



Public Health
England

Protecting and improving the nation's health

Investigation of complaints about the North West Breast Screening Quality Assurance Reference Centre

4th November 2014

4th November 2014

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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Executive summary

Public Health England (PHE) received two letters of complaint regarding the work of the North West Breast Screening Quality Assurance Reference Centre dated 13 and 14 June 2014. They relate to activities of the QARC in their assessment of North Lancashire and South Cumbria Breast Screening Programme, which is provided by University Hospitals Morecambe Bay Foundation Trust (UHMBT). The complainants are clinical members of staff in the Breast Screening Unit.

As a result of these complaints an investigation was undertaken by the National QA Integration lead, Deputy QA Integration lead supported by independent senior breast screening radiologist with experience in breast screening quality assurance.

The terms of reference for the investigation were to answer the following questions: External review into the North Lancashire and South Cumbria Breast Screening Programme (November 2014).

1. Is there any evidence that the NW Breast QA Team was biased in their interpretation of the data and evidence that was presented as part of the 2012 QA visit to UHMBT?
2. Is there any evidence that the NW Breast QA Team was biased in carrying out; and interpreting the findings of the review of the audit that had been conducted by complainant (A) in April/May 2014?
3. Did the NW QA team respond appropriately to the request to review the audit findings carried out by complainant (A)?
4. Are there any lessons to be learnt regarding the above episode which can improve the performance of QA in the future?

The investigation team concluded that there was no evidence of intentional bias. However, the team formed the view that there was evidence that NW QA team failed to:

- respond appropriately to the request;
- analyse the data adequately;
- report findings appropriately;
- support the trust to feedback findings to the breast screening team in an appropriate manner.

The investigation team is of the opinion that if NW QARC had completed this investigation to an appropriate standard the conclusion of their report (that performance between clinicians in the trust for the period under investigation was comparable to regional performance) would have been different and they would have recommended a further investigation. The investigation team are aware of the pressure placed on the

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NW QA team by the Medical Director of UHMBT to produce a response which he in turn he could provide to CQC. This pressure contributed to the fact that the review of the complainants audit was not of an adequate standard.

The investigation team believe that the underlying reason why the NW QARC failed to perform to a level expected was because the professional leads¹ undertaking the investigation had not received adequate training, did not operate according to a set of standard protocols or guidance and were not subject to adequate management or oversight.

In addition, there is a weakness of the existing model of QA, where Professional leads on honorary contracts recruited from the region are asked to quality assure neighbouring units. In the NW this included visiting other QA Professional Leads. In other regions, this risk is mitigated by using QA Professional Leads from other regions in circumstances of perceived conflict of interest.

Recommendations

1. Alternative models to provide professional expert input should be considered, so that professionals are exposed to practice outside of their immediate region and that conflict of interests of professionals being asked to QA close colleagues practice is avoided.
2. PHE permanent staff that have been trained and have knowledge of protocols and procedures should lead investigations and should be supported by QA professional leads.
3. Professional leads providing expert advice to PHE should be trained and should be able to demonstrate that they have the appropriate expertise to undertake the role. This includes an understanding of data and its limitations.
4. Whenever an investigation is requested due attention should be taken in developing terms of reference and key questions that will be addressed by an investigation.
5. Although there are not always guidance and protocols to deal with every circumstance, frameworks such as “Management of incidents in NHS Screening programmes²” provide adequate guidance and should be referred to and used.
6. A nationally agreed methodology should be developed to look at the performance of radiologists at assessment.

¹ Professional leads refer to staff who provide expert advice to QA and are on honorary contracts, rather than being permanent employees of PHE. This will include consultant radiologists, radiographers, medical physicists and breast-care nurses who usually work 0.1 session/week for the QARC

² Managing Incidents in NHS Screening Programmes (Sept 2013) <http://www.screening.nhs.uk/incidents>

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7. QA teams should seek expert advice on analysis of data where this is non-routine data.
8. Staff should be aware of the difficulty on interpreting small numbers and should seek advice from senior colleagues before committing to a view.
9. Management and governance arrangements need to be strengthened for cancer QARCs.
10. There needs to be explicit requirement of staff working in QARC to report upwards concerns and incidents and to seek advice.
11. Consideration should be given whether or not it is appropriate to have senior leadership and management roles in QARCs undertaken by professional leads who are not employees of PHE.

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NOTE: The data which was re-analysed as part of this investigation concerns both patients and clinicians and is therefore subject to information governance requirements and is presented in a separate confidential report.

1. Background to this investigation

- 1.1. Public Health England received two letters of complaint regarding the work of the North West Breast Screening QARC dated 13 and 14 June 2014. They relate to activities of the QARC in their assessment of North Lancashire and South Cumbria Breast Screening Programme, which is provided by University Hospitals Morecambe Bay Foundation Trust (UHMBT). The complainants are clinical members of staff in the Breast Screening Unit.
- 1.2. The complaints about the North West QARC followed one of the complainants raising concerns with both the CQC and the medical director of her employing organisation, University Hospitals Morecambe Bay Foundation Trust (UHMBT), about what she believed to be the poor performance of a colleague (X) in respect of a higher than anticipated rate of interval breast cancers following recalls for assessment.
- 1.3. In March 2014, complainant (A) had audited a number of assessment cases and reported her findings directly to the medical director because she was concerned that she had identified a significant number which were attributable to one radiologist (X). In early April, the medical director contacted the NW Quality Assurance Director (QAD) seeking his advice on the assertions made by the complainant (A) and asking for information about acceptable error rates and a review of the complainant's findings.
- 1.4. After a short period of data gathering, NW QA radiologists (1 and 2) visited the unit on 2 May 2014 to review the cases which had been audited by complainant (A). A report was produced by NW QARC which concluded that 'interval cancer after assessment rates in this service (and of radiologist (X) in particular) are comparable to those seen in other services in the North West³.
- 1.5. The complainants subsequently made assertions of bias in the NW QA review of the audit verbally to the Trust and in writing to the PHE National QA Integration Lead for cancer and non-cancer screening.

³ This sentence was subsequently retracted by NW Breast QA Director see para 5.3.4

2. Context

- 2.1. This investigation is one of two linked investigations into quality of breast screening services in the North West area. There is also a detailed review underway of screen reading and assessment at the breast screening unit provided by UHMBT. This second investigation is a cross-organisational process under the chairmanship of NHS England. The review of the unit is being led by two PHE Quality Assurance Directors from outside the North West. The review will provide an opinion on whether film reading and current clinical practice at the assessment stage is operating within national standards.
- 2.2. Preliminary recommendations from the first stages of the review of the unit identified six immediate actions required in order to mitigate risk and improve quality. Reviewers have considered assessment practice over the last year and a significant proportion of assessment practice from September 2011. The findings will be presented to NHS England and UHMBT in early November.
- 2.3. Although concerns about the quality of breast screening services at UHMBT were only identified to the PHE National QA Integration lead by the complainants in June 2014, there is a long history of concern with the quality of other services at UHMBT. The Trust was placed in special measures by the Care Quality Commission (CQC) in June 2014. The maternity and neonatal services of the Trust are the subject of an independent enquiry chaired by Dr Bill Kirkup CBE and commissioned by the Department of Health. The independent enquiry is currently inviting interviewees to attend to give information and answer questions. Complainant (A) has recently been an interviewee of the Investigation Panel.
- 2.4. Sir Robert Francis QC is currently leading a review of how whistle blowers are treated in the NHS and it is understood that complainant (A) has also submitted evidence to that review.

3. Investigation of complaints about the North West Quality Assurance Reference Centre

3.1. The Complaints about NW QARC

3.1.1. The complainants allege that NW QARC was biased in carrying out QA tasks. The concerns can be summarised as:

- The radiological component of the 2012 QA visit to North Lancashire and South Cumbria Breast Screening Programme was not adequately assessed and the findings of the report of the visit do not reflect the information that was provided to QA visitors on the day of the visit.
- Issues of bias in relation to how the review of the audit was undertaken in May 2014, how it was analysed and how the outcomes were fed back.

3.1.2. Complainant (A) submitted further details of complaint by e-mail on 27 July 2014 which covered 12 points. These are attached at appendix 1. However, it should be noted that these were received after the terms of reference for the investigation had been agreed and shared with the staff against whom the allegations were made. Nevertheless the 12 points raised by the complainant were included in the evidence pack assessed by the investigation teams and its independent expert.

3.2. Terms of Reference for the Investigation

3.2.1. The scope of the investigation was to address the following:

- Is there any evidence that the NW QA team was biased in their interpretation of the data and evidence that was presented as part of the 2012 QA visit?
- Is there any evidence that the NW QA team was biased in carrying out and interpreting the findings of the review of the audit that had been conducted by the complainant?
- Did the NW QA team respond appropriately to the request to review the audit findings carried out by complainant (A)?
- Are there any lessons to be learnt regarding the above episode which can improve the performance of QA in the future?

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- 3.2.2. The investigation team was led by _____, National QA Integration Lead for cancer and non-cancer screening and supported by _____, Deputy national QA Integration Lead.
- 3.2.3. In view of the nature of the complaints a senior national radiologist was identified as an independent expert to work with the team undertaking the investigation to:
- advise the investigation team on expected actions of a QA team;
 - interpret findings;
 - sense check any clinical information;
 - guide the team in areas for further investigation.

3.3. Method of investigation

- 3.3.1. A recorded interview was carried out with both complainants with a representative from the Society of Radiographers present. The purpose of the interview was to enable the investigation team to gain an understanding of the detail of the concerns and the evidence underpinning the allegations that the NW QARC staff members were biased in their actions.
- 3.3.2. Individual recorded interviews were carried out with the North West Breast Screening Quality Assurance Director and the two North West QA radiologists to establish the facts and to enable the investigation team to understand the process used to undertake the 2012 QA visit and the May 2014 review of the complainants audit.
- 3.3.3. All evidence was drawn together into a briefing pack (contents attached at appendix 2) which included: notes of interviews, correspondence from the complainants, data used during QA activities, and reports.
- 3.3.4. The evidence was reviewed by the investigation team and independent expert prior to a table top analysis on 19 September 2014. The findings from an independent review of the cases considered in the original audit were also available at this meeting. The table top exercise sought to answer the questions posed in the terms of reference; generate findings and develop recommendations.

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4. Key events/timeline

Date	Event
July 2012	QA visit report on North Lancashire and South Cumbria Breast Screening Programme.
21 March 2014	QA radiologist (1) interviewed and recruited to post of NW QA radiologist.
4 April 2014	Trust Medical Director request QARC review the complainant (A)'s audit.
4 April 2014	QAD asked QA radiologist (1) to review data but not visit the unit. QAD briefs NW QA Director.
7 April 2014	QA radiologist (1) requests more information from the Medical Director
10 April 2014	QA radiologist (1) informed by the Clinical Director that CQC aware of the issue and requires a response from the Trust within 5 days.
11 April 2014	Complainant (A) supplies audit information to QA radiologist (1) by e-mail and they have a follow up telephone call.
14 April 2014	QA radiologist (1) provides progress report for QAD and QA radiologist (2) with comments, identifies further information needed and suggested actions, including QA to review the audit cases.
14 April 2014	Medical Director rings both QAD and QA radiologist (1) asking for more information as CQC response required by 16 April. QAD and QA radiologist (1) emphasise that the analysis is on-going and QA should resist the pressure to respond before the investigation is complete
17 April 2014	QA notify the Trust that they will visit 2 May and ask the Clinical Director to ensure the audit cases are prepared for review
22 April 2014	Complainant (1) emails the Medical Director, copying , with more information and asks whether an SI has been logged.
2 May 2014	QA radiologists (1 and 2) visit the unit and review the audit cases
9 May 2014	Trust receive NW QA report on the review of the audit
14 May 2014	Email from complainant (A) to QA radiologists (1 and 2) requesting details of the audit cases so she can correlate with her findings and complete her audit

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Date	Event
14 May 2014	QA radiologists (1 and 2) ask the QAD to respond to complainant (A) and he confirms he will send the request to the Medical Director
15 May 2014	The Medical Director suggests to the QAD that somebody goes through the data so that complainant (A) can be aware of how the evidence was used to reach the report conclusions.
15 May 2014	E-mail discussion between QAD and QA radiologists (1 and 2) which concludes in agreement to prepare list with limited identifiers that show where reviewers agreed and disagreed and remove any comments which would identify specific radiologists
18 May 2014	QA supply list to the Trust
28 May 2014	QAD informs the PHE National Lead about issues relating to the North Lancashire and South Cumbria Breast Screening Programme
6 June 2014	The Lancashire Area Team Screening and Immunisation Lead informs PHE National QA Integration Lead that she had received a complaint of bias regarding NW QARC.
11 June 2014	The PHE National QA Integration Lead emails the complainants and invites them to send her details of their complaint
13 and 18 June 2014	Complainants letters submitted to PHE National QA Integration Lead

5. Commentary and findings

5.1. 2012 QA visit

- 5.1.1. The complainants suggest that the 2012 QA visit report findings on North Lancashire and South Cumbria Breast Screening Programme did not adequately reflect the information that was provided to QA visitors. They also suggest that the fact that significant data and information was missing was not acknowledged in the report. The complainants believe that it was the role of QA to ensure that data were made available. Their interpretation of this is that the relationships between the Clinical Director of the Breast Screening Unit, the NW Breast Screening QA Director and the NW QA Radiologist (2) affected the ability of NW QARC to produce an independent report and therefore the report was not a true reflection of the unit.
- 5.1.2. The investigation team found that the radiological element of the QA visit was conducted according to Quality Assurance guidelines for breast cancer screening radiology (NHSBSP publication number 59) published March 2011. Radiological performance is assessed through examination of data, peer review of selected cases, attendance at a multidisciplinary meeting and discussion with the radiology team.
- 5.1.3. Data which was presented by the QAD at the feedback session on the day of the visit was good and included an overview of performance since the previous visit in 2009. It focused on the areas of: round length and waiting times; uptake; diagnostic outcomes; and surgical performance. It included 2008/11 trend data and provided appropriate confidence intervals. It did not include interval cancer data. The trend data showed a continuing problem with low cancer detection in the prevalent round and a recommendation to continue efforts to improve this detection rate was made in the final report.
- 5.1.4. The NHSBSP Guideline no. 59 states that data relating to interval cancer rates for the last three complete screening years should be available to the visiting QA radiologist. It is the responsibility of the director of the screening service, supported by the regional QARC to ensure that this information is available and has been carefully checked for accuracy and completeness by staff from QARC and the screening programme.
- 5.1.5. In 2012 the collection of form 4s for interval cancer data was new. The NW Breast QAD confirmed at interview that his predecessor had not asked for interval cancer data from units for a number of years and that

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when he came into post there was a large catch up exercise required from the units. This accords with the complainants comments that in the 6 months before the visit the NW QARC's data co-ordinator had sent a number of e-mails to the unit asking for interval cancer data to be returned urgently. However, the complainants also commented that interval cancer review meetings in the unit had become sporadic and that there was an accumulation of interval cancers waiting to be reviewed. They also stated that form 4s were not completed in interval cancer meetings and this delayed completion of the paperwork.

- 5.1.6. The investigation team found that the NW QA radiologist (2) did undertake her role of peer reviewing screening cases adequately and according to guidance. Her review of film reading was more detailed than would normally be expected. At the pre-visit she reported that she had reviewed 10 assessment cases for each radiologist; all grade 2 and 3 interval cancers; all previously assessed interval cancers; 10 excision biopsies; 10 benign biopsies; all early recall cases; and single reader detected cancers. From her pre-visit she had identified a number of concerns which she raised on the day of the visit. These included: cancer detection rate in the prevalent round; the standardised detection rate was only meeting the minimum standard; the recall rate was increasing; and film reading numbers were low for some individuals.
- 5.1.7. Complainant (B) reported that because she had been recorded as a mammographer and not an advanced practitioner during the visit this meant that her voice was diminished in the process. She reported that the NW QA radiologist (2) did not speak to the advanced practitioners at the pre-visit. Her invite to the radiology interview session at the time of the full visit had been rescinded by an administrator in QA shortly before the day.
- 5.1.8. The NW QA radiologist (2) noted in her interview that on the day of the full visit she met with all the advanced practitioners because she was aware she had not met them at the pre-visit. She noted that they were particularly unhappy and as a group they believed that they had been prevented from seeing her at the pre-visit. Complainant (B) commented that the NW QA radiologist (2) had made best efforts on the day of the full visit and had been very helpful. However, she was surprised that issues raised in the meeting were then not reflected in the report.
- 5.1.9. Complainant (A) suggested that the NW QA report identifies a failed localisation performed at a neighbouring hospital but documentation was not available. She suggest that as visits are planned 6 months in advance the documentation should have been available and that NW QA

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should have been more concerned about this missing information. The investigation team do not believe that this is a significant issue and the QA team were not at fault for not pursuing the Unit to locate the documentation given the other issues considered at the time of the visit.

5.1.10. The NW Breast QAD and the NW QA radiologist (2) commented that the atmosphere in the unit at the time of the visit was extremely difficult. The NW Breast QAD noted that there were obvious tensions between the surgeons and radiologists, and the advanced practitioners. He commented that QA could not explore personal relationships and it should only be highlighted if it impacts on the delivery of national standards, quality and safety. The NW Breast QAD reported that he did comment on communication problems in his feedback and also highlighted issues with the operation of the MDT. There is no evidence however, that he raised his concerns privately with either the medical director or executive director of the Trust.

5.2. 2014 Audit Review

5.2.1. On 4 April the medical director of UHMBT phoned the NW Breast QAD to ask for advice regarding an audit which complainant (A) had undertaken. The complainant believed that her audit indicated that a single radiologist (X) within the unit was responsible for missing a significant number of cancers. The NW Breast QAD who was about to start annual leave passed the request to a newly appointed NW QA radiologist (1). The medical director emailed the NW QA radiologist (1) later that day and outlined the audit as one which 'focussed on those patients with interval cancers who were recalled for assessment and cleared but who have subsequently developed cancer at the same site'. He went on to say that 'the data is presented in a way that I cannot understand the error rate'.

5.2.2. The investigation team believes that the NW Breast QAD should have given more consideration to the request and asked whether the situation as described was indication of a potential serious incident. Although the NW Breast QAD immediately requested QA staff to analyse data held at the QARC, there is no evidence to suggest that on receiving the request the he systematically considered what question or concerns the QA team should respond to; developed terms of reference for an investigation or considered what governance arrangements should be put in place to oversee the investigation. There was also no consideration of how the results of the NW Breast QA team would be fed back to the trust.

5.2.3. As the NW Breast QAD was going on leave much of the initial response was undertaken by the NW QA radiologist (1) who had been recruited on

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21 March 2014. The NW Breast QAD had briefed the NW QA radiologist (1) to liaise with the NW QA data analyst and the medical director but asked him not to visit the Trust or report any initial findings. The NW Breast QAD confirmed that he had briefed his manager (NW QA Director for Bowel and Cervical Cancer) prior to going on leave but it is unclear whether the NW QA radiologist (1) had been given an alternative senior person to communicate with during the absence of the NW Breast QAD.

- 5.2.4. In responding to the request to provide a QA opinion on the audit findings, the NW QA radiologist (1) sought more information from the Trust on 7 April. On 10 April, after NW QA radiologist had a conversation with the Clinical Director he became aware that the CQC had written to the trust requiring a response within 5 days about the 'missing cancers' and the safety or otherwise of the Unit. The medical director contacted both the NW Breast QAD and the QA radiologist (1) on 14 April asking for more information as the trust were required to respond to the CQC by 16 April.
- 5.2.5. The investigation team believe that as a result of the perceived pressure from the CQC and annual leave of NW Breast QAD, that the initial phase of this investigation was inadequately prepared and thought through. If adequate time had been taken in determining the terms of reference and methodology of the review then the NW team may have considered that formally interviewing the author of the audit (complainant (A)) as part of their review, and ascertaining both her concerns about current quality in the unit and how she had conducted the audit may have led to a more considered response to this incident in the trust and NW QARC.
- 5.2.6. In addition, the investigation team believe that if the QA team's review in May 2014 had been placed in an appropriate Trust governance framework such as reporting into a patient safety reporting system or 'potential incident' meeting then it is likely that more consideration would have been given to managing pressure from CQC and dealing with the communication of findings of the audit to unit staff. Taking this approach may have also have provided a reassurance to complainant (A) that her concerns were being taken seriously.

5.3. Review of audit conducted on 2 May 2014 (appendix 3)

- 5.3.1. In view of the need to maintain patient and clinician confidentiality, the data considered in this section is presented in a confidential data supplement. The findings from the confidential data supplement will be shared with UHMBT, NHS England and CQC. In addition PHE have

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agreed to share the findings with complainant (A) in a confidential session to ensure data protection.

5.3.2. After a short period of information and data collection the NW QA radiologist (1) provided a progress paper for the NW Breast QAD on 14 April which included:

- audit performed by complainant (A)
- QA table of interval cancers from assessment, same side over same time period
- QA data: 2005/08 interval cancer audit all programmes
- QA data: form 4 audit 2005/11
- FRQA data film readers for the unit 2010/13 and 2013/14
- FRQA first reader scatter graph 2010/13

He was still awaiting numbers of assessments by each radiologist over the same time period; and number of cancers identified by the unit over the same time period.

5.3.3. It was agreed that the NW QA radiologists (1 and 2) would visit the unit to review the audit cases identified in complainant (A)'s audit on 2 May 2014. The Clinical Director was contacted by email on 17 April and asked to ensure that the cases were prepared for the visit. The NW QA radiologists prepared a summary of their findings from the audit review and submitted this to the NW Breast QAD for his use in drawing up a final report. The medical director of UHMBT was then provided with a final report of the NW QA review on 9 May 2014 'Review of Interval Cancers from Assessment in the North Lancashire and South Cumbria Breast Screening Service 2005-2011' (Performed on 2 May 2014).

5.3.4. The NW Breast QAD concluded the report with the comment 'Interval cancer after assessment rates in this service (and of radiologist 3 (X) in particular) are comparable to other services seen in the North West'. However, he noted in his interview that a few days later he realised his calculation had used the wrong numerator, as previously assessed cancers detected at the next screening round had not been included. A few days later the NW Breast QAD informed the HR Director at UHMBT about his concerns that X was an outlier.

5.3.5. The investigation team's consideration of the report concludes that it would have benefited from the inclusion of: an introduction and context; a clear statement on what question or issue the report was addressing; an acknowledgement of the original audit conducted by complainant (A);

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terms of reference, including who the report was for and who was responsible for taking action as a result of its findings.

5.3.6. The background and methods section is sparse. It would have been helpful if the following information had been included:

- information on current performance of the unit and any concerns on performance either based on reported information from staff members or through analysis of data held by the QARC;
- the period under question i.e. when women were seen in the breast screening programme, not the period when interval or screened detected cancers were found;
- whether it was looking at past or present performance;
- the categorisation of interval cancers should have been in this section;
- the use of Form 4 and when this had started in the Trust and how they were being used;
- any additional information which was been used to inform the question whether or not there were concerns regarding practitioner performance at assessment either in the past or present.

5.3.7. The methodology section would have benefited from discussing the difficulty of interpretation of small numbers and whether or not conclusions could be drawn from a review of a small number of cases.

5.3.8. Although it is clear from the information presented to the investigation team that the NW QA radiologists had looked at the number of assessments that had been undertaken they did not refer to this information in their report. This is important in drawing any conclusions on the significance or otherwise of their findings.

5.3.9. The investigation team consider that the methodology used in the Review of Interval Cancers from Assessment in the North Lancashire and South Cumbria Breast Screening Service 2005-2011 (May 2014) report is flawed. The findings appear to focus on whether or not the NW QA Radiologists have reached the same conclusion as the complainant in the review of each film rather than whether or not there appears to be a propensity of missed cancers of category 2 (2=uncertain at assessment or 3= suspicious at assessment) by an individual radiologist. An appropriate analysis should have allocated the missed cancers by radiologist and by category 1, 2, 3, different site as illustrated in table below.

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Table 1:

	Categorisation of assessment films by NW QA team of missed cancer cases.				
	Category 1 – Benign	Category 2 - Equivocal	Category 3 -	Different site	TOTAL
Radiologist 1					
Radiologist 2					
Radiologist 3					
TOTAL					

This would have enabled a view to be drawn whether or not the numbers of missed cancers by category 2 or 3 by radiologists required further investigation.

5.3.10. Table 1 in the report is unhelpful and it is unclear what question is being addressed. The comment section of the report would have been better presented as recommendations. It was inappropriate to comment on whether or not there was a cover up. This was a response to a specific allegation made by claimant (A) however, it would have been more appropriate to document the cases where a letter had gone to the GP rather than make comment.

5.4. Feedback of results

5.4.1. Complainant (A) believes that the manner in which she received feedback on the review of her audit is inadequate. She states that she has not been given the information in order to understand why some lesions were discounted by the QA radiologists (1 and 2) and the manner in which the findings were presented means that she has been unable to learn from the audit.

5.4.2. Complainant (A) reports that a copy of the review was shared with her by the medical director on 13 May which showed that 50% of her observations were incorrect. She noted that if her work was incorrect then this made her worried about whether she needed retraining but that it also meant that there would be no actions for the women. On 14 May she e-mailed the NW QA radiologists (1 and 2) requesting feedback so that she could understand the discrepancies and complete her audit.

5.4.3. E-mail discussion on 15 April 2014 between the NW Breast QAD and the two radiologists indicates the reluctance of the QA team to provide personal feedback to complainant (A). The medical director suggested a

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compromise position that someone goes through the data with her, possibly the films and other related evidence, so that she can be aware of how the evidence was used to reach the conclusions in the report'. The NW QA team believed that it was the responsibility of the Trust to provide feedback.

- 5.4.4. This e-mail discussion concluded with an agreement to share the audit cases in simplified format, removing all comments and anything which would identify the assessing radiologist. A list was sent to the trust which was then shared with the radiological team in a forum on 2 June 2014 which was chaired by the deputy medical director and which the NW QA team did not attend.
- 5.4.5. The investigation team believe that it was a failing of the process of audit review not to have considered how findings would be fed back to complainant (A). It would have been appropriate for her to receive personal feedback from the reviewers so that she had the opportunity for her questions to be answered and in order for her to learn from the exercise and complete her audit.

6. Conclusions

6.1. QA Visit 2012

- 6.1.1. The view of the investigation team was that 2012 QA visit was conducted to a comparable standard of other QA teams. There was no evidence of intentional bias or lack of impartiality in the way the visit was conducted or reported. In fact the NW QA radiologist (2) took additional steps to ensure a comprehensive look at the service by reviewing additional films as part of the QA visit.
- 6.1.2. Suggestions raised by the complainants that failure to consider interval cancer rates was due to bias of the QA team are unjustified, as at the time of the 2012 QA visit, use of Form 4 was in its infancy and not systematically collected or analysed in QARCs. Moreover the QAD had taken considerable effort to improve both reporting and analysis of this data since he had been in post and this was reflected in the data that was collected as part of the information booklet compiled for the visit.
- 6.1.3. There is evidence that the NW QA team were aware at the time of the QA visit that the working environment was poor and relationships between staff members in the breast unit were strained, however this was not included in the report or communicated to senior management in the trust. The investigation team felt that this was an omission to the QA report. However, the investigation team felt that this was due to lack of training and protocols for how QA staff should communicate and deal with these circumstances on a QA visit, it did not reflect bias or lack of impartiality in the approach of the NW Breast QAD and his team.

6.2. May 2014 review of audit

- 6.2.1. The investigation team felt that the response of NW QA team to a concern raised by a consultant radiologist about an apparent high number of missed cancers by a colleague was not of the standard that would be expected of a QA team.
- 6.2.2. The investigation team did not think that the NW QA team acted in a biased manner or deliberately attempted to cover up problems in the unit.
- 6.2.3. The investigation team felt that if the investigation had been carried out to the expected standard, the NW QA team would have advised a further investigation of current work within the Breast Screening Unit in UHMBT.

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- 6.2.4. The individual whose performance was of concern had been a QA radiologist for NW QARC until the end of March 2014 and therefore an appropriate response would have been to ask QA radiologists from another area to conduct this review in order to ensure there could be no perceptions of bias.
- 6.2.5. The investigation team felt that underlying the sub-standard approach to this investigation was that staff leading this investigation had not received relevant training and were not working to standard protocols or guidance. NW QARC was operating in a manner that it had before moving into PHE, where it behaved as a stand - alone service and senior staff in the QARC did not consider asking for advice or referring concerns to more senior management within PHE. However, this was coupled with weak management and oversight of QARCs at a national level as it coincided with significant change in management roles within national office of NHS Cancer Screening Programmes which made it difficult for QA staff to escalate issues appropriately.

7. Lessons identified

This investigation has provided further insight into a number of weaknesses in the existing model of QA. The findings contribute to the development of recommendations that are applicable nationally and provide a number of extremely useful lessons which are the responsibility of PHE to address. These recommendations will be implemented as part of the QA review which is currently being undertaken.

7.1. Model of Quality assurance

- 7.1.1. The model of QA recruits professional leads from each QARC area to act as QA professionals. This means that professional leads know their colleagues who they are asked to visit and QA. It will also mean that relatively frequently they will be asked to QA a fellow QA professional's service. This could lead to actual or perceived conflict of interest and difficulty for the QA service and professional leads if they wish to comment on sub-optimal performance of a QA colleague. This weakness in the model needs to be addressed, such as through the use of professional leads from other areas.
- 7.1.2. In the case of the investigation into the audit, the fact that the individual whose performance was of concern had been a NW QA radiologist should have alerted to the NW Breast QAD to the potential conflict of interest and he should have identified professional leads from another team to undertake the review.
- 7.1.3. The approach to investigation appears to have been entirely developed by the QA professional leads, the QA Coordinator who is a permanent member of PHE staff and has been working in Breast QA for many years does not seem to have been consulted or involved in the decision-making or the development of the methodology. The NW Breast QAD is a clinician with an honorary contract and not a permanent PHE employee. He had been given line management responsibility for PHE staff. The balance of decision-making and responsibility appears to rest very heavily with professional leads and the NW Breast QA Director who has an honorary contract. Staff who are part of the PHE establishment and who are employed to run QA services do not seem to have oversight or say how QA is delivered in the QARC.
- 7.1.4. **Recommendations:**

Alternative models to provide professional expert input should be considered, so that professionals are exposed to practice outside of their

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immediate region and that perceived conflict of interest of professionals being asked to QA close colleagues practice is avoided.

Staff who are part of the PHE establishment and who have been trained and have knowledge of protocols and procedures should lead investigations and should be supported by QA professional leads.

7.2. Professional Lead and staff competence, training and induction

7.2.1. The Professional leads undertaking the review were clinicians who hold honorary contracts with PHE. One of the two NW QA radiologists who led on the review had just been appointed. He had an induction programme shortly after recruitment but this was mainly administration and did not include incident investigation.

There is no national standardised job description, recruitment process, induction and training process for professional leads that provide expert advice to QA.

7.2.2. Recommendations:

Professional leads providing expert advice to PHE should be trained and should be able to demonstrate that they have the appropriate expertise to undertake the role. This includes an understanding of data and its limitations.

7.3. Standard operating procedures, protocols and guidance

7.3.1. The investigation of this incident was not carried out according to recognised procedures, policies or guidance. There was a failure to develop terms of reference including identifying the questions that should be addressed by the investigation. There was a failure to consider whether or not the investigation was better dealt with by establishing an incident or investigation team or whether the trust had engaged with their patient safety colleagues in a formal process.

7.3.2. If time had been taken to develop and agree terms of reference and questions to be addressed, then it is likely that some of the problems with this piece of work would have been averted. If the piece of work had been undertaken within an agreed framework such as an incident or investigation, then the team would have had an opportunity to have tested out their methodology with a more experienced team and inadequacies may have been identified.

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7.3.3. **Recommendations:**

Whenever an investigation is requested due attention should be taken in developing terms of reference and key questions that will be addressed by an investigation.

Although there are not always guidance and protocols to deal with every circumstance, frameworks such as “Management of incidents in NHS Screening programmes” provide adequate guidance and should be referred to and used.

7.4. Analysis of data

7.4.1. There have been a number of serious incidents nationally where the performance of individual radiologists at assessment stage have caused concern. Most notably this occurred in the case of East Lancashire Breast Screening Programme. However, even though this occurred in 2010 there is not a nationally agreed methodology or an agreed acceptable error rate for the performance of individual radiologists at assessment.

7.4.2. Analysis of data, such as in ‘**Review of Interval Cancers from Assessment in the North Lancashire and South Cumbria Breast Screening Service 2005-2011**’ (May 2014) report, is complex. The NW QA team should have sought expert advice both regarding the methodology and their analysis.

7.4.3. **Recommendations:**

A nationally agreed methodology should be developed to look at the performance of radiologists at assessment.

QA Teams should seek expert advice on analysis of data where this is non-routine data.

Staff should be aware of the difficulty on interpreting small numbers and should seek advice from senior colleagues before committing to a view.

7.5. Management and oversight of QA function

7.5.1. Management structures across cancer QARCs vary across England. Since transfer to PHE on April 2013, a federated model of governance has persisted. QARCs still operate as semi-autonomous organisations rather than being part of a management structure with clear reporting

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arrangements for QA Directors. This federated arrangement is compounded by leadership positions in QARCs being held by non-PHE employees but by professional leads that are on honorary contracts.

7.5.2. There was a lack of oversight by the senior managers in PHE of what was occurring in NW QARC and this particular incident. This was because of the lack of clarity around reporting and expectation of managers of staff within the QARC what they should be reporting upwards.

7.5.3. **Recommendations:**

Management and governance arrangements need to be strengthened for cancer QARCs.

There needs to be explicit requirement of staff working in QARC to report upwards concerns and incidents and to seek advice.

Consideration should be given whether or not it is appropriate to have senior leadership and management roles in QARCs undertaken by clinicians / professional leads who are not employees of PHE.

Appendix 1

Submitted to PHE by Complainant (A) on 27 July 2014

Role of Northwest QA in the interim review conducted at UHMB in May 2014

1. QA has reported in July 2012 that interval cancer rate in our unit was above the regional average. It is important to know which data was seen by the QA to make this observation. Did they see the data, which was discovered in the recent audit, or is there anything else we haven't seen so far?
2. In the recent QA review (May 2014), the QA had mentioned that interval cancer rate of the Lancaster unit is within regional average. This is contradictory to the QA report in 2012. Why is that? Is this new statistics? If so why is this new statistics used here to answer a question relating to 2012?
3. When looking at statistics, why did the QA not look at the number of cases assessed by each radiologist? Did they compare the number of cases seen by each radiologist in other units when they mentioned that the miss rate was comparable? If so, which unit?
4. QA report in 2012 (page 9, para 1 & 2) mentions that data for failed localization and false negative assessment from screening were incomplete (form 4's). Has the QA probed the reason for this data not being made available to the QA radiologist? If the QA had probed further, what was the outcome, as it has not been conveyed to the rest of the team?
5. The QA initially informed me that they would interview everyone reg. the missed cancer concerns I had raised. This was mentioned to me by a QA radiologist identified as the person undertaking the review? Why was this decision changed? Why was another radiologist added to the same team who was also the same radiologist who failed in 2012 to see the data which I uncovered?
6. You had mentioned that the QA did not interview anyone to maintain its independence and impartiality. However the following points need clarification as impartiality has not been applied in the QA's interaction to the Clinical Lead:
 - i) Why did the QA director persistently indicate to the medical director that the Clinical Lead needs to be included in the preparations for the review in spite of knowing that she was the person being investigated? I believe that emails were exchanged to this effect but I haven't seen them (Only a scrutiny of the emails between the QAD and the Medical Director will bring out the truth).

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- ii) In spite of the Clinical Lead not working on a Friday, why was she allowed to receive the QA team on 2nd May (Friday), stay in the department throughout and then see off the QA in the absence of any other consultants (this has been observed by other staff)?
7. The trust had requested the QA director for a session with the QA including the breast surgeons, audit personnel and me to discuss the findings of the QA report. Why did the QA refuse this in spite of the trust agreeing to fund this?
8. The Medical Director informed me that the decision not to reveal the QA radiologists' comments on the images to me was taken by the QA Director. Why did the QA refuse to share with me the comments by the QA radiologists about each of the x sets of mammograms and leave me with a truncated summary in spite of me providing the details of all the patients?
9. It is common knowledge for anyone working in breast screening that form 4's of interval cancer review are completed by a team of radiologists and advance practitioners and never by a single person. My audit involved collation of this recorded data, held in the unit and the same data was presented in a tabular form. I also took the extra precaution of cross checking the data with the screening films. In other words, I have not modified, added or deleted any information, and I believe that this relevant data was kept hidden. The QA has cut down the number of 24 to 12 in their review. Essentially this means that the decision taken by the unit was wrong by 50%, which raises serious questions about the unit itself (if the QA was right). But attempts were made to make it look as if it was my own observations and decisions, and thus questioning my intentions in bringing up the concerns.
10. One of the cases taken out of the list of 24 by the QA is a Lymphoma. Lymphoma is only a histological diagnosis and everyone knows that it is a type of cancer. It defies belief that the QA chose to exclude this as a non-- cancer in order to reduce the Clinical Lead's missed cancer numbers.
11. The QA appears to have taken a different approach when it comes to a look--back exercise. When the Clinical Lead was the QA radiologist who inspected Carlisle breast screening unit, a look back exercise was initiated after 2 cases were flagged up. During that period, it is clear from the data gathered that the Clinical Lead was missing most cases in her own practice at the same time doing least number of assessments. Is the QA not aware of this? Why is the QA acting differently?
12. It is well known that the Clinical Lead inspected the Accrington breast-screening unit as the QA radiologist and gave it an all clear before a major scandal broke

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out. The Burns report criticizes the QA inspection heavily. Why did the QA allow the Clinical Lead to continue as QA radiologist in spite of criticisms in a national enquiry (Page 54-Burns report)?

The QA appears to suggest that if the overall performance of a unit is acceptable, there is no need to probe further. The Northwest QA seems to have forgotten the Burns report which mentions: 'Performance of individual team members can be lost within a programme's global results and it is quite feasible for underperformance of an individual to be masked' (Burns report on Accrington breast screening, Page 54; para 8.12).

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Appendix 2

Briefing Pack Contents

Minutes, technical information and other documents			
No	Date	Title	
1	03/07/14	Terms of reference – Investigation of North West Breast QA Team performance and conduct in the quality assurance of UHMB BSU	Sent in 1 st Despatch
2	14/08/14	Terms of reference – Expert input	Sent in 1 st Despatch
3	27/07/14	Notes from the meeting held on 24 July with the complainants	Sent in 1 st Despatch
4	13/08/14	Notes from the meeting held on 4 August with (QAD)	Sent in 1 st Despatch
5	14/08/14	Notes from the meeting held on 11 August with (QA Radiologist)	Sent in 1 st Despatch
6	11/8/14	Notes from the meeting held on 11 August with (QA Radiologist)	Sent in 2 nd Despatch
7	02/05/14	Review of interval cancers from assessment in the North Lancashire and South Cumbria Breast Screening Service 2005/2011	Sent in 1 st Despatch
8	04/04/14 to 20/05/14	Original documents and analysis used in preparation of May report (in separate file)	Sent in 3 rd Despatch
9	05/05/12	Report of the QA visit to North Lancashire and South Cumbria Breast Screening Programme	Sent in 1 st Despatch
10	05/05/12	Presentation from QAD for the feedback session	Sent in 1 st Despatch
11	June 2010	Cancer guidelines for breast cancer screening assessment NHSBSP No.49	Sent in 2 nd Despatch
12	12/12/11	National Audit of cancer intervals	Sent in 1 st Despatch
13	March 2011	Quality assurance guidelines for breast cancer screening radiology NHSBSP No.59	Sent in 2 nd Despatch
14	05/07/09	N. Lancashire & S. Cumbria Breast Screening Programme : Pre-Visit Data Booklet	Sent in 1 st Despatch
15	01/04/09	Report of the QA Visit to N. Lancashire & S. Cumbria Breast Screening Programme	Sent in 1 st Despatch
16	01/04/09	Possible False Negative Review Forms	Sent in 2 nd Despatch

Correspondence (letters and emails)			
No	Date	From & To	Title and summary
1	13/06/14	Complainant (A) to	Letter of complaint
2	14/06/14	Complainant (B) to	Letter of complaint

Investigation of complaints about the North West Breast Screening Quality Assurance Reference Centre

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				Despatch
3	04/04/14 to 20/05/14	Email correspondence between NW QARC and UHMBT	In separate file	To Follow
4	10/07/14	to QAD, QA radiologists (1 and 2)	Letters to QA staff informing them of the investigation	Sent in 2nd Despatch

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Appendix 3



Cancer Screening Programmes

Review of Interval Cancers from Assessment in the North Lancashire and South Cumbria Breast Screening Service 2005-2011

Performed on 2 May 2014 by

NW Quality Assurance Radiology Co-ordinators,

Public Health England

4th November 2014

Background and methods

24 women had been identified by the breast screening service as having been diagnosed with breast cancer in the three year period after assessment of an abnormality found at breast screening, i.e. had interval cancers after assessment. The cancers were diagnosed in the period 2005 to 2011.

In each case we reviewed the original screening mammograms and assessment films before viewing the symptomatic imaging. We also had access to the screening notes, NBSS database, the interval cancer paperwork completed by the local team at interval cancer review and the pathology reports.

Findings

In 11 of the 24 cases the presenting symptomatic interval cancer was considered to be different to the abnormality previously assessed. These cases therefore did not require completion of a 'Form 4'.

In one case the symptomatic lesion was the same as the assessed lesion but the final histology showed a lymphoma. This case was therefore not an interval cancer and should not have been classified as such.

This therefore leaves only 12 cases in which we believe that the lesion previously assessed was the same lesion as the symptomatic interval cancer, that is, 12 false negative assessments.

The breakdown of these per radiologist is shown in Table 1 below.

Table 1 - False negative assessments

Radiologist	Total	Review agreed with outcome	Review disagree with outcome	Comments
Radiologist 1	1	0	1	
Radiologist 2	2	1	1	
Radiologist 3	8	4	4	+ 1 case of lymphoma
Radiologist 4	1	0	1	

In five of these cases we considered that the assessment process had been optimal, i.e. based on the imaging available, the decision to return the patient to routine recall was reasonable and the same decision may have been made by any other similarly trained radiologist given the same scenario.

Examples of such cases include lesions that did not appear to persist on further views and ultrasound was normal, and a lesion in which the imaging was probably benign and a fine needle aspirate was reported as C2 (benign).

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In seven cases, based on the imaging available, we disagreed with the decision to return the patient to routine recall, as we felt this decision was not in keeping with that of a similarly trained radiologist given the same scenario.

In all but one of these cases the assessments had been completed in accordance with the 2005 NHSBSP guidelines.

In each case we also reviewed the interval classification documented by the unit at the original interval cancer review. The original screening mammograms were classified according to the national classification system, as follows:

Category 1: Normal/benign Normal or benign mammographic features.

Category 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.

Category 3: Suspicious features An abnormality is seen on the mammogram which has features suggesting malignancy, e.g. pleomorphic microcalcification or spiculate mass.

In four cases we disagreed with the classification: two cases classified as category 1 we classified as category 2; one case classified as category 2 we classified as category 1; and one case classified as category 3 we classified as category 2.

In Table 2 on page 4 we have outlined the four cases assessed by Radiologist 3 which we felt were false negative assessments.

Comments

Only 12 of the 24 interval cancers arose from lesions previously assessed over this six year time period. Eight of these were assessed by Radiologist 3, two by Radiologist 2, one by Radiologist 1 and one by Radiologist 4.

There were seven cases of false negative assessment where we disagreed with the decision to return the woman to routine recall. Four of these were assessed by Radiologist 3, one by Radiologist 1, one by Radiologist 2 and one by Radiologist 4.

Of the four cases assessed by Radiologist 3, three were in 2008 and one in 2009. Double reporting of assessments was only introduced in 2011.

There was good documentation of the interval cancer classification. All cases had been reviewed by at least two people and usually a group.

There appears to have been some confusion regarding the 'Form 4' as this had sometimes been completed unnecessarily for interval cancers arising at a different site to that assessed.

There was no evidence of a “cover up” as there was in fact evidence that patients were being appropriately informed of interval cancers.

In some cases we felt that there was insufficient use of further views, e.g. only one coned compression view was performed even if the lesion was visible on both screening mammogram views. It is recommended that the radiologists review their assessment protocol and make any

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changes necessary to ensure that abnormalities visible on two views on the screening images are not dismissed on the basis of an apparently normal single further view.

The unit introduced double reading of assessments in 2011. This is not currently mandated by NHSBSP guidelines and was noted as an area of good practice at the last QA visit in 2012. We recommend that this should continue.

Comment by _____, NW Director of Breast Screening Quality Assurance: Interval cancer after assessment rates in this service (and of Radiologist 3 in particular) are comparable to those seen in other services in the North West.

Table 2 -Radiologist 3 cases where reviewers disagree with the assessment outcome.

Case	Assessed to NHSBSP guidelines?	Comments	Interval cancer category at review
9	Yes	FCV shows persistent abnormality. Reassured by normal US but ? scanned correct site. GP wrote to Radiologist 3. Case reviewed at interval panel and Radiologist 3 replied admitted false negative assessment. Patient informed.	3
11	Yes	Small spiculate mass. Hard to find on FCV (big breast) but present on CC FCV. Should have had a stereo biopsy.	2
12	Yes	Mass over pectoral muscle. Not on CC or lateral extended CC. ? Only upper outer quadrant scanned as no medial extended CC performed. US was normal. Not visible on symptomatic mammos but symptomatic US suggests it lies high at 12 o'clock. Not sure stereo biopsy possible hence all relied on US.	3
13	Yes	CC FCV looks glandular but unchanged from screening CC. FCV in MLO may have helped. Should have had stereo biopsy. Put through consensus afterwards and all local radiologists agreed with assess outcome. GP wrote Radiologist 3. Reviewed at interval cancer panel, Radiologist 3 replied informing of missed cancer. Patient informed.	2

FCV = focal compression view; MLO = mediolateral oblique (mammogram); CC = craniocaudal (mammogram); US = ultrasound scan

RDD/CB

2/5/2014

Appendix 4

Description of roles and responsibilities of North West QA Team

NW Bowel and cervical screening QARC Director – Consultant in Public Health, PHE employee

NW Breast Screening QARC Director – Consultant Radiologist on an honorary contract to PHE

QA Radiologist (professional lead) – consultant radiologist on an honorary contract to PHE

NW Breast QARC coordinator – FT PHE employee

NW Breast QARC data analyst – FT PHE employee

