

To: Rt. Hon. Victoria Atkins, M.P.  
Secretary of State for Health and  
Social Care

NHS England  
Wellington House  
133-155 Waterloo Road  
London  
SE1 8UG

cc. Jonathan Marron  
Director-General, Department of  
Health and Social Care

3 March 2024

Dear Secretary of State,

## **Referrals into the very high risk breast screening programme: action the NHS is taking to support affected women**

Following the conversation that we had last week and the verbal briefings to Department officials on 13 February 2024 and Special Advisors on 23 February 2024, we are writing to update you on the issue that we have identified.

This is in respect of the failure to refer for annual MRI surveillance a number of women who have been treated with radiotherapy to their chest for Hodgkin Lymphoma.

Women who have had this treatment between the ages of 10 and 35 are at higher risk of developing breast cancer than the general population and should be referred to the very high risk service within the Breast Screening Programme.

A cohort of women who received radiotherapy between 1962 and 2003 were initially identified as a potential at risk group in 2003, and now a sub group of those women, 1,487 in total as of February 2024, have been identified as not currently receiving annual MRI testing who should be.


NHS England is taking this very seriously and the NHS will do everything possible to ensure these women will be offered appropriate screening, at speed, in a compassionate and respectful way which is tailored to their clinical history.

### **Background**

In 2000, research showed that women who had received radiotherapy treatment to their chest for Hodgkin Lymphoma were at higher risk of developing breast cancer.

In 2003, the Chief Medical Officer commissioned a patient notification exercise (PNE) and the process of identifying women was co-ordinated by the then cancer networks and surveillance for this group of women was conducted through symptomatic services. Women do not start annual MRI testing immediately following treatment – but between 8 and 15 years after treatment depending on their age at the time they were treated. This is because the increased risk does not emerge until approximately 10 years later.





In 2007 the Department of Health's Cancer Reform Strategy (CRS) was published which indicated that the way surveillance was conducted for women at very high risk of breast cancer in the symptomatic breast service was variable, and it recommended that the NHS breast cancer screening programme took responsibility for annual testing for women referred to it.

NHS England was established in 2013 and took over responsibility for commissioning NHS Breast Screening services as part of its delegated public health responsibilities under s7A of the 2006 Act. In 2015/16 NHS Breast Screening Programme took on responsibility for very high risk screening in line with Cancer Reform Strategy guidance having undertaken pilot work and put in place the necessary IT changes and the appropriate clinical pathways.

Before 2021, the NHS Breast Screening Programme was reliant on referrals from individual genetic services, family history clinics and radiotherapy centres and relied on women that are at very high risk being identified by the centres and being referred to the local Breast Screening Office (BSO) who undertake checks to ensure that the woman meets the requirements of the programme, and if confirmed, they are logged into the screening IT system and-called/ recalled annually.

To improve the identification and referral of women, following a pilot in 2018, the Breast Screening after Radiotherapy Dataset (BARD) team (an initiative led by a team of oncologists and data analysts in Manchester) became fully operational in 2021. BARD is a confidential database of women in England who have received radiotherapy involving breast tissue when aged between 10 to 35 years. It uses national datasets that are now available and undertakes checks with treating centres to ensure all women at increased risk of breast cancer following radiotherapy are referred to the NHS Breast Screening Programme in line with national guidelines.

It is these two improvements (the establishment of BARD and the NHS' introduction of a VHR pathway) that has allowed us to identify the issue. Once BARD was established they reviewed the data originally collected by researchers in 2003 to check whether eligible women had been referred to the VHR pathway and identified this issue. Details of this were shared with NHS England in late September 2023 and since then detailed analysis of data across multiple IT systems has been undertaken to triangulate information about clinical history, current status and residency in order to identify the identity of the individuals in the affected cohorts and to ensure the appropriate follow up was put in place.

### **Number of women affected**

A first cohort of 5,002 affected women has been identified. These are women identified through the original patient notification exercise:

- 2,213 have sadly died as of December 2023.
- 15 are untraceable on patient demographic information received.
- 887 are already in the very high risk pathway and are receiving annual MRI invitations.

- 233 had bilateral mastectomy so no longer need MRIs (157 of these women are recorded as having had a bilateral mastectomy but were not on the VHR pathway, and therefore will be contacted for duty of candour but will not be invited for an MRI).
- 28 fell outside the qualifying parameters.
- 102 no longer live in England.
- 37 had unknown address and/or GP practice.

Therefore, there are **1,487 women** (as of February 2024) for NHS England to contact who need annual MRIs but are not currently on the very high risk pathway. The vast majority of this group of women are currently receiving screening on a three yearly basis.

Of those alive in 2015, 647 (20%) have had a diagnosis of Breast cancer. Of these women, as at February 2024, 113 had died, and 24 had the cause of death recorded as breast cancer. This should be considered a subset of the total known deaths since 2015 (351 deaths).


We do not have data for those who sadly passed away before 2015 (1,862 cases) and are in the process of requesting this.

Of the women who are alive and have had a diagnosis of breast cancer, of those with known staging data recorded at the cancer registry the majority were detected at stage 1 or stage 2.

BARD have also identified two further smaller cohorts (people treated between 2003 and 2013 and 2014 and 2023). Information on these women is still being processed, which is a complex manual task of cross checking on multiple databases. These women will not be contacted in the first batch of letters as we are working at speed and with urgency to complete the necessary checks on each woman's individual screening history and treatment to check if they are eligible for more regular testing. If we identify women who have not been offered annual testing when they should be we will contact them and put in place the appropriate pathway for regular testing. Our current understanding is that the majority of women in these cohorts have either been referred or are not yet eligible for more regular testing.

### **Assurance and clinical advice**

Details of this issue was identified to NHS England in September 2023. An NHS England Incident Management Team (IMT) was established in October 2023 and has been receiving advice from a Clinical Advisory Group (CAG) of NHS clinicians including expert consultant breast radiologists, oncologists, surgeons, and breast care nurse specialists who have met on a number of occasions. In addition, we have been working on confirming the women affected by this issue using their individual screening and cancer history so as to inform, as accurately as possible, appropriate, compassionate communication and clinically informed follow-up.



This is important because the CAG strongly advised we should only contact those women who were eligible and had not been offered annual appointments and do what we can to avoid unnecessarily creating anxiety and distress by contacting women incorrectly. This was a key point of learning from the 2018 Breast Screening Incident where women were contacted and advised they had not been invited for screening, when in fact they were not eligible. This caused significant distress to women and NHS England wanted to avoid this based on the advice from CAG.

As recommended by the CAG, NHS England has subsequently undertaken the very detailed assurance process described above. That process was completed on 17 February 2024 and we are now in a position to proceed with an accurate and verified list of women who require entry into the VHR breast screening pathway.

### **Immediate next steps and summary of proposed engagement planned to contact affected women**

Having completed the detailed review of the information that we have about women treated between 1962 and 2003, we are now in a position to contact women in this cohort.

We are committed to contacting affected women in a kind, caring and compassionate way to explain that we think they may have not been referred into the very high risk programme and that we think, based on the records we have, that they are eligible. This letter will be tailored depending on age and breast cancer status amongst other factors.


On Monday 4 March, NHS England will issue letters to affected women explaining the situation and advising them that they are eligible for more regular testing. All women will receive an apology that this situation has occurred. These letters will likely arrive from Tuesday 5 March, subject to the speed of local post services.

Breast screening services will follow up and make initial contact with affected women in their area within 3 - 7 days.

The clinical advice we have received is that women should be given an appointment within 6 months, however considering the seriousness of the situation we are aiming to offer all women an appointment within 3 months.

In addition to the 1,487 women who will be invited for an MRI, NHS England will issue letters to the additional 157 women who have had a bilateral mastectomy and were not on the VHR pathway explaining that they should have been part of the NHS Breast Screening Very High Risk pathway and give a commitment to review their case. NHS England has asked Trusts to complete this review by July 2024.

Where affected women are known to have had a diagnosis of breast cancer the letters will state that their cases will also be reviewed by the responsible trust who will then be responsible for any Duty of Candour conversations.



Separate processes are being devised for communication with affected women who have moved to the devolved nations or the Crown Dependencies. These will be established in partnership. Some of the affected women have moved abroad, and learning from previous incidents we will explore how these women can be identified as eligible for support and more regular testing, if they return to England.

For those affected women who have died the relevant trust will endeavour to identify and contact the next of kin in line with Duty of Candour.

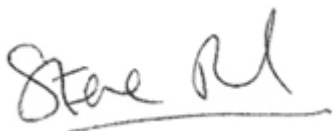
NHS England has set up a helpline for affected women, the details of which will be included in letters sent to them.

More widely, we are committed to learning all lessons from this issue. NHS England will undertake a review of the process that refers these women into the most appropriate service for their risk to mitigate any future impact of this issue.

We are determined to support the women affected by this issue, as we know you are.

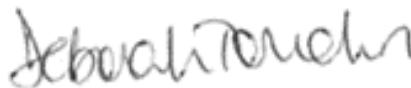
The NHS will now act rapidly with the information that we have and we will continue to provide you with updates on the matter as our actions progress.

Yours sincerely,



**Steve Russell**

National Director for Vaccination and  
Screening and Chief Delivery Officer



**Deborah Tomalin**

Director of Screening