NHS Cumbria
Cumbria Teaching Primary Care Trust

A Report into the Investigation and Management of a Serious Untoward Incident relating to the North Cumbria Breast Screening Programme in June 2010

1. Executive Summary

A review of breast imaging carried out at North Cumbria University Hospitals Trust has identified 16 cases of breast cancer. There is evidence that consultant radiologists at North Cumbria University Hospitals Trust failed to follow current best practice. Six women have still to be reassessed.

1.1 Introduction and Background

In Cumbria, breast screening is offered via the North Cumbria programme, provided by North Cumbria University Hospitals Trust (for North Cumbria) and the North Lancashire and South Cumbria programme provided by University Hospitals of Morecambe Bay NHS Trust (for South Cumbria). The North Cumbria programme covers fewer than half the number of women covered by the North Lancashire and South Cumbria programme and is one of the smallest programmes in the North West.

All UK women aged 50-70yrs who are registered with a GP are invited for screening every three years. The programme will be extended by 2012 to include all women aged 47-73 years.

For some women, the mammogram identifies abnormalities which require further investigation and they are invited for further tests at assessment centres run by the screening programme's multidisciplinary teams. Further investigations may include another mammogram, clinical breast examination, ultrasound and biopsy. The programmes recall rate is the percentage of women who are asked to attend for these further tests.

2. Identification of the Problem

2.1 Reasons for the Interim Visit

In June 2010 a North West QA (Quality Assurance) radiologist made an interim radiology visit to the North Cumbria programme. This visit was requested by the NHS North West QA Reference Centre to investigate the following concerns:

- Routine annual monitoring statistics were of concern. The programme had detected no *in situ* (non-invasive) cancers in the prevalent (1st ever) screen for ages 50-70 and less than the minimum standard for small invasive cancers in the prevalent round for the same cohort.

- There had been longstanding difficulties in recruiting breast radiologists and there was a need to discuss progress on recruitment with North Cumbria University Hospitals Trust.

- During 2009 national guidance had been circulated that by April 1st 2010 units using fine needle aspiration and cytology alone should move to core biopsy as their primary diagnostic technique. The visit would enable the QA radiologist to audit implementation of the guidance.

- The North Cumbria programme had a high recall rate for women requiring further examination after their routine mammogram. For women following their first screen, North Cumbria had the highest recall value in the country with 34 women recalled for every cancer detected, compared to an average of 17.

2.2 Findings of the Interim Visit

Assessment Review

The visiting QA radiologist carried out a review of North Cumbria University Hospitals Trust assessment clinic cases taken from April and May 2010. One hundred and twenty cases were prepared from which 60 cases were reviewed.

Not all the assessment cases prepared by North Cumbria University Hospitals Trust for the visiting QA radiologist were reviewed since serious concerns found during the initial stages of this process meant that a decision was taken to halt the review in order to provide urgent feedback. It was also considered that all the cases would require further formal, documented review.

Summary of QA Radiologist's Key Concerns

Following the visit, a report from the QA radiologist was sent to the Chief Executive of North Cumbria University Hospitals Trust on 28 June 2010 and Cumbria's Director of Public Health on 29 June 2010 summarising the following concerns:

- **NHS Breast Screening Programme assessment protocols were not being adhered to.**

- **The QA radiologist's review of North Cumbria University Hospitals Trust assessment clinic cases had identified a woman with a potential Ductal Carcinoma *in situ* (DCIS - non invasive cancer) and the woman needed to be recalled urgently for assessment and biopsy.**

These issues are described in more detail below.

Breast Screening Programme assessment protocols

The initial review demonstrated that the National Breast Screening Service assessment guideline pathways* were not being followed adequately by the consultant radiologists at North Cumbria University Hospitals Trust. The QA radiologist's opinion was that not enough women were undergoing needle biopsy after being recalled for examination following their routine mammogram. The QA Radiologist therefore felt that a review of assessments over a longer period was warranted.

> **At the time of this incident, current assessment practice was set out in the Second Edition of the NHS Breast Screening Programme Clinical Assessment Guidelines (Wilson & Liston, 2005) and in particular the flow chart labelled as Figure 2 on page 7.*

The initial review identified a woman with a potential Ductal Carcinoma *in situ* (DCIS - non invasive cancer). It was felt that the woman needed to be recalled urgently for assessment and biopsy and the review was halted at this point in order to provide urgent feedback. It was also considered that all the cases would require further formal, documented review.

The findings were discussed with the Breast Screening Programme National Office and with NHS North West. In view of the serious concerns raised about practice, and as it was not clearly attributable to any single radiologist at that point, it was recommended that the assessment clinics be suspended pending further investigation. This meant that routine screening would also need to be suspended.

3. Investigation of the Problem

A multi-agency group was convened in response to the QA radiologist's findings. Members were drawn from North Cumbria University Hospitals Trust (NCUHT), NHS Cumbria, the North West QA Service and NHS North West.

This multi-agency group was jointly chaired by the NHS Cumbria Director of Public Health and the Chief Executive of North Cumbria University Hospitals Trust. The group has overseen the investigation into this incident. The group's terms of reference are appended.

3.1 Key Issues which Required Action

The following areas required immediate attention. They are described in more detail below.

- The advice from the QA Team and the National Director of NHS Cancer Screening to suspend the North Cumbria breast screening programme while the incident was investigated.
- The development of a plan for the management of women part way through screening who still required assessment at the time of suspension.
- A review of records of women in the current three years screening round who had been recalled for further examination following their routine mammogram, and reassessment of women identified as having had an inadequate assessment.
- The development of a plan for the management of women who had been seen in the North Cumbria University Hospitals Trust symptomatic clinic where radiology was provided by the same team of radiologists.
- The development of a plan for the ongoing arrangements for symptomatic women.
- The development of a communications strategy so that women in North Cumbria were aware of what was happening with regard to the breast screening programme.
- Consideration of the future configuration of breast screening services for North Cumbria following the conclusion of the review.
- Arrangements for the completion of a detailed review of governance systems following the conclusion of the incident review.

3.2 Suspension of the Screening Programme

Following the recommendation from the QA Service and the National Director of NHS Cancer Screening to suspend the North Cumbria programme, on 29 June, the Director of Public Health formally instructed North Cumbria University Hospitals Trust to stop the programme immediately. Those women who had already been sent an invitation were informed in writing that the service had been temporarily suspended.

3.3 Management of women part way through screening who required assessment

Women part way through the screening programme at the time of suspension had their mammograms assessed by a radiologist from another breast screening programme whose services were secured specifically for this task.

3.4 Summary of groups of women whose screening records were reassessed following the suspension

The initial QA visit focused on assessment of women being seen in the North Cumbria Breast Screening Programme. The review recommended by the North West QA team and by the National Director of NHS Cancer Screening Programmes was of all women who had attended for assessment during the current screening round (1,537 women). In addition, it was felt prudent to include women who had attended for assessment in the previous screening round and who had not been seen by the programme since. This group consisted of women who had not attended for appointments and also who had reached the age of 70 years, the current upper age limit for routine screening. There were 158 women in this group.

The central issue addressed by this exercise was to examine the extent to which there were problems with the assessment process.

Although no concerns around any other aspects of the programme were raised by the QA radiologist during her initial visit, whilst the screening programme was suspended it was considered prudent by the review team to examine a sample of records of women who had not been involved in the assessment process in order to provide further reassurance. Therefore the records of an additional 1,000 women are currently being examined. These random samples comprise 500 women who had routine mammographic screening and 500 women who are attending for annual screens (250 women with a strong family history of breast cancer and 250 women undergoing annual surveillance following treatment for breast cancer). The findings of the review of these women's records will be the subject of a further report which will be made publicly available.

Because the initial QA visit highlighted concerns with assessment clinic practices, this report covers only the findings and recommendations that followed from the examination of the screening records of women who had attended these assessment clinics.

Figure 1 shows the groups of women whose records have been examined or are currently being examined.

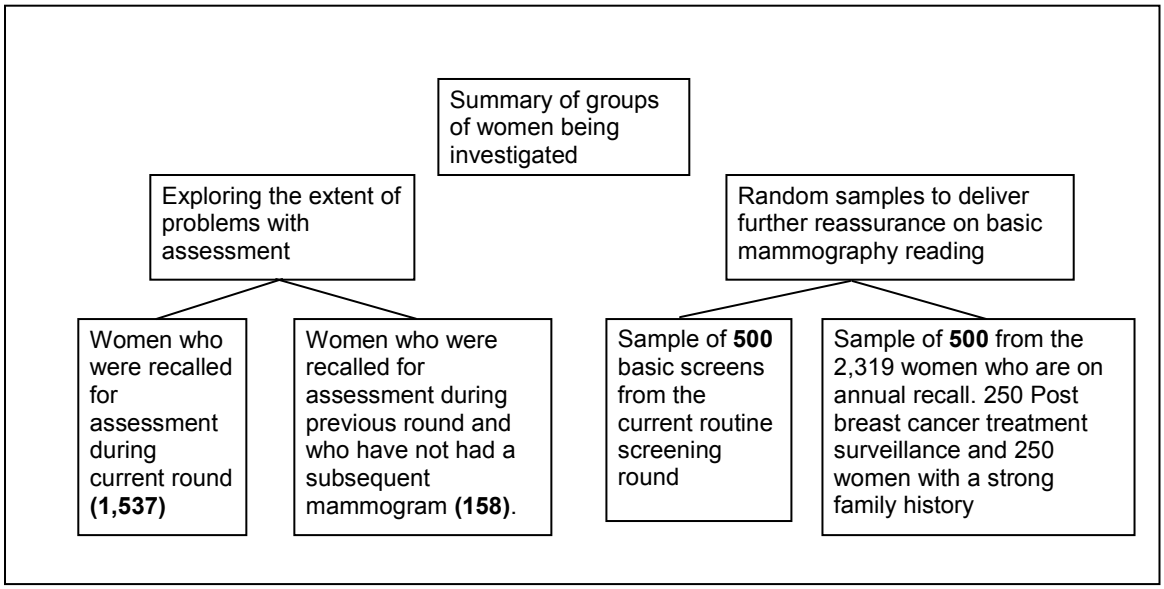

Figure 1. Groups of women involved in the investigation

3.5 Review of records of the 1,695 assessment cases

Mammograms for these women (1,537 from the current round and 158 from the previous round) were reviewed by breast radiologists from outside Cumbria. Where required, women were invited to return for further examination by breast consultants from outside Cumbria at clinics run by North Cumbria University Hospitals Trust. When, upon receiving reassessment, cancers were found, women were offered treatment.

Figure 2 shows the results of the review of the 1,695 assessment records that were reviewed.

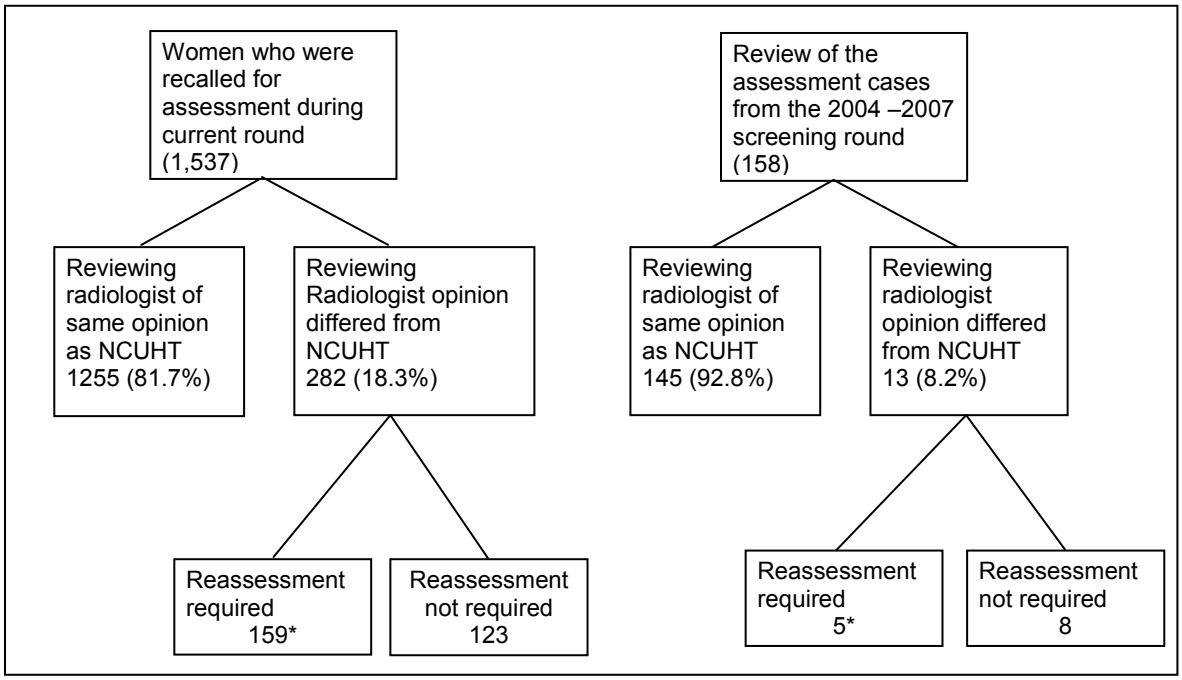

Figure 2 Results of review of assessment cases

*Reassessment process still on-going at time of publication

3.6 Development of a Communications Strategy

The communication teams from North Cumbria University Hospitals Trust, NHS Cumbria and NHS North West, with advice from the communication team at the Breast Screening National Office worked together to develop a communications strategy to ensure that women in Cumbria were aware of what was happening to the breast screening programme.

A dedicated telephone helpline, staffed by breast care nurses, was created and remains in place.

3.7 Commissioning of Future Breast Screening Service for North Cumbria

As commissioners of health services, NHS Cumbria expressed its intention to use the commissioning process to ensure that a re-established breast screening programme in North Cumbria was robust and reflected the outcome and recommendations of the incident investigation.

3.8 Governance Review

During the investigation into this incident, North Cumbria University Hospitals Trust have begun a comprehensive review of their internal governance arrangements in order to identify the underlying factors that led to this incident and put in place safeguards to ensure similar issues do not arise again.

4. Findings of the Investigation

Sixteen cancers have been found as a result of the review process so far (see table 1). These were all within the group of 1,537 women who had had been assessed in the current screening round. Of these, seven were diagnosed with invasive breast cancer and seven were found to have Ductal Carcinoma *in situ* (DCIS - non-invasive breast cancer). In all but one case, the cancers were at the site of the abnormality that had been assessed following the original mammograms. In the remaining case the suspicious abnormality was present on the screening mammograms but disregarded, and a benign abnormality on the other side was assessed. A further two women were diagnosed with interval cancers. These women had suspicious abnormalities on their screening mammograms that were assessed, but not biopsied, and the cancers were subsequently diagnosed when the women presented to their GP with symptoms.

Table 1. Outcome of the 1,537 Assessment Cases from Current Round which were reassessed.

Outcome	Number
Invasive Breast Cancer	7
Ductal Carcinoma *in situ*	7
Interval Cancers (both invasive)	2

Nine patients were not reassessed either because the patient declined or due to personal circumstances.

The final results are still awaited for two women from the current round and four women from the 2004-07 screening round.

Potential Contributory Factors

Over the review period, the screening programme failed to diagnose cancers that it could have reasonably been expected to diagnose.

There is evidence suggesting that consultant radiologists at North Cumbria University Hospitals Trust failed to follow current best practice and this has contributed to the delay in diagnosis of 16 cases of breast cancer. The radiologists had a higher threshold for consideration of biopsy than would be considered as acceptable current practice. Six women have still to be reassessed.

In line with the QA radiologist's initial findings, the investigation confirmed that not enough women were undergoing biopsy at this point in their assessment. The Second Edition of the NHS Breast Screening Programme Clinical Assessment Guidelines (Wilson & Liston, 2005), current at the time of this incident, sets out how suspicious lesions on breast screening mammograms should be investigated. The guideline requires that abnormalities which are not clearly benign should be biopsied.

5. Recommendations for Breast Screening in Cumbria

It is recommended that:

- **A safe and effective breast screening programme should be re-established in North Cumbria as soon as practicable. In re-establishing this programme, a larger screening programme which demonstrates centre-of-excellence qualities should be commissioned to provide screening and assessment services locally.**

- **The new service should include plans for catch up so that women whose screens have been delayed are seen as soon as possible.**

- **The new screening programme should reflect national plans for digital mammography and age expansion.**

- **Screening, diagnosis and treatment services should continue to be delivered locally within North Cumbria.**

- **A review of clinical governance procedures should be carried out by North Cumbria University Hospitals Trust in other services provided by the hospitals trust to ensure proper processes are in place. The results of this review should be presented to the NCUHT and NHS Cumbria Trust Boards.**

- **No North Cumbria University Hospitals Trust consultant radiologists involved in this incident should be involved in breast imaging until they have completed additional training delivered by a recognised NHS Breast Screening Programme.**

Appendix

North Cumbria Breast Screening Service Incident Team Terms of Reference

This enquiry is being carried out by University Hospitals of North Cumbria NHS Trust and NHS Cumbria. It is jointly chaired by the Director of Public Health and the Chief Executive of North Cumbria University Hospitals NHS Trust.

Core Membership is as follows:

Chief Executive, North Cumbria University Hospitals NHS Trust
Chief Operating Officer, North Cumbria University Hospitals NHS Trust
Director of Radiology Services, North Cumbria University Hospitals NHS Trust
Medical Director, North Cumbria University Hospitals NHS Trust
Business Manager of Breast Screening Service, North Cumbria University Hospitals NHS Trust
Risk Manager, North Cumbria University Hospitals NHS Trust
Administration Team, North Cumbria University Hospitals NHS Trust

Chief Executive, NHS Cumbria
Director of Public Health, NHS Cumbria
Associate Director of Public Health (Health Protection), NHS Cumbria
Director of Corporate Affairs, NHS Cumbria
Medical Director, NHS Cumbria

Regional QA Representative(s), NHS North West
QA Radiologist, NHS North West

Key Actions are as follows:

- To identify the principal causes of serious service failure declared by NHS Cumbria on 29 June 2010, acting on advice from the National Screening Programme Quality Assurance Service by the use of the Root Cause Analysis Tool.
- To identify groups of women whose screening was of an unacceptable standard.
- To ensure robust arrangements are in place to re-assess these women as necessary.
- To ensure robust arrangements are in place to deal with women part way through the screening process when the programme was suspended.
- To ensure robust arrangements are in place to manage the assessment of women who present with breast symptoms.
- To develop an action plan to deal with the Quality Assurance concerns raised in the Regional Review and ensure that a system for breast screening that is both robust and fit for purpose is put in place.
- To identify issues regarding individual failures which require action.
- To develop a process to identify whether there are areas of concern relating to clinical governance or quality assurance within other service areas in the Acute Trust.
- To produce a report into the incident.

References

NHS Breast Screening Programme Clinical Assessment Guidelines
Wilson R, Liston J [Eds]. Clinical Guidelines for Breast Cancer Screening Assessment.

NHS Breast Screening Programme Publication No 49, Second Edition. January 2005.

Available at:

http://www.cancerscreening.nhs.uk/breastscreen/publications/assessment.html

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