Public Health England

**Internal PHE investigation into the national breast screening incident of 2018**

The national breast screening incident announced in May 2018 was in response to a system failure of the NHS Breast Screening Programme (NHSBSP) to offer over 120,000 women their final screen in the 36 months before their 71st birthday (that is up to age 70 years and 364 days), a requirement set out in national service specifications from November 2013 onwards. This issue was initially identified by PHE when investigating concerns about the operation of the Age X trial. Further investigation carried out jointly between PHE, NHS England and the Department of Health and Social Care (DHSC) identified that the principal cause of the incident was not the Age X trial itself. Rather it was a mismatch between how age is expressed in national service specifications and how age is defined by the underlying IT and other operational systems that choose which women to invite for a screen. Attempts to correct this mismatch so as to ensure that women received their final invitation in the 36 months before their 71st birthday turned out not to have succeeded.

This internal PHE review has sought to identify the underlying factors which have contributed to the national incident. Other than those leading the Age X trial, interviews were undertaken only with PHE staff as an independent review is taking a pan-system approach and will report directly to the Secretary of State. The findings of this internal review are summarised in this report which describes the mismatch in definitions of age then identifies the most important underlying causes.

It should be noted that, whilst the national service specification was published in 2013, and that was therefore when the mismatch occurred, the patient notification exercise for the incident went back to 2009 for two reasons:

- 2009 was when the Age X trial started and, as it was initially thought that there was a coding problem with the trial algorithm, it was concluded that it would be appropriate to start then; and
- the Tripartite Oversight Group (PHE, NHS England and DHSC) decided on a precautionary approach given the lack of clarity in the offer to women and a Ministerial desire to ensure no women were missed. The first year that all parts of England had completed the extension of breast screening from age 64 to 70 was 2009, making it the first possible point there could have been a reasonable expectation of the offer of a screen extending to 70 years and 11 months.

This decision was agreed with Ministers and officials at DHSC and NHS England.

**Principal cause:**

The principal cause was a mismatch between how age is expressed in national service specifications from 2013 onwards and how age has been defined by the operational systems that choose which women to invite for a screen. The national service specifications indicate that the last invitation that a woman should receive from the routine programme should be in the 36 months preceding her 71st birthday. However, the operational systems in place from the start of

the programme (which dates back to 1988) have used calendar year of birth instead of birth date to decide which women to invite for a screen. The result is that a woman's final invitation is in the calendar year in which she turns either 68, 69 or 70. A woman invited in the early part of the year in which she turns 68 but whose birthday is later that same year will actually receive her final invitation when she is still age 67. The national service specifications will not therefore be met in her case as this is not within 36 months of her 71st birthday.

From interviews with relevant PHE staff, together with a review of contemporaneous correspondence, the process of producing the national service specifications in April and November 2013 was led by the Department of Health (DH, now DHSC). The documents had the DH and NHS Commissioning Board (NHSCB, now NHS England) logos on the front and refer to the relevant statutory provisions under which the specifications were made. Staff in the NHS Cancer Screening team who transferred into PHE in April 2013 helped produce the documents working with colleagues in NHSCB and DH.

In 2016, a new IT system, Breast Screening Select, gave much greater visibility to the ages at which women were being invited for screening. This highlighted discrepancies in some women being invited well below the age of 50 which were a priority for services to address, along with concerns about slippage in the three year interval for screening, termed 'round length'. As a result, the PHE screening team issued guidance in October 2017 about managing round length. This reiterated the age definition in the service specification and included guidance on strengthening the use of failsafe systems to ensure that women received an invitation within 3 years of their previous screen up to their 71st birthday

However, in reviewing these increasing concerns, the PHE screening team commissioned a data run from NHS Digital in October 2017 to look at the upper age at which women were being invited for a screen. This was completed in January 2018 and demonstrated that not all women were receiving a screen in the 36 months before their 71st birthday. As it transpired, the failsafe systems were not compatible with the algorithm used by the Age X trial which operates in 67 of 80 breast screening services in England. The Age X trial algorithm had the unforeseen effect of preventing these women from receiving their further invitation. This was why it appeared at first that the Age X trial was the cause of this incident.

**Underlying causes:**

The following are the key issues which emerge from the internal investigation.

1. **A lack of clarity about the NHSBSP offer to women since the programme's inception in 1988.**
   a) The nation-wide offer to women was not specifically defined from the start. For its first 25 years, there was no nationally-agreed service specification for the NHSBSP. Instead there was a broad expectation that screening should be offered at three year intervals from approximately the age of 50 to approximately the age of 65, later extended to approximately the age of 70. In fact this was a 6 year age extension because it was achieved simply by adding two screening rounds each being three years. This situation led to a lack of transparency and consistency about some key variables, including the definition of age used within the programme. It allowed the emergence of differences between policy decisions, reasonable public expectations and operational practice in delivery of the programme. Prior to the introduction of the Breast Screening Select IT system in 2016, these differences were often not visible to those managing the breast screening programme nationally.

b) The 2013 national service specification introduced a definition of the upper age limit that was not in line with the existing operational systems used by the breast screening programme. The first attempt to produce a single national service specification was in 2013 as a result of the changes set out in the Health and Social Care Act. An initial version in April 2013 was superseded by an updated one in November 2013 which added the statement that the service should "ensure that women who have already attended for screening are offered screening again within 36 months of their previous screen until they reach the age of 71." In the early investigation of this incident, PHE's advice was that this statement should be taken to represent the reasonable public expectation of the programme, that the last invitation should be received within 36 months of a woman's 71st birthday. This advice was supported by NHSE and DHSC. The production of these 2013 national service specifications was led by DH and ultimately agreed between DH and the NHSCB. There is no evidence that this was intended as a change in policy on the age at which women should stop receiving invitations routinely. However, it appears to be the point at which a clear difference was introduced between the overt description of what the NHSBSP should offer and the way it operated in practice.

c) Absence of evidence for a specific upper age limit for breast screening. The academic evidence and the advice from UK National Screening Committee appears not to have considered the specific age range for breast screening as opposed to the general view that the programme should serve women between 50 and 70. The reality was that women may have received invitations between 49 and 67, or between 52 and 70, depending on their birth date and when their practice was screened in a three year cycle. It is not clear whether there is evidence to favour either of these. The review led by Sir Michael Marmot in 2012, commissioned by the Government and Cancer Research UK, appears to have mostly considered evidence up to age 69, and this also appears to have been the case for the Government's Breast Screening Advisory Committee in 2006. Both are likely to have assumed the birth-age definition. The evidence did not, therefore, lead to a precise definition of the appropriate upper age limit for screening.

**2. Lack of clear shared understanding of governance of the breast screening programme**

a) The creation of the Section7A arrangements in 2013. Breast Screening was one of the defined National Public Health Functions which the 2013 changes defined as being delivered through the Section 7A arrangements. Section 7A is a formal agreement between DH (now DHSC) and the NHS Commissioning Board (now NHS England) to provide funding for the NHS to deliver a range of national clinical public health functions including screening and immunisation. PHE is not a party to the S7A agreements but provides a range of key services that support DHSC and NHS England in the delivery of the Agreement. These include providing the secretariat to the UK National Screening Committee, advising on the evidence to underpin specifications, and quality assurance for the programme.

The arrangements are clear that providers of screening services are contractually responsible to local commissioners, who are in turn responsible to NHS England. NHS England are responsible to DHSC and ultimately to the Secretary of State through a formal agreement of which the national service specifications form a part. PHE's role is in providing specialist advice and quality assurance and in leading the work on the IT systems that support screening. The documents in 2013-14 and the governance review in 2016 led by DH reiterate this role although interviewees and documents have shown that some people misunderstood this and felt PHE had a performance management role.

As a result, the usual processes of commissioning, performance management and regulation that apply to the majority of healthcare services have not always been applied in the same way to the breast screening programme.

b) Quality assurance. Part of the confusion seems to stem from a misunderstanding of the role of the quality assurance function that transferred into PHE in 2013. This function, as set out in Professor Bentley's Report of 2015, is a professionally-led process to facilitate improvement primarily aimed at supporting providers. It does not undertake regulatory or performance management functions which rest with CQC and NHS England respectively. This confusion is partly understandable as previously the QA teams reported to the SHA Regional Director of Public Health, a Director on the Board of Strategic Health Authorities, and, in fulfilment of that role, was expected to intervene where quality assurance demonstrated major concerns. This responsibility transferred to NHS England in 2013 on abolition of the SHAs.

c) PHE corporate oversight. A focused review of PHE's oversight of the breast screening programme has looked at the papers at PHE's then National Executive meeting and relevant sub-committees. It was appropriate that one major issue of the governance of the Age X trial was considered at the Executive in November 2013, and there are no other issues that this review has identified that would be appropriate to have been discussed there. Most screening issues, such as the Section 7A agreement and national service specification and its mismatch with the operational IT definition, were for assurance through the Section 7A oversight mechanisms. Specific pieces of work related to PHE's specific support and advice function were either carried out by Internal Audit as part of the programme agreed with them or were shared with DH specialist teams for review, such as the 2015 and 2017 screening IT strategies. There could have been greater visibility for the implementation of Breast Screening Select which would now be picked up in the ICT report to PHE's resourcing sub-committee and in the DH-PHE Section 7A services scorecard that is considered by PHE's Delivery Board.

## 3. Complexity in the operation of ageing IT legacy systems

a) Ageing IT systems. In 2013, responsibility was transferred from DH for two outdated IT systems which supported the delivery of breast screening. These were the National Health Application and Infrastructure Services (NHAIS) system, which transferred to the NHS CB, and the National Breast Screening Service site (NBSS), which transferred to PHE. These two legacy systems remain and require replacement to allow for better functionality and performance. Although PHE and NHS Digital have introduced improvements to address the legacy problems and risks, there are multiple practical issues and risk associated with their operation.

b) Variation in systems used in local breast screening services. There were also different systems used by local breast screening services to invite women for a screen. This was from the start of the programme in 1988, the most notable being that 67 of the 80 local services used a system called the Recall Interval/Safety Period (RISP) whilst others especially in Anglia and Gateshead used a different system, replaced in 2010 by a more reliable one called Next Test Due Date (NTDD). In 2010, DH, through the NHS cancer screening team, also commissioned changes to the IT algorithms to enable the Age X trial to operate. The detail of the coding was complex as all women were coded to receive a further screen in the calendar year they reached either 71, 72 or 73 and then a further code

was written to suspend women in the control arm of the trial from receiving an invitation for a further three years. For simplicity, this was only implemented in the services using RISP, but it was this code which subsequently prevented the failsafe systems introduced later from ensuring that all women received a final screening invitation in the 36 months before their 71st birthday.

**c)** Improvements in IT. Since 2013, PHE has introduced two important new IT systems, Breast Screening Select and Breast Screening Information System, on top of the two legacy IT systems. These have created much greater functionality and resilience and have allowed for greater visibility of women's age at invitation. It was these improvements, coupled with detailed analysis of data and discussions with providers, that identified the issues underlying this incident.

**Conclusion**

The NHS breast screening incident had as its principal cause a mismatch between the definition of age in national service specifications and that used by the routine operational systems which choose which women to invite for a screen. This was underpinned by the lack of a single national service specification, including specific definitions of age, from the start of the programme in 1988 accompanied by the development of variation in practice between local breast screening services prior to the 2013 health system changes. At this point, variation was firmly embedded with few people in senior roles fully understanding the detailed operation of the programme. This was compounded by misinterpretation of the roles and responsibilities of different organisations through the Section 7A arrangements, including the quality assurance functions. There has also been a lack of a strategic approach to the replacement and development of IT underlying screening programmes which has been separate from the arrangements for IT for the majority of healthcare services.

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