



# Government response to the Independent Breast Screening Review recommendations

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# Foreword

Following publication of the report from the Independent Breast Screening Review on 13 December 2018 and the written ministerial statement that I made at the time, I am now pleased to be able to publish the Government's substantive response to each of the 15 recommendations made in the report.

I would like to take this opportunity to reiterate my thanks to the two chairs of the review, Lynda Thomas and Professor Martin Gore CBE, and the vice chair Peter Wyman CBE DL for their comprehensive report. We would particularly like to pay tribute to Professor Gore, who sadly passed away on 10 January 2019.

Martin was an integral and well-loved member of the health community throughout his career, which involved several invaluable pieces of work for the Department of Health and Social Care. He approached the Chairmanship of the Independent Breast Screening Review with an admirable drive to find the answers for the women affected and with a forensic attention to detail. Martin was respected in the department and throughout the health system both nationally and internationally. He was one of the founding fathers of medical oncology and made a huge difference to many people's lives, helping them live longer and better. He will be greatly missed.

The purpose of screening is to reduce mortality and morbidity in members of the population who appear healthy and have no symptoms, by detecting conditions at an earlier, more treatable stage. Approximately 11 million people in England are invited to participate in a screening programme each year. One of these programmes is our world-leading breast screening service, which invites more than 2.5 million women for a test every year. Screening saves around one life from breast cancer for every 200 women screened; which equates to 1,300 lives saved from breast cancer each year in the UK.

As I said at the time, it is essential that we take all necessary actions to learn from any problems identified in the breast screening programme. In responding to these recommendations, we have also taken account of the findings from the recent investigation into adult screening programmes conducted by the National Audit Office, which was published on 1 February 2019. In some cases, similar issues were highlighted about where improvements can be made in terms of how our national screening programmes are delivered.

Some of the areas highlighted for improvement require a more considered response and I am therefore pleased with the progress that Professor Sir Mike Richards is already making with his review into cancer screening. Where possible, improvements to the programme are already being taken forward, whilst for others it is appropriate to wait for Professor Richards to report and this is reflected in our response.

## **Government response to Independent Breast Screening Review recommendations**

We are rightly proud of our breast screening programme and all who work in it. It is imperative that we quickly put in place any improvements that are needed to maintain our position of excellence and continue to save lives now and for generations to come.

**Steve Brine, Minister for Public Health and Primary Care**

# 1. Breast screening policy

Recommendation 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.

- 1.1 The Government agrees with the recommendation.
- 1.2 The UK National Screening Committee is considering the age at which automatic screening invitations should cease. It has carried out a review of international literature and practice relating to women between 69 and 71. The committee will summarise the evidence and share with expert stakeholders in order to provide a view to Ministers in March 2019. This will be followed by work with commissioners and providers to develop a consistent UK offer. Until this has been agreed, the current service specification will remain and the upper age limit for the national breast screening programme in England will continue to be defined as 70 years and 364 days.
- 1.3 Based on outcome of the work at 1.2 above, the Secretary of State for Health, NHS England and Public Health England, under section 7A of the National Health Service Act 2006 ('the 2006 Act') as amended by the Health and Social Care Act 2012, will confirm that the current National Service Specification for the breast screening programme in England reflects this age definition.
- 1.4 NHS England will ensure that any revisions to the National Service Specification are appropriate and consider the implementation requirements before approving. The specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply. This revised specification will be completed and published as soon as possible.

Recommendation 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.

- 1.5 The Government agrees with the recommendation.

- 1.6 NHS England will communicate the breast screening National Service Specification to local NHS commissioners and breast screening providers and publish it on NHS England's website.
- 1.7 NHS England will ensure any relevant NHS England-held training processes and programme materials reflect the National Service Specification.
- 1.8 Public Health England will continue to ensure that the National Service Specification, and the upper age range it includes, is used as the basis for providing quality assurance of the National Breast Screening Programme to NHS providers and commissioners. Public Health England's quality assurance role, as also set out in the investigation by the National Audit Office, will support communication of any changes to providers.

Recommendation 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.

- 1.9 The Government agrees with the recommendation.
- 1.10 The Government will ensure that all public information that refers to the breast screening programme published by the NHS, Public Health England or the Department of Health and Social Care, clearly sets out what the breast screening 'offer' to women is, including providing the necessary clarity on when they are likely to receive their final screening invitation and from what age they are entitled to self-refer.
- 1.11 As highlighted in the Review, there has been a lack of a defined offer to women since the beginning of the breast screening programme in 1988 until the 2013 National Service Specification. The Review was right to highlight that this confusion was created, in part, by the public-facing information reflecting different understandings. The Government recognises that we must have clarity about what women should expect from the breast screening programme and that this should be reflected in all facets of the programme, including all the programme's public-facing documents and information.
- 1.12 Public Health England has already undertaken an interim review of its printed and online professional guidance and public information materials to ensure they consistently specify the invitation age range from 50 up to a woman's 71st birthday, in line with the current National Service Specification. In addition, NHS England has communicated to service providers through their local teams that any

local communications aimed at the eligible screening population should also include and reflect the age at which women are invited to screening.

- 1.13 Following any recommendation made by the UK National Screening Committee, Public Health England and NHS England will ensure that all government-produced information in written and electronic formats aligns with the UK National Screening Committee's advice and the National Service Specification.

## 2. IT and processes

Recommendation 2.1: In the immediate term, a review should be conducted by PHE, 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, in particular “Don’t just design your part of a service. Consider people’s entire experience, and the infrastructure and processes involved...”.

- 2.1 The Government agrees with the recommendation.
- 2.2 The Review rightly recognised the hard work and dedication of staff in the breast screening centres, whilst highlighting that manual entry of data and overly complex user interfaces can lead, despite their best efforts, to women missing invitations to a screening. This was also reiterated in the recent investigation into screening carried out by the National Audit Office. The Government is determined to take steps to minimise this potential for user error.
- 2.3 A senior cross-health service group, led by Public Health England, will focus on reducing the manual inputting of data and making the system more user-friendly. This work will be supported by breast screening unit staff to make sure the views of the frontline users, who use the systems every day, are at the forefront of deliberations. As part of this process, unused functionality has already been identified and work has begun to remove these superfluous functions to streamline the system, making it simpler for the end user. This review group will make recommendations by June 2019.
- 2.4 A longer-term solution is the introduction of a new IT system for the breast screening programme that will aim to minimise the need for manual entry as well as provide easier, more rapid access to performance data, allowing issues to be identified more easily. The usual procurement and development process for government IT projects will be followed, engaging with end users at all stages.

Recommendation 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.

- 2.5 The Government agrees with the recommendation.
- 2.6 Following the report from the Independent Breast Screening Review and the parallel investigation into adult screening services carried out by the National Audit Office, the Government has initiated a strategic review of the IT requirements to support our national screening programmes. This review is being undertaken within the context of the cross-system Digital Transformation Portfolio and in partnership with Public Health England, NHS England and NHS Digital and will fall under the auspices of the recently announced NHS X. In preparation, a business case for future capital investment is being prepared that will consider the development of a new platform for screening IT programmes.
- 2.7 The review will be carried out in parallel to the review of adult cancer screening programmes being undertaken by Professor Sir Mike Richards and will be informed by Professor Richards' interim recommendations (to be published in April). Any decisions on screening IT will follow on from the outcome of Mike Richards' review and recommendations that he makes about how the cancer screening programmes should be delivered. Decisions on screening IT will build on existing work that has been undertaken on replacing the National Breast Screening System.
- 2.8 The Government recognises the need for joined-up oversight and governance of the IT systems across organisations that support delivery of our national screening programmes. The Government will confirm what any new governance structure will look like once the strategic review of screening IT has completed. The Government agrees that any 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.

Recommendation 2.3: Once a decision has been taken about the specific ages at which women should be invited to breast screenings (see recommendation 1), the IT system/s should be reviewed to ensure they function to deliver that policy.

- 2.9 The Government agrees with this recommendation.
- 2.10 The Review highlighted that the breast screening incident was primarily caused by a discrepancy between the upper age limit as set out in the breast screening programme's National Service Specification since November 2013 and the way the current programme has been run since it was created.

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- 2.11 Following confirmation that, in the interim, the upper age limit for breast screening should remain as 70 years and 364 days, Public Health England is working with NHS Digital and Hitachi (who operate the current systems) to align the systems with this definition.
- 2.12 Public Health England has hardcoded into the IT system the age parameters used for failsafe to ensure that all services identify eligible women who are aged 52 years and 364 days and 70 years and 364 days who have not been screened in the previous 36 months.
- 2.13 This process compliments a new monthly assurance process at a local level that has been implemented to monitor 35 key indicators, including age, to make sure that women are invited in accordance with the National Service Specification. Exceptions are identified and communicated by Public Health England to NHS England to action with breast screening units as indicated. There is national oversight of the results through a monthly assurance panel chaired by Public Health England and comprising representatives of NHS England and NHS Digital. Concerns arising from this group will be escalated to the most appropriate part of the system. As the National Audit Office reported, NHS commissioners are expected to act on any concerns raised by breast screening units or by Public Health England.
- 2.14 Further work is being undertaken in parallel by Public Health England and NHS England to ensure other risks for missing a final invitation are identified and managed, including programme slippage.
- 2.15 NHS England, supported by Public Health England's quality assurance function and visits to breast screening units every 3-5 years, will remain vigilant for any indication that the staff and IT services that support breast screening are not inviting women up to the upper age limit, as set out in the National Service Specification for the programme.
- 2.16 The Department of Health and Social Care, NHS England and Public Health England will also receive reports on the proportion of eligible women being invited for their final screen by 70 and 364 days at each Section 7A Accountability Meeting to ensure awareness.

Recommendation 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* (user need; privacy and security; interoperability and openness; and inclusion).

- 2.17 The Government agrees with the recommendation.

2.18 The Government can confirm that any new IT systems introduced to support our national screening programmes will follow the principles set out in the Secretary of State for Health's vision for digital, data and technology in health and care.

## 3. Governance

Recommendation 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 of Public Health England's governance so far as it affects screening programmes.

- 3.1 The Government agrees with the recommendation
- 3.2 Officials from the Department for Health and Social Care and Public Health England are engaging with Professor Sir Mike Richards to ensure that his review gives consideration to the governance of all screening programmes and takes into account the findings from the National Audit Office's investigation into screening and the national Cancer Strategy.
- 3.3 The Terms of Reference for Mike Richards' Review include making recommendations, if needed, on how NHS England interacts with Public Health England and the Department of Health and Social Care to translate screening policy into implementation and on how screening programmes should be commissioned, delivered, performance managed and quality assured in the future.
- 3.4 The Tailored Review of Public Health England concluded that "Public Health England performs necessary functions and has made good progress with integrating the staff, cultures, working practices and physical assets of the variety of organisations from which it was created, building an organisation that provides expert advice on all aspects on health protection and improvement". Its recommendations have now been shared with Professor Sir Mike Richards, so he can consider its relevance to his review.

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

- 3.5 The Government agrees with the recommendation.
- 3.6 The Government agrees that the indicator in the section 7A agreement should be very clear about the population that is eligible for screening. The population eligible for screening is based on people registered with their GPs, from data obtained from the National Health Application and Infrastructure Services

database. The performance indicator is based on the percentage of those people invited that receive a screen.

- 3.7 The Department of Health and Social Care and NHS England, with advice from Public Health England, will review the relevant indicator and update it for use in assessing performance against the 19/20 NHS Public Health Functions Agreement. Any revision to the indicator will reflect the recommendation from the UK National Screening Committee on the upper age limit for breast screening, as reflected in the National Service Specification.

Recommendation 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.

- 3.8 The Government agrees with the recommendation.
- 3.9 As with the related recommendations in 1.3 and 2.3, the Government is committed to making sure that the offer to women is clear, reflected in public-facing materials and implemented consistently across all breast screening services, including in the policy and related programme guidance and training. Public Health England's Screening Quality Assurance Service will reflect any changes in the programme policy and confirmatory training will be held with relevant teams once any changes are made and to support their visits to breast screening units every 3-5 years.
- 3.10 In the interim, Public Health England has developed bespoke training and supportive documentation on the new assurance process for screening Quality Assurance staff and the screening and immunisation teams embedded in NHS England.

Recommendation 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.

- 3.11 The Government agrees with the recommendation.
- 3.12 The Government agrees that providers should deliver the service that is set out in the National Service Specification. The Review highlighted the discrepancy between the National Service Specifications from 2013 and the way that the breast screening programme was being delivered in practice. Once the updated National Service Specification has been published, all providers should be very clear about

the service that they are expected to deliver and NHS England will take the necessary measures to ensure that it is consistently implemented in provider contracts through its local commissioning teams. The Government notes that similar issues were highlighted in the report from the National Audit Office's investigation into adult health screening.

- 3.13 More generally, the Government agrees that contract management processes should be sufficiently robust to ensure that providers do deliver against the National Service Specification and hold providers to account where they fail to do so.
- 3.14 NHS England is taking steps to ensure that there is effective oversight of commissioning arrangements through a refresh of its internal governance. A new Breast Screening Programme Board within NHS England will, as part of its remit, be tasked with overseeing implementation of the new National Service Specification across breast screening providers. The new Programme Board will include representation from partner organisations, including Public Health England, and provide a route of escalation from Public Health England's Screening Quality Assurance Service.
- 3.15 The terms of reference of Professor Sir Mike Richards' review include reviewing both the current arrangements for national commissioner oversight of screening programmes and how screening programmes should be commissioned, delivered, performance managed and quality assured in the future.

## 4. Handling of the incident

Recommendation 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.

- 4.1 The Government agrees with the recommendation.
- 4.2 The Government agrees that incident response protocols should be reviewed to ensure that they are aligned with each other and with the processes for responding to incidents in the national screening programmes.
- 4.3 As with any incident, NHS England and Public Health England will complete an internal lessons learned process on the incident response. The key findings of these will be made available to Professor Sir Mike Richards' review of screening programmes and which will consider whether further recommendations are necessary.
- 4.4 The new Breast Screening Programme Board within NHS England will ensure that there is a clear route of escalation for any concerns that are identified locally that could have wider national implications. The new Programme Board will include representation from partner organisations, including Public Health England, and provide a route of escalation from Public Health England's Screening Quality Assurance Service.

Recommendation 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.

- 4.5 The Government agrees with the recommendation.
- 4.6 After the incident response protocols have been reviewed, NHS England will communicate any updates to those delivering operational changes arising from the review of incident responses and from the lessons learned activities, with support from Public Health England.

## 5. Impact on women

Recommendation 5.1: 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 to provide clarity over this and ensure the women have the support they need.

- 5.1 The Government agrees with the recommendation.
- 5.2 The Government can confirm that the incident's clinical review process, to assess potential harms to those women affected by the incident who have been diagnosed with cancer, will be completed as sensitively and as quickly as possible. This work had been paused pending publication of the report from the Independent Breast Screening Review, in recognition that the Review's findings could have impacted the process.
- 5.3 In line with the conclusion of the Review that the incident, and therefore any associated harm, can only have occurred following the publication of November 2013 National Service Specification, the incident start date has been revised. The revised start date for the incident is now the formal date that the specification was due to come into force, 1 April 2014.
- 5.4 Public Health England has completed the initial stage of the review to identify the women with cancer whose outcome may have been adversely affected by the incident. This process has provisionally identified which women in the revised cohort affected by the incident will require a further investigation to determine if any harm has occurred. These women will be offered the chance to share their detailed personal clinical history within a local clinical review process, which will end with an offer for the affected woman to meet with their treating physician to discuss whether the missed screen could have impacted their prognosis. This applies equally to next of kin, where contact can reasonably be made, in relation to those affected who have sadly since died. The initial contact to all women is due to be commenced in 2019. It is accepted that not all women will be in a position to have their individual meetings by this date as they may still be undergoing active treatment.

## 6. AgeX trial

Recommendation 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.

- 6.1 The Government agrees with the recommendation.
- 6.2 The breast screening age extension randomisation trial began in 2008 and is investigating the clinical benefit and cost-effectiveness of extending the programme to women aged 47-49 years and 71-73 years. The Government agrees that the AgeX trial should continue until its planned end date.
- 6.3 The randomisation trial is led by researchers at the University of Oxford and will give directly comparable mortality data on the effectiveness of screening in these age groups, including the benefits and harms. The results, which will be available in 2026, will provide internationally important evidence on whether screening in the extended age ranges is effective or not. The trial will become the world's largest randomised controlled trial on any subject. It is already larger than any previous breast screening trial, with over 1.5 million women recruited.
- 6.4 The UK National Screening Committee will carefully consider the results of this trial and make any necessary recommendations for the breast screening programmes.

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