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# External review into North Lancashire and South Cumbria Breast Screening Programme

# About the NHS Cancer Screening Programmes

The national office of the NHS Cancer Screening Programmes and the quality assurance service is part of Public Health England. Their role is to provide national management, coordination, and quality assurance of the three cancer screening programmes for breast, cervical, and bowel cancer.

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# Executive Summary

## Aim of the External Review

The aim of this independent external review is to provide an expert opinion on whether film reading and current clinical practice at the assessment stage in the breast screening service provided by University Hospital of Morecambe Bay Trust (UHMBT) is operating safely and within national standards. The terms of reference are shown in appendix 1.

## Background to the Review

This independent external review was requested by UHMBT and NHS England, as the breast screening commissioners, following receipt of allegations from two “whistle blowers” regarding concerns of unsafe practice in the breast screening programme at UHMBT.

Concerns were raised in a number of areas:

- Film Reading: Concerns about individual and consensus film reading performance including cancer detection rates, recall rates and missed cancers.
- Assessment: Concerns about poor working practice in assessment clinics. In particular these related to the results of an audit of 24 interval cancers arising in women previously assessed (2005-11) carried out by one of the whistle blowers showing an excess of false negative assessments by one radiologist (Radiologist C).
- Interval Cancer Review Process: Concerns were raised regarding the processes for identification, review and recording of categorisation of interval cancers.
- Working Environment: Concerns were raised regarding a difficult working environment, the management approach, and the lack of an audit culture within the service.

## Methodology

The request for an external review was made to the Breast Screening Quality Assurance (QA) Directors in the East and West Midlands at the end of June 2014. The team carrying out the external review are listed in appendix 2 and included staff with extensive experience in breast screening radiology and quality assurance with expertise in programme assessment, performance and data analysis. The timeline for the external review is shown in appendix 3. This review looked at evidence and data that provides information on current practice, where current is defined as assessments that have been carried out in the most recent screening round and data from the last 3 years.

## Key Findings

### Overall Conclusion

Film reading and clinical practice at the assessment stage in the breast screening service provided by UHMBT is currently operating within national minimum standards, however the working environment is extremely poor and if it is not addressed urgently the service is unlikely to be able to continue to provide a safe service to the women of North Lancashire and South Cumbria.

### Film Reading

Film reading in the breast screening service in UHMBT meets national standards with good overall cancer detection rates. There is no evidence of significant outlier performance for any individual film reader in current practice in relation to cancer detection rates and missed cancers. Film reader documentation requires improvement.

### Assessment Practice

Assessment practice in UHMBT is meeting national minimal standards.

There are quality issues in the service that need addressing. These include poor assessment clinic documentation, ultrasound equipment quality and MDT discussion / interpretation of biopsy results.

An extensive review of cases in the most recent screening round found none where assessment was regarded as substandard (defined as a significant deviation from NHSBSP protocols).

A proportion of cases reviewed (5.1%) were regarded as suboptimal assessment (defined as a minor deviation from NHSBSP protocols). Primarily these suboptimal assessments were in cases assessed by Radiologist C (6.2%) and Radiologist F (7.1%). Whilst not desirable, it should be noted that it would not be considered unusual in such an extensive review over three years of assessment practice that

some suboptimal assessments are found. For a small number of cases reviewed recall for reassessment has been advised.

## **Interval Cancer Review Process**

The external review raised no concerns regarding the categorisation of interval cancers.

## **Working Environment and Audit Culture**

There are serious concerns regarding the management arrangements, working relations and audit culture within the unit that if not immediately addressed will have an impact on the future safety of the service.

# **Summary of Key Recommendations**

## **Screening Schedule**

To facilitate the significant review of processes, as well as culture and leadership changes that are urgently required, screening schedules should be slowed down for a short time period to ease pressure on the service.

## **Review of Managerial Arrangements**

A review of the managerial arrangements for the service is urgently required to ensure adequate inclusive leadership to support the recommended changes to processes.

## **Improvement to Working Environment**

We are aware that the Trust has been trying to address this issue through team building workshops. It is essential that this support continues alongside the recommended changes to processes in order to achieve a professional working environment focussed on patient care.

## **Refresher Training**

It is recommended that Radiologist C & Radiologist F have a short period (to be determined) of refresher training in assessment clinic processes at another breast screening service outside of the

region. These should address the areas of suboptimal practice for each radiologist as identified in the report.

## **External Visit to Another Breast Screening Service**

To support the recommendations made regarding changes to processes the opportunity should be given for all relevant staff to visit another breast screening service. All radiologists working in assessment should attend an assessment clinic and all film readers should attend a film reading consensus meeting at another service outside of the region.

## **Documentation**

Action is required to improve the quality of documentation by film readers when recommending recall, and in recording findings and management plans in assessment clinics.

## **Ultrasound Equipment**

A clear action plan for the recommended replacement of ultrasound equipment needs to be put in place as soon as possible.

## **Assessment Clinics**

**Scheduling:** There should be a greater transparency regarding how cases are scheduled for the assessment clinic; the service should consider passing this responsibility to an advanced practitioner and ensure that there is an even distribution of complex cases across all assessment clinics.

**Processes:** Use of at least 2 views of any possible mammographic abnormality is now appropriate for the best quality assessment. There appears to be under sampling particularly for ultrasound core biopsies. In line with current accepted practice a minimum of two passes should be undertaken for all cases and the services protocol updated accordingly.

Double reading of assessment cases that are considered benign /normal and being returned to normal screen is very good practice. However at present women are not being informed that this is occurring, and that they may be called back following review. In future, women should be clearly informed of this way of working.

## **Audit Arrangements**

A review should be carried out and a clear and robust action plan for delivery of audit at the service should be drawn up. This review should include a review of the role and responsibilities of the



designated audit lead, a clear schedule for required mandatory audits, a process for feedback and discussion of the audit data, as well as a clear and transparent process for carrying out additional audits within the service.

## **MDT interpretation of needle biopsy results and National Pathology Audit Outlier Status**

The review team has concerns in relation to interpretation of B1 (normal) and B2 (benign) non-operative needle biopsy results and appropriate MDT discussion and decision making following review of assessment cases. These concerns are supported by the service being both a low B1 rate outlier and a high B2 rate outlier in the National Pathology Audit Report (2014). This requires further investigation and a 3 month retrospective audit of at least 100 B1 / B2 cases is recommended.

# Technical Report: Summary of Findings

## Overall Conclusion

Film reading and clinical practice at the assessment stage in the breast screening service provided by UHMBT is currently operating within national minimum standards, however the working environment is extremely poor and if it is not addressed urgently the service is unlikely to be able to continue to provide a safe service to the women of North Lancashire and South Cumbria.

### 1. Film Reading

***Concerns about individual and consensus film reading performance including cancer detection rates, recall rates and missed cancers.***

#### **Unit performance from statistical review**

Statistics from the most recent year available (April 2013 – March 2014) confirm that overall cancer detection rates are good. The standardised detection ratio (SDR) was 1.57; target 1.40. Small cancer detection at the prevalent screen remains low (SDR 1.06; minimum standard 1.0) but overall small cancer detection was above QA target standards at the incident screen (SDR 1.43 including women of all ages or 1.38 50-70 only) which comprises the largest cohort of women.

Increasing recall rates at the prevalent screen appears to have been a pragmatic response to encourage small cancer detection at the prevalent screen.

#### **Individual performance (from film reader statistics)**

Most UHMBT readers demonstrate poorer performance in terms of positive predictive value (PPV) of referral compared to peers in East and West Midlands. This is due to higher recall rates, as there is little evidence for low cancer detection at the individual level i.e., film reading specificity is poorer than levels of sensitivity.

### **Individual missed cancer rates at first read (from film reader statistics)**

No UHMBT readers were performing significantly different to their peers in East and West Midlands in terms of missed cancer rates over 2010-13 or the most recent period 2013-14.

### **Overview of cancers missed by first reader by external review radiologists**

No film reader is missing significantly more cancers than their peers. There was no specific feature or type of case which was repeatedly dismissed as normal by any film reader.

### **Panel consensus meeting statistics**

The recall rates for individuals working within the Tuesday consensus meeting were higher than the aggregated recall rate from staff attending the Thursday consensus meeting.

There was a natural propensity of *most* readers attending the Thursday consensus meeting to recall more cases when reading independently.

## **Conclusion**

There is no evidence for significant outlier performance for any individual film reader in current practice in relation to cancer detection rates and missed cancers.

Recall rates are higher for some film readers, in particular those attending the Tuesday consensus meeting.

There are differing views regarding the cause of the disparity in recall rates between the film reading team members, some attributing it to a deliberate attempt to increase small cancer detection rates, others attributing it to a different culture between the two consensus meetings.

The conscious effort to maximise small cancer detection via increasing recall rates has not led to significant increases in cancer detection at the prevalent screen. Visiting high performing services to view processes may be helpful with a focus on maximising screening specificity going forwards.

The quality of documentation by film readers when recommending recall is poor.

## 2. Assessment

***Concerns about poor working practice in assessment clinics. In particular these related to the results of an audit of 24 interval cancers arising in women previously assessed (2005-11) showing an excess of false negative assessments by one radiologist (Radiologist C).***

### a) Review of Historical Assessment Practice:

This included: All films and images of the 24 cases from the false negative assessment interval cancer audit as submitted by one of the whistle blowers (R1); cases screened and assessed 2005-8 arising as interval cancers 2005-11 (R2); cases screened and assessed 2007-2011 arising as interval cancers 2012-13 (R3).

The majority of the cases reviewed did not constitute false negative assessment as they were previously assessed for a different site or feature.

Although the number of cases is small, the review of historical cases of false negative assessment cases for Radiologist C revealed some recurring themes about mammographic interpretation of spiculate lesions, the quality of ultrasound and ultrasound guided core biopsy carried out and repeated under sampling at core biopsy. These were then used to focus the review of current practice at assessment.

### b) Review of Current Assessment Practice

This included the following extensive case reviews:

#### **R4 Assessment clinic cases April 2013 – March 2014**

Review of two assessment clinics for each radiologist comprising approximately 20 cases; review of 10 clinics comprising approximately 100 cases for Radiologist C due to the whistle blower allegations; review of 3 additional assessment clinics for Radiologist F from the same time period due to the findings of an initial review of cases.

No cases were classified as substandard assessment (significant deviation from NHSBSP protocols)

6 cases were classified as suboptimal assessment (minor deviation from NHSBSP protocols)

Recall for repeat assessment was recommended for less than 5 women, the details are contained in the 'Confidential Data Supplement.

**R5 Non-cancer diagnosis assessment cases (September - December 2011) where no biopsy was undertaken by radiologists C, D & F**

No cases were classified as substandard assessment (significant deviation from NHSBSP protocols)

11 of 228 cases were classified as suboptimal assessment (minor deviation from NHSBSP protocols)

Recall for repeat assessment was recommended for less than 5 women, the details are contained in the 'Confidential Data Supplement.

**R6 Non-cancer diagnosis assessment cases (January – March 2013) where no biopsy was undertaken by Radiologist C**

No cases were classified as substandard assessment (significant deviation from NHSBSP protocols)

17 of 201 cases were classified as suboptimal assessment (minor deviation from NHSBSP protocols)

Recall for repeat assessment was recommended for less than 5 women, the details are contained in the 'Confidential Data Supplement.

**Summary of review of assessment cases in most recent screening round:**

Overall

34 of 665 assessment cases (5.1%) reviewed in the most recent screening round (2011-14) represented suboptimal assessments.

Radiologist C

356 of 793 (44.9%) of cases in the most recent screening round (2011-14) have been reviewed.

22 of 356 assessment cases (6.2%) reviewed in the most recent screening round (2011-14) represented suboptimal assessments.

Themes identified in suboptimal assessments included:

- Interpretation of ultrasound imaging and under sampling
- Ability to correlate mammogram and ultrasound appearances
- Appreciation of and decision making in relation to possible distortions

### Radiologist F

9 of 126 assessment cases (7.1%) reviewed in the most recent screening round (2011-14) represented suboptimal assessments.

Themes identified in suboptimal assessments included:

- Insufficient use of additional views and acceptance of non-representative views
- Limited documentation to explain decision making
- Incomplete correlation of mammogram and ultrasound findings

### Radiologist D

3 of 104 assessment cases (2.9%) reviewed in the most recent screening round (2011-14) represented suboptimal assessments.

### Radiologists B, E, H & I

None of the 79 assessment cases reviewed in the most recent screening round (2011-14) represented suboptimal assessments.

## **General Observations from Case Reviews:**

### Evidence of good practice

Calcium retrieval rates by stereotactic core biopsies performed in the main by advanced practitioners were very good, even in apparently difficult biopsies

The introduction of double reading of any cases returned to normal screen from assessment from 2011.

### Poor documentation

The film reader does not record their level of concern when recalling a woman

Assessment sheets are poor with no diagram available to record the site of abnormality.

Documentation of the size, location and abnormality was poor. There is no documentation about the assessor's opinion about future management resultant on the outcome of the biopsy.

### Use of additional views in assessment clinics

Only one additional view was performed in a significant number of cases.

### Equipment in assessment

Ultrasound images were difficult to interpret with almost all lesions looking apparently solid.

### Cases recalled to assessment

The reviewers found that in their opinion, 7.2% of cases recalled to assessment were unjustified recalls.

### Core Biopsy Reporting and MDT discussion and outcomes

The histology reports often do not appear to represent the lesion biopsied e.g. mass or distortion. There appeared to be very few repeat biopsies in the cases reviewed, which may follow on from an apparently high B2 rate. This may be of concern. The service have a significantly low B1 (normal) rate and high B2 (benign) rate (>3 standard deviations) on non-operative needle biopsy reports as shown in the National Pathology Audit Report (2014) which requires further investigation.

The Report also highlights a relatively high use of fine needle aspiration for cytology which is only recommended on rare occasions in the NHSBSP.

## **Conclusion**

Assessment practice in UHMBT is meeting national minimal standards.

There are quality issues in the service that need addressing. These include poor assessment clinic documentation, ultrasound equipment quality and MDT discussion / interpretation of biopsy results.

An extensive review of cases in the most recent screening round found none where assessment was regarded as substandard (defined as a significant deviation from NHSBSP protocols).

A proportion of cases reviewed (5.1%) were regarded as suboptimal assessment (defined as a minor deviation from NHSBSP protocols). Primarily these suboptimal assessments were in cases assessed by Radiologist C (6.2%) and Radiologist F (7.1%). Whilst not desirable, it should be noted that it would not be considered unusual in such an extensive review over three years of assessment practice that some suboptimal assessments are found. For a small number of cases reviewed recall for reassessment has been advised.

### 3. Interval Cancer Review Process

***Concerns were raised regarding the processes for identification, review and recording of categorisation of interval cancers.***

#### **External Radiological Review of Interval Cancer Classifications (2005-2008)**

The reviewers agreed with the majority of classifications of these cases.

21 classifications (14.6%) were changed of those cases reviewed. This degree of difference is not unexpected in such a large review of interval cancer categorisations.

#### **Conclusion**

The external review raised no concerns regarding the categorisation of interval cancers

### 4. Working Environment

***Concerns were raised regarding a difficult working environment, the management approach, and the lack of an audit culture within the service.***

#### **Issues Raised from Questionnaires and Structured Interviews**

##### Management Arrangements

The current management arrangements are not working. It would appear likely that the current Director of Breast Screening is not taking on the responsibilities incumbent with the role as outlined in Organising a Screening Programme<sup>1</sup>. In order for the service to recover from this current low and move forward and improve, it is important that a leader is identified that has the time and the application to undertake these responsibilities and do so in an inclusive manner. This should enable staff to feel empowered to challenge poor quality where they see it, while always maintaining the high professional standards set out by the individual professional bodies.

##### Audit Culture

There is not an embedded audit culture across the service, with reports that some team members are suspicious of an individual's motives for doing such work. Historically there has been disagreement between staff members as to which radiologist has responsibility for leading on audit which resulted in no one taking the lead. In general, the staff did not appear to know their own performance data or

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<sup>1</sup> NHSBSP 52: Organising a breast screening programme, December 2002



be particularly well informed regarding the performance of the service and how this compares regionally and nationally.

### Working Relations

The interpersonal relationships between certain individuals in the radiological team were described to the visiting team as difficult. There appears to be little respect for each other's professional opinions, a reluctance to challenge opinions of colleagues resulting in defensive decision making as a consequence. This must be having a degree of impact on patient care.

### **Conclusion**

There are serious concerns regarding the management arrangements, working relations and audit culture within the unit that if not immediately addressed are likely to have an impact on the future safety of the service.

# Technical Report: Recommendations

Following the initial external visit to the service in August 2014 the following immediate recommendations were made to the service in early September 2014:

## Immediate Interim Recommendations

The following immediate steps have been identified by the external QA review team which if implemented should make the service more robust. It is acknowledged that these will only be effective within a good working environment where behaviour is professional and the focus of the service is centred on patient care.

### Process

1. Documentation by all film readers is very limited. Although the documentation at assessment clinics by the advanced practitioners is good, this is not the case for the radiologists in the packets accessed by the review team. The following changes should be made to the documentation at film reading and assessment;
  - a. the film reader should document the abnormality noted and record their level of suspicion at the point of initial film reading
  - b. A clear paper record (as well as NBSS direct entry) of each mammographic, ultrasound and clinical finding along with a diagram with appropriate measurements of radiological abnormalities should be made in every case. This will assist clear and accurate presentation at MDT.
  - c. at the time of biopsy the acceptable outcome from subsequent histology should be documented e.g. B2 result required or will accept B1 result

**PRIORITY: Immediate (by 15<sup>th</sup> September 2014)**

**Evidence required – Completed documentation from film reading and from assessment clinics to be viewed by NW QARC**

**Examples of film reading & assessment proformas (Nottingham & Derby) provided as a guide**

2. There appears to be a misinterpretation of the use / value of additional mammographic views specifically that: A) at least 2 views of any possible mammographic abnormality are now appropriate, for the best quality assessment. Both local audit and advice from the QA team, is supported by the reviewers that this represents best practice. B) Additional views can appear to

be normal / benign in some cases, even when a lesion is present, and the level of concern from the original screening mammogram should play an important part in the decision as to whether a biopsy is still indicated.

**PRIORITY: Immediate (by 15<sup>th</sup> September)**

***Introduction of a unit policy where at least 2 views are carried out in the assessment of any possible mammographic abnormality***

***Evidence required - a) SOP to be forwarded to NW QARC; b) Prospective audit of all cases where <2 views carried out in the assessment of any possible mammographic abnormality documenting any mitigating circumstances***

3. There appears to be under sampling particularly for ultrasound core biopsies. In line with current accepted practice a minimum of two passes should be undertaken for all cases and the services protocol updated accordingly.

**PRIORITY: Immediate (by 15<sup>th</sup> September)**

***Introduction of a unit policy where the aim is for a minimum of 2 passes to be carried when undertaking ultrasound core biopsies***

***Evidence required –a) SOP to be forwarded to NW QARC; b) Prospective audit of all core biopsies where <2 cores obtained documenting any mitigating circumstances***

4. Double reading of assessment cases that are considered benign /normal and being returned to normal screen is very good practice. However at present women are not being informed that this is occurring, and that they may be called back following review. In future, women should be clearly informed of this way of working.

**PRIORITY: Soon (by September 30th)**

***Evidence required –a) SOP to be forwarded to NW QARC; b) Prospective audit of all assessment cases where double reading has not taken place by two radiologists documenting any mitigating circumstances***

5. There should be a greater transparency regarding how cases are scheduled for the assessment clinic; the service should consider passing this responsibility to an advanced practitioner and ensure that there is an even distribution of complex cases across all assessment clinics.

**PRIORITY: Soon (by September 30th)**

***Evidence required – SOP to be forwarded to NW QARC***

Equipment:

6. It was reported that the current ultrasound machines are of a poor quality and that it is not always possible to distinguish solid from cystic lesions. This poor performance is particularly evident to those who use the equipment at other sites such as Barrow. An assessment of the fitness of this equipment to support a modern breast screening service should be undertaken and if required replacement units secured.

**PRIORITY: Soon (by October 31<sup>st</sup> 2014)**

***Evidence required – Details of the assessment and any resultant required action to be forwarded to NW QARC***

## **Additional Recommendations from Final Report**

The following recommendations are in addition to the immediate recommendations already made:

a) Screening schedule

To facilitate the significant review of processes, as well as culture and leadership changes that are urgently required, screening schedules should be slowed down for a short time period to ease pressure on the service.

***PRIORITY: Urgent (by 15<sup>th</sup> December 2014)***

***Evidence required – A copy of the revised screening schedule to achieve this to be forwarded to NW QARC***

b) Review of managerial arrangements

A review of the managerial arrangements for the service is urgently required to ensure adequate inclusive leadership to support the recommended changes to processes.

**PRIORITY: Urgent (by 15<sup>th</sup> December 2014)**

**Evidence required – An action plan to be forwarded to NW QARC**

c) Improvement to working environment

We are aware that the Trust has been trying to address this issue through team building workshops. It is essential that this support continues alongside the recommended changes to processes in order to achieve a professional working environment focussed on patient care.

d) Refresher Training

It is recommended that Radiologist C & Radiologist F have a short period (to be determined) of refresher training in assessment clinic processes at another breast screening service outside of the region. These should address the areas of suboptimal practice for each radiologist as identified in the report.

**PRIORITY: Urgent (by 15<sup>th</sup> December 2014)**

**Evidence required – An action plan to be forwarded to NW QARC**

e) External visits to another breast screening service

To support the recommendations made regarding changes to processes the opportunity should be given for all relevant staff to visit another breast screening service. All radiologists working in assessment should attend an assessment clinic and all film readers should attend a film reading consensus meeting at another service outside of the region.

**PRIORITY: Urgent (by 15<sup>th</sup> December 2014)**

**Evidence required – An action plan to be forwarded to NW QARC**

f) Ultrasound Equipment

A clear action plan for the recommended replacement of ultrasound equipment needs to be put in place as soon as possible.

**PRIORITY: Urgent (by 15<sup>th</sup> December 2014)**

***Evidence required – An action plan to be forwarded to NW QARC***

g) Audit Arrangements

A review should be carried out and a clear and robust action plan for delivery of audit at the service should be drawn up. This review should include a review of the role and responsibilities of the designated audit lead, a clear schedule for required mandatory audits, a process for feedback and discussion of the audit data, as well as a clear and transparent process for carrying out additional audits within the service.

***PRIORITY: Soon (by 16<sup>th</sup> February 2015)***

***Evidence required – A copy of the action plan to be forwarded to NW QARC***

h) MDT interpretation of needle biopsy results and National Pathology Audit Outlier Status

The review team has concerns in relation to interpretation of B1 (normal) and B2 (benign) non-operative needle biopsy results and appropriate MDT discussion and decision making following review of assessment cases. UHMBT have 1333 biopsies over past 3 years reported as B1 or B2 (111 cases per quarter on average). These concerns are supported by the service being both a low B1 rate outlier and a high B2 rate outlier in the National Pathology Audit Report (2014). This requires further investigation.

***PRIORITY: Soon (by 16<sup>th</sup> February 2015)***

***Evidence required – A completed retrospective audit of consecutive cases with B1 and B2 results returned to routine recall for a three month period in 2013 or a minimum number of 100 cases with evidence of MDT discussion of the audit results and resultant action plan to be forwarded to NW QARC***

## Technical Report: Methodology of Review

This external review focussed on specific areas of concern that had been raised in relation to the breast screening service at UHMBT. It is not a comprehensive review of all aspects of the service such as that which would be carried out at a scheduled routine external quality assurance visit.

The review was carried out using the following methodology:

- Questionnaire replies and structured interviews
- Documentation review
- Statistical review
- Radiology review
- Review of audits

### Questionnaires and Interviews

In order to evaluate whether the concerns and opinions raised by the whistle blowers were more widely held by any other members of staff in the unit, an initial questionnaire was designed for completion by all staff prior to the visit (appendix 4). This was designed to establish how the service operates and to gain an insight into how the whole team performs. The questionnaire was also informative to the team regarding which specific groups of cases would be most useful to review.

The questionnaire was emailed to 77 members of staff. Fifty members of staff responded (65%).

To give staff an opportunity to voice their opinions regarding the provision of breast screening at the UHMBT service, all team members in all disciplines were offered the opportunity of a timed scripted interview where all participants were asked the same questions relevant to their professional area (appendices 5 & 6). There was representation from many staff groups in the screening service including radiology, radiography, nursing, pathology and surgery. At the start of each interview the maximum length of the interview was explained to the interviewee as was the instruction not to record the meeting. It was also explained that the information imparted would be completely confidential to the review team and not be further published or reported in a manner that made it attributable to the individual. As a result, the external team conducted 19 structured interviews which included 7 film readers.

## **Documentation Review**

In order to facilitate an assessment of whether the service followed their local standard operating procedures and whether these align with current NHS Breast Screening Programme (NHSBSP) guidance, relevant documentation was requested. A documentation review was undertaken prior to the visit by the external review team. These included protocols for assessment clinics, interval cancer review, film reading and consensus meetings. The QA visit reports from 2009 and 2012 were examined for contextual purposes.

## **Statistical Review**

Data were requested from the North West QA Reference Centre to enable an analysis of the performance of UHMBT against regional and national averages to be undertaken. Individual film reader performance data were also examined and aggregated with film readers from two other English regions to provide comparative statistics in the absence of national comparative data. Film readers are assigned a numerical identity but not named in this report.

The following datasets were used to inform the review:

- The national Department of Health Korner Returns (KC62) for years 2006-14 (annual and 3-year aggregates) were requested to provide key programme outcome data.
- Rates of interval cancers and the radiological categorisations of these cases were requested from the North West QA Reference Centre
- The assessment report (ASSeX) and Histology QA standard reports (BQA) generated from the data recorded on the National Breast Screening computer System (NBSS) were requested for the past three years to provide baseline data on the workload of individual radiologists.
- Rates of missed cancers were requested at regional, unit and individual level from North West QA Reference Centre (NWQARC).
- Historic screening round length data was also requested from NWQARC and examined to assess its possible impact on rates of interval cancer incidence.

## **Radiology Review – Case Selection**

The case selection for the radiological imaging review performed by the consultant radiologists was informed from the outcomes of the statistical review, the allegations made by the whistle blowers and the issues arising from the questionnaires. Further cases were requested for review as a result of the initial findings and following the receipt of additional information from one of the whistle blowers and at the request of the medical director . The review was undertaken by two experienced breast screening radiologists. Radiologists working in assessment are identified by a letter, but not named in this report.



Film Reading:

Arbitrated cancers which were missed by one film reader for the period April 2012 - September 2013

Assessment:

a) Historical practice

All films and images of the 24 cases from the false negative assessment interval cancer audit as submitted by one of the whistle blowers (R1)

Cases screened and assessed 1<sup>st</sup> April 2005 - 30<sup>th</sup> March 2008 arising as interval cancers between May 2005 and July 2011 (R2)

Cases screened and assessed 1<sup>st</sup> April 2009 - 30<sup>th</sup> March 2011 arising as screen detected cancers between April 2012 and September 2013 (R3)

b) Current practice (most recent screening round)

All images/packets for 10 assessment clinics (approximately 100 cases) for Radiologist C, approximately one per month over the twelve-month period April 2013-March 2014 (R4)

All images/packets for 2 assessment clinics (approximately 20 cases) for all other breast screening radiologists still working within the service over the same twelve month period April 2013-March 2014. A review of cases from 3 additional assessment clinics for Radiologist F from the same time period was carried out due to the findings of the initial review of cases (R4).

Cancers diagnosed on short-term recall since 2010 were requested but there were no cancers in this category

Following the initial review of assessment clinic practice the following additional reviews were carried out due to some concerns over practice:

Assessment clinics from September - December 2011 for 3 radiologists (C, D, F) where women had been returned to routine recall and no biopsy had been performed (R5)

Assessment clinics from January 2012 - March 2013 for Radiologist C where women had been returned to routine recall and no biopsy had been performed (R6)

At the request of the medical director and one of the whistle blowers, some additional cases were reviewed (R7 & R8)

### Interval Cancer Classification

A selection of interval cancers deriving from the screening years April 2005 - 2008 so as to examine the radiological classification assigned by the service locally and assess agreement

## **Radiology Review – Process**

In view of the time constraints, the reviewing radiologists independently reviewed all cancers which had been previously assessed (n = 90). The results were immediately inputted onto a customised database and then cross-matched to see if the opinions were mainly concordant. As this was indeed the case, the rest of the review was completed by dividing the remaining cases between the radiologists. A small number of cases were discussed when consensus was required.

To support the review of interval cancers and arbitration cancers NHSBSP interval cancer forms were completed. For assessment cases, the latest version of the 'form 4' (appendix 7) was used. For film reading cases a simple form was developed for the purpose of this review (appendix 8).

## **Review of Local Audit**

The structured questionnaire asked questions regarding audit practice within the service and requested details of the audits conducted. In addition to audits submitted by the whistle blowers, several further audits were submitted for consideration including:

Audit of assessment practice (February 2014)

Audit of malignant cases from consensus (January 2013)

Double reporting of patients discharged from the assessment clinic: The North Lancashire and South Cumbria Experience (May 2013)

Audit of ultrasound guided breast biopsies (2014)

The results of the most recent patient satisfaction surveys were also reviewed.

The review of these audits allowed the external team to determine the degree of audit culture within the service and also assess recent performance in relation to the audits submitted.

# Detailed Technical Report

## 1) Film Reading

### a) UHMBT Breast Screening Unit Performance

#### Methodology

To facilitate an initial review of programme performance prior to focussed case review by the external radiology team, rates of cancer detection, recall to assessment and interval cancers were analysed. This provided a contextual overview of performance prior to more detailed analysis of individual film reader performance incorporating initial film reader statistics and data relating to performance in assessment.

The national Korner Returns (KC62) for years 2006-13 (annual and 3-year aggregates) were requested to provide key programme outcome data. Data were requested from the NWQARC on rates of interval cancers and radiological categorisations of these cases. To assess workload of individual radiologists, the assessment report (ASSeX) and Histology reports (BQA) were requested for the past three years. Rates of missed cancers were requested at the regional, unit and individual level. Historic screening round length data was also examined to assess its possible impact on rates of interval cancer incidence.

Analysis of performance was undertaken in two stages. Firstly, data at service level were compared, wherever possible, to comparative regional and national averages, whilst individual level film reader statistics were combined with peers from two other regions (East and West Midlands) to examine whether performance was within normal variation or otherwise. Secondly, to help substantiate the findings of the paper-based performance review, a comprehensive radiological image review was undertaken by two external radiologists of the most recent performance to date and the findings analysed. These data allowed the external team to form an opinion as to whether the unit were currently operating safely and within national standards.

#### i) Cancer Detection and Recall Rates - Prevalent Screen

Figure 1 shows annual standardised detection ratios (SDRs) for invasive cancers at the prevalent (first round) screen. The national minimum standard of 1.0 was achieved for 6 of 7 years between 2006 and 2013. However, the unit's performance was poorer in comparison to the regional average with the service only reaching the target standard of performance in 2011/12 (>1.4). For comparison, the national median SDR was 1.43. Numbers screened

averaged around 3,300 annually, so the statistics are reliable and not affected by statistical instability due to small numbers.

Acceptance rates (not shown) at the service were good exceeding the regional average over the aggregate periods 74.7% (2006-09) and 72.6% (2009-12). Therefore, this should not have had any adverse impact on rates of cancer detection.

Performance with regards to small invasive cancer detection at the prevalent screen was markedly poorer than expected with failure to reach the *minimum* invasive cancer detection rate ( $\geq 2/1000$ ) over 6 of 7 years studied. A rational response by the unit to improve the detection of small cancers was to increase the recall rate (figure 2). Unit recall rates for the prevalent screen are shown in figure 1 and demonstrate consecutive annual increases in recall at the prevalent screen between 2006 and 2012. Recall rates were higher than the minimum standard (10%) from 2010/11 onwards. Comparative increases in recall occurred between the periods 2006-09 and 2009-12 at both the prevalent and incident screens; 7.9% (prevalent 06-09), 11.0% (prevalent 09-12), 3.3% (incident 06-09), 4.3 (incident 09-12). The 2012 QA visit report stated:

*“There has been a steady decline in the cancer detection rate in the prevalent round over the last few years and the unit has failed to meet the minimum standard for the last two years. In addition, the most recent interval cancer data show that the unit has a rate above the regional average. As a result, the recall rate to assessment has increased as the unit seeks to address this and is now above the minimum standard. The unit will need to continue in their efforts to address this issue”.*

Consequently, there was a conscious effort on the part of the unit to increase cancer detection at the prevalent screen and small cancer detection in particular. However, increasing recalls did not lead to increases in small cancer detection. This has clearly had an impact on individual film reader specificity as shown in figure 5.

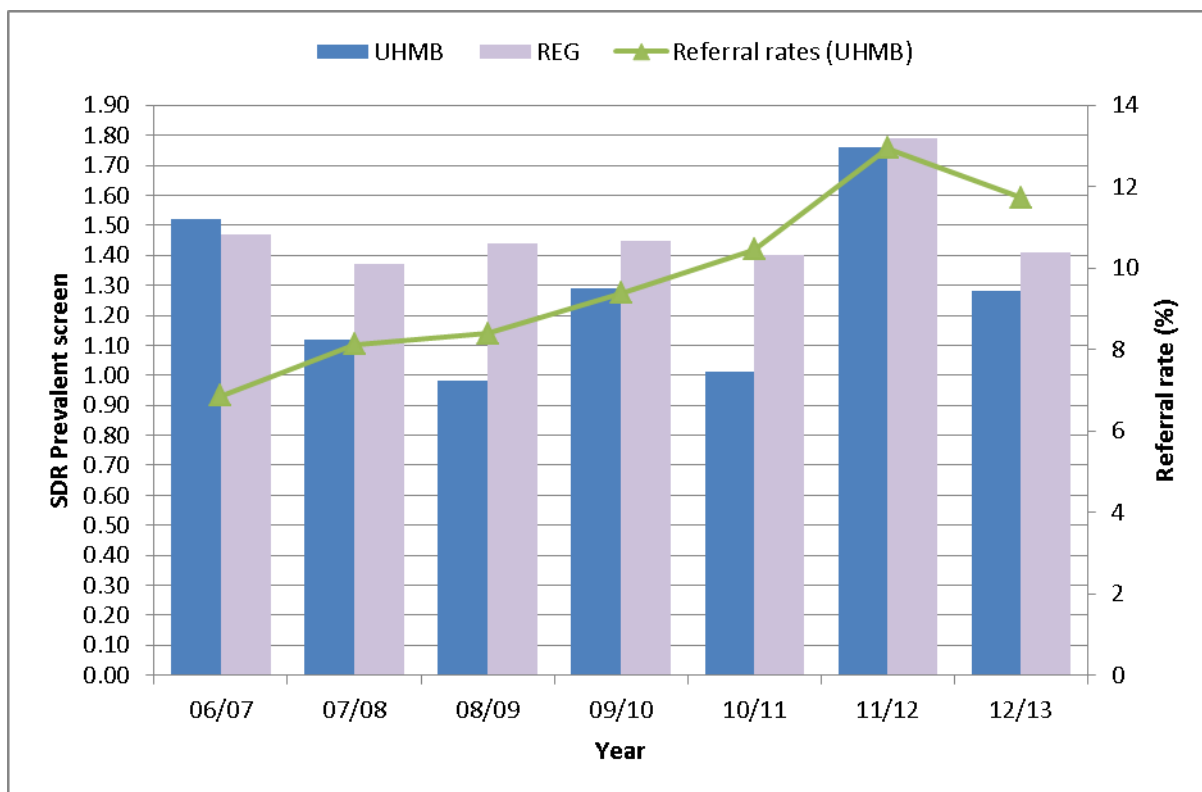


Figure 1: Comparative SDRs at the prevalent screen and referral rates (UHMB and region)

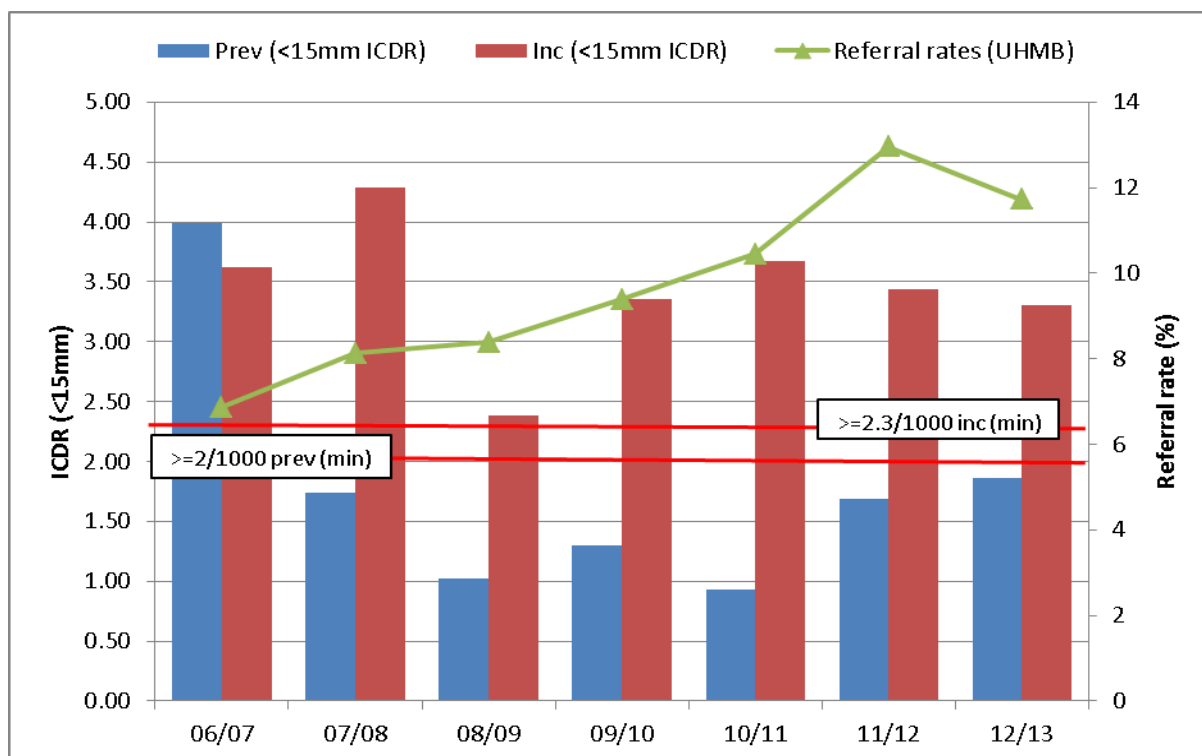


Figure 2: Annual rates of small cancer detection at the prevalent and incident screen and referral rates at the prevalent screen (2006-2013)

Rates of DCIS detection are generally positively correlated with small cancer detection (Evans et al 2002<sup>2</sup>) and a low rate of non-invasive disease (particularly high grade) may mean small invasive foci are missed. Over 2006 to 2012 aggregated rates of non-invasive disease detection rose as shown in table 1 yet small cancer detection fell. Hence, this is unlikely to be the reason for modest rates of small cancer detection.

Screen	Year Group	Non-invasive CDR per 1000 Min standard ≥0.5/1000 (N Lancs)	Non-invasive CDR per 1000 (Region)	SDR (<15mm) Min standard ≥1.0	95% LCL	95% UCL
Prevalent SDR	2006-09	1.19	1.78	0.89	0.60	1.31
	2009-12	2.03	1.78	0.74	0.48	1.15
Incident SDR	2006-09	1.29	1.37	1.47	1.28	1.70
	2009-12	1.60	1.42	1.53	1.34	1.75
Combined SDR	2006-09			1.37	1.20	1.56
	2009-12			1.41	1.24	1.60

Table 1: Rates of non-invasive disease detection and small cancer SDRs (2006-9 and 2009-12)

## ii) Cancer Detection - Incident Screen

Whilst rates of cancer detection were modest at the prevalent screen, cancer detection was good at the incident screen compared to their peers in the North West region and well above the achievable minimum standard over both 2006-09 and 2009-12 (identifier PLN). As the incident screen is numerically the largest cohort of women, this meant that overall cancer detection at the service was good.

The SDR at the incident screen compared well to England average performance over both 2006-09: 1.49 (UHMBT), 1.47 (England) and 2009-12: 1.73 (UHMBT), 1.44 (England).

<sup>2</sup> Evans AJ<sup>1</sup>, Blanks RG. Should breast screening programmes limit their detection of ductal carcinoma in situ? *Clin Radiol.* 2002 Dec;57(12):1086-9

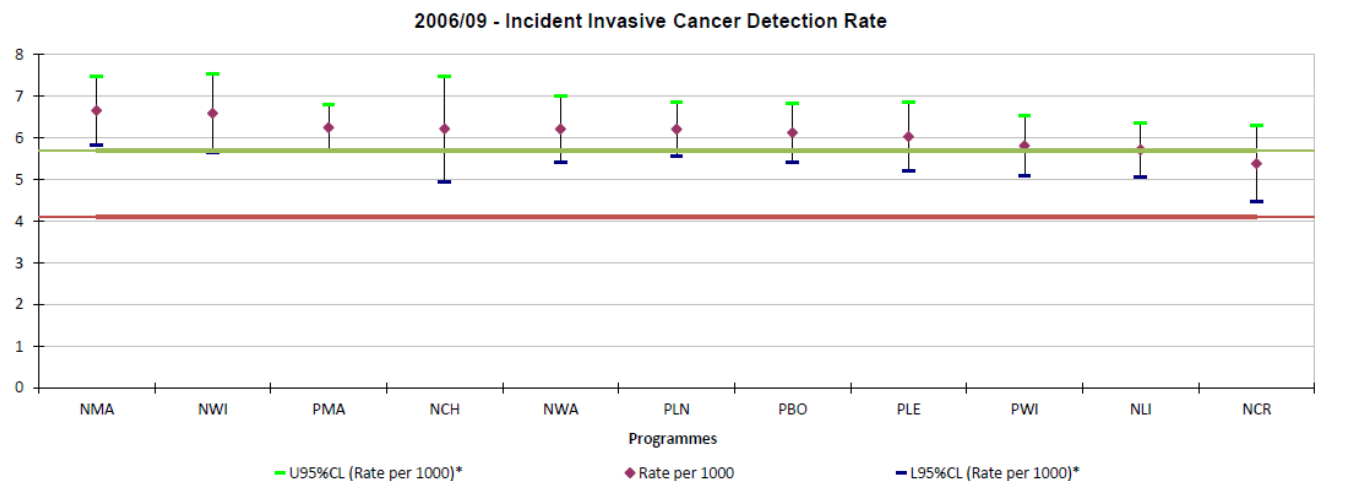


Figure 3: Comparative rates of invasive cancer detection at the incident screen within the North West region (2006-2009) UHMBT identified as PLN

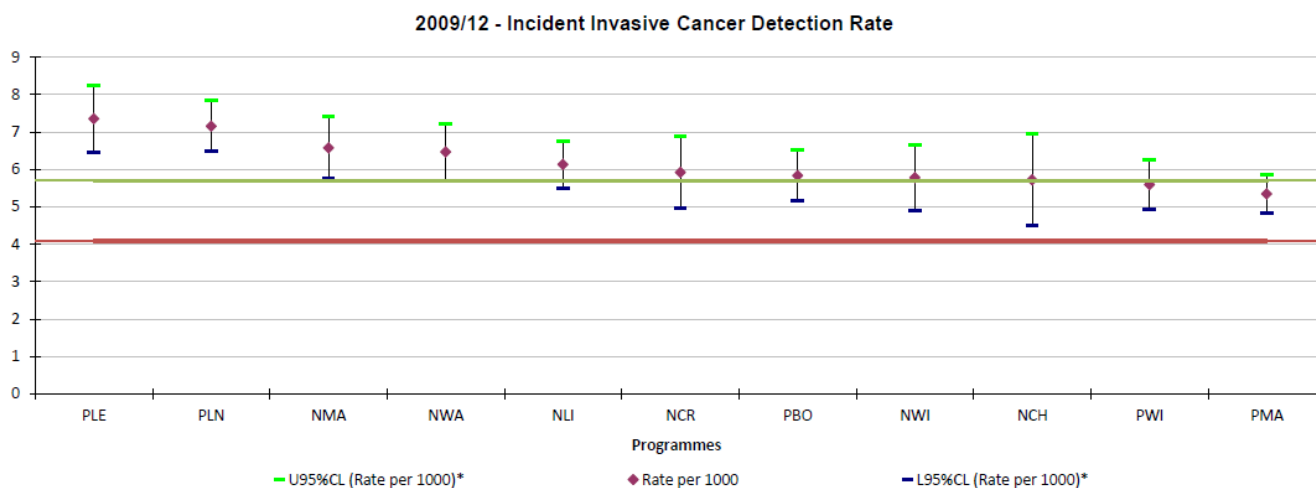


Figure 4: Comparative rates of invasive cancer detection at the incident screen within the North West region (2009-2012) UHMBT identified as PLN

### Overview of unit film reading performance from statistical review

- Whilst small cancer detection was low at the prevalent screen, overall small cancer detection was above QA target standards between 2006 and 2012 at the incident screen which comprises the largest cohort of women.
- Increasing recall rates at the prevalent screen was a pragmatic response to encourage small cancer detection.
- Overall cancer detection rates were good compared to England averages.

## b) Individual Film Reader Performance

### i) Cancer Detection and Recall Rates – Statistical Review

#### Methodology

Film reading performance was assessed for all readers at UHMBT over 2006-09 and 2010-13 to assess changes in performance over time. The estimated positive predicted value (PPV) of referral and referral rate were produced with isobars demonstrating cancer detection rates.

#### Positive Predictive Value of Referral

Figure 5 illustrates that for most film readers, rates of referral increased whilst PPV of referral decreased over the two aggregated periods reflecting poorer discrimination over time. Some film readers are shown to have worked over both periods and red markers demonstrate that performance over 2006-09 was generally superior to 2010-13 (yellow markers) in terms of PPV of referral. However, cancer detection rates increased for 6/7 film readers who read over both periods as shown in table 2.



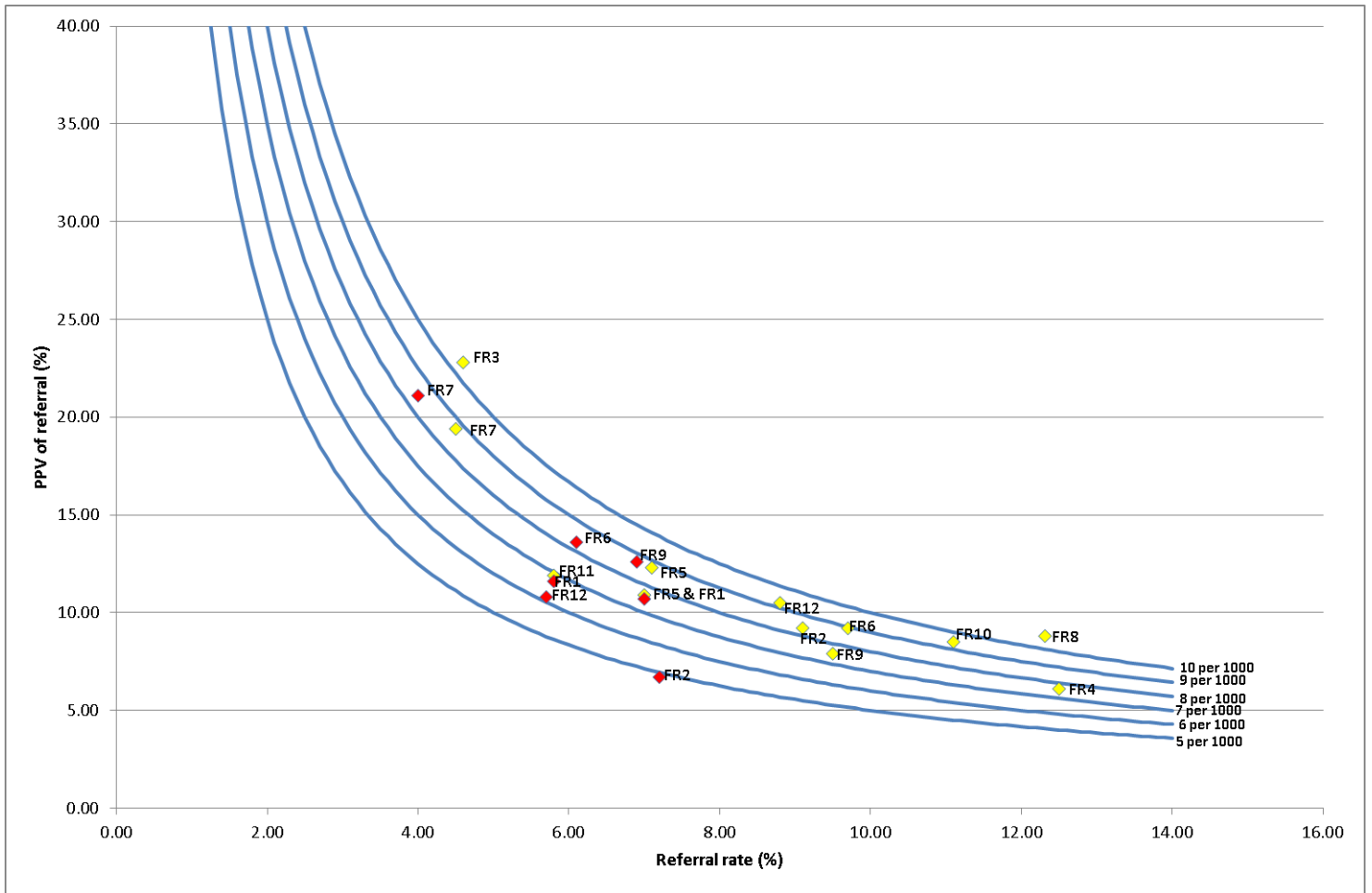


Figure 5: PPV of referral and referral rates 2006-09 (red triangles) 2010-13 (yellow triangles)

<b>Film reader</b>	<b>Cancer detection rate (2006-09)</b>	<b>Cancer detection rate (2010-13)</b>	<b>Difference</b>	<b>Comments</b>
FR1	6.7	7.6	+ 13%	Commenced reading 2002 and increase recall from 5.8% to 7.0% (21%) which has increased CDR
FR2	4.8	8.3	+ 73%	Commenced film reading 2007 so increase partly due to increasing experience
FR5	7.5	8.7	+ 16%	Commenced reading 2000 recall rate around 7% both periods so good increase in cancer detection overall
FR6	8.3	8.9	+ 7%	Good cancer detection when recall 6.1% (06-09). Similar CDR when recall increased to 9.7% (10-13)
FR7	8.4	8.8	+ 5%	Good cancer detection over both periods and recall increased slightly from 4.0% (06-09) to 4.5% (10-13)
FR9	8.6	7.5	-13%	Cancer detection fell and recall increased (6.9% to 9.5%)
FR12	6.2	9.2	+ 48%	Large increase in CDR coincides with large increase in recall (5.7% to 8.8%)

*Table 2: Comparative film reader performance in terms of cancers detected 2006-09 and 2010-13*

*\*\*Film readers 3,4,8,10 and 11 excluded from table 2 as only read over one period. These readers included in figure 5*

Over the aggregated years 2006-09 and 2009-12, SDRs at the prevalent screen increased from 1.17 (CI 0.88-1.77) to 1.37 (CI 1.04-1.70) suggestive that the increase in referral correlated with an increase in cancer detection. It is noticeable that increases in recall rates for Film Reader 6 by 59% led to a very modest increase in cancer detection; hence this reader demonstrated better performance over 2006-09 with lower rates of recall and good rates of cancer detection.

## ii) Cancer Detection and Recall Rates – Statistical Comparison with Peers

### Methodology

To provide contemporary comparative statistics of film reader performance, data for UHMBT was combined with individual outcomes from all readers in the East and West Midlands for the period 2010-13. Additional data was also included for UHMBT staff over the most recent period available (2013-14) to establish whether performance had changed since 2010-13. Data for East and West Midlands over this period is not included as it is not yet complete.

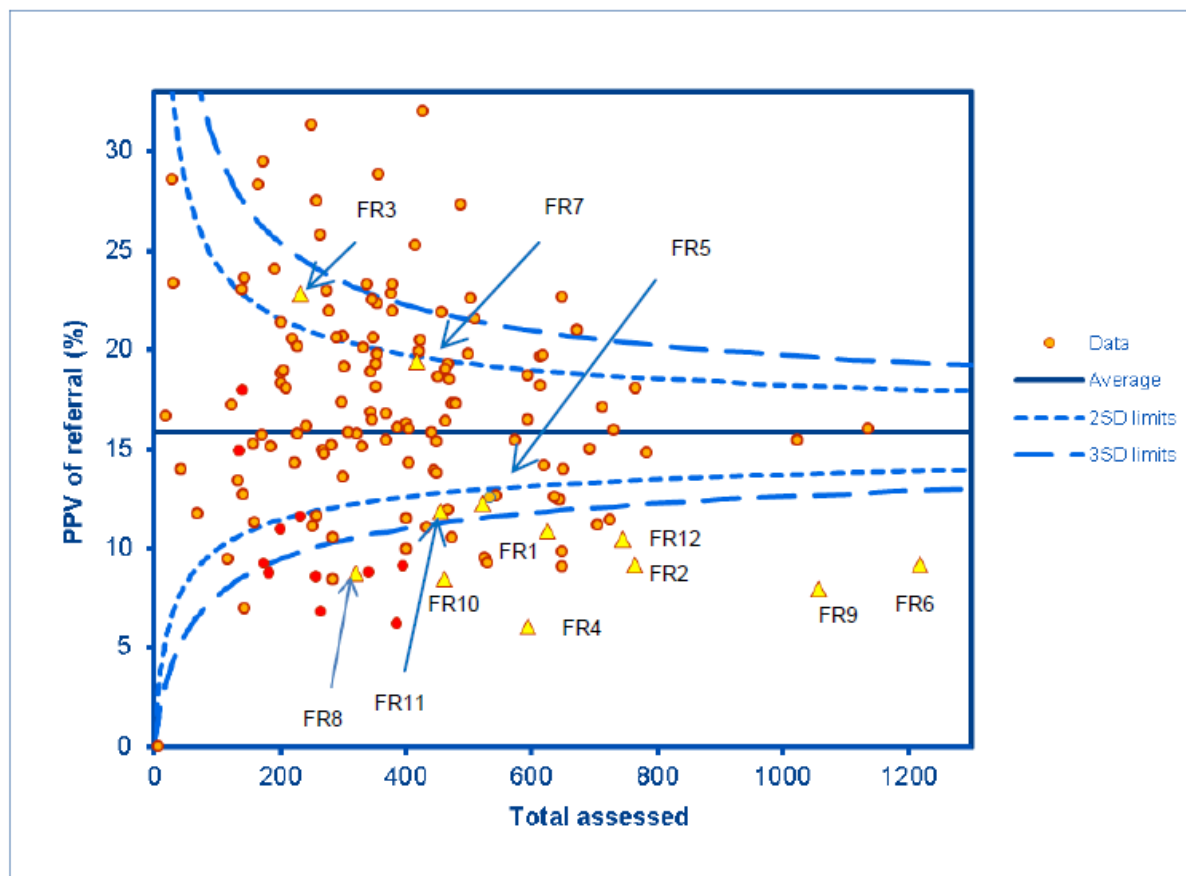


Figure 6: PPV of referral for combined film readers (2010-13) and Lancaster (2013-14) UHMBT readers 2010-13 (yellow triangles), 2013-14 (red circles)

Combining results from 2010-13 with results of UHMB readers over 2013-14 (figure 6), the average PPV of referral was 15.9% comprising 135 film readers. The majority of film readers in North Lancs had PPV of referral below this average (n. 10/12). Over 2010-13, 2 film readers

were outliers with performance more than 2 standard deviation from the mean whilst 8 were very high outliers (>3 sd). Comparing 1 year (2013-14), with 3 year performance (2010-13), most readers who were outliers over the 3 year period remained outliers over the most recent year (table 3). Only one film reader at the service was not an outlier over either period.

Film reader(s)	Performance (2010-13 and 2013-14)
FR2, FR9, FR4, FR8, FR6, FR10, FR12	Outlier >3sd both periods
FR5	Outlier (>2sd) 2010-13, not outlier 2013-14
FR11	Outlier (>2sd) both periods
FR7	Not outlier

Table 3: Film reading performance (PPV of referral) 2010-13 compared to 2013-14

Table 4 summarises performance of all film readers at UMBHT over 2010-13 with 2013-14. Between the two comparable periods, overall recall rates have fallen from 8.2% to 7.6% which remains much higher than the remainder of the film readers over 2010-13 (4.2%). PPV of referral has decreased for 7 film readers despite rates of recall falling for 4 of these readers.

Film Reader	Recall (%) 2010-2013	PPV (%) 2010-2013	CDR/1000 2010-2013	Recall (%) 2013-2014	PPV (%) 2013-2014	CDR/1000 2013-2014
FR1	7.0	10.9	7.6	6.5	11.0	7.1
FR2	9.1	9.2	8.3	9.5	8.8	8.4
FR4	12.5	6.1	7.6	8.4	8.6	7.3
FR5	7.1	12.3	8.7	6.1	14.9	9.1
FR6	9.7	9.2	8.9	6.0	8.8	5.3
FR7	4.5	19.4	8.8	3.7	18.0	6.7
FR8	12.3	8.8	10.8	9.1	6.8	6.2
FR9	9.5	7.9	7.5	11.4	6.2	7.1
FR10	11.1	8.5	9.4	8.0	9.2	7.4
FR11	5.8	11.9	6.9	6.1	11.6	7.1
FR12	8.8	10.5	9.2	8.4	9.1	7.7
<b>All PLN</b>	<b>8.2</b>	<b>10.4</b>	<b>8.5</b>	<b>7.6</b>	<b>9.5</b>	<b>7.2</b>
<b>All readers (exc. PLN)</b>	<b>4.2</b>	<b>17.1</b>	<b>7.2</b>	-	-	-

Table 4: Comparative film reading performance by individual 2010-13 and 2013-14

### Overview of Individual PPV of Referral (from film reader statistics)

- Combining film reader statistics with peers in the East and West Midlands, most UHMBT readers demonstrate significantly poorer performance in terms of PPV of referral. This is due to recall rates, which on average are almost double the remainder of their peers in the other regions.
- Rates of cancer detection at the individual level on average exceed rates in the remainder of the cohort: 8.5/1000 (UHMBT) 7.2/1000 (remainder). Only one reader had individual rates slightly lower than 7.2/1000. Hence, there is little evidence for low cancer detection at the individual level. Hence, film reading specificity is poorer than levels of sensitivity.

## iii) Cancers Missed by First Reader: Statistical Review

### Methodology

The programme employs double reading of screening images as the failure of one reader to identify all abnormalities if single reading is employed is acknowledged. Hence, individual “miss rates” can be calculated based on those abnormalities not recalled by the first reader (blinded read) but recalled by the second reader and subsequently confirmed recall at arbitration. This gives a gauge of film reading sensitivity.

Rates are calculated as the miss rate per 1000 films read. Figure 7 has combined data with the East and West Midlands for 2010-13 with film readers in the unit over 2010-13 and 2013-14 to allow contemporary examination of performance.

### Results

As shown in figure 7, no film readers in the service are outliers for rates of missed cancers over the period 2010-13 and over 2013-14 only one reader was a very low outlier (FR9) which reflects optimal performance as no abnormalities were missed at the first read over the period.

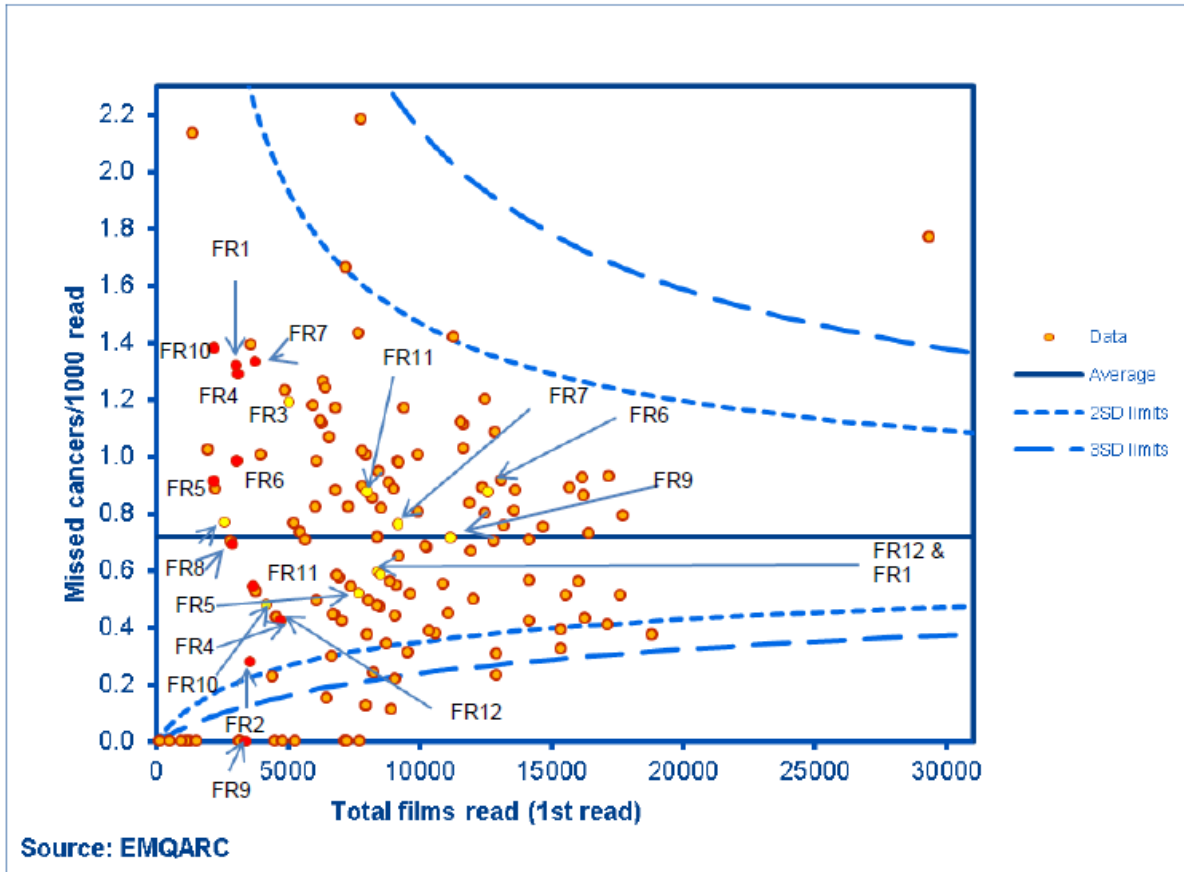


Figure 7: Missed rates for combined film readers (2010-13) and Lancaster (2013-14) UHMBT readers 2010-13 (yellow triangles), 2013-14 (red circles) – average missed rate 0.7/1000

Film reader	Total films Read 2010-2013	Total missed cancers 2010-2013	Missed cancer rate/1000 2010-2013	Total films Read 2013-2014	Total missed cancers 2013-2014	Missed cancer rate/1000 2013-2014
1	8895	5	0.6	3098	4	<b>1.3</b>
2	8409	4	0.5	3562	1	0.3
3	5034	6	1.2	-	-	-
4	4741	2	0.4	3031	4	<b>1.3</b>
5	7370	4	0.5	2186	2	<b>0.9</b>
6	12571	11	0.9	3044	3	<b>1.0</b>
7	9171	7	0.8	3747	5	<b>1.3</b>
8	2594	2	0.8	2886	2	0.7
9	11163	8	0.7	3384	0	0.0
10	4164	2	0.5	2173	3	<b>1.4</b>
11	7841	7	0.9	3807	2	0.5
12	8511	5	0.6	4689	2	0.4
<b>All PLN</b>	<b>90464</b>	<b>63</b>	<b>0.7</b>	<b>35607</b>	<b>28</b>	<b>0.8</b>
<b>All Readers exc. PLN</b>	<b>1116893</b>	<b>800</b>	<b>0.7</b>	-	-	-

Table 5; Missed cancer rates 2010-13 and 2013-14

### Overview of Individual Missed Cancer Rates at First Read (from Film Reader Statistics)

- Combining film reader statistics with peers in the East and West Midlands, *no* UHMBT readers were significantly different to their peers in terms of missed cancer rates over 2010-13 or the most recent period 2013-14.
- One film reader missed no cancers over the most recent year of film reading reflecting good sensitivity.

### iii) Cancers Only Detected by One Reader: External Radiological Review

#### Methodology

Audit period: 1 April 2012-30<sup>th</sup> September 2013

Total cancers missed by first or second film reader (not concordant recall): 56 (50 available for the review)

Calculations: Rates of missed cancers were calculated as a proportion of total women assessed over the period.

Films were reviewed by the external team to establish whether one individual was missing more cancers repeatedly than their peers and to establish whether any specific radiological features were regularly misinterpreted. The external reviewers categorised all “missed cancers” using the standard NHSBSP classifications which are used as standard in the NHSBSP:

- R1 Normal
- R2 Benign
- R3 Indeterminate
- R4 Suspicious
- R5 Malignant

Film Reader	Total films 1st read	Total films 2nd read	Total missed 1st read	Total missed 2nd read	Total missed 1st read /1000	Total missed 2nd read /1000	Total missed rate
FR1	4745	7352	4	2	0.8	0.3	0.5
FR2	4506	5336	2	0	0.4	0.0	0.2
FR4	4599	4592	4	1	0.9	0.2	0.5
FR5	2852	5414	3	1	1.1	0.2	0.5
FR6	5380	3732	5	3	0.9	0.8	0.9
FR7	6010	5093	8	7	1.3	1.4	1.4
FR8	4246	3726	4	0	0.9	0.0	0.5
FR9	4932	1849	0	0	0.0	0.0	0.0
FR10	3708	4367	3	0	0.8	0.0	0.4
FR11	5686	4695	3	2	0.5	0.4	0.5
FR12	4336	4841	2	2	0.5	0.4	0.4
<b>Total</b>	<b>51000</b>	<b>50997</b>	<b>38</b>	<b>18</b>	<b>0.7</b>	<b>0.4</b>	<b>0.5</b>

Table 6: Cancers detected by only one reader (i.e. missed at 1<sup>st</sup> or 2<sup>nd</sup> read by film reader)

The “miss rates” at first read reflect the film reader statistics and demonstrate that no film reader is missing significantly more cancers than their peers. Of missed cancers at first read, 59% were categorised *indeterminate* (n. 20) whilst 26% were reported *suspicious* (n. 9) and 15% (n.5) were categorised *malignant*.



### Overview of Cancers Missed by First Reader by External Radiologist

- The “miss rates” at first read reflect the film reader statistics and demonstrate that no film reader is missing significantly more cancers than their peers.
- There are no NHSBSP targets for individual film reader “miss rates” and double reading is the standard protocol due to the acceptance that not all film readers will detect every possible cancer on presentation. There is no national comparative film reader data available.
- There was no specific feature or type of case which was repeatedly dismissed as normal by any film reader.
- The NHSBSP accept that not all cancers will be identified by a single film reader which is why double reading of all images, with arbitration of cases where there is discordance, is the accepted standard of practice in the programme to maximise cancer detection.
- 5/34 cases missed at first read and 4/18 at second read were interpreted as malignant with the remainder indeterminate or suspicious following review.

## b) Statistical Review: Assessing Consensus Meetings

The presentation of an audit to the review team demonstrated higher rates of recall to assessment following panel consensus from the Tuesday meeting in comparison to the Thursday meeting amounting to 62% versus 45%. Similarly higher recalls from the Tuesday consensus meeting were observed from an audit conducted in 2013 (61% versus 38%). Further allegations suggested that the rates were attributable to certain personalities being present in the meetings.

### Methodology

Audit period: April 2010 – March 2013

Method: Recall rates from the first (initial) film read were examined to see if film readers had similar rates of recalls based on which consensus meeting they attended.

ID	Total films read	Total RC	Total cancers	Recall rate %	PPV for recall %
FR1	8895	625	68	7.0	10.9
FR7	9171	417	81	4.5	19.4
FR10	4164	461	39	11.1	8.5
FR11	7841	455	54	5.8	11.9
FR12	8511	745	78	8.8	10.5
<b>Thursday consensus meeting total</b>	<b>38582</b>	<b>2703</b>	<b>320</b>	<b>7.0</b>	<b>10.5</b>
FR2	8409	764	70	9.1	9.2
FR4	4741	594	36	12.5	6.1
FR5	7370	522	64	7.1	12.3
FR6	12571	1218	112	9.7	9.2
FR9	11163	1057	84	9.5	7.9
<b>Tuesday consensus meeting total</b>	<b>44254</b>	<b>4155</b>	<b>366</b>	<b>9.4</b>	<b>8.8</b>
ALL READERS (Emids/Wmids/unit)	1207357	54799	8861	4.5	16.2

Table 7: Film reader performance of initial mammograms (first read) by consensus meeting grouping (2010-13) (Grey shading – readers attend Tuesday consensus meetings, blue shading – readers attend Thursday consensus meetings)

### Overview of Panel Consensus Meeting Statistics

- The recall rates for individuals working within the Tuesday meeting was 9.4% which was higher than the aggregated recall rate from staff attending the Thursday meeting (7.0%).
- The range of rates at the individual level was quite diverse between groups with 4/5 readers having a recall rate of  $\geq 9\%$  attending the Tuesday meeting compared to 1/5 readers attending the Thursday consensus meeting.
- There was a natural propensity of *most* readers to recall more cases in the Tuesday consensus meeting.

## 2) Assessment Practice

### Background

#### Current Guidance in the NHSBSP

The Quality Assurance Guidelines for Breast Cancer Screening Radiology (NHSBSP pub 59, March 2011) introduced the mandatory formal audit of false negative assessment cases. These constitute women who have been previously assessed for the same side and site as a cancer which subsequently presents as an interval cancer or cancer at the following screening episode. These cases are required to be reported to the QA reference centre within 3 months of ascertainment. After publication of the guidance, an audit form was developed, known as form 4 (see appendix 7). This allowed comparison of procedures undertaken at the original assessment and following audit, what would be considered appropriate to constitute adequate assessment now (in hindsight).

This information is used to form a summary opinion as follows:

Optimal assessment (follows NHSBSP protocols)

Suboptimal assessment (minor deviation from NHSBSP protocols)

Substandard assessment (significant deviation from NHSBSP protocols)

Reassessment required (where review of assessment practice is being undertaken)

The suboptimal and substandard categories of assessment do not have a formal definition. They are used as a guide for reviewers to the quality and completeness of an assessment episode, combined with the level of suspicion of the abnormality undergoing assessment. Therefore a suboptimal assessment may or may not require reassessment following review. Typically substandard assessment will require reassessment.

There are a small number of suboptimal assessments included in this review that owing to the level of suspicion of malignancy have been recalled for reassessment. For the remaining assessments categorised as suboptimal, whilst practice in assessment was not ideal, the level of suspicion did not warrant reassessment in the opinion of the reviewers.

#### Statistical Interpretation of False Negative Assessment Rates

It is not routine practice or currently required to record rates of false negative assessments in the NHSBSP, either at unit or individual level.

There is no nationally agreed methodology of how to calculate missed cancer rates from assessment or definition of what “missed cancers” constitute.

The numbers of “missed cancers”, however defined, are likely to be extremely small at the individual level, even if many years performance are aggregated for comparison, which leads to inherent statistical instability.

Interval cancers which were previously assessed undergo radiological audit to categorise them into the following groups: 1 (normal/benign) 2 (uncertain) 3 (suspicious)

There is always a degree of subjectivity around categorisation which can compromise direct comparison of rates at the individual, screening service or regional level. Due to the very small numbers of cases which constitute false negative assessment interval cancers (category 3s), statistical analysis is difficult. The range of false negative assessment in the literature is varied and based on small scale studies (0.49% Ciatto, 0.56% Burrell, 0.76% Warren, 2.76% Duijm and 2.97% Duijm<sup>3</sup>).

Screen detected cancers, which were previously assessed for the same abnormality, require completion of a “form 4”. Following audit of these cases, only those which have a categorical outcome of substandard assessment or requiring re-assessment may constitute “missed cancers”. Many cases of “false negative assessment” presented to the external review team were categorically not false negative due to presentation at a different site or side as previously assessed. A very small number of cases on review were for the same lesion although assessment at the time was optimal.

## External Radiological Review of Assessment Cases

### a) Historical Practice

In response to allegations of higher rates of false negative assessment by some radiologists in the UHMBT screening programme, individual assessment case reviews were conducted. The following reviews of historical assessment cases were carried out and were used to inform the reviewers of areas of potential concern to focus on in their review of current practice:

R1: All films and images of the 24 cases from the false negative assessment interval cancer audit as submitted by one of the whistle blowers.

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<sup>3</sup> Ciatto S et al, Br Cancer Res Treat 2007;105(1) 37-43; HC Burrell et al, Clin Rad 2001;56:385-388; R Warren et al, J Med Screening 2004;11(4)180-6; Duijm L et al, Br J Cancer 2004;91(10)1795-9; Duijm Let al, Eur J Cancer 2009;45(5)774-81

R2: Cases screened and assessed 1<sup>st</sup> April 2005 - 30<sup>th</sup> March 2008 arising as interval cancers between May 2005 and July 2011.

R3: Cases screened and assessed 1<sup>st</sup> April 2007 - 30<sup>th</sup> March 2011 arising as screen detected cancers between April 2012 and September 2013.

## b) Current Practice (Most Recent Screening Round)

Initially the following reviews of assessment cases from the most recent screening round were carried out:

R4: All images / packets for 10 assessment clinics for Radiologist C, approximately one per month over the twelve-month period April 2013-March 2014 (approximately 100 cases). All images/packets for 2 assessment clinics for all other radiologists (A, B, D, E, F, G) still working within the service over the same twelve month period April 2013-March 2014 (approximately 20 cases per radiologist). Review of 3 additional assessment clinics for Radiologist F from the same time period was carried out due to the findings of the initial review of cases

Cancers diagnosed on short-term recall since 2010 were requested but there were no cancers in this category.

With some concerns raised particularly regarding Radiologist C, but also Radiologist D (a small number of false negative assessment cases) and Radiologist F (3 recent suboptimal assessments and 3 recent cases reviewed as requested by the medical director – see R7) it was felt very important to review more cases from these radiologists from the most recent screening round.

R5: Assessment clinics from September - December 2011 for 3 radiologists (C, D, F) where women had been returned to routine recall and no biopsy had been performed.

In view of the initial review findings and the whistle blower allegations in relation to the assessment practice of Radiologist C, the reviewers felt it was important to review still further assessment cases from the intervening period in the most recent screening round, January 2012 to March 2013.

R6: Assessment clinics from January 2012 - March 2013 for Radiologist C where women had been returned to routine recall and no biopsy had been performed.

At the request of the medical director and one of the whistle blowers, some additional cases were reviewed:

R7: The medical director asked the external radiologists to review 3 cases assessed by Radiologist F. These cases had been identified when a second radiologist had disagreed with the outcome of assessment (return to normal screen) by the first radiologist. The service have introduced “consensus return to normal screen” for women considered benign at assessment which demonstrates very good practice. The second consultant countersigns the assessment sheet either at the time of clinic or subsequently to agree with the decision.

R8: 7 cases were identified by one of the whistle blowers as false negative assessments which needed review by the external team. Following this, examination of a further 15 more recent interval cancers was requested.

## c) Reviews of Historical Practice

### **R1: 24 interval cancers submitted for audit by the whistleblower**

#### Methodology

The precise methodology used by the whistleblower for identifying this audit group is uncertain. It appears that approximately 60 interval cancers with “form 4s” were reviewed (the exact time period is not known). The clients were initially assessed between 2005 and 2011. The whistle blower felt that these 24 cases represented false negative assessments.

All 24 diagnostic symptomatic images were compared with images at previous assessment and the previous assessment process was reviewed using “form 4s” where appropriate.

### **R2: Previously assessed cases (2005 – 2008) arising as interval cancers (2005 – 2011)**

#### Methodology

Audit period: Women screened and assessed 1<sup>st</sup> April 2005 - 30<sup>th</sup> March 2008 arising as interval cancers between May 2005 and July 2011.

Cases reviewed: 65 / 67 cases available for review (Radiologists A, C, D, E, F). 20 of the cases reviewed here are also included in the review of “24 audit cases” which were initially presented for review by the whistle blower.

Appraisal of assessment: Adequate assessment was defined as an appropriate process was followed such that another clinician working at the same time period would have felt it reasonable to arrive at the same outcome with the information available.

In parallel with the review of current assessment clinics management, all radiologists' diagnostic practice was compared to standards and recommendations in the NHSBSP Guidance "Clinical guidelines for breast cancer screening assessment (second edition), publication 49, 2005. "Form 4s" are required for completion in the NHSBSP to audit cases which subsequently arise as interval cancers or screen detected cancers that were assessed at the previous screen for the **same site and side** (appendix 7). These forms were completed to establish whether assessment practice at the time was "optimal", "suboptimal" or "substandard".

### R3: Previously assessed cases (2009-11) arising as screen detected at the subsequent screen (2012-13)

#### Methodology

Audit period: Women screened and assessed 1<sup>st</sup> April 2007 - 30<sup>th</sup> March 2011 arising as screen detected cancers between April 2012 and September 2013.

Cases reviewed: 25 / 27 cases were available for review (Radiologists A, B, C, D, E, F, G).

Appraisal of Assessment: Adequate assessment was defined as an appropriate process was followed such that another clinician working at the same time period would have felt it reasonable to arrive at the same outcome with the information available.

In parallel with the review of current assessment clinics management, all radiologists' diagnostic practice was compared to standards and recommendations in the NHSBSP Guidance "Clinical guidelines for breast cancer screening assessment (second edition), publication 49, 2005. "Form 4s" are required for completion in the NHSBSP to audit cases which subsequently arise as interval cancers or screen detected cancers that were assessed at the previous screen for the **same site and side** (appendix 7). These forms were completed to establish whether

assessment practice at the time was “optimal”, “suboptimal” or “substandard”.

## **Results of Reviews of Historical Practice**

The detailed results of these reviews (R1, R2 and R3) are contained in the ‘Confidential Data Supplement: The performance of North Lancashire and South Cumbria Breast Screening Unit at assessment for women screened prior to current screening round (July 2011)’.

### **General observations from review of historical practice in R1, R2 and R3**

Although the number of cases is small, the review of historical cases of false negative assessment cases for Radiologist C revealed some recurring themes about mammographic interpretation of spiculate lesions, the quality of ultrasound and ultrasound guided core biopsy carried out and repeated under sampling at core biopsy. These were then used to focus the review of current practice at assessment.



## b) Current Practice

### R4: Review of assessment practice most recent screening round

#### Methodology

Audit period: 1<sup>st</sup> April 2013 - 30<sup>th</sup> March 2014

Cases reviewed: 236 / 251 assessment cases were available for review. These included 2 assessment clinics for each radiologist comprising approximately 20 cases (Radiologists B,D,E,F,H, I) and 10 clinics comprising approximately 100 cases for Radiologist C due to whistle blower allegations. Following the initial review findings for Radiologist F, 3 additional assessment clinics were reviewed from this time period.

Appraisal of Assessment: Adequate assessment was defined as an appropriate process was followed such that another clinician working at the same time period would have felt it reasonable to arrive at the same outcome with the information available.

In parallel with the review of current assessment clinics management, all radiologists' diagnostic practice was compared to standards and recommendations in the NHSBSP Guidance "Clinical guidelines for breast cancer screening assessment (third edition), publication 49, 2010. "Form 4s" are required for completion in the NHSBSP to audit cases which subsequently arise as interval cancers or screen detected cancers that were assessed at the previous screen for the **same site and side** (appendix 7). These forms were completed to establish whether assessment practice at the time was "optimal", "suboptimal" or "substandard".

## Results

Rad	Total Cases	Total Reviewed	Justified recall		Optimal Assessment	Suboptimal Assessment	Substandard Assessment
H	21	20	17	85.0	20	0	0
B	23	20	20	100.0	20	0	0
C	100	93	87	93.5	89	3	0
D	21	21	19	90.5	21	0	0
I	21	20	20	100.0	20	0	0
E	21	19	16	84.2	19	0	0
F	44	43	40	93.0	40	3	0
<b>Total</b>	<b>251</b>	<b>236</b>	<b>219</b>	<b>92.8</b>	<b>229</b>	<b>6</b>	<b>0</b>

Table 8: Review of assessment practice most recent screening round

No cases were classified as substandard assessment (significant deviation from NHSBSP protocols)

6 cases were classified as suboptimal assessment (minor deviation from NHSBSP protocols)

Recall for repeat assessment was recommended for less than 5 women, the details are contained in the 'Confidential Data Supplement.

### General Observations from Review of Assessment Practice

#### a) Poor documentation

Although the reader marks the abnormality identified on the screening mammograms at the time of reading with a "screen shot(s)" saved to the Picture Archiving Computer System (PACS), the reader does not record their level of concern. This means that potentially something that the reader thought was M4 "suspicious" or even M5 "malignant" could be returned to routine screening at consensus.

Assessment sheets are poor with no diagram available to record the site of abnormality. Documentation of the size, location and abnormality was poor which disadvantages decision making at MDT discussion.

There is no documentation about the assessor's opinion about future management resultant on the outcome of the biopsy. This would help inform MDT discussion, especially if the case is presented by a different radiologist.

#### b) Practice in assessment

Only one additional view was performed in a significant number of cases. Although it is not specified in national guidance, each possible abnormality recalled requires thorough investigation. It is unusual for 1 additional view to be sufficient for decision making, especially if the area is very small and/or seen on 2 views. Also it is well known that a possible abnormality can be “smoothed away” on 1 view, and another or different view may give very important additional information for assessment.

c) Equipment in assessment

Ultrasound images were difficult to interpret with almost all lesions looking apparently solid. Consultants were asked how they felt about the quality of their ultrasound equipment and all thought it was sub-optimal although better than their previous machine. Subsequent to the visit, ultrasound equipment was reviewed internally in response to the external review team’s immediate recommendation (see appendix 9). The review indicated that one machine needs replacement immediately with a further machine requiring replacement in the next 12-18 months and currently is only really suitable for symptomatic practice.

d) Cases recalled to assessment

The reviewers found that in their opinion, 7.2% of cases recalled to assessment were unjustified recalls. A significant number of these included small benign masses < 10mm without additional radiological features and some abnormalities that were present on previous examinations. The reviewers acknowledge that this is a reflection of attempts to increase small cancer detection.

e) MDT and histological outcomes

It was difficult to understand why a “benign (B2) result” was given in many cases. The case reviews were carried out by radiologists and there was no intention to review pathology slides. However, descriptions used in the histology reports of the cases reviewed often did not appear to represent the lesion biopsied e.g., a mass or distortion. Some histology reports also stated “discussed at MDT and concordant”- as a result it is unclear whether unverified reports are being brought to the MDT meeting. There appeared to be very few repeat biopsies in the cases reviewed, which may follow on from an apparently high B2 rate. This may be of concern. The service have a significantly low B1 (normal) rate and high B2 (benign) rate (>3 standard deviations) on non-operative needle biopsy reports as shown in the National Pathology Audit Report <sup>4</sup> (2014) which requires further investigation.

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<sup>4</sup> National breast screening pathology audit 2014: Performance for the period 2010-13: PHE publication 2014

The Report also highlights that 123 breast fine needle cytology aspirates (FNAC) were performed over 2010-13. This represents relatively high use of breast FNA which is only recommended on rare occasions in the NHSBSP.

f) Evidence of good practice

Calcium retrieval rates by stereotactic core biopsies performed in the main by advanced practitioners were very good, even in apparently difficult biopsies.

The introduction of double reading of any cases returned to normal screen from assessment from 2011 is an example of excellent practice. An audit of outcomes arising from this protocol was brought to our attention. 13 (0.3%) of 4,445 women assessed were referred for arbitration and 4 of these underwent second assessment of which one invasive cancer was diagnosed.

## R5: Review of assessment practice most recent screening round where routine recall without needle biopsy

### Methodology

Audit period: September - December 2011

Cases reviewed: Assessment clinics were reviewed with films couriered for review off site for scrutiny. All cases were requested where women had returned to routine recall where no biopsy had been performed. 228 cases were reviewed for 3 radiologists (C, D, F)

Appraisal of Assessment: Adequate assessment was defined as an appropriate process was followed such that another clinician working at the same time period would have felt it reasonable to arrive at the same outcome with the information available.

In parallel with the review of current assessment clinics management, all radiologists' diagnostic practice was compared to standards and recommendations in the NHSBSP Guidance "Clinical guidelines for breast cancer screening assessment (third edition), publication 49, 2010. "Form 4s" are required for completion in the NHSBSP to audit cases which subsequently arise as interval cancers or screen detected cancers that were assessed at the previous screen for the **same site and side** (appendix 7). These forms were completed to establish whether

assessment practice at the time was “optimal”, “suboptimal” or “substandard”.

## Results

Assessed By	Total Reviewed	Optimal Assessment	Suboptimal Assessment	Substandard Assessment
Radiologist C	62	60	2	0
Radiologist D	83	80	3	0
Radiologist F	83	77	6	0
<b>Total</b>	<b>228</b>	<b>217</b>	<b>11</b>	<b>0</b>

*Table 9: Outcome of audit of assessment clinic practice September-December 2011*

No cases were classified as substandard assessment (significant deviation from NHSBSP protocols)

11 cases were classified as suboptimal assessment (minor deviation from NHSBSP protocols)

Recall for repeat assessment was recommended for less than 5 women, the details are contained in the ‘Confidential Data Supplement

## General Observations from Review of Assessment Practice

The principle findings across all 3 radiologists were:

- There was only one view or poor additional views to assess the area of interest. In 6 cases there had already been a recent rescreen in 2014 and the area was unchanged / benign.
- The reviewers noted that on a number of occasions if a cyst could not be aspirated then a fine needle aspiration (FNA) for cytology was sent and subsequently the C2 (benign) result was accepted at MDT discussion. Best practice now involves core biopsy for any solid breast abnormality.
- There were again noted a number of B2 (benign) results that were difficult to understand, where at MDT discussion the appearances were felt to be concordant.

## R6: Review of assessment practice most recent screening round where routine recall without needle biopsy

### Methodology

Audit period: January 2012 - March 2013

Cases reviewed: Assessment clinics cases were reviewed where women had returned to routine recall and no biopsy had been performed. 201 of 207 cases for Radiologist C were available for review.

Appraisal of Assessment: Adequate assessment was defined as an appropriate process was followed such that another clinician working at the same time period would have felt it reasonable to arrive at the same outcome with the information available.

In parallel with the review of current assessment clinics management, all radiologists' diagnostic practice was compared to standards and recommendations in the NHSBSP Guidance "Clinical guidelines for breast cancer screening assessment (third edition), publication 49, 2010. "Form 4s" are required for completion in the NHSBSP to audit cases which subsequently arise as interval cancers or screen detected cancers that were assessed at the previous screen for the **same site and side** (appendix 7). These forms were completed to establish whether assessment practice at the time was "optimal", "suboptimal" or "substandard".

### Results

Total Cases	Total Reviewed	Optimal Assessment	Suboptimal Assessment	Substandard Assessment
207	201	184	17	0

Table 10: Review of assessment practice most recent screening round where routine recall without needle biopsy

No cases were classified as substandard assessment (significant deviation from NHSBSP protocols)

17 cases were classified as suboptimal assessment (minor deviation from NHSBSP protocols)

Recall for repeat assessment was recommended for less than 5 women, the details are contained in the 'Confidential Data Supplement.

## General Observation from Review of Assessment Practice

Two cases with small, ill-defined rather dominant masses where “cysts” were seen, but no correlation was made to ensure that these were the same as the lesion recalled.

## R7: Review of cases requested by the medical director

### Background

The medical director asked the external radiologists to review 3 cases assessed by Radiologist F. These cases had been identified when the second radiologist had disagreed with the outcome of assessment by the first radiologist. The service have introduced “consensus return to normal screen” for women considered benign at assessment which demonstrates very good practice. The second consultant countersigns the assessment sheet either at the time of clinic or subsequently to agree with the decision.

### External Radiological Opinion

The reviewers agreed that in all three cases recall was justified either for additional mammographic views, for core biopsy, or both of these. In two cases a biopsy was indicated.

These cases demonstrate that the consensus of cases returning to routine recall at assessment can be very valuable and demonstrates how its use is an example of excellent practice. It does however require good team working which was not always evident in the cases reviewed.

## **R8: Review of cases requested by whistle blower**

### **Background**

7 cases were identified by one of the whistle blowers as false negative assessment which needed review by the external team. Following this, examination of a further 15 more recent interval cancers was requested.

### **Results**

5 of the 7 cases had previously been reviewed by the team and the further 2 were examined. Of the 7 cases, only one was a cancer developing at the same site and side as the subsequent presentation of cancer and the process of assessment was deemed optimal (hence no cases constituted false negative assessment).

15 more recent interval cancers were reviewed but in the absence of complete data for this period, the audit was of limited value.



### 3) Interval Cancer Review Process

#### Background

All interval cancers are routinely audited comparing the diagnostic image to the previous screening image to assign a radiological category. The majority of interval cancers arising within a screening service will be “true intervals” (category 1) developing in the period between screens and not visible on the previous screening mammogram.

Programmes audit their interval cancers according to the national classifications:

Radiological classification	Definition
1 Normal/benign	Normal or benign mammographic features
2 Uncertain	A feature is seen with hindsight on the screening mammogram that is difficult to perceive or that does not have clearly benign or clearly malignant features. All film–screen readers may have difficulty perceiving or interpreting such subtle mammographic appearances, e.g. asymmetric soft tissue density or parenchymal distortion.
3 Suspicious	An abnormality is seen on the mammogram which has features suggesting malignancy, e.g. pleomorphic microcalcification or spiculate mass.
U Unclassifiable	Unclassifiable due to the absence of a diagnostic image

Comparability of interval cancer categorisations is difficult owing to the degree of subjectivity inherent in the method employed and radiological interpretation. This was demonstrated by a national audit of interval cancer review practice<sup>5</sup> (June 2013). This reported the following findings which exemplify the degree of subjectivity in the radiological categorisation of interval cancers:

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<sup>5</sup> Jacquie Jenkins “National audit of interval cancer review practice” presented at National Interval Cancer Study Day June 2013

- Key differences in the thresholds needed to achieve an interval cancer category by reviewing panel (from 50% to majority decision)
- Of 4 regions who conduct regional interval cancer reviews, services changed their classifications in this forum as follows: 24% said rarely (<5%), 68% said sometimes (5-10% cases) 8% said often (10-20% cases)

## External Radiological Review of Interval Cancer Classifications Deriving from the Years 2005-2008

### Method

Audit period:	Interval cancers arising within 36 months of a previous screen in women screened April 2005-March 2008 (diagnosed to 2011). This comprised the most recent, complete screening round of interval cancers available.
Audit group:	233 interval cancers of which 144 (62%) were reviewed: Category 1: 103 / 185 (56%) Category 2: 29 / 34 (85%) Category 3: 12 / 14 (86%)
Methodology:	All diagnostic images were compared to previous screening episode images to assign a radiological classification.

### Radiological Overview of Interval Cancer Classifications

- The reviewers agreed with the majority of classifications of cases as shown in appendix 10.
- 21 (14.6%) classifications were changed of those reviewed:
  - 6 category 3s were downgraded: five to category 2, one to category 1
  - 15 category 1s were upgraded: thirteen to category 2, two to category 3
- For such a large review of interval cancer categorisations this degree of difference is not unexpected. The categories can be quite subjective, even when carefully applying the nationally agreed classifications, as previously demonstrated in national survey results.

## 4) Working Environment

### Culture and Management of the Service

Optimal breast screening performance requires effective team working both within and between professional groups working across the breast multi-disciplinary team. Organisationally, a culture of professional debate between members of the multi-disciplinary team is required to maximise outcomes and ensure that the service remains patient centred. Additionally, it is clear from experience of national incidents that a culture of audit and awareness of personal performance, bench-marked to comparative regional and national data is required to maintain a high quality service.

The NHSBSP publication *Organising a Screening Programme*<sup>1</sup> defines the role of the Director of Breast Screening and recognises that this is a critical leadership role for the programme which requires that robust oversight processes are in place to ensure that performance across the programme is monitored and that the policies in place within the service are optimal and universally applied.

As outlined previously the external review team circulated a pre-visit interview to staff to examine management areas such as audit, working relationships, team meetings, continuing professional development and appraisals. The responses to these questionnaires informed many aspects of the visit including the structured interview script which explored these themes further and also questioned the working environment, professional respect and culture.

The following issues were identified from the questionnaire responses and structured interviews:

a) Management Arrangements

It is clear that the current management arrangements are not working. A number of the staff we had contact with raised concerns regarding the managerial style of the current Director of Breast Screening. It was also reported that this individual has taken on other senior roles within the Trust which may have impacted on the time available to carry out breast imaging duties and in addition management of the service.

A number of staff reported concerns regarding an uneven distribution of cases between the different assessment clinics both in number and complexity.

b) Audit Culture

There is not an embedded audit culture across the service, with reports that some team members are suspicious of an individual's motives for doing such work. Historically there has been disagreement between staff members as to which radiologist has responsibility for leading on audit which resulted in no one taking the lead. In general, the staff did not appear to know their own performance data or be particularly well informed regarding the performance of the service and how this compares regionally and nationally.

c) Working Relations

The interpersonal relationships between certain individuals in the radiological team were described to the visiting team as difficult. It was reported that there appears to be a lack of respect for each other's opinions shown at times both within the department and wider within the multi-disciplinary team meetings. Some staff stated that there is now a reluctance to challenge the professional opinions of colleagues for fear of reprisals. Some staff stated they are now very defensive in their decision making as they are afraid of the consequences of making a mistake. This all appears to contribute to a culture of fear and mistrust primarily within radiology but which pervades throughout the service.

d) Equipment

It was evident to the visiting team that the quality of ultrasound images was poor with all lesions appearing solid. From the interviews it would appear that this has been the situation for some time but that no effective action appears to have been taken. Staff may not have complained about the equipment as it was reported by some staff to be significantly better than the equipment that it replaced in 2012, but also it was stated by some staff that there was not an environment where they felt able to raise such concerns. Following an immediate recommendation to assess the quality of the equipment it would appear that neither of the machines used within the department are fit for purpose within screening.

## **Appendix 1: Terms of Reference**

# **Terms of Reference for the review of screen reading and assessment at the breast screening unit at UHMBT**

### **1. Background**

Information presented to the Medical Director of UHMBT and the Breast Screening Quality Assurance team raises concerns regarding the quality of screen reading and second stage assessment at the Breast Screening Unit at UHMBT.

An investigation team has been established under the leadership of the Director of Nursing, NHS England Lancashire Area Team to assess whether the Unit is operating to national standards. PHE is providing advice and support to this team. QA Directors from the West and East Midlands will lead a review of the professional practice undertaken in the breast screening unit as covered by the NHSBSP, supported by QA Radiologists and a QA Radiographer from other regions. They will take advice from other senior breast screening radiologists identified through professional bodies.

### **2. The Scope of the PHE Review**

The review will cover:

- Data and selected case reviews regarding film reading performance
- Data and selected case reviews regarding assessment practice
- Questionnaires for staff and subsequent structured interviews to gather information regarding highlighted topics including the working environment within the unit and the lack of audit
- Data and selected case review of interval cancers

This information will be used to provide an opinion on whether film reading and current clinical practice at the assessment stage in the Breast Screening Unit provided by UHMBT is operating safely and within national standards. The review will look at evidence and data that provides information on current practice, where current is defined as assessments that have been carried out in the last year and data from at least the last 3 years.

### **3. Plan**

Stage 1: To review the QA report, NW QARC data and the initial audit provided to the Trust's Medical Director. Other data and unit policies will be requested.

Stage 2: Questionnaire for completion by all radiology and radiography staff and other relevant personnel. To be sent electronically week commencing 7<sup>th</sup> July – ask for returns within 2 weeks.

Stage 3: Based on information from stage 1 and 2 the detailed Unit review will be planned. It is likely to entail a review of cases from each of the areas identified above, including those relevant to film reading performance, assessment and interval cancers, including those identified in the original audit, along with a review of a proportion of cases for all who carry out assessment in the unit.

30<sup>th</sup> June 2014

## **Appendix 2: External Review Team**

### External Review Team

Mark Sibbering	Director of Quality Assurance (East Midlands)
Olive Kearins	Director of Quality Assurance (West Midlands)
Anne Turnbull	Consultant Radiologist, QA Coordinator Radiology (East Midlands)
Eleanor Cornford	Consultant Radiologist
Gillian Baxter	QA Coordinator Radiography (East Midlands)
Jacque Jenkins	Assistant Director of Quality Assurance (East Midlands)
Alison Murphy	QA Data Analyst (East Midlands)

**Appendix 3: Timeline for UHMB External Review**

<b>Task</b>	<b>Date</b>
Preliminary meeting to discuss review and ToR	3 <sup>rd</sup> July
Agree questionnaire	4 <sup>th</sup> July
Send out Questionnaire to all staff	Monday 7 <sup>th</sup> July
Send request for cases to be reviewed to NWQARC	Wed 9 <sup>th</sup> July
Rework FRQA data for East/West Mids and UHMB staff	Thurs 10 <sup>th</sup> July
Deadline for submission of questionnaires and summary analysis	Friday 18 <sup>th</sup> July
Request protocols for assessment, right results, consensus etc..	Monday 14 <sup>th</sup> July
Analysis of initial data (taking into account QA visit reports) with short summary paper	July/August
Contact unit with details of cases (sx numbers) and associated paperwork required for the radiology review	Friday 18 <sup>th</sup> July (or asap after that date)
Liaise with service to organise radiologists access to PACs and NBSS	W/c Monday 21 July
Send interval cancer numbers for review	Tuesday 29 <sup>th</sup> July
Review team meeting in Derby	Thursday 31 <sup>st</sup> July
Start of review visit UHMB	Friday 8 <sup>th</sup> August
Radiology review	Fri 8 <sup>th</sup> –Tues 12 <sup>th</sup> Aug
Interviews with staff	Friday 8 <sup>th</sup> , Mon 11th, Tues 12 <sup>th</sup> Aug
Review of radiology review data and all data	Friday 15 <sup>th</sup> August
Meeting of review team to summarise review	Monday 18 <sup>th</sup> August
2 <sup>nd</sup> radiology review	19 <sup>th</sup> -21 <sup>th</sup> Sept
Writing up of final report	September /October
Final report issued	7 <sup>th</sup> November



## **Appendix 4: External visit questionnaire**

### **Questionnaire for all staff employed at University Hospitals of Morecambe Bay Breast Screening Service**

Please complete all sections relevant to your role as fully as you feel able. We would welcome any comments you may wish to make. This is **CONFIDENTIAL** to the external visiting team to assist with their review of aspects of the UHMBT breast screening service.

#### ***For completion by all staff***

1. Name	
2. Job title	
3. Date started in post	
4. Total days/sessions worked per week	
5. Date questionnaire completed	

#### ***For completion by film readers***

6. How many of your sessions per week are committed to film reading?	
7. When did you commence film reading?	
8. Are you involved in film reading arbitration?	
9. When did you commence this role?	
10. How is screen reading undertaken (single, double, consensus or arbitration (panel or single radiologist)?	
11. Is there adequate protected sessional time for screen reading without interruption?	
12. How is the right result recorded?	
13. Film reading consensus meetings a) How are they conducted?	

<p>b) How are they documented?</p> <p>c) How is the outcome reached?</p>	
<p>14. Do you participate in interval cancer review meetings?</p>	
<p>15. How often are they held?</p>	
<p>16. Interval cancer review meetings</p> <p>a) How are they conducted?</p> <p>b) How are they documented?</p> <p>c) How is the outcome reached?</p>	

***For completion by staff in screening assessment***

<p>17. How many clinics are undertaken per week?</p>	
<p>18. Which staff attend?</p>	
<p>19. What is your role in screening assessment clinics?</p>	
<p>20. Is there a meeting before the clinic to discuss management of cases? If so, do you input to this meeting?</p>	
<p>21. Have you any comments about how assessment clinics are run?</p>	
<p>22. Are all assessment clinics run the same way? If not, can you describe the differences?</p>	

23. Are all biopsies done at a single attendance?	
24. Is there anything that is done particularly well at assessment clinics?	
25. Is anything that could be improved at assessment clinics?	

***For staff involved in audit within the service***

26. Are you happy with your own individual performance? Please give more details to support your answer if possible	
27. Have you led or participated in an audit of your own work or that of any aspect of departmental work in the last 5 years?	
28. If yes, what was this and were the results presented/discussed with the team?	

***For staff who attend Multi-disciplinary Team Meetings***

29. Do you attend the multidisciplinary team meeting(s)?  What input do you make to this?	
30. Are all cases in which needle biopsy has been undertaken discussed?	
31. Are all women placed on short term recall following assessment discussed?	
32. Are MDT management decisions adequately documented?	
33. Please describe the working relationships within the breast screening team. What are the positives and the negatives for your own day to day working life?	

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***Other team/departmental meetings (for completion by all staff members other than film readers)***

<p>34. Do you participate in other team meetings e.g. clerical, radiographic, nursing, surgical staff meetings?</p> <p>a) How often are these held?</p> <p>b) Are these useful?</p>	
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***For staff who undergo Continuing Professional Development***

<p>35. Have you attended an update course or meeting in the last 3 years? If so, what was this and was there any funding available to you?</p>	
<p>36. Have you had an appraisal in the last 12 months?</p> <p>Who conducted the appraisal?</p>	
<p>37. Was the appraisal satisfactory for you?</p> <p>Any comments?</p>	

***Any other queries/questions? (for completion by all staff members)***

<p>38. Some individuals will be routinely visited by the review team. If you are not requested for a confidential interview, would you like a confidential interview with the external visitors?</p>	
<p>39. Are there any specific issues you would like the external reviewers to consider/look into?</p> <p>What are these?</p>	

40. Is there anything else that you would like to mention that has not been addressed in this questionnaire? – please add below.	

Thank you for taking the time to complete this questionnaire. It is your chance to help inform this external review. Your honest input and feedback is much appreciated.

**Please return to: Jacquie Jenkins (Deputy Director of QA, East Midlands) – [Jacquie.jenkins@phe.gov.uk](mailto:Jacquie.jenkins@phe.gov.uk) Please return by Friday 18<sup>th</sup> July**

## **Appendix 5: Structured interview template A**

NAME:

### **Interviews Radiologists / Consultant Practitioner/Advanced Practitioners**

#### Introduction

Thank you for cooperating and assisting us with the review.

Our remit is to provide an opinion on whether film reading and current clinical practice at the assessment stage in the Lancaster Breast Screening Unit is operating safely and within national standards.

To achieve that we are requesting interviews with multidisciplinary staff including Radiologists and Advanced Practitioners involved in assessment and film reading.

The interview is to build on the information from your questionnaire.

This interview will last for a maximum of 40 minutes.

It will be treated as strictly confidential.

Please be open and honest in your responses.

Brief notes will be taken during the interview to provide a record for our use during the review, but these will not be published.

Is your mobile phone and any other electronic device switched off please?

#### Introduction

I understand you are a .....*Consultant Radiologist/Consultant Practitioner/ Senior Mammographer*  
.....

When did you start at the Lancaster service?

Do you have any additional roles within the service or the hospital?

*(e.g. advanced skills, management, audit lead etc)*

### Working Environment

Please can you describe the current working environment in the Lancaster Breast Screening Unit.? *(If negative)* How long has it been this way and what, in your opinion has been the main contributing factor?

Is this affecting your personal or the unit's current performance?

### Film Reading Arbitration

I understand that in your unit film reading arbitration is by consensus.

Please tell us about the consensus meetings in the unit.

Do you have any concerns about film reading and consensus in your service?

Does the person recalling give their level of concern re the abnormality?

### Assessment Clinic Process

How are assessment clinics organised?

How are cases allocated for these clinics?

Has any patient satisfaction audit been done?

In assessment clinics how are decisions made regarding biopsy of different abnormalities?

When did the double reporting of normal cases from assessment begin and why? How is this review undertaken and discussed/actioned if necessary?

Do you have any concerns about assessment clinics?

### Interval Cancer Review Process

What is your understanding of the interval cancer review process as recommended by the NHSBSP? (Disclosure of audit 2006, QA Guidance for breast screening radiology, no 59, 2011 & NHSBSP invitation letter)

How do you think your process matches up to that?

#### False Negative Assessment Review Process

What is your understanding of the false negative assessment review process as recommended by the NHSBSP? (Publication 59 as above & Jim Steele doc)

How do you think your process matches up to that?

#### Film Reading & Assessment Performance

How do you think your personal performance compares with others regionally and nationally?

How do you think your unit's performance compares with others regionally and nationally?

#### Audit:

Do you feel there is a lack of audit in your service?

Why?

What is the role of the standard operating procedure for conducting an audit, which seems to have been introduced recently?

#### Overall

Do you think the service is safe and why?

Do you think your professional opinion is respected by others (same and different professional areas) .if not, why?

What do you think is the culture of the service – please explain.

#### Open Discussion

Is there anything else you would like to discuss in relation to the scope of the terms of reference of our review?



## **Appendix 6: Structured interview template B**

NAME:

### **Interviewers**

#### **Introduction**

Thank you for cooperating and assisting us with the review.

Our remit is to provide an opinion on whether film reading and current clinical practice at the assessment stage in the Lancaster Breast Screening Unit is operating safely and within national standards.

To achieve that are interviewing Radiologists and Advanced Practitioners involved in assessment and film reading.

We are also interviewing other MDT staff to assess the current working environment within the unit

The interview is to build on the information from your questionnaire.

This interview will last for a maximum of X minutes.

It will be treated as strictly confidential.

Please be open and honest in your responses.

Brief notes will be taken during the interview to provide a record for our use during the review, but these will not be published. Is your mobile phone and any other electronic device switched off please?

#### **Introduction**

I understand you are

*Surgeon / BC Nurse / Pathologist / Radiographer / MDT Coordinator /*

*Assistant Practitioner / Admin Manager / Head of Breast Screening*

When did you start at the Lancaster service?

#### **Working Environment**

Please can you describe the current working environment in the Lancaster Breast Screening Unit.?

*(If negative)* How long has it been this way and what, in your opinion has been the main contributing factor?

Is this affecting your personal or the unit's current performance? How?

Have any of these issues impacted on the quality of care?

Do you have any specific concerns about assessment clinics?

Do you have any concerns about the MDT meeting?

Are repeat biopsies discussed at the MDT meeting?

How do you think your unit's performance compares with others regionally and nationally?

### Overall

Do you think the service is safe and why?

Do you think your professional opinion is respected by others (same and different professional areas) .if not, why?

What do you think is the culture of the service – please explain.

### Open Discussion

Is there anything else you would like to discuss in relation to the scope of the terms of reference of our review?

Other specific questions from questionnaire

**Appendix 7: Form 4**

**NHSBSP ASSESSMENT REVIEW**

**Form 4**

**Patient name**  **Unit**  **Screening No**

Assessment date	<input type="text"/>	<input type="checkbox"/>	Mass
Justified recall?	<input type="text" value="Y/N"/>	<input type="checkbox"/>	Microcalcification
Assessed by	<input type="text"/>	<input type="checkbox"/>	Distortion

ORIGINAL ASSESSMENT		REVIEW	
Examination	Performed Y/N	Opinion 1-5 (see below)	Comment on assessment
Further views			
Ultrasound			
Biopsy			
Clinical Examination			
Discussed at MDT			

**Opinion:**    1 = adequate            2 = underutilised            3 = malpositioned            4 = misinterpreted  
                   5 = undersampled

**Outcome after assessment:**        **RR**            **ER**            **RFR**

<u>OVERALL ANALYSIS:</u>	Consider	- optimal assessment - NHSBSP Guidelines not followed - Major deviation from guidelines or interpretation issues
Comment:		

**Reviewed by** ..... **Date** .....

**Appendix 8: Proforma used to assess film reader performance**

NHSBSP FILM READING

Screening No

Features	Ill Defined Mass	<input type="checkbox"/>
	Well Defined Mass	<input type="checkbox"/>
	Spiculate Mass	<input type="checkbox"/>
	Asymmetry	<input type="checkbox"/>
	P/Deformity	<input type="checkbox"/>
	Microcalcification	<input type="checkbox"/>
	Microcalcification with Mass	<input type="checkbox"/>
	Lymph Node	<input type="checkbox"/>

Opinion:     1 = Normal    2 = Benign    3 = Uncertain   4 = Suspicious  
                  5 = Malignant

Final outcome:     RR            RC

## Appendix 9: UHMBT recommendation regarding equipment and action to date

■ Off Track-Urgent Action Required (Priority 1)

### North Lancs Breast Screening Service

PHE  
Recommendations  
23rd  
August 2014

No.	Recommendation	Time scales	Progress Report/Comments	Responsibility and Action date	Priority Level	Evidence Required	RAG Status
6	Equipment - review of current ultrasound equipment should be undertaken to ensure that it is 'fit for purpose', of optimum quality, and enable the operator to distinguish solid from cystic lesions. The equipment should be assessed in order to establish whether it is able to support a modern breast screening service, and replacement to be undertaken if required	Testing and results return by 03/09/14 , replacement as soon as possible following recommendations if required	Stephen Russell US Medical Physics expert from Christie Hospitals, Manchester attending site on Friday 29/08/14. Stephen Russell attended site 29/08/14, await full report, but indications that existing kit at RLI is satisfactory in the short term, likely to recommend replacement in the next 18 months. We are going to call in the applications specialist to review optimisation of settings with staff and then invite Stephen back to consolidate this learning. Report received from Christies - advised that the Logiq p5 system could remain in use for another twelve to eighteen months ideally used for symptomatic scans rather than assessments but the Logiq 5 Pro should be replaced as soon as possible; ideally both systems should be replaced at the earliest opportunity. Quotes requested for replacement but indicative prices for GE S8 machine with elastography (as suggested by Stephen Russell) would be around £55K. A Logic 9, which is the next spec, would be around £65K with elastography. Demonstration equipment will be arranged once specification documentation is completed, this is in the process of being completed and Procurement aware. <a href="#">Specification document completed and trials of four ultrasound machines are currently being arranged- expectation is that an order for the agreed machine would be placed in November. When GE are on site to demo their new machine w/c 06/10 their applications specialist will also work with the clinicians to ensure they are using optimal settings when scanning with the existing GE machines. Stephen Russell will then be called back to site to consolidate this learning.</a>	Anne Boyle to organise assessment and US training for staff. Senior management team to implement any recommendations from the assessment by medical physics. Requirement to review capital expenditure to replace the Logiq 5 Pro system at RLI - to discuss with Medical Director and DGM for CCS. Demonstration equipment will be booked for trial by 26/09/14. <a href="#">Unavailability of equipment to trial means that it will take until at least the end of October to complete these. Arrangements for Stephen Russell to visit site to be made by end of October (when dates for all trials confirmed).</a>	1	Quality assurance measures and evaluation results show equipment is of optimum quality to provide imaging to support a modern breast screening service. Clinical audit of images to be undertaken.	

## Appendix 10: Radiological overview of interval cancer classifications

### Interval Cancers with a previous screen 01.04.2005 to 31.03.2008 - reviewed at 1st visit

Unit Class.	Unit Total	%	QA Review													Total QA Reporte 1; 2; 3
			Class 1			Class 2			Class 3			Class U		Not done/Missing		
			No.	%	Prev Assess.	No.	%	Prev Assess.	No.	%	Prev Assess.	No.	Prev Assess.	No.	Prev Assess.	
Class 1	185	79.4	88		2	13		2	2		0	16	0	66	0	103
Class 2	34	14.6	0		0	29		6	0		0	3	0	2	0	29
Class 3	14	6.0	1		0	5		2	6		3	0	0	2	0	12
<b>Total</b>	<b>233</b>	<b>-</b>	<b>89</b>	<b>61.8</b>	<b>2</b>	<b>47</b>	<b>32.6</b>	<b>10</b>	<b>8</b>	<b>5.56</b>	<b>3</b>	<b>19</b>	<b>0</b>	<b>70</b>	<b>0</b>	<b>144</b>

Highlighted cases indicate upgrade/downgrade from local unit classifications

15 cases with an original classification of 1 were upgraded; class 2 = 13 and class 3 = 2

6 cases with an original classification of 3 was downgraded; class 1 = 1 and class 2 = 5

## **Appendix 11: Glossary of terms**

### **Benign Open Biopsy**

The number of women who underwent an open biopsy, the outcome of which was benign.

### **Cancer Detection Rate**

The number of cancers detected per 1,000 women with technically adequate screens. This can also be split into the invasive cancer detection rate and non-invasive cancer detection rate.

### **Incident Screen**

Women invited and/or screened for the second or subsequent time as a result of an invitation in the period specified. Pre-2003 this meant one view mammography in most units.

### **Invasive Cancer**

A malignant tumour that has penetrated surrounding normal tissue.

### **Interval Cancer**

A cancer presenting between the previous negative screening episode and the next screening episode due date (within 36 months of a previous negative screen)

### **Non-invasive Cancer**

The breast cancer cells are completely contained within the site of origin and have not spread into surrounding breast tissue e.g. Ductal Carcinoma in situ (DCIS) and Lobular Carcinoma in situ (LCIS).

### **Open Biopsy Rate**

The number of women who have surgery without a definitive diagnosis of cancer. This can be split into benign and malignant.

### **Positive Predictive Value (PPV)**

The number of cancers detected, expressed as a percentage of women recalled for further assessment after the initial screening mammogram.

### **Non-operative Diagnosis**

The number of women pathologically diagnosed with cancer prior to surgery/treatment. This is often achieved following a wide bore needle core biopsy (B5 result). This means that women can have a definite diagnosis made and consider the treatment options available, before undergoing any surgery or other therapy.

### **Prevalent Screen**

Women invited and/or screened for the first time as a result of an invitation by the NHSBSP.

### **Recall Rate to Assessment**

The number of women recalled for further assessment after a screen, expressed as a percentage of the number of women screened.

### **Short-term Recall**

A non-routine assessment, a minimum of 12 months after the initial screen.

### **Short-term Recall From Initial Screen**

The number of women placed on short-term recall as a final outcome of the initial screening mammogram.

### **Short-term Recall Rate From Assessment**

The number of women placed on short-term recall as a final outcome of assessment.

### **Short-term Recall Rate From Short-term Recall**

The number of women placed on short-term recall as a final outcome of a short-term recall assessment.

### **Small Invasive Cancer Rate (<15mm)**

The number of women with invasive cancer measuring less than 15mm in diameter.



### **Standardised Detection Ratio (SDR)**

SDR is an age-standardised measure in which the observed number of invasive breast cancers detected is compared with the number which would have been expected if the age-specific detection rates achieved by the Swedish Two-County Randomised Control Trial applied. The SDR adjusts the observed cancer detection rates according to the age structure of the screened population. An SDR of 1.0 would indicate parity with the Two-County Study, where a large reduction in mortality was achieved.

### **Suboptimal Assessment**

An assessment carried out where there is a minor deviation from NHSBSP protocols.

### **Substandard Assessment**

An assessment carried out where there is a significant deviation from NHSBSP protocols.

### **Uptake Rate**

The percentage of invitations that resulted in technically adequate screens.