

Title	Report on 2014 Incident in the Oxfordshire Breast Screening Service
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Status	For information
History	<p>An incident in the OBSS was notified to the Trust Board in July 2014. The Board has been updated in the private Board session in the intervening period.</p> <p>This report provides the Trust Board with a final account of the incident.</p>

Board Lead(s)	Dr Tony Berendt, Medical Director			
Key purpose	Strategy	Assurance	Policy	Performance

Executive Summary

<ul style="list-style-type: none">• The purpose of this paper is to summarise the full outcomes of, and learning from, an incident reported in the Oxfordshire Breast Screening Service (OBSS) in 2014.
<ul style="list-style-type: none">• Concerns were initially raised by clinicians within the Oxfordshire Breast Screening Service (OBSS) during March 2014, regarding a number of cases of potentially missed breast cancer. There was some initial fact finding conducted informally within the OBSS team, prior to notification to Divisional leadership and thence to the Interim Medical Director in April 2014.
<ul style="list-style-type: none">• The concerns that were raised related to one radiologist's practice (hereafter called "the index clinician") in the screening assessment and symptomatic services.
<ul style="list-style-type: none">• Immediate steps were taken to ensure patient safety, with the cooperation of the index clinician who ceased work in the assessment service within OBSS, given that this appeared to be the primary area of concern.
<ul style="list-style-type: none">• A Trust incident management group was convened, with the involvement of the National Screening Service and commissioners.
<ul style="list-style-type: none">• Initially an independent external quality assurance (QA) radiologist was asked to undertake a review of:<ul style="list-style-type: none">a. All of the cases where concern had been expressed (21 in total)b. An additional 60 cases chosen at random from assessment clinics performed by the index clinician. <p>Of the 21 cases, 4 were of concern, and 3 of the 60 cases chosen at random, raised concerns on independent review.</p>
<ul style="list-style-type: none">• It was agreed on the basis of this initial review that a broader external retrospective review (a "lookback") of assessments carried out by the index clinician should be undertaken. The process for, and outcomes of, this lookback are described in this paper.
<ul style="list-style-type: none">• The primary focus of the lookback was to identify any women who could potentially be at risk and who might benefit from recall for reassessment. A low threshold for recall was adopted, to optimise safety. The lookback was not however intended to provide a detailed evaluation of the quality of previous assessments.
<ul style="list-style-type: none">• Summary of lookback and recall for reassessment<ul style="list-style-type: none">i. Overall, of 960 assessments carried out by the index clinician from May 2011 to March 2014, 555 were reviewed in the lookback by external assessors during July and August 2014. A further 60 had already been included in the initial external review. The remaining women were filtered out of the review by virtue of already having been screened through other routes, or already being within the breast service care pathways.ii. Of these 555, 27 women were identified as being appropriate for recall for a reassessment within OBIC, along with 3 out of 60 from the initial external review.

A total of 30 women were therefore invited back to the department for reassessment during August 2014.

- iii. Of the 30 women invited to recall, one could not be contacted and 29 reassessments were therefore carried out. This led to 6 diagnoses of breast cancer with all 6 women being immediately referred for appropriate treatment. A total of 10 patients from 960 were therefore found to have been affected by this incident.

- The Trust was open with women affected about the concerns raised, the need for the lookback, and the nature of the recall process. Communications went to local media at the point the recall was announced, and to provide information on the outcome of the recall. The primary concern was to ensure all potentially affected women had been considered through the various reviews or pathways.

- Additional reviews of performance data, from other areas of the index clinician's practice, were undertaken by the incident management group. These concluded that there was no evidence to justify concerns about these other elements of the individual's practice, and that the issue of concern was limited to the screening assessment element. The index clinician has therefore continued to perform clinical duties which fall outside that process.

- The Oxfordshire Breast Screening Service underwent a Quality Assurance review from the Quality Assurance Reference Centre in November 2014. This report did not deal with the incident in detail but it did note: "*The Oxford BSU is a high performing unit meeting the vast majority of data and monitoring quality requirements of the BSP. The unit team work well together and senior management within the trust are well engaged with BSU issues*". It went on to comment "*The Trust has recently undertaken a screening incident investigation which has impacted on some women being screened. It is not appropriate for further detail to appear in this report and a separate report is in preparation. However it should be noted that many aspects of the issue identified and its subsequent investigation and management has had a profound effect on workload and morale in the department*"

- The primary focus of investigation within the Trust was patient safety and recall, however following that process, an investigation into the index clinician's practice in respect of the assessment service was completed during 2015-16, following established HR processes (MHPS). This review examined the quality of the screening assessments carried out. It concluded that the errors made in the assessment service were due to human error and that the standard of assessment undertaken in these cases fell below the expected level as a result of those errors. The index clinician has not returned to this element of clinical practice within the Trust.

- Following notification of this incident, since March 2014, when women attend the assessment clinic their imaging is now reviewed by **two** radiologists as an additional safety net, before the woman is discharged to 'routine recall', greatly increasing the level of assurance that the risk of future errors of this type is very low. In addition, quarterly reporting of all false negative reports to the Quality Assurance Reference Centre ensures there are additional safeguards for identifying errors.

- The incident highlighted a number of useful learning points for the OBSS and the Trust, including:
- the need for prompt escalation when quality concerns arise and the additional complexities introduced when these appear related to the practice of an individual;
- the value of prompt reporting to the National Screening Service when incidents arise in screening programmes;
- the value of open and pro-active communications with affected patients and the media;
- the delays that can arise in the closure of HR related investigations even when safety and quality-related matters have been dealt with openly, rapidly and effectively.

1. Introduction.

- 1.1. The purpose of this paper is to provide a detailed account of the 2014 incident in the Oxfordshire Breast Screening Service in which a total of 10 women were established to have had a delayed diagnosis of breast cancer through the human errors of a single practitioner, with assessments dating back to 2010.
- 1.2. The paper will set out the background to the incident, how it came to light and was managed, the numbers of patients affected, and the impact on the service.
- 1.3. It will also seek to establish lessons learned for the future.

2. Breast radiology services

2.1. Within the Oxford Breast Imaging Centre (OBIC) of Oxford University Hospitals NHS Trust (OUH), there are two distinct services that are separately commissioned and provided.

2.1.1. **Breast screening.** This work is carried out by the Oxfordshire Breast Screening Service (OBSS), which is part of the National Breast Screening Service (NBSS), commissioned by NHS England. Breast radiologists take part in two different practices within breast screening:

- 2.1.1.1. *Film reading.* This is where the radiologist reviews the mammograms from women attending for *screening*. In most cases these are deemed within normal limits. When they are not, women are recalled for *assessment*.
- 2.1.1.2. *Assessment service.* This is where women who already have an area of suspicion on their screening mammogram are further investigated. This may take the form of additional views on mammography, breast ultrasound, and biopsy (removal of a small piece of tissue for a pathologist to examine) of an abnormality seen on ultrasound (or in some cases, biopsy of abnormalities only seen on X-ray under X-ray guidance). These investigations are carried out by a breast radiologist who reviews the mammogram (s/he may not have been the original film reader) and makes a clinical judgement, in the course of the assessment, of which other tests to perform.

2.1.2. **Symptomatic service.** This work is carried out by the radiologist as part of the multi-disciplinary assessment of women referred to the Trust by their GP because they have found a breast lump or have other symptoms. Women are initially examined by a breast surgeon, and are then sent for imaging (mammogram and/or ultrasound) by a breast radiologist, who may carry out other tests (eg biopsy) at the same time.

2.2. Initial identification of concerns within the OBSS.

- 2.2.1. Concerns were initially raised within the Oxfordshire Breast Screening Service (OBSS) during March 2014 regarding a number of cases of missed breast cancer. These were first identified within the OBSS team, prompting some initial fact finding conducted informally within the team, prior to notification to Divisional leadership and thence to the Interim Medical Director in April 2014.
- 2.2.2. Overall the OBSS is considered to be a high performing Unit, but the National Breast Screening Service has recognised, from past serious incidents elsewhere in the country, that overall metrics can sometimes

mask variations in individual performance. In this case, concerns were raised in respect of the practice of one of the breast radiologists, hereafter referred to as the index clinician.

- 2.2.3. Five cases were identified where women who attended the OBSS had been recalled for additional assessment on the basis of a suspicious mammogram (X-ray of the breast). This assessment had been negative, but despite this the women subsequently presented with a breast lump, proven to be breast cancer, at the same site that was previously assessed. The presentation of the women with a symptomatic cancer took place before the next planned screening attendance.¹
- 2.2.4. An event of this kind of called an “interval cancer”, because the cancer presents in the interval between one screening appointment and another. Interval cancers always raise the question, in hindsight, as to whether an opportunity for earlier diagnosis of the cancer had been missed (an alternative being that the cancer has developed rapidly and that even in hindsight, there is no evidence of it on the previous screening tests).
- 2.2.5. Review of the assessment process for these cases suggested that an opportunity for diagnosis of breast cancer at the time of the first assessment may indeed have been missed, related to the assessments carried out.
- 2.2.6. The concerns that were raised related to the index clinician’s practice in the screening assessment and symptomatic services, and not to the breast screening service as a whole.
- 2.2.7. As a result, the Trust put in place processes to identify and manage any risk to patients, at the same time as pursuing its obligations towards its patients, commissioners (NHS England), and the National Breast Screening Service (NBSS).
- 2.2.8. The Trust also had obligations towards its employee (the index clinician) and has throughout made every effort to act reasonably, preserving the confidentiality of the index clinician, in accordance with the appropriate Trust policies and procedures.

2.3. Initial review by external quality assurance (QA) radiologist

- 2.3.1. An independent QA radiologist, nominated by the National Breast Screening Service QARC (Quality Assurance Reference Centre) was asked to undertake a review of all of the cases where concern had been expressed (21 in total), together with a review of an additional 60 cases taken at random from assessment clinics performed by the index clinician. It was felt that this would provide useful information in determining the next actions to take, if any were required.
- 2.3.2. The random sample of 60 cases was selected by QARC from among 784 women identified as having been assessed by the index clinician from January 2012 to March 2014. The review was undertaken by an external QA radiologist on 19 June 2014. It was concluded that there indeed were significant grounds for concern, and that a further review of all relevant cases would be required.

¹ Of the five interval cancers initially identified it was subsequently concluded that only four were of concern and that in one case there was no concern about the assessment process for that individual.

- 2.3.3. Overall the independent QA radiologist concluded that there was substantial evidence to show that the index clinician had been **screen reading** at an acceptable level of accuracy, and that there was no evidence to suggest that this was unsafe.
- 2.3.4. However the reviewer found that the index clinician's practice of **assessment** was concerning, concluding that based on a review of the published literature there were more cases of false negative assessment (potential missed diagnoses) than expected, and that the quality of assessment in those and other cases was concerning. A detailed lookback was therefore undertaken to consider all the assessments undertaken by the index clinician in the preceding three years.
- 2.3.5. Some of the concerns raised related to patients in the symptomatic service. The Reviewer concluded that there was insufficient evidence to confirm or deny that the index clinician had been practising to an acceptable level in the symptomatic service. Further analysis was therefore required in order to assess whether a full review of this aspect of the index clinician's practice (work in the symptomatic service) should be undertaken. This analysis is described below.

2.4. **Operational management of lookback and reassessment**

- 2.4.1. It was agreed on the basis of the external review's conclusions that a lookback exercise should be undertaken to review assessments carried out by the index clinician, in order to identify any women who should be recalled for an early repeat assessment. The process for, and outcomes of, this review are described below.
- 2.4.2. The priority was to identify as quickly as possible any women who could be at risk, and to make prompt arrangements for their reassessment and, if necessary, treatment.
- 2.4.3. The lookback was undertaken under the direction of the Breast Screening Incident Management Group and with a methodology provided by QARC. A project manager was appointed to support and coordinate the lookback and recall process.
- 2.4.4. Whilst the investigations were ongoing, the Trust agreed voluntary restrictions on clinical practice with the index clinician, who ceased to carry out assessments. There was no restriction on film reading which was deemed safe to continue, based on benchmarking using high quality NBSS data. No restrictions were placed on symptomatic practice although this was kept under review in case data of concern arose during the investigation.

2.5. **Separate investigation into the index clinician's practice.**

- 2.5.1. A separate investigation into the practice of the index clinician was undertaken under the Trust's Performance Management Procedure for Medical staff. This investigation focussed on the circumstances around the false negative diagnoses arising within the breast radiology service and whether these raised any concerns regarding conduct or capability of the index clinician.
- 2.5.2. This process ran partly in parallel, and partly after the immediate patient safety investigations and analysis were completed. The process is a

prescribed one, and can be lengthy, however this was concluded in 2015/16.

3. Root Cause Analysis

3.1. Background false negatives and interval cancers

- 3.1.1. The occurrence of interval cancers is not in itself an indication of either systemic failures or failures in individual clinical practice. Even when operating optimally, screening cannot be 100% accurate in detecting all abnormalities and it is possible that some cancers develop later that were not present at the time of screening.
- 3.1.2. Cancer detection rates of 10 per 1000 are theoretically the highest true rate possible, since cancer prevalence in Oxford is at approximately that level. However, only good readers regularly achieve rates of 8 per 1000 or above.

3.2. Individual clinical practice

- 3.1.3. In addition to the anticipated and unavoidable levels of false negative results during assessments, it is also possible that additional false negatives could arise through deficiencies in clinical practice on the part of the assessor. In relation to this incident, all the interval cancers initially identified occurred in patients who had been assessed by the same (index) clinician, leading to the suggestion that this could be the case.
- 3.1.4. An assessment of whether the number of interval cancers and false negative results falls within normal statistical bounds and whether there were any deficiencies in clinical practice, is complex.
- 3.1.5. It was the view of those who reviewed the cases, that human error on the part of the index clinician was responsible for the original cases of concern (presenting symptomatically as interval cancers) and for the subsequent cases of missed cancer found in the lookback exercise.

3.3. System safeguards

- 3.3.1. It is important that sufficient safeguards are in place to prevent or detect any errors that may occur during assessment. One such safeguard in the assessment system is the involvement of two radiologists in OBSS assessment clinics to prevent reliance on the judgement of a single clinician. The screening mammogram of each woman is reviewed by the two radiologists and together they decide which additional imaging procedures are to be performed. The relevant NBSS protocols² are followed and each woman is assessed in person by one radiologist who decides whether or not a biopsy is required on the basis of the original mammogram and the additional imaging performed in the assessment clinic.
- 3.3.2. Following this incident, since March 2014 an additional procedure is now in place. The imaging of each woman (screening mammogram and additional imaging) is now reviewed by both radiologists within the assessment clinic before the woman is discharged to 'routine recall' i.e. to have their next screening mammogram in three years' time.

² 'Clinical Guidelines for Breast Cancer Screening Assessment' (3rd edition, June 2010)

- 3.3.3. This recognised good practice was introduced following discussion with the unit at the University Hospital Southampton NHS Trust where it is already in place and this has now been incorporated into the Oxford unit's Standard Operating Procedure. This change in practice to greater safety cannot totally remove the possibility of errors in assessment, but is a higher standard of scrutiny than applied in many other parts of the country, and is more than is required by the current NHSBSP regulations for assessment, which are under consideration.
- 3.3.4. A key factor in early detection of weaknesses in assessment is the presence of sufficient internal processes for highlighting and investigating interval cancers and for correlating any patterns that may exist between individual instances. In this regard practice within the department seems to have worked effectively in that it was through routine internal review within the department that these concerns emerged. Two forms of review are regularly used within the department as outlined below.
- 3.3.5. *Interval cancer review*
- 3.3.5.1. This process is carried out in line with the protocols laid down in the NHS Breast Screening Programme's 'Quality Assurance Guidelines for Breast Cancer Screening Radiology' (2nd edition, March 2011).
- 3.3.5.2. These reviews take place approximately every three months and examine all interval cancers that have emerged within that period. Members of the unit individually review and score (normal/benign, uncertain or suspicious features) the most recent and preceding screening scans for each patient, initially without knowledge of the location in which a cancer was ultimately identified. The results of these reviews are then pooled and assessed to generate the consensus view of the unit.
- 3.3.5.3. Interval cancers where there has been a false negative assessment are the subject of a specific formal audit.
- 3.3.5.4. This is regarded overall as a process for education across the unit, highlighting key issues with a view to preventing future errors where possible. The NHSBSP emphasises the value of this process in assisting film readers to improve their skills in detecting small cancers. No specific actions or sanctions in relation to individuals are associated with the identification of errors through this process. This understanding encourages candour and transparency in highlighting issues.
- 3.3.5.5. Interval cancers are, however, formally notified to Public Health England. The unit is required to send quarterly data to QARC on:
- Category 3 interval cancers
 - Interval cancers previously assessed
 - Screen detected cancers previously assessed
- 3.3.5.6. Information is collated on a regular basis by the regional QA units and is sent to the regional QA radiologist before each QA visit (every three years) and at the time of the interim visit or review (between each three yearly QA visit). An annual return is also sent to the national office and the data are shared with the programme directors of individual screening units with recommendations where appropriate. Data are, however, presented for the unit as a whole and not for the individual radiologist.
- 3.3.6. *Discrepancy meetings*

- 3.3.6.1. These meetings are held on a monthly basis and can review any instances of potential misreporting that are identified. These may be submitted by members of the unit or by surgeons. Radiologists may submit examples from their own practice or those of colleagues. Instances put forward are coordinated by a single member of the department acting as the convenor.
- 3.3.6.2. Criteria for inclusion are not as rigidly defined as for interval cancer reviews and therefore thresholds for submission may vary. The most recent terms of reference for discrepancy meetings exclude interval cancers on the basis that these are looked at via the process outlined above. This is in line with the view of the national breast screening radiologists group.
- 3.3.6.3. Members of the unit score cases individually on the basis of an agreed directorate system used across all Trust radiology departments. This rates the grade of error (no error, minor, moderate or major) and the clinical significance (none, minor, more important or major). Results are then collated and discussed to generate an overall view for the unit.
- 3.3.6.4. Like the review of interval cancers, this operates primarily as a learning process for the unit to encourage frank and transparent discussions. Success is reliant on the voluntary submission of cases. The results are, however, reported regularly to the Radiology Clinical Governance Group. In addition, directorate policy is that errors of clinical significance grade 3 (major) highlighted at discrepancy meetings are reviewed by the discrepancy lead with patient notes to confirm their significance before being reported on Datix, the Trust's incident reporting system, for further investigation as appropriate.
- 3.3.6.5. The convenor also keeps a confidential record of the number of errors made by an individual radiologist over the course of the year. At year end, these data are sent to the directorate clinical governance lead for amalgamation. The data are forwarded to departmental CSU leads and the Directorate Clinical Lead. Each radiologist receives a numerical summary of their individual errors, to be discussed at annual appraisal.
- 3.3.7. A new breast screening QARC radiology annual questionnaire has been produced, which was used in Oxford during the three yearly QA visit in November 2014 and specifies four specific audits which are to be undertaken as follows:
- Film reader QA, single reader detected cancer audit
 - Previously assessed screen detected cancer review
 - Previously assessed interval cancer review
 - Short-term recall cancer audit
- 3.3.8. The timeline in this incident suggests that one of the four initial interval cancers occurred in August 2013, some months in advance of the other three which were clustered in January to March 2014. This first case was discussed at a discrepancy meeting in October 2013. It is unlikely, however, that any additional action could have been initiated at this stage based only on a single interval cancer.
- 3.3.9. A further question arises as to whether it was fortuitous that the further interval cancers were in fact clustered, thereby highlighting the existence of a potential issue in relation to their previous assessments. Should this not have been the

case, however, then it is likely that this would have emerged via QA reporting to the unit which, as noted above, collates data on interval cancers. However, it has been recommended that OBIC includes an annual review of interval and discrepancy outcomes into its own processes to allow any trends and patterns to become visible locally more quickly.

3.3.10. It should be noted that the National Screening Programme recommends:

“Analysis of interval cancer data should take place on a regional basis, as the number of interval cancers occurring in individual screening units each year is relatively small and analysis of them is likely to be meaningful only when several years’ data are available. Individual screening units should nevertheless continue actively to participate in the collection and collation of interval cancer data.”³

3.3.11. One further improvement to practice would be that, in retrospect, this issue could have been escalated to the Trust’s senior clinical leadership at an earlier stage. However the resulting delay was not considered to be material to the clinical management or prognosis of the additional cases of missed breast cancer that were identified as a consequence of the lookback and recall of patients.

4. Lookback Arrangements

4.1. Lookback protocols

4.1.1. Protocols for carrying out the lookback of assessments were provided by the South Central Quality Assurance Reference Centre (QARC). They outlined the evidence that should be reviewed during the lookback and what categories these should be placed into.

4.1.2. The grading system outlined in the protocols rates assessments as:

4.1.2.1. No cause for concern

4.1.2.2. Minor/insignificant acceptable variance in practice

4.1.2.3. Moderate cause for concern

4.1.2.4. Serious cause for concern.

4.1.3. It should be noted that a slightly different set of categories were ultimately used in the lookback but that these were consistent with those outlined on the review proforma sheets provided by QARC. The final categories used categorised assessments as optimal, suboptimal or substandard.

4.1.4. The protocols do not explicitly define the criteria for including assessments in each category but state that the reasons for rating assessments as providing moderate or serious cause for concern should be described.

4.1.5. The protocols note that whilst a single experienced radiologist should make these decisions, assessments providing moderate or serious cause for concern should be reviewed by a second experienced radiologist before the patients are recalled. During the review all assessments identified for recall were reviewed by a second and third reviewer working together.

4.1.6. These protocols were provided to all the external reviewers who were requested to comply with these in undertaking the lookback process.

³ p14 ‘Quality Assurance Guidelines for Breast Cancer Screening Radiology’ (2nd edition, March 2011)

4.2. Identification of assessments requiring review in the lookback

4.2.1. Women whose assessments required inclusion in the review were identified in line with the QARC protocols as summarised in Table 1 below. NBSS provided an initial list of 900 patients (excluding those already included in the initial external review) with further exclusions, based on NBSS records as outlined below, reducing the number to 653. These exclusions identified women who had already had further routine screening or assessment, such that they were not felt to be at risk.

Table 1

Total assessments undertaken by individual May 2011- March 2014	960
Remove women included in initial external review	60
Remove women who had outcome classified as “under care/treatment from NBSS”	137
Remove women who had subsequent screening with a normal result	73
Remove women who had early recall screening or re-assessed by other radiologists	18
Remove women who had assessment undertaken by the index clinician and another radiologist ie had already been assessed by two assessors	19
Total remaining assessments	653
Remove women subsequently seen by symptomatic breast service (via OUH CRIS review)	29
Total assessments for inclusion in review	624

4.2.2. In line with the QARC protocols a further review of the list against the CRIS radiology system took place within OUH to identify any further patients who had had subsequent treatment or screening assessments. In particular this removed any women who had had assessments under the Trust’s symptomatic service which NBSS would not be aware of. This removed a further 29 women from the list and left 624 assessments to be looked at during the course of the review exercise.

4.2.3. As indicated here, the review did not include those women who, following their assessment, had been recalled again for routine screening and had had a normal result at that stage. As regular screening continued as usual during the course of the review, there were in fact a further 66 women from the list who underwent screening with a normal result during the course of the process. They were also ultimately excluded from the assessments reviewed, as indicated in the outcome summary below.

4.3. Lookback process

- 4.3.1. The lookback was carried out during the period 16 July 2014 to 8 August 2014. The timescale of the lookback was extended slightly from that initially anticipated, due to some difficulties in identifying experienced external assessors who were available to undertake the work during the timescale required.
- 4.3.2. Excluding the 60 examined by the initial external reviewer, five other external assessors were involved in undertaking the review. Three of these assessors carried out the majority of first reviews, with two others working together to undertake second reviews, where it was proposed that a patient be recalled or where specifically requested by the first reviewer.

5. Outcome of lookback

5.1. Summary of lookback outcomes

Table 2 below provides an overview of the results of the assessment review.

Table 2

	1 st Review				2 nd Review	
	Total	No Action	Reassess	2 nd Opinion	Routine Recall	Reassess
Optimal	440	438	0	2	2	0
Suboptimal	37	26	4	7	10	1
Substandard	20	5	10	5	10	5
Not Rated	58	13	34	11	24	21
Total Reviewed	555	482	48	25	46	27

Recently Screened	66
Otherwise Excluded	3
Overall Total	624

- 5.2. It is very important in considering these results to recognise that the primary purpose of this exercise was to identify any women who could potentially be at risk and who might benefit from a further assessment. It was not to provide a detailed evaluation of the quality of previous assessments. For example, all women who had recently attended the department for a new screening appointment were excluded from the review as they were deemed not be at risk as a result of any flaws that may have existed in a previous assessment. This clearly would not have been the approach taken should the primary goal have been to provide an overall view of the standard to which assessments had been conducted.
- 5.3 Of the 624 assessments initially identified, 69 (11.1%) were excluded from the review either because they had been recently screened or for other reasons.
- 5.4 Of the 555 other assessments which were reviewed 440 (79.3%) were felt to be optimal, 37 (6.7%) suboptimal, 20 (3.6%) substandard and 58 (10.5%) were not rated. It should be noted, however, that a large proportion of those assessments not rated were those put forward for reassessment and so it is likely that these were felt to be suboptimal or substandard whilst not being separately rated by the reviewers.
- 5.5 The proportion of assessments rated as optimal varied from 68.0% to 91.5% between the three reviewers who carried out the majority of first assessments. It is unlikely, however, that this variation impacted on the choice of women for recall or had any effect on detecting error since this decision involved the opinion of at least two reviewers in every case. It should be emphasised again that rating the quality of assessments was not the primary function of this review.
- 5.6 At first review, 482 (86.8%) of the women whose assessments were reviewed were deemed appropriate for return to routine recall. A further 48 (8.6%) were proposed for recall for reassessment and 25 (4.5%) required a second opinion. In seven cases this was because the initial reviewer was unable to view the images on the CRIS system and separate arrangements needed to be made.
- 5.7 All assessments proposed for recall along with those for which a second opinion was requested – a total of 73 assessments (13.2% of the original 555), underwent

a second review. Of these 46 (63.0%) were regarded as suitable for routine recall with 27 (36.0%) to be recalled for reassessment. This suggests that first reviewers took an appropriately conservative view in putting assessments forward for recall or second opinion.

5.8 Overall therefore, of the 555 assessments reviewed in the lookback, 528 (95.1%) were returned to routine recall with 27 (4.9%) being recalled for reassessment.

5.9 In addition there were 3 women identified for recall as part of the initial external review of 60 patients, and so the total number of women identified to be brought back for assessment as part of the recall process was 30.

6. Statistical Analysis of Symptomatic Service

6.1. Report on symptomatic service

6.2.1 A separate analysis was undertaken to establish whether there was any significant cause for concern in relation to the breast symptomatic service and whether there was sufficient evidence to justify a full review of the practice of the index clinician in the symptomatic service

6.2.2 A statistical analysis was undertaken by a Specialist Registrar in Public Health, overseen by the Incident Investigation Group, to assess whether there was any statistically significant variation in cancer detection rates amongst the clinicians contributing to the symptomatic service. Because the pool of symptomatic women would be randomly distributed among the different clinicians, if the index clinician's cancer detection rate was particularly low, this could indicate that an in depth review of the index clinician's practice in this area was merited.

6.2.3 The analysis was carried out by correlating diagnoses of breast cancer from the pathology database (of breast tissue excisions and biopsies) with information about the patient's investigations as carried out in the symptomatic breast clinic, and recorded on the CRIS radiology database.

6.2.4 The cancer detection rates of OBIC clinicians working within the symptomatic service ranged from 5.02% to 7.93% with an average 6.11%. The index clinician had an **above** average detection rate of 6.94%, falling within a 95% confidence interval around the mean of the detection rates.

6.2.5 In case these findings were confounded by different clinicians seeing patients with a different age mix, the case-mix of the individual clinicians was indirectly age-standardised against that of the patient population in the CRIS database. This did not lead to any significant difference to the conclusions to be drawn regarding the detection rates of the clinicians.

6.2.6 This work concluded that, taking into account the assumptions and limitations of the review, there was no evidence to support under-detection of cancer by the index clinician amongst patients in the symptomatic service.

6.2.7 The work was commended by the Breast Screening Incident Management Group (that included external representation including from QARC), and its conclusions were adopted.

6.2. Actions regarding symptomatic service

6.3.1 The work on the symptomatic service was received by the Breast Screening Incident Management Group on 30 July 2014. It was noted that this review

had revealed no evidence to support under-detection of cancer on the part of the index clinician.

- 6.3.2 Members of the group were satisfied that they could not envisage a plausible interpretation of the findings under which there was actual underperformance in spite of this evidence. It was therefore agreed that a full review of the index clinician's practice within the symptomatic service was not required.

7. Recall and Reassessment Process

7.1. Communications process for recall

- 7.2.1 The recall was initiated on 12 August 2014 with letters sent out to all 30 women to invite them to attend the department for reassessment.
- 7.2.2 The four women whose interval cancers had initiated the investigation were also contacted in advance of the wider public statement to ensure that they were aware of the wider picture relating to their own treatment.
- 7.2.3 In parallel with this a public statement was issued and the local media were briefed. The Trust was pleased that the story was reported in a responsible and supportive way that did not unnecessarily increase anxiety amongst women who had used the service or discourage women from attending for their routine screening appointments.
- 7.2.4 An information leaflet was also prepared to be made available to patients attending Trust clinics or GPs surgeries and requesting additional information.
- 7.2.5 The Trust also put in place two helplines. One was staffed by clinicians from OBIC with the number provided only to the women being recalled and GPs. This allowed them to discuss any concerns, seek additional information and confirm the arrangements for their reassessments. The other was staffed by the Trust's chaplaincy team and was widely publicised to provide information and reassurance for other women who had used the screening service and the wider public.

7.2. Recall process

- 7.3.1 The recall operated smoothly for the majority of women and dedicated clinic capacity was made available during the weeks of 18 and 25 of August 2014 and all but two women were seen during these two weeks. Provisional reassessment dates were arranged for all women but there was flexibility for patients to reschedule these as convenient for them.
- 7.3.2 Of the thirty women there was one patient that the service was unable to contact. This individual could not be reached via any of the most recent contact details that were available for her and investigation showed that she was no longer registered with a GP. She had previously moved to the country from abroad and it was suspected that she might have left the UK again although this could not be confirmed. At the Breast Screening Incident Management Group meeting on 9 October 2014 it was agreed that all reasonable efforts had been made to contact this individual.

7.3. Reassessment protocols

- 7.4.1 The majority of reassessments (24 of 29) were carried out during the week of 18 August with the final appointment taking place on 4 September to accommodate the patient's availability.
- 7.4.2 At reassessment additional mammograms were taken for all women and an ultrasound was carried out. Biopsies were taken where this was indicated.
- 7.4.3 The reason for the recall was reiterated to all women attending and an opportunity provided to discuss this further with clinicians within OBIC. Arrangements were made to ensure that specialist breast care nurses were available to speak to any of the women attending for reassessments should they be required.

8. Outcome of Reassessment

8.1. Summary of reassessment outcomes

- 8.1.1. Of the 29 women reassessed, biopsies were carried out in 10 cases. In a further case a biopsy was attempted unsuccessfully but a subsequent MRI showed normal breasts. Biopsies were offered for reassurance to a further four women with benign-appearing, unchanged lesions, but the patients declined the offer.
- 8.1.2. Of the 10 biopsies carried out, four were found to be benign with the other six women referred for treatment.
- 8.1.3. Overall of 29 patients reassessed, from the original 960 patients considered, six cancers requiring treatment were identified with 22 of the other 23 women referred for routine recall. A final patient was listed for early recall.

8.2.1. Overall these results suggest that there were 10 false negative assessments out of 960 assessments in total, an overall rate of 1.04%. However there is no national standard or target for these rates and nor is there an agreed figure for the overall national rate. In the initial external review, it was suggested "that approximately 0.6% of assessments in the UK screening programme will be false negative in normal practice, but this is based on a paucity of data." Published literature quotes figures ranging from 0.5% to 3% but there is a recognised lack of data in relation to this.

8.2.2. It could be suggested that there are 34 cases (4 interval cancers and 30 identified as requiring reassessment) where there was evidence of substandard assessment. This represents 3.54% of the 960 total assessments. It should be highlighted, however, that the methodology of the review was not focussed on a comprehensive evaluation of the quality of assessments carried out; many assessments were excluded from the review on the basis that the women in question had already been screened again or had had separate assessments.

9. Individual investigation of index clinician.

- 9.1. It was considered important to establish the circumstances of the errors that had been made and a separate investigation was undertaken through the Trust's Performance Procedure for Medical Staff.
- 9.2. This review examined the quality of the screening assessments carried out. It concluded that the errors made in the assessment service were due to human error and that the standard of assessment undertaken in these cases fell below the expected level as a result of those errors. The index clinician has not returned to this element of clinical practice within the Trust.

10. Recommendations

10.1. Summary of recommendations

- 10.1.1. Following the conclusion of the review a series of recommendations were made by the regional QA team, which have been implemented as follows:
 - 10.1.1.1. *Assessment clinics must be "double-read". Clinics should be operated by two radiologists working in a pair in line with national recommendations.* The OBSS has been doing this since March 2014, with clinics having 2 radiologists working in a pair with the exception of Thursdays. On Thursdays, a radiologist works single handed, however there is always an additional radiologist in the department who double reads the cases at the time of the clinic. When the department appoints another radiologist, all clinics will be operated with two radiologists
 - 10.1.1.2. *The Unit should undertake regular review and audit of individual performance on interval and screen detected cancers that had previously been recalled for assessment (false negative assessments) on a quarterly basis. The outcome of the review should be shared with QARC and the regional QA radiologist.* This review takes place quarterly as recommended. The last review meeting was 17/2/2016. Attendance is recorded and each radiologist has the opportunity to reflect on the cases. False negative assessments and Category 3 interval cancers are emailed quarterly to the regional QA team.
 - 10.1.1.3. *The investigation reviewed 624 cases assessed by the consultant in the last three years, and 30 women recalled back for further assessment. The Unit should put in place measures to follow up outcomes for the rest of women reviewed as part of this investigation in their future routine assessments or early recalls.* A follow up process is in place.
 - 10.1.1.4. *The Director of Breast Screening must notify QA immediately in the event of any concerns about clinical performance.* Director of Breast Screening unit is aware of the need to report any concerns and of Trust policy. There are no concerns at present
 - 10.1.1.5. *All breast screening radiologists should attend regular training/clinical courses as recommended by the Royal College of Radiology.* Study leave for courses is discussed within the department to ensure that everyone has an opportunity to attend regular training/clinical course updates. Individuals keep records of attendances at these courses and present them at annual appraisal, as well as to the QA team every 3 years.
 - 10.1.1.6. *Individuals' performance information should be made available for annual consultant appraisal.* Individual performance data is provided for the whole

region and is reviewed. In addition, quarterly performance data is produced by the departmental audit lead for submission with appraisal documentation.

10.1.1.7. *Any consideration of circumstances under which the radiologist concerned could recommence screening assessment practice should be discussed with, and agreed by, QA.* There are no current plans for the radiologist concerned to recommence screening assessments.

10.1.2. These recommendations were supported by OBIC and, as noted above, have been embedded as current practice within the department.

11. Conclusions

11.1. Summary of lookback, recall and reassessment

11.1.1. Overall, of 960 assessments carried out by the clinician in question from May 2011 to March 2014, 555 were reviewed by external assessors during July and August 2014 with a further 60 already having been included in the initial external review. The remaining women were filtered out of the review by virtue of already having been screened through other routes, or already being within the breast service care pathways.

11.1.2. Of these 555, 27 women were identified as being appropriate for recall for a reassessment within OBIC along with 3 from the initial external review. A total of 30 women were therefore invited back to the department for reassessment during August 2014.

11.1.3. Of the 30 women recalled one could not be contacted and 29 reassessments were therefore carried out. This led to six further diagnoses of cancer with all six women being immediately referred for appropriate treatment.

11.2. Evaluation, learning and recommendations regarding lookback and recall

11.2.1. Overall the lookback and recall process was successful, being carried out in a timely fashion with effective communications and minimising unnecessary anxiety to users of the screening service and the wider public.

11.2.2. The most significant delay in the lookback was as the result of difficulties in identifying suitable independent external assessors with availability to undertake the review. This was exacerbated by the need for the lookback to take place during the summer holiday period. Support in identifying assessors was received from PHE/NBSS and, with a gradual widening of the geographical area in which suitable radiologists were contacted, appropriate individuals were found.

11.2.3. Preparation of the appropriate records for the lookback was a significant undertaking and was greatly supported by the effort and professionalism of staff within OBIC. All staff involved in the lookback exercise and preparations for the recall are also to be credited with the discretion with which they handled sensitive information to ensure that this did not emerge prior to the recall. This would undoubtedly have caused widespread distress at a point when the Trust was not in a position to know which women might be at risk.

11.2.4. As noted above, during the course of the review, different assessors took slightly varying approaches to the completion of lookback documentation. This did not affect the decision-making regarding the women requiring recall

but does make it more difficult to draw conclusions (from this part of the process) regarding the overall quality of the assessments being reviewed. One recommendation for any similar lookback in future would be to be more clear and directive in ensuring consistency between assessors in applying the review protocols.

11.2.5. Once the women to be recalled were identified, arrangements for them to be assessed were very prompt, with clinics cleared and additional clinics provided so that capacity was in place to see them rapidly.

11.2.6. Communications during the recall process have been recognised as working highly effectively with a clear plan and timeline developed by the Incident Management Group (on which the Communications Department was represented) and implemented by the Communications Department. In particular, early and transparent communication with the local media helped to ensure that the story was reported in an accurate and responsible manner, supporting the effectiveness of the recall process whilst not unjustifiably raising anxiety for patients and the public. A similar approach is recommended for communications in any similar circumstances in the future.

11.2.7. Other steps were also taken to try to ensure that the women being recalled felt supported and well informed. A dedicated helpline was established, staffed by clinicians with appropriate expertise and breast care nurses were available to speak with women recalled at reassessment appointments.

11.3. **Learning for future incidents.** There has been significant learning for the future.

11.3.1. Timely reporting of incidents, and of concerns at clinical outcomes or practice if they arise, are of critical importance in reducing the potential for patient harm. In this case, the trigger for reporting concerns was the clustered appearance of three interval cancers within a two month period in Jan-March 2014. Investigation occurred with relatively little delay after this.

11.3.2. Routine clinical governance mechanisms, in which clinical teams review outcomes and processes, are the cornerstone of safe practice provided teams recognise the need for prompt reporting

11.3.3. When national screening services are involved, it is important that clinical leads, clinical governance risk practitioners, and Directorate and Divisional managers are all aware of the external reporting requirements that complement the Trust processes.

11.3.4. Equally, the investigational processes that result may be dictated both by the national screening services and by the Trust. In this respect the experience of the Incident Management Group was a useful one in providing direction and support to Trust processes.

11.3.5. Proactive engagement with media, and with patients affected by the incident, was helpful to reduce overall levels of public anxiety.

11.3.6. The assignment of a senior manager to act as project manager for the lookback and recall processes was invaluable.

11.3.7. The Trust had to balance its duties of care and confidentiality to affected patients, to concerned relatives and members of the public, and to any of its employees caught up in the incident. At times this led to delays in the more internally-directed processes such as the investigation into the index clinician's

practice. This has led to delay in being able to inform the women affected by the incident of the Trust's final position in respect of the care it delivered, but there have been no delays to the offering of necessary diagnosis and treatment. Active management of the timescales of investigations remains important and in the context of multiple competing commitments, a challenge.

11.3.8. Specific learning for the Oxfordshire Breast Screening Service is set out in section 10.1.1. These actions have already been incorporated into standard practice.

Dr Tony Berendt
Medical Director

4th May 2016

Initial paper produced by:

Neil Scotchmer
FT Programme Manager

Appendix A

Oxford University Hospitals NHS Trust

Breast Screening Incident Management Group

Terms of Reference

Background. The BSIMG has been established following the reporting of a number of cases of interval breast cancer in the Oxfordshire Breast Screening Service, all occurring in women who had had a supplementary assessment at their last routine screening appointment.

Roles and actions.

1. To advise and agree on immediate actions to make the service safe
2. To confirm whether the reportable cases of interval cancer represent a reasonable cause for concern, particularly regarding the adequacy of their previous screening assessment.
3. To establish whether there is reasonable cause for concern over additional patients seen in
the Breast Screening Service, in particular whether others are at risk of having had inadequate assessments.
4. In the event that there are concerns that additional patients are so at risk, to advise the Trust, and oversee its actions, to identify those patients and to take appropriate action to ensure their safety
5. To advise the Trust, specifically through the Interim Medical Director, on necessary actions
to ensure that the screening service is safe
6. To review the circumstances by which concerns came to light
7. To establish the root causes of the incident
8. To oversee the progress of the plans made to restore the effective functioning of the Oxfordshire Breast Screening Service
9. To facilitate liaison with other partner organisations as required, for example, other Trusts
10. To agree timescales for the closure of the incident
11. To identify lessons learned from the incident and its handling
12. To assure the Board, stakeholders, patients and the public of the safety of the breast screening service, and of the completion of the above actions

Membership

Trust:

Interim Medical Director (Chair)

Head of Clinical Governance

Director, Oxford Breast Screening Unit
Radiology Clinical Unit Operations Manager

National Breast Screening Service

Quality lead, National Breast Screening Service (Public Health
England) Quality Assurance Radiologist, NBSS
Breast Cancer Screening Quality Assurance Manager, NBSS (Public Health England)

Commissioners

Consultant in Public Health, Screening and Immunisations, NHS England TV Area Team
Quality and Safety Manager, NHS England TV Area Team
Director of Quality, Oxfordshire Clinical Commissioning Group

The group can co-opt or request the attendance of other members as required, for example, of other stakeholder organisations.

Frequency of meetings

According to need, approximately monthly but more frequently if necessary

Quoracy

Chair
One Trust management, one NBSS, and one NHS England representative

Reporting arrangements

While the investigation remains strictly confidential, reporting will be via the Chair of the Group to the OUH Chief Executive

Once the matter is in the public domain, reporting will be as follows:

- a. Serious Incident Requiring Investigation: to Clinical Governance Committee, TME, and the Board
- b. Any individual performance related issues: to the Medical Director and the Board as set out in Trust policy

Tony Berendt

Revised 12/8/14