't for the screening'. It hasn't affected me at all"*  
Unaffected, 76, Peterborough

### Mildly Affected women

- Mildly affected respondents feel that the error has impacted them much more strongly; they felt let down and forgotten;
- Many felt intense anxiety and worry that they might have cancer in the lead up to their catch-up screening / results;
- This negative impact was stronger for those who have had cancer in the past, or have friends / family that have been diagnosed - the risk of being diagnosed feels a lot closer to home for them.

*"Cancer may invade my body again and finding that I'd been forgotten made me feel bad. Never getting an invitation to correct that made me feel worse. Normally I can't fault the NHS so I feel very let down by it"*  
Mildly Affected, 75, Norfolk

### Severely Affected women

- Severely affected respondents understandably feel that the error has significantly impacted their lives; they were all subsequently diagnosed with breast cancer and have had to undergo treatment / surgery;
- All feel that their cancer could potentially have been detected earlier if it weren't for the error; and as such, many feel that they could have been spared such harsh treatment / surgery;
- However, some are mindful that they do not know for certain whether their cancer would have been caught at the missed screening.

*"I feel let down. It has upset me. If this had been found early - [the] impact on my general health would have been less"*  
Severely Affected, 71, Middlesex

## A ‘spotlight’ look at the severely affected indicates that many feel the error potentially delayed their cancer diagnosis

*“I feel let down by the public health which has not done its job adequately - the fact that my breast cancer could have been diagnosed 12 months earlier and lump removal may have been an option”*

Severely Affected, 72, Manchester

*“If I’d had the screening and they’d picked up an early lump before I did, it’s possible it could have been removed with less traumatic consequences. We are always told that if you go to a screening they can pick it up early”*

Severely Affected, 77, Midlands

Sonya feels that the system has failed her. She can’t help questioning whether the cancer could have been spotted earlier, and whether it wouldn’t have spread so much that she might not have needed such extensive surgery.

*“I would have been more upset if in middle of chemo and if felt sick - I would have felt angry. Because I had just been told I was cancer-free I was less angry. It possibly could have been caught earlier if I had [been] tested - as had two types of breast cancer”*

Severely Affected, 72, Hampshire

Anne was diagnosed one year after the missed screening. She spotted a lump and went to the GP. She believes that her cancer would have been spotted earlier and that she could have avoided having a mastectomy - she feels let down by the system.

Eleanor was diagnosed at 73 after finding a lump. She feels very angry about the error and that she went to all her previous screenings in the past, and yet missed the screening which might have found it. She wants to know more about how and why the error happened.

Lindsay was diagnosed after her catch-up screening. She is unsure whether her cancer would have been diagnosed at the missed screening, due to the 6 year gap. She sees it as bad luck, rather than being upset about it.

Julie was diagnosed in 2017 after going to her GP. She went through very harsh treatment and is now cancer free. She believes she might have been diagnosed earlier if it weren’t for the error, but cannot say for sure and as such, doesn’t believe in a blame culture.

[Pseudonyms have been used to protect respondents’ anonymity]

## Some felt no negative impact, but many experienced physical and emotional impacts

Qual findings

*“My cancer could have been caught and I wouldn't have had to have such harsh treatment”*

Severely Affected, 72, Manchester

*“I'm constantly aware that cancer may invade my body again and finding that I'd been forgotten made me feel bad. Never getting an invitation to correct that has made me feel even worse”*

Mildly Affected, 75, Norfolk

*“No I don't feel it impacted on me. It was a mistake which was covered quickly”*

Unaffected, 79, Devon

*“At first I wasn't terribly worried, but when my friend and neighbour fell ill and had to be operated on I got more and more anxious”*

Mildly Affected, 74, Norfolk

*“I don't think it really has [impacted me] at all to be perfectly honest . . . It hasn't made me think ‘oh I could have had cancer if it wasn't for the screening’”*

Unaffected, 76, Peterborough

*“It just makes me very cross, the fact that it happened. I'd like to know why it happened and how”*

Severely Affected, 77, Midlands

*“It's not impacted me at all, other than beneficially... because I wouldn't have had anything done otherwise. Unless I'd have found anything, I wouldn't have requested a scan (over 70)”*

Unaffected, 79, Yorkshire

*“it's difficult to say because there was 6 years in between the error and the catch up screening. They may have picked it up, but they might not of”*

Severely Affected, 76, Moray

*“I thought ‘here we go again, more battles with the NHS’, I have had enough . . . I am still disappointed by the professionals. They got it wrong”*

Mildly Affected, 74, Norfolk

*“It has altered my life. I wonder ‘why me?’ It has upset me. If I'd had the screening would it have been noticed earlier? Would I have been saved harsh treatment?”*

Severely Affected, 71, Middlesex

*“I'm disillusioned and disappointed . . . there is a slight worry in my mind that I could have missed something in this period”*

Mildly Affected, 75, South East

*“I don't think it has actually [impacted me] as I wasn't aware, I intended to make an appointment, which I hadn't done... but when the letter arrived I realised that I needed to”*

Unaffected, 73, Oxfordshire

4  
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## Qual findings

## Despite upset and frustration from some, most feel that the error was responded to as best as it could have been

### Unaffected women

- Most unaffected respondents were highly satisfied with the way the error was responded to;
- Although a couple were concerned about how the error could have arisen in the first place, all think that it was handled as best as it could have been - acknowledging that mistakes happen;
- They don't have any suggestions for how else the error could have been responded to - they "can't see what else they could have done".

*"The error happening is the worrying aspect. Things can go wrong in any system - but no back up checks for so long - took a long time for them to know about the error. People have pulled together to put it right and make sure people are screened. I am satisfied with the response"*

Unaffected, 72, Shropshire

### Mildly Affected women

- Mildly affected respondents were much less satisfied with the way the error was responded to, citing feelings of disappointment and frustration;
- This is due to the fact that many of them had to take matters into their own hands to arrange their catch-up appointments, and some still haven't been able to schedule them in yet;
- Nevertheless, despite their frustration, many don't know what else could have been done in response the error
- However, others would have liked the way the catch up appointments are scheduled to have been better organised and more prompt.

*"Because I took matters into my own hands it turned out ok - if you left it to them I wouldn't have been satisfied. I might have had to wait months for the appointment. It was the uncertainty with them - I wasn't prepared to wait"*

Mildly Affected, 72, Essex

### Severely Affected women

- Severely affected respondents have mixed feelings about the response to the error;
- Some felt that the response was sufficient and that they couldn't have done anything more other than the letters/ leaflets, helpline and catch-up appointments;
- However, others are dissatisfied, reporting that the response left them feeling "ignored" and "forgotten" - they are upset that effort wasn't made to find out who had breast cancer, instead letters were simply sent out to everyone;
- Some want more information about the review process and what progress has been made; Others think they should receive some sort of compensation, monetary or otherwise.

*"It hasn't really been dealt with has it - if they got a list of people who were not called for this screening which they must have. Now could they not have followed up and found out how many of those people have been diagnosed with breast cancer"*

Severely Affected, 77, Midlands

# — Future considerations



## Improvement ideas (from those affected)

1

Letters to be personal; send letters which acknowledge whether they have been diagnosed with cancer or not.

2

Provide objectives and timings for the review and any progress updates they can expect to receive.

3

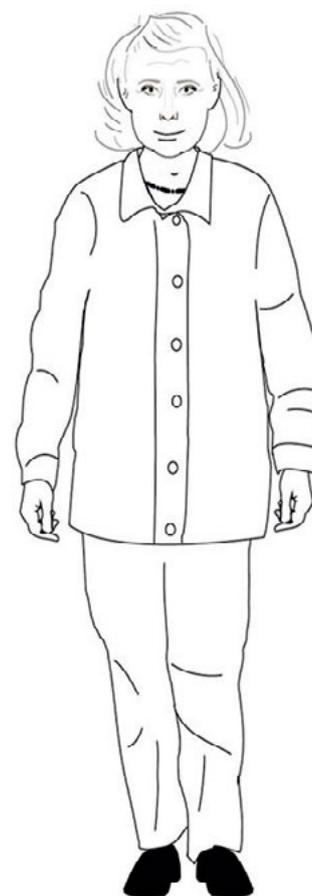
Provide more information on what steps have been / will be implemented to ensure the error does not occur again.

4

Ensure all women get their catch-up screening invitation letter within 3 weeks.

5

A couple who were diagnosed with cancer would have liked the information about the error to have come from their doctor - this would have been a more personal and sensitive approach.





# Case studies from the qualitative interviews



# Case Study 1: *Katie did not feel affected by the error; she thought it was handled well*

Unaffected



## Katie, 72 years old, Kent

Katie attended breast screenings on a regular basis, considering it a good way to identify any potential health issues. She felt more comfortable getting checked frequently, rather than waiting until she detected a problem. She felt unaffected by the error.

### How Katie realised there had been an error

- Katie was made aware of the error through the media
- She couldn't keep track of when her last appointment was, so was unsure if the error affected her personally

### Experiences of the letter / helpline

- Katie felt that the letter was informative and laid out her options in a very clear way
- She also called the Breast Cancer Care helpline to get her final appointment sorted, and spoke to a 'polite and helpful' man, who was quick to advise
- She felt that her questions were answered in an appropriate way, and that the helpline was a useful tool

### Perceptions of the error and its subsequent impact

- Katie was not upset about the error, and felt that the issue was dealt with in the best way possible
- She still trusts the Programme but wants to know why the error happened, and how it developed
- In the end, she did not attend her catch up appointment, as she felt it was not a priority due to other health concerns and appointments

*"I was satisfied that they were doing their best. I don't really see that there was anymore that they could do. It must have been a panic from their point of view. It was a job and a half on their hands"*

*"It was perfectly clear as to what your options were - it was informative and there was no ambiguity. Made the risks and benefits clear. The options were there and it was down to you to make your own mind up"*

*"I didn't feel an impact in any way, shape or form. The only niggle is how long it took them to discover [the error]. But overall, the programme is a great thing to have; it saves lives. The impact on me was negligible at best"*



7

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# Case Study 2: Claire did not feel affected by the error; she found the letter to be reassuring

Unaffected



## Claire, 72 years old, Shropshire

Claire had previously been attending screenings, as she was aware that breast cancer could develop at anytime, and that missing a screening could allow the cancer to develop further without treatment. When she had not been contacted for an appointment for a few years, she became concerned and questioned if she could have been affected by the error, once she learned of it.

### How Claire realised there had been an error

- Claire had begun to think about chasing up a screening appointment when she heard about the error in the media
- She was comforted that the missed appointments were not her own fault - that it was not the case that she was neglecting her healthcare
- She received her letter shortly afterwards, which reassured her and let her know that the issue was being dealt with

### Experiences of the letter / helpline

- Claire felt that the letter was straightforward and honest, with no jargon
- She was reassured by the promise of a follow-up appointment
- She also called the PHE helpline to ensure that her new address had been recorded and to learn when she would be invited to a catch-up appointment
- Her experience with the helpline was positive, and the female responder was reassuring and reasonable

### Perceptions of the error and its subsequent impact

- Claire attended the catch-up appointment but (at the time of the interview) still had not received her results - 6 weeks after attending
- She would attend further screenings in future, to take advantage of every opportunity to stay healthy
- She has not been personally affected by the error and her trust has not been damaged; she has seen the reparations that have been made to ensure this error does not happen again

*"[The helpline was] very good indeed. Unhurried response; it was clear and straightforward. They were well-spoken - gave me confidence in them. They repeated things too- which was good. Didn't march through it, so I understood"*

*"The error happening is the worrying aspect. Things can go wrong in any system - but no back up checks for so long - it took a long time for them to know about the error. Should be a fail-safe somehow. People have pulled together to put it right and make sure people are screened. I am satisfied with the response"*

*"No real impact in my case... [but there has] been a niggle... keeps coming up again and again. Have to make a call or email e.g. to get appointment as went away. 6 weeks and still waiting for results. Overall it is not a lasting impact. Will get sorted"*

## Case Study 3: Sandra was affected by the error; she feels forgotten and let down that she still hasn't had a follow up appointment

**Mildly Affected**



### Sandra, 75 years old, Norfolk

Sandra was conscious that she was a high-risk case for breast cancer as she had already been diagnosed with another form of cancer in the past, and her grandmother had suffered from breast cancer. She attended breast screenings frequently, and would have attended the most recent appointment, had the error not occurred.

#### How Sandra realised there had been an error

- Sandra first learned of the error when she received the letter - she had heard about the issue in the media but had assumed it did not relate to her
- She had been diagnosed with cancer in the past, so always had the worry in the back of her mind about cancer coming back
- When she received the letter, she could not remember when her last appointment had been, as she had been dealing with other health issues

#### Experiences of the letter / helpline

- Sandra felt the letter was slightly unclear; it did not explicitly say that her appointment had been missed, rather that it was a possibility
- She called the PHE helpline and her call was answered quickly by a friendly person who told her that the relevant details would be passed on
- She was told that she would receive a letter about a catch up appointment but that letter never arrived

#### Perceptions of the error and its subsequent impact

- At the time of the interview, Sandra had still not been invited to a follow up screening
- She was 'hurt' that there was no follow up appointment, and 'felt forgotten'
- She emphasises that this error must not happen again, and that it is unethical to tell people that they will be guaranteed a follow up appointment, when this is untrue

*"When I got the letter, I was shocked. I felt terrible that I had been forgotten. I don't blame the NHS, but I felt worried as I had [been diagnosed with] cancer before, so thought I was high-risk. I felt upset and worried"*

*"I'm constantly aware that cancer may invade my body again and finding that I'd been forgotten made me feel bad. Never getting an invitation to correct that has made me feel even worse. Normally I can't fault the NHS so I feel very let down by it"*

*"My level of trust has been affected - so many were affected by the error and I am worried that others have not been told for sure, or got their catch up appointments. I can't trust them fully. Bit haphazard. Who trusts someone who forgets they exist?"*



9

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## Case Study 4: *Madeline was affected by the error; she has lost confidence in the programme and is still waiting for her catch-up screening appointment*

**Mildly Affected**



### Madeline, 74 years old, Norfolk

Madeline attended breast screenings every time she was called after the year 2000, when she moved back to the UK after living abroad. She had previously been diagnosed with having a benign cyst after a dark mark had appeared on the scan.

#### How Madeline realised there had been an error

- Madeline realised that it had been 3 years since her last screening, and had previously asked her GP about how to keep on top of appointments
- She had heard something about the error on the news, but was not sure if she had been affected
- Her concerns were confirmed when she spoke to a friend; the error made her feel angry, as she'd done her best to inform herself about the screenings

#### Experiences of the letter / helpline

- Madeline felt that the letter was quite clear; it was obvious that there had been an error of inputting and was clear about the risks of missing screenings
- She called the helpline and spoke to an 'average' person who was fairly helpful
- She had hoped to have been fast-tracked to a local hospital for an appointment, but this was not possible

#### Perceptions of the error and its subsequent impact

- Madeline was conscious that she was unlikely to receive a sincere apology from the people responsible for the error
- At the time of the interview, she had still not been given a date for her catch-up appointment
- She no longer has confidence in the Programme and her level of trust in those in charge has changed entirely

*"At first I wasn't terribly worried, but when my friend and neighbour fell ill and had to be operated on, I got more and more anxious, I thought it could happen to me... what are they doing?"*

*"Not very [satisfied] because apart from listening to what I have to say and asking a few questions, the helpline didn't actually move the problem on at all, it didn't contribute to the resolution of the situation. I personally do not think it's sufficient as I've had to chase them up after lots of silence"*

*"I don't think there's anything more you can do because no one is going to hold their hands up and say they're very sorry. I'd like to people to admit when they've made a mistake in our local practice, patients never ever get an apology. You're not to complain"*

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## Case Study 5: Sonya was severely affected by the error; she was diagnosed with cancer and wonders if it could have been detected earlier

**Severely Affected**



### Sonya, 71 years old, Middlesex

Sonya was very health-cautious and frequently attended breast screenings prior to the error. In 2017, she found a lump in her breast and attended a meeting with her GP whereupon he subsequently sent her to hospital for a mammogram and a bioscopy. It was discovered that she had breast cancer. She is now in remission but the illness has had a lasting impact on her diabetic health.

#### How Sonya realised there had been an error

- Sonya was not told that she could ask to attend breast screenings at age 70+
- She was unaware of the scale of the error at first, as she does not watch the news
- She got a letter in May 2017 informing her of the mistake, but had already been diagnosed with breast cancer
- She felt the letter should have been sent to her doctor so that they could contact her directly

#### Experiences of the letter / helpline

- Sonya did not find the letter very explanatory nor useful
- The wording was apologetic, but she felt it could have caused some recipients to panic
- When she called the PHE helpline, it was mentioned that she may have been eligible for compensation
- She spoke with a 'kind and understanding' man who recommended that she called the Macmillan line

#### Perceptions of the error and its subsequent impact

- Sonya felt that there was no point in being angry at the situation - 'mistakes happen'
- However, she wonders if the cancer could have been detected earlier, and possibly lessened in severity
- She considers the error a failure and hopes that it is fixed as soon as possible
- She thinks the error should have been more widely publicised - and that the investigation findings should be shared

*"You rely on the system to call you in. I feel let down. I have got breast cancer and need to get it sorted. If I had been invited, the cancer would have still been there, but may not have spread so much or [required] such extensive surgery. The system failed me"*

*"There seems to be a long time between letters; information on why it happened would have been good... Not enough information on what is going on. My level of trust has not changed [but] I will have a screening every year now. I hope the technical issues has been fixed"*

*"It has altered my life. I wonder 'why me?' and it has upset me. If I'd had the screening, would [the cancer] have been noticed earlier? Would I have been saved harsh treatment? I relied on the system to call me in and to work. The impact on my general health would have been less"*

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## Case Study 6: Julie was severely affected by the error; she was diagnosed with breast cancer and was surprised that PHE didn't acknowledge this in the communications

**Severely Affected**



### Julie, 72 years old, Hampshire

Julie attended every breast screening appointment as she has a history of cancer in her family. She had heard from a friend that women were not invited to screenings after the age of 70, therefore so assumed she had had her last screening. She, sadly, developed breast cancer prior to finding out about the error.

#### How Julie realised there had been an error

- Julie learned about the error when she was already having radiotherapy for her breast cancer
- She was surprised that those who sent the letter did not already know that she had cancer
- Had she not already been under the care of a Cancer Care Team she would have attended the catch up appointment

#### Experiences of the letter / helpline

- Julie was not satisfied that the communications did not refer to her diagnosis; she didn't need to be invited to a catch up screening
- She called the PHE helpline to inform them of her diagnosis and ask how the investigation would be handled
- The staff member was as unclear about who Julie should be getting into contact with to find out more
- She was transferred to Macmillan and then received a helpful response

#### Perceptions of the error and its subsequent impact

- Julie accepts that she will never know if the error led to her developing cancer, but tries to remain positive
- She admits she would have felt more angry if she was mid-treatment, but as she was just told that she was cancer-free, she was more forgiving
- She does, however, question if her illness could have been caught earlier, had it not been for the scale of the error

*"The letter was clear. The phone people listened to me. They did let me talk to a nurse. Just have to accept it - can't dwell on it. I need to move on. I am trying to be positive about it all"*

*"I received a letter in July/August 2017 saying that I was part of an error - and that they will investigate. I am just happy to be cancer-free. I was invited to a follow up appointment, but then the hospital sent me a letter acknowledging that I had cancer so they cancelled it on my behalf"*

*"They have realised it and held their hands up. They feel they need to try and rectify it. Not all would have got cancer since. They are trying to get everyone a catch up appointment. It shouldn't have happened - but this is computers for you. Not fool proof!"*

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