

Briefing Paper – National Breast Screening Serious Incident, May 2018

1. Purpose

1.1 The purpose of this paper is to provide members of the four Hampshire and Isle of Wight (HIOW) Scrutiny Committees with an overview of the national breast screening serious incident and management response. It also aims to provide elected members and local authority public health teams with information that will enable them to respond appropriately to queries from members of the public and signpost them to relevant sources of support.

2. Contents

2.1 The briefing paper includes:

- a description of the cause of the national serious incident which relates to the way in which women were invited for screening
- a description of the national response to manage the women who have been affected by this incident
- an explanation of the technical 'fix' for the invitation system that has been put in place to prevent reoccurrence
- an overview of the number of women in the Hampshire and Isle of Wight population who been affected
- an update on local management arrangements to recall and support the women affected by the incident
- contact details for further professional, public and media queries
- four appendix documents which provide further information for those who may be unfamiliar with the breast screening programme. These include an explanation of the screening process and the role of the National Screening Committee in deciding whether a screening programme should be developed; the breast screening pathway; and an overview of local breast screening service provision and delivery in Hampshire and the Isle of Wight.

3. The problem

3.1 On 2 May 2018, the Secretary of State reported to the House of Commons that a serious incident had occurred in the national Breast Screening Programme. A large number of women had not received their final invitation for a screen when they were aged between 68 and 70 years. An independent review has been set up by the Secretary of State.

3.2 The issue was identified in January 2018 whilst data from the age extension trial (AgeX) was being reviewed. Public Health England (PHE) identified that the AgeX trial algorithm could incorrectly randomise women out of the trial before they had reached their 71st birthday. A similar issue was occurring in some local programmes due to incorrect specification of batches and the failsafe criteria resulting in some local services not inviting all of the eligible women in the three years before their 71st birthday.

4. The national response

4.1 Public Health England is leading the management of the incident. A multi-agency incident team at a national level has been established to manage the incident which includes NHS England, NHS Digital, NHS Improvement, Department of Health and Social Care and a representative from the provider teams. Richard Gleave, Chief Operating Officer and Deputy Chief Executive of Public Health England is the chair of the multiagency group

4.2 An expert clinical advisory group has been providing support since the issue was identified.

4.3 Public Health England, together with NHS Digital, has led on the implementation of a 'fix' to the IT system; the patient notification; provision of helpline support for the women affected by this incident affected women and developing the mechanism for assessment of harm to the women concerned.

- 4.4 NHS England and NHS Improvement are leading on 'service response' aspects within the management of the incident. This means making sure that breast screening capacity is made available for women affected by the incident who want to be screened and ensuring capacity for subsequent diagnostic and treatment services is made available. This needs to be done in a timely way without impacting on the routine screening service for women aged 50-70 years.
- The Helpline:** A national telephone helpline (0800 169 2692) has been set up. It provides initial advice and support to women and to relatives, including those of women who have died. It directs callers to a range of support services when needed including taking details from women who want a screening appointment, specialist cancer clinical advice from local breast care services, Breast Care UK, Macmillan and from PHE clinical staff. After the initial peaks of calls, response times are now good and performance is being closely monitored.
- 4.5 **Patient recall:** On the advice of the Clinical Advisory Group, patients have been divided into two categories – those aged under 72 years on the 1 April 2018 and those aged 72 years and over. Those aged under 72 years have been sent a letter from Public Health England explaining that they will be sent a screening invitation. Those aged 72 years or over are being sent a letter asking them to contact the national helpline if they would like to self refer for a screening appointment. Around 200,000 letters will be sent out in total and all letters will have been sent out by the end of May 2018. Patients can expect to have been screened by the end of October 2018.
- 4.6 **Patient numbers:** Public Health England (nationally) is working to provide an accurate estimate of the numbers affected by the incident and the footprint on which this should be shared. This should be available by June 2018.
- 4.7 **Assessment of Harm:** Public Health England has designed an individual clinical review process which will link to duty of candour and the arrangements for compensation that the Secretary of State highlighted. The process and timescale will be shared with local Directors of Public Health, when known.
- 4.8 **Co-ordination of response:** All organisations are working closely together. The incident response is being managed nationally as a multi-agency group chaired by Public Health England. There are mechanisms for local questions to be raised nationally through a national contact point and via daily regional teleconferences. Providers have weekly teleconferences with local commissioners who are working to support them in finding the additional capacity needed. Answers to questions and decision outcomes / developments are being cascaded down to commissioners and providers via the regional teleconferences and via an operational bulletin update including 'frequently asked questions' which is cascaded directly on a weekly basis.
- 4.9 **Additional capacity:** NHS England and NHS Improvement are working closely with providers to secure additional breast screening capacity where feasible in addition to maintaining the routine service. There is a national shortage of specific staff groups which may limit the additional capacity available. All providers are required to maintain national standards, processes and accreditation in the delivery of the additional capacity. Securing additional capacity is being handled carefully as breast screening is a system not a test and appropriate governance and failsafe systems will be required to ensure it works effectively across the pathway.

5. The 'fix'

- 5.1 Public Health England has carried out a thorough investigation of the whole breast screening system and a detailed analysis of the data from 2009 to March 2018.
- 5.2 The starting date of 2009 is the point at which all breast screening services in England had completed the age extension to invite women aged 50-70.

5.3 In the 2013/14 national service specification, it was clarified that 70 meant up to the woman's 71st birthday.

5.4 A number of IT improvements and changes to processes across all services have now been made nationally to the screening invitation system to 'fix' the issue. These include:

- An interim fix to the Age X algorithm to prevent women from being placed in the control arm of the trial before they reach their 71st birthday. This was implemented by NHS Digital to the national breast screening system on the 9th May 2018. A permanent fix will be put in place by September.
- A manual failsafe check to identify women who were given a particular code in the AgeX trial from 1 April 2018 to 9 May 2018 to ensure appropriate action can be taken.
- Breast screening services have been reminded of the importance of using monthly failsafes for women aged 70 years and 11 months and this is being audited monthly by Public Health England's Screening Quality Assurance Service.

6. Hampshire and Isle of Wight women

As Public Health England are still finalising the numbers involved (see above), local figures are provisional and not yet in the public domain. Working estimates, for the purposes of planning the additional capacity, suggest around 9,000 women from Hampshire and the Isle of Wight are included in the incident. The number is also approximate because the figures are provided by programmes and do not neatly match to local authority areas. Details of the programmes and sites for screening and included in Appendix D.

7. Hampshire and Isle of Wight arrangements

7.1 NHS England (Wessex) is the commissioner of the breast screening programme at a local level. Commissioning is led by the Public Health Commissioning Team, headed by the Head of Public Health Commissioning, with an embedded specialist Public Health England Screening and Immunisation Team which is led by a Consultant in Public Health.

7.2 The Public Health Commissioning Team is a small team which is responsible for commissioning a wide range of screening and immunisations for the Wessex population. The breast screening incident local management response is being treated as a priority by the team and other priorities may need to be delayed or deferred as a result.

7.3 Providers in Hampshire and the Isle of Wight are currently working up capacity plans to offer screening appointments to all of the women affected by the incident in the local area. All but one have sufficient additional capacity in place to offer screening appointments to the under 72 year olds before the end of July.

7.4 Commissioners are working closely with the provider in Portsmouth to secure additional capacity / staff for the women (of all ages) affected by the incident. Additional capacity is being managed strategically at a regional and national level by NHS England and NHS Improvement.

7.5 At this stage, Hampshire and Isle of Wight providers are unable to confirm whether all of the patients in the 72 and over group will be screened by October but they are working hard to achieve this. Situation reports are made daily and show a steady increase in capacity. A further assessment will be made in mid / late June, following a number of anticipated developments over the coming weeks. These developments include:

- providers receiving the detailed patient lists from Public Health England which will enable them to verify whether available screening appointments are located where the women can access them. (Please see appendix D)
- clarification of the additional funding that has been identified and whether it is possible to lift national caps on agency costs to allow for additional staff to be employed
- clarification of additional staffing / service provision

7.6 Commissioners are working closely with all providers to minimise impact on the routine breast screening programme for 50-70 year olds. However, there are severe and long term, national staffing shortages within some of the roles required for breast screening so resources may need to be prioritised.

8. Contact details

8.1 It would be helpful if queries could be directed to the relevant contact points as set out below.

- Enquiries from members of the public should be referred to the national Public Health England telephone helpline which is 0800 169 2692.
- Enquiries from the media should be referred to Public Health England Press Office on 020 7654 8400 in hours. 0208 200 4400 Out of hours.
- Local authority queries and concerns should be conveyed via the Directors of Public Health to PHE Centre Directors who will forward them to national team, or to the local Screening and Immunisation Lead.

9. Appendices

9.1 For those who are less familiar with the breast screening programme, four appendices have been included to provide background information.

- Appendix A outlines the role of the National Screening Committee in deciding whether there should be a screening programme for a particular condition.
- Appendix B outlines what NHS population screening is, how it works and its strengths and limitations. It also outlines key stages in a screening pathway.
- Appendix C outlines the specific screening pathway for the breast screening programme.
- Appendix D outlines the commissioning and delivery arrangements for the breast screening programme in Hampshire and the Isle of Wight.

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 18 May 2018