

**AN INDEPENDENT EXTERNAL REVIEW  
OF THE BREAST SCREENING UNIT AT  
EAST LANCASHIRE NHS TRUST**

**(FINAL VERSION 5)**

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## Foreword

I interviewed a small number of patients affected by the events at the East Lancashire Breast Screening Unit. One of them, an articulate, confident younger woman reflected on her experience with these words

*“.....I was hardly able to breathe all the way to my appointment..... By the time I got there I had forced myself to think through all the worst possible implications for me, my partner and my family that would come with having a breast removed and being terminally ill ..... I just knew I had a cancer and fell to pieces when the doctor told me I needed an ultrasound..... I cried so much I needed counselling when I found out I didn't have a cancer .....at the end I felt like I had been in a big washing machine and spat out when it had finished with me .....”*

In the event this lady did not have a cancer but one year later she still had a vivid and painful memory of what was clearly a terrifying ordeal. 86 women were directly affected by the service failure initially identified at East Lancashire in 2009 – 20 of them were told they had a cancer. Regrettably this was not the full extent of the consequences for local women as will be detailed in the body of this report.

There have been enough large scale service failures in the NHS in the recent past to convince even the most complacent of Boards that however good they believe their governance systems to be, there is a high probability that somewhere in their organizations patients are being put at risk, not by ignorance of what to do but by poor compliance with how things should be done.

What is required now is not more policy or erudite debate about alternative culture changing strategies. Neither should the pursuit and achievement of safer and more patient centred services be driven by fear of consequences for the reputation of Institutions and the careers of senior staff. What will drive this agenda is the sense of anger, outrage and remorse felt by the vast majority of caring managers and clinicians across the NHS for the appalling pain and suffering which is too often inflicted on patients whose care has been inexcusably poor. It is good to report that this has been the response within the Breast Screening Unit at East Lancashire.

Frank G Burns CBE

December 2010

## **1. BACKGROUND TO THE REVIEW**

- 1.1 The National Breast Screening Programme (NBSP) covers the whole of the UK and has been in place since 1988. The Programme offers women between the ages of 50 and 70 (currently being expanded to the range 47 to 73 years) an opportunity to be screened for breast cancer every 3 years at one of 82 units covering the whole of the UK.
- 1.2 Since the Programme started, in excess of 19 million women have been screened and 117,000 cancers have been detected and treated. Research into the success of the Programme suggests that 1,400 lives per annum are saved (1 for every 500 women screened).
- 1.3 The NBSP has the benefit of a dedicated quality assurance process with staff based in each NHS Region with specific responsibility for monitoring the performance of each unit within their area.
- 1.4 As with all cancers the thought of developing breast cancer generates considerable anxiety and fear in many women and their attendance for a routine 3 yearly screen will focus and accentuate these fears during the screening process. Overall up to 10% of women screened will be recalled for an assessment because the screening film shows a potential abnormality that requires further investigation. These 'recalled' women will feel particularly anxious and vulnerable and it will be a considerable relief to those who eventually discover that the further tests at the assessment clinic have shown there is no cancer present.
- 1.5 The NBSP does not claim 100% success in detecting early signs of cancer and some cancers, though present at the time of screening, are too small and subtle to be detected. Over the years since the beginning of the programme diagnostic techniques and imaging equipment have continuously improved to the point that more of the women with a potential cancer are being referred from screening to assessment. Moreover the assessment process, if properly carried out, is now so thorough and sophisticated that a woman who is given the all clear at assessment can, with a great degree of confidence, be reassured that she does not have a cancer. For many of the women who are among the 16,000 plus per annum who are diagnosed with cancer through the screening programme, early detection will mean less traumatic treatment and will also improve chances of survival.
- 1.6 In the last few months of 2008, breast screening staff at the East Lancashire Hospital Trust (ELHT) Breast Screening Unit found it necessary to intervene in 2 specific assessment cases where the consultant assessing the cases (Dr X) had not followed the national assessment guidelines and failed to detect a cancer present in each case. This prompted a major reappraisal of the work of the consultant concerned by 2 independent clinical experts. The expert review covered the

period August 2006 to December 2008 and reached the following broad conclusions:-

- Out of 278 cases discharged from assessment clinics as ‘free of cancer’ by Dr X over this period 254 had not been assessed exactly as per the national guidelines
  - In the case of 86 women the assessment by Dr X was so incomplete that they were required to re-attend and be re-assessed before the expert reviewers could be sure about the presence, or otherwise, of a cancer.
  - In all, of all the cases reviewed by the clinical experts, 20 women who had been discharged by Dr X as cancer free were found to have had a breast cancer present at the time of the initial assessment.
- 1.7 The personal impact of being recalled for a second assessment on the women affected cannot be overstated. The confirmation for 20 of these women that they did in fact have a cancer, despite being reassured initially that they were clear, will have been devastating.
- 1.8 Beyond the women directly affected, the extensive local and national publicity about this incident may have undermined the confidence of some women about the thoroughness of breast screening procedures and raised questions about the competence and training of the staff involved. A critical success factor for the NBSP is the extent to which women can be persuaded to accept the invitation for screening (currently acceptance rates are around 73% on average but they are as low as 54% in London). **It follows that it is of critical importance that women across the UK are reassured that whatever went wrong at ELHT is identified and quickly eliminated as a potential risk in all other units.**
- 1.9 The purpose of this second independent review is, therefore, to examine closely all the factors that are relevant to the series of mistaken diagnoses at ELHT and in particular to identify if, and how, failings in governance processes (both locally and nationally) may have been a factor and how such weaknesses are best corrected. The more immediate purpose is to reassure the women of East Lancashire that their local screening unit has put in place all the changes necessary to ensure that there can be no repetition of recent errors and that the unit now offers a completely safe and reliable service.

### **Terms of reference and report structure**

- 1.10 The full terms for reference for this review are attached at appendix 1. In a more succinct summary the purposes of the review are as follows
- To review the robustness of the response by both the East Lancashire NHS Trust and NHS Northwest Breast Screening Quality Assurance Unit to the

- To establish definitive causes for this serious failure in expected service standards and in particular to review the effectiveness of clinical and management governance processes that should have prevented such a serious service failure
- To confirm and provide public reassurance that the ELHT Breast Screening Unit is now providing services to the required standard
- To make recommendations on any changes or improvement in governance processes that are necessary for the prevention of such incidents in the future.

1.11 To fully comply with these terms of reference the review has necessarily involved discussion and interviews with a wide range of people and examination of a considerable number of documents. The report provides analysis and commentary on sequential events as they unfolded and attempts to offer an in depth review of the related governance processes. For ease of reading the report is structured so as to chronicle events in the earlier sections and provide a commentary on governance processes in later sections. In more detail the report structure is as follows

An examination of how the incident came to light

A commentary on how well the incident was dealt with

An analysis of why the missed cancers were not diagnosed

An assessment of the various management and governance processes that failed to detect the problem – specifically in regard to the responsibilities of

The East Lancashire Breast Screening Unit

East Lancashire Hospitals NHS Trust

The North West Regional Breast Screening QA team

The National Breast Screening Programme

1.12 The final substantive section of the report, documents the changes made within the East Lancashire Breast Screening Unit since completion of the Incident Team report and concludes with a judgment on whether the unit is now safe and ‘fit for purpose’

1.13 Some sections of the report will be completed with a discussion of the main conclusions reached about the particular issues covered in that section and all sections of the report will finish with a list of specific recommendations where these are made.

1.14 **Some of the findings in this report raise the possibility of weaknesses in process or policy implementation on a wider, national, scale. Where this is the case the report clearly identifies possible concerns and suggested action to respond to these concerns. It must be understood however that such conclusions are based on what occurred at East Lancashire and do not reflect an exhaustive investigation of processes outside East Lancashire. As such the relevant national bodies will need to form their own view of whether a particular issue raised is a matter for concern or action at a regional or national level.**

## **2. EXECUTIVE SUMMARY OF CONCLUSIONS**

2.1 This section of the report provides an immediate and very broad summary of the main conclusions of this review as to the reasons so many patients were incorrectly diagnosed and why local and national governance processes failed to prevent this from happening. The main body of the report which follows provides a more detailed commentary on the conclusions reached.

### **Immediate Management of the Incident**

In relation to the objectives of the incident team as set out in the relevant national guidance the incident was well handled and well led. The incident team did an excellent job

### **Root Cause**

2.2 There was a straightforward and a single root cause for the missed cancers. One particular consultant in the unit (Dr X) failed to update his practical screening assessment skills in line with changing practice. Over a period of many years going back to at least 2001 he routinely failed to carry out a full and complete assessment (as stipulated in national guidelines) on significant numbers of his patients.

### **Governance failings**

2.3 There were a number of key failings of local and national governance processes that, had they not been present, might have brought the problems to light at a much earlier stage. These failings were

#### ***Failure of colleagues to raise concerns***

2.3.1 Senior medical staff and radiography staff in the ELHT Breast Screening Unit were aware that Dr X's breast assessment practice was not in accordance with national guidelines. Because Dr X was the senior consultant (as well as the Director of the unit) and because the overall cancer detection rates for the unit were above national 'targets' these colleagues did not suspect that cancers were being missed and as such were not sufficiently concerned to initiate any external intervention.

### ***Consultant appraisal***

2.3.2 The annual appraisal process for consultant staff at ELHT has been neither comprehensive nor effective from the time appraisal was introduced in April 2001 right through to the present day. Dr X's need for additional training to improve his assessment practice was discussed during an annual appraisal in 2005 but he did not make the necessary arrangements to undertake this training and no follow up mechanism existed between appraisals to ensure he did this. Dr X, in common with all his colleagues in the Radiology Department was not appraised at all in 2006 or 2007.

### ***External Quality Assurance Process***

2.3.3 The NBSP has the benefit of a dedicated external Quality Assurance Process which operates at a Regional level across England. The North West Regional QA team which has direct responsibility for quality assuring the breast screening service at ELHT was not sufficiently challenging or proactive in relation to searching for evidence of potential clinical problems in the radiology service. Too much reliance was placed on the assurance offered by the unit's overall performance against national assumptions for cancer detection rates. Statistically satisfactory performance against national detection cancer rates may have induced a degree of complacency and lack of rigour in relation to the assessment of radiology standards at ELHT. For example there is a requirement in the national visiting guidelines for the regional QA radiologist to review the training and development of individual consultant radiologists and there is no evidence that this has ever been properly undertaken.

2.3.4 Taking into account all the national guidance there is a significant disparity between the 'failsafe' clinical governance and assurance mechanisms built into the screening process and the considerably less rigorous approach to the routine audit of assessment clinics. This is surprising given the outcome of the 2006 review of missed cancers in the Breast Screening Unit at Altnagelvin Hospital where, as is the case in ELHT, non compliance with the national assessment clinic guidelines by a single doctor was found to be the cause.



## **Current standards of care**

2.4 In the light of the steps already implemented to improve the focus of the unit on standards of clinical care it is the conclusion of this review that the Breast Screening Unit at East Lancashire NHS Trust is now safe and 'fit for purpose'. To provide additional assurance to the public a recommendation is made that will provide continuous independent monitoring of the service until the next scheduled visit of the external Quality Assurance Team in early 2012.

### **3. HOW THE INCIDENT CAME TO LIGHT**

3.1 Over the period between 1988 (when the East Lancashire Breast Screening Unit was set up) and December 2008, no major concerns about radiological standards at the unit were identified as cause for investigation.

3.2 The unit was consistently at or above national minimum radiological targets and praised for its standards of radiological practice by the external expert radiologists attached to the Regional Quality Assurance Team following on site assurance visits in 2003, 2006 and 2009.

3.3 No concerns about missed cancers were expressed throughout this period either within the Screening Unit itself or within the Trust.

3.4 A specific and related sequence of events eventually triggered the investigation into Dr X's clinical practice

3.4.1 in the winter of 2006/07 Dr X was involved in an internal investigation (unrelated to his clinical practice) which undoubtedly had a serious effect on his morale and his attitude to work. This incident resulted in a period of stress related sickness in the early part of 2007. There is a strong consensus of opinion across all Dr X's colleagues that Dr X's attitude to work was adversely affected by this incident and his morale and appetite for work deteriorated gradually from this point in time.

3.4.2 In September 2008 Dr X voluntarily relinquished his position as Director of the ELHT Screening Programme. A position he had held since he was appointed in 1992.

3.4.3 It is clear that the new Director came into his role with some concerns about the practice of Dr X which were triggered by a combination of his gradual and worsening deterioration in morale and some 'grumbling' from surgical colleagues about a small number of reporting discrepancies in the symptomatic clinics. Prior to this point the only tangible evidence available to the new Director that Dr X's problems may have been affecting patients was a report of a false negative assessment (diagnostic

error) by Dr X in November 2007 that at the time had been regarded as an isolated incident.

- 3.4.4 The new Director's concerns at the time of taking up his post were sufficient to prompt him to undertake a personal audit of Dr X's screening results for the 2 most recent years (2006/07 and 2007/08) which served to reassure him that Dr X's screening performance was satisfactory. This audit did not include any review of Dr X's assessment clinics.
  - 3.4.5 Shortly after taking up post in September 2008 the new Director reorganized the screening assessment clinics. Whereas previously two consultants were present at each clinic the new arrangement meant that each of the three consultants conducted a single handed clinic. The purpose of this change was to increase overall clinic numbers to assist with meeting a national target to see women in the assessment clinic within 3 weeks of the screening appointment.
  - 3.4.6 In December 2008 the new Director received a report from a surgical Multi-Disciplinary Team meeting (MDT) of a potential false negative interval cancer which had presented in November 2008 (i.e. a cancer that presents as a symptomatic referral to the surgeons that was present but not detected at a previous screening visit/assessment in February 2007). This prompted a closer internal look at Dr X's assessment clinic outcomes for December which resulted in the discovery of two false negative assessments in a single clinic.
- 3.5 In the light of the cluster of 3 cases coming to light in a single month the new Unit Director immediately withdrew Dr X from the assessment clinics. Following discussions with the Associate Medical Director with responsibility for the Radiology Directorate (who is also a radiologist) and another senior radiologist, it was confirmed that Dr X should cease his involvement with assessment clinics and symptomatic breast clinics pending further enquiries. This was formalized in February 2009 at which point the Trust Medical Director became involved. File notes made at the time confirm that at this stage the Medical Director was not made aware that actual Cancers had been missed and was content to support an adjustment of Dr X's job plan to exclude him from the assessment clinics. It is clear from the record of these discussions that senior radiology colleagues were of the view that Dr X's problems were directly related to his poor morale and associated health problems.
- 3.6 At this point Dr X was allowed to continue his film screening sessions given the absence of any evidence that his performance in this area was deficient (and the positive outcome of the audit of this work recently undertaken by the new Director)

- 3.7 The Medical Director became aware only in April 2009 that cancers had been missed by Dr X in the assessment clinic and took advice from outside the Trust as to the significance of 2 false negatives assessments in a single clinic. Based on the advice she received she made the decision to report the matter to the Regional Quality Assurance unit which then instigated an external clinical review of Dr X's assessment clinics.
- 3.8 The Trust Chief Executive was not advised at all of the concerns about Dr X's practice until mid April (4 months after the decision to remove Dr X from the assessment clinics) and it was on the recommendation of the CE that the Medical Director took the external advice which prompted the decision to report the matter to the Regional QA team.
- 3.9 In January 2009 there was a planned triennial inspection of the Screening Unit by the North West QA team. The QA team was not made aware of the ongoing discussions within the Radiology Directorate about Dr X's practice and conducted their inspection in ignorance of these concerns. Moreover, at the time of the QA visit neither the Medical Director nor the Chief Executive was aware of the decision taken by the new Director to remove Dr X from the assessment clinic. The Unit Director's reason for not immediately informing either the Trust management or the QA team of his decision to withdraw Dr X from assessment clinics was his concern not to formalize the situation until histology results confirmed beyond doubt that the cluster of 3 cases which had come to light in December 2009 were definitely false negative cases.

### **MAIN CONCLUSIONS ON HOW THE INCIDENT CAME TO LIGHT**

- 3.10 The false negative assessment that came to light in 2007 should have been the subject of an internal incident report in accordance with the very comprehensive and very detailed Incident Reporting policy of the Trust. Had the incident been reported in accordance with the reporting policy in force at the time it would have been necessary for the person reporting the incident to 'grade' the incident in line with a standard frequency/impact matrix. This particular incident is likely to have fallen within the grading band that would prompt an internal *Root Cause Analysis*.
- 3.11 A Root Cause Analysis would have been undertaken by staff not directly involved in the incident and if conducted according to its literal title may have discovered the actual root cause of the incident was not 'isolated' to this one incident. The person who should have reported the incident was Dr X himself but he did not do so.
- 3.12 A full and proper internal response to the false negative assessment which came to light in November 2007 could, in theory, have exposed the degree to which Dr X's assessment practice was deficient. This incident serves to illustrate for Trust Boards the need for them to have in place robust assurance processes that go well beyond the knowledge that a good policy exists. Boards need to be sure that their

good policies on ‘paper’ are properly and consistently implemented. The case also serves to illustrate the potential for incident reporting systems to point Trusts in the direction of a serious patient safety concern.

- 3.13 The new Director of the Screening unit acted promptly and appropriately in judging that it was necessary to withdraw Dr X from screening assessment and symptomatic breast clinics immediately he was in possession of what he regarded as tangible evidence that Dr X had been making diagnostic errors. Notwithstanding comments made below about the subsequent process the new Director is to be commended for his decisiveness at this critical point in the process.
- 3.14 In implementing the decision in December 2008 to withdraw Dr X from assessment and (subsequently) symptomatic breast clinics the new Director obtained the agreement of the Associate Medical Director. This was appropriate as far as it went but it was wholly inappropriate that this decision was made and implemented without the involvement or the knowledge of either the Chief Executive or the Medical Director (the latter not being involved until February 2009 and not being made aware of the fact that cancers had been missed until April 2009). The Trust has a very detailed policy for the handling of concerns about clinical performance (issued in 2005). The policy reflects the content of the equivalent national policy *Maintaining High Professional Standards* which was also issued in 2005. Both these documents are absolutely explicit that any serious concerns about the performance of a consultant should be immediately referred to the CEO and handled from the outset by the Medical Director.
- 3.15 One obvious and important outcome of immediate referral to the CEO and Medical Director is that decisions about handling are more likely to be fully objective and reflect official procedures. This is exemplified by the perverse decision (taken before the Medical Director was aware of the situation) not to brief the Regional QA team of the situation ahead of the planned triennial QA visit in January 2009 and to allow this visit to proceed in complete ignorance of the fact that the most senior radiologist in the unit had been withdrawn from assessment clinics because of concerns about his clinical performance. It is also regrettable that the Associate Medical Director and the Clinical Director for Radiology failed to ensure that the Medical Director (when they reported their concerns to her in February 2009) was fully aware of the fact that there were specific cases known about where cancers had been missed at assessment.
- 3.16 In the document *Guidelines for managing incidents in the Breast Screening Programme* published by the NBSF in 2004 (and revised in January 2009) there is an unambiguous statement that the “Regional QA Director must be notified immediately of a suspected problem ..... where there is a concern about the professional competence of an individual”. This explicit requirement was not complied with by ELHT until 4 months after specific concerns about Dr X came to light. The response of the Director of the Regional QA team when eventually

notified by the Medical Director (17 April) was to initiate the screening incident procedure immediately and, as what he was told on 17 April 2009 was what was known in December 2008, it must be concluded that the delay in notifying the Regional QA Director caused a delay of 4 months in the full investigation of the concerns and a delay of 4 months in initiating treatment for the women who were subsequently found to have an undiagnosed cancer.

- 3.17 From the moment he took up his post in September 2008 the new Screening Director for ELHT began to make a series of immediate and significant improvements in the management of the unit and, as will be seen later in this report, has responded quickly and appropriately to failings in processes already documented in relation to this incident. He is a committed and enthusiastic clinician who enjoys the confidence of all his colleagues in the unit and also of the Trust management team and colleagues within the regional QA team. He was appointed (without any process) in September 2008 with no job description, no explicit time for the role incorporated in his job Plan at the time and was left to get on with this new role with no access to any formal training or induction either locally, regionally or nationally. The concerns about Dr X came to a head 4 months after the new Director had taken up post and, without the benefit of any formal induction or training in his role, it is not surprising that he was unfamiliar with the detailed requirements of the voluminous (albeit excellent and comprehensive) national guidance concerning the Breast Screening Programme.
- 3.18 The role of Director of Screening at a Breast Screening unit is self evidently of critical importance to the success of the breast screening programme. The extent to which this is a fact is evidenced by the list of responsibilities attached to the role in the publication *Organising a Breast Cancer Screening Programme* which was issued by the National Breast Screening Programme (NBSP) in December 2002. Surprisingly there appears to be no policy or advice relating to the method of appointment of Screening Directors, no formal assessment by any representative of the national Programme as to the suitability of candidates for the role, no requirement for formal induction and training and no arrangements for the formal appraisal of the incumbents. None of this detracts from the excellent job now being done by the new Director but some of these issues will be revisited in later sections of this report in regard to the way the role was fulfilled by Dr X when he was Director of Screening.

## **RECOMMENDATIONS RELATING TO HOW THE INCIDENT CAME TO LIGHT**

- R3.1 The Board of East Lancashire NHS Trust should take immediate action to be fully assured that all staff employed by the Trust are fully cognizant with the content of the Trust policy on incident reporting and how to properly fulfill their individual responsibilities for implementation of the requirement of this policy.*

- R3.2 *The Board of East Lancashire NHS Trust should take immediate action to be fully assured that all Board members, Executive Directors, Divisional Managers, Directorate Managers and all consultant staff are fully cognizant with the content of the current Trust policy for dealing with concerns about handling clinical performance and how to properly fulfill their individual and collective responsibilities when concerns come to light.*
- R3.3 *The National Director of the Breast Screening Programme should take steps to remind all Directors of Screening Units that the Regional Director of Quality Assurance must be notified immediately in the event of any concerns about the clinical performance of a Breast Radiologist.*
- R3.4 *A number of recommendations will be made about the appointment, tenure, training and appraisal of Directors of Screening in a later section of this report.*

#### **4. THE RESPONSE TO THE INCIDENT BY EAST LANCASHIRE NHS TRUST AND THE NORTH WEST BREAST SCREENING QUALITY ASSURANCE UNIT**

- 4.1 The Regional Director of QA on being notified of the concerns about Dr X's practice immediately and appropriately advised ELHT that the concerns should be investigated formally as a 'Breast Screening Incident' in accordance with the NBSP *Guidelines for managing an incident in the Breast Screening Programme*.
- 4.2 The incident was thenceforth managed strictly and properly in accordance with this guidance as described in the following paragraphs.

##### **Establishing the Incident Team**

- 4.3 An incident team was set up comprising representatives of ELHT, the Regional QA team, the 2 local Primary Care Trusts whose populations are served by the ELHT Screening unit and NHS Northwest. The incident team was advised at all stages by 2 very experienced independent Breast radiologists both of whom had been, for many years, the designated QA radiologists for the North West Regional Breast QA Team.

##### **Initial review of Dr X's work**

- 4.4 An immediate decision was taken at the initial meeting of the incident team held on 29<sup>th</sup> April (only 9 days after the incident was formally declared) that the 2 QA radiologists should review the decisions made in relation to all patients discharged to 'routine recall' without a biopsy from all the screening assessment clinics held at ELHT since 1 August 2008 through to the date in December 2008 when Dr X ceased to undertake assessment clinics. It was clearly reasonable to assume that

where a patient had had a biopsy at the clinic the possibility for error in diagnosis was negligible.

- 4.5 The start date for this ‘look back’ exercise was determined by an initial view that Dr X’s errors of diagnosis may have been precipitated by the change from double clinics (with 2 consultants present) to single clinics (with only one consultant present) which was initiated when the new Director of Screening was appointed in September 2008.
- 4.6 The decision to initially review the work of all three consultants at the ELHT unit was also important given need to see if the errors which had come to light reflected a real difference in performance between Dr X and the other breast radiologists.

This initial review was carried out on 14 May 2009 and it confirmed that

“..... the error rate of Dr X was significantly higher than the other 2 radiologists and overall was outside acceptable practice”

- 4.7 The 2 radiologists conducting the review compared the assessment process used by Dr X with the nationally recommended guidance. Out of the 42 cases relating to Dr X only 9 (21%) had had a fully satisfactory assessment and of those who had not had a fully compliant assessment 15 cases (36%) required re-attendance and full reassessment before the 2 QA radiologists could be sure about the true diagnosis. There were 15 cases where the initial assessment had not been fully compliant with national guidance but the 2 QA radiologists were confident that there was no clinical evidence to justify re attendance and re assessment of those cases.
- 4.8 The 15 women requiring reassessment were reassessed on 19 June 2009 and 3 women were found to have a cancer that should have been detected at the initial assessment by Dr X.

#### **Extension of the review period**

- 4.9 In the light of the extent of non compliance by Dr X with the nationally recommended assessment pathway the incident team decided to extend the period of the review of cases back by a full year to cover the period 1/8/07 to 31/7/08. In this review only Dr X’s cases were looked at.
- 4.10 This second review was undertaken on 5 June 2009 and of the 123 cases looked at only 7 cases had had a fully satisfactory assessment and of those who had not had a fully compliant assessment 41 cases required re attendance and reassessment before the 2 QA radiologists could be sure about the true diagnosis. 75 women had not had a fully compliant assessment but the 2 QA radiologists were

confident that there was no clinical evidence to justify re attendance and re assessment of those cases.

- 4.11 The 41 women requiring reassessment were seen at clinics held on 26<sup>th</sup> and 29<sup>th</sup> June and 4 women were found to have a cancer that should have been detected at the initial assessment by Dr X

#### **Further extension of the review period**

- 4.12 The 2 reviews undertaken on 14 May and 5 June had covered a period of 17 months and there was no evidence that Dr X's assessment practice had been fully compliant with national guidelines at any time in this period. In the light of this, the incident team had to determine the maximum period over which to review Dr X's assessment clinics in order to identify all the women who had attended his assessment clinic in the past who might still have an undiagnosed breast cancer. As women are invited for screening every 3 years the team judged that the review should be extended to the beginning of the then current screening round (1 August 2006) in order to be confident that all women potentially affected by Dr X's poor assessment practice had been reviewed. Women who may have had a cancer missed prior to 1 August 2006 (if they had not themselves presented with symptoms) would have had the missed cancer detected at their appointment in the current screening round or would be picked up through the decision to review all Dr Xs assessments from 1 August 2006 until the date he ceased undertaking assessment clinics in December 2008 .
- 4.13 The review period was therefore extended back to 1/8/2006 and an additional 111 cases were reviewed on 9 July. Of the 111 cases only 3 had had a fully satisfactory assessment. 78 cases had not had an assessment that was fully compliant with the national guidelines but were not recalled for assessment because the 2 QA radiologists were confident that there was no clinical evidence to do so. 30 cases required re-attendance and full reassessment before the QA radiologists could be sure about the true diagnosis
- 4.14 The 30 cases requiring reassessment were seen on 10 August 2009 and, of these, 9 were found to have a cancer that should have been detected at the initial assessment by Dr X.



## Summary of full review Outcome

<u>Review date</u>	<u>reviewed</u> (Dr X)	<u>reassessment date</u>	<u>reassessed</u>	<u>cancers</u>
14 May 2009	42	19 June 2009	15	3
5 June 2009	123	26&29 June 2009	41	4
9 July 2009	111	10 August	30	9

4.15 In a period of just under 4 months from the declaration of an ‘incident’ on 20 April 2009, 276 cases were reviewed and 82 women underwent a full reassessment.

4.16 The total of 20 missed cancers overall which were identified in this review includes the 4 cases that prompted ELHT to initiate the investigations into Dr Xs practice.

4.17 The review covered the period 1 August 2006 to 31 December 2008 (28 months). This involved reviewing the notes and films of 276 patients discharged as cancer free without a biopsy from 94 assessment clinics undertaken by Dr X. In total Dr X had seen 390 patients at these clinics

4.18 Of the 276 cases reviewed 254 (92%) had not been assessed in full compliance with national guidelines. This is 65% of all the 390 attendances.

4.19 A total of 86 of women required re attendance and reassessment before the QA radiologists could be certain about the diagnosis. This equates to 31% of discharged cases and 22% of all patients attending Dr X’s clinics.

## Incident Review findings concerning Dr X’s clinical practice

4.20 Insofar as screening assessment was concerned Dr X’s clinical practice was found to be deficient in a number of ways. His practice was assessed against the *National clinical guidelines for breast cancer screening assessment* issued by the NBSP to all screening units in 2005. These guidelines provide comprehensive advice on the indications for the use of a range of diagnostic options available for breast assessment including

Additional, enhanced view, mammograms  
Clinical examination  
Ultrasound examination  
Ultrasound guided core needle biopsy  
Stereotactic (X-ray guided) core needle biopsy

4.21 The specific deficiencies in Dr X's assessment practice identified by the 2 QA radiologists were as follows

4.21.1 In the 190 cases that were not fully compliant with the national guidance but which did not require reassessment the patients should have had an ultrasound examination prior to discharge to confirm the diagnosis that no cancer was present

4.21.2 In the 86 cases called for reassessment no ultrasound examination had been undertaken despite some signs of an abnormality on the mammograms that needed further investigation

4.21.3 Of the 86 cases recalled for reassessment 49 women required a core biopsy in addition to ultrasound examination before a definitive diagnosis could be made

4.21.4 Although not specifically examined by the QA radiologists it has also become evident that in the cases where Dr X had requested a biopsy he had invariably ordered a Stereotactic biopsy when many of the cases could have had an ultrasound guided biopsy. (the significance of this is discussed in later sections)

4.22 In parallel with the review of the screening assessment clinics the incident team considered the outcome of a number of other reviews undertaken in relation to other aspects of Dr X's radiology practice

#### Screening mammograms

4.23 The QA radiologists reviewed the audit of 2 years screening films previously undertaken by the new Director of the unit and concurred with his conclusion that there was no evidence that women had not been called for assessment when indicated. Further reassurance in this respect is provided by the fact that all screening films are read separately by 2 experienced clinicians with a third clinician involved in the arbitration reading.

#### PERFORMS

4.24 All breast screening radiologists are encouraged to participate in an external quality assurance process (PERFORMS) which assesses performance in the reading of screening mammograms. Broadly speaking the participating radiologist is presented with a set of films which are at the challenging end of the spectrum and gets confidential feedback on their performance. The scheme is voluntary but the participation of breast radiologists is 'expected' by the NBSP and is encouraged by the Royal College of Radiologists. During the course of the QA team review it was discovered that Dr X's participation in PERFORMS had been

spasmodic since 2003. He had not participated at all in 2003, 2004 and 2005 and only partially in 2006 and 2007. He again did not participate at all in 2008. Although his results when he did participate gave no major cause for concern (which is consistent with the local audit of his actual screen reading) his non participation is a concern as is the fact that the QA team were not made aware of this by Dr X.

#### Symptomatic Breast work

- 4.25 Dr X also provided specialist radiology input to the symptomatic breast clinics (surgical clinics where women are referred who have been to their GP with breast symptoms). One of the QA radiologists audited 6 months of this work (July to December 2008) and concluded that the work was of an acceptable standard. Further reassurance in relation to symptomatic work derives from the fact that the these clinics are multi disciplinary in nature, involve discussion of cases between the radiologist and the surgeon and that the final decision on diagnosis is made by the surgeon

#### Other radiology work

- 4.26 Dr X undertook a range of general radiology work other than breast work and this work was audited by appropriate senior members of the ELHT radiology staff. A random sample of 20% of CT and MRI films (171 films in all) reported by Dr X over a 6 month period July to December 2009 were reviewed by 7 different radiologists with relevant experience. Findings of the review were shared with the Royal College of Radiologists which concurred with the conclusion reached that Dr X's general radiology practice was of a satisfactory standard

### **Further action to protect patients**

- 4.27 As the findings in relation to Dr X's practice emerged during the course of the 'look back' exercise the Trust consulted with the National Clinical Assessment Authority and the General Medical Council about further restrictions to Dr X's practice. He was relieved of all breast assessment work on the advice of the GMC until such time as all enquiries are complete and informed decisions can be made as to Dr X's future.

### **Management of the affected patients**

- 4.28 It is clear from the record and from detailed discussions with the Incident Team members that an extraordinary degree of care was taken to manage the women who needed to be recalled with care and compassion. Based on discussions with a very small sample of the women directly affected it seems the team largely succeeded in this objective. Allowing for the fact that, however well it was handled, it was impossible for this to be anything other than an extremely

distressing process for all the women affected the recall process seems to have been well managed. The team faced the usual dilemma of how to recall the women without causing premature anxiety for them (and for the wider community) and rightly chose to invoke routine audit processes as the reason initially given to the women for the recall.

A full and completely honest explanation of why it had been necessary to recall them together with a full apology was provided to the women when the Trust was in a position to confirm the outcome of their reassessment. The strategy adopted by the incident team was to ensure that when public announcements were made it was possible to state categorically for the reassurance of all women who had been screened at East Lancs that all affected women had already been reassessed and were aware of their new diagnosis.

## **MAIN CONCLUSIONS ON THE IMMEDIATE MANAGEMENT OF THE INCIDENT**

4.29 The management of the incident was conducted largely in accordance with the specific guidance *Guidelines for managing incidents in the Breast Screening Programme* which was issued by the NHSBSP in revised form in January 2009. In making a judgement about how well the incident was managed it is important to appreciate the complexity of factors that the incident team were dealing with

- Identifying which women are potentially at risk in a way which strikes a responsible balance between ensuring all affected women are identified and not creating needless and avoidable anxiety for women not likely to have been affected.
- Balancing the urgency to identify potentially undiagnosed cancers in a substantial 'look back' exercise with the need to ensure avoidance of too much disruption to the day to day workload of the Breast Screening Unit which needed to remain focussed on its task of identifying cancers in new patients

4.30 At the time the incident was declared the Incident Team was aware of 4 missed cancers at assessment clinics in February 07, November 08 and 2 in December 08. The decision to was taken to undertake an initial 'look back' exercise to August 08 to compare Dr X's results with his 2 consultant colleagues and to test the possibility that the changeover to single consultant clinics in September 2008 had 'caused' a deterioration in Dr X's practice. In the circumstances and ignoring the benefit of hindsight this is a reasonable initial step. The 'look back' exercise was quickly and efficiently extended in two tranches back to August 2006 as soon as it became clear that it was necessary to do so. The decision to extend the look back period to August 2006 was specifically related to the need to review a full screening round so as to be sure that all the women who had attended the ELHT

Breast Screening Unit and who might still have an undiagnosed cancer had been reviewed.

- 4.31 Overall in a period of less than 4 months the cases of 276 patients were reviewed by 2 independent Radiologists (both of whom had clinical responsibilities in their own Screening Units) and 86 women were recalled to 4 specially arranged clinics for a full reassessment. Within this time frame the Incident Team also garnered the evidence necessary to make a judgement that Dr X's clinical practice in symptomatic breast clinics, breast screening film reading and general radiology was of an acceptable standard.
- 4.32 The Incident Team met 4 times on 29 April 2009, 18 May 2009, 4 August 2009 and 24 August 2009. The team was well led by the Regional Director the Breast Screening QA team and maintained a very consistent focus on its task of establishing the extent of the clinical deficiencies they were dealing with, identifying the potentially undiagnosed women and on the sensitive management of communication with these women and with the wider public when the incident became public knowledge.
- 4.33 All in all it is fair to conclude that in relation to the objectives set by the Incident Team, the Incident was very well handled and the Incident Team did an excellent job. The process was managed efficiently and sensitively despite the inevitable pressure on all those directly involved both in terms of the additional workload (particularly on the clinical staff involved) and the potential for significant and understandable public abreaction to the missed cancers.**

## **RECOMMENDATIONS RELATED TO THE IMMEDIATE MANAGEMENT OF THE INCIDENT**

*R4.1 The NHS Breast screening programme should mandate that all clinical staff involved in reading mammograms participate in the external PERFORMS QA process. Individual results should be available to the Director of the Screening Unit and be presented as a mandatory component of the individual's appraisal portfolio.*

## **5. WHY THE CANCERS WERE NOT DIAGNOSED AT THE ASSESSMENT CLINICS**

5.1 Notwithstanding the many failures of clinical and organisational governance that will be catalogued in this report it is important to be clear that the fundamental reason for the missed cancers was poor diagnostic practice by an individual specialist (Dr X).

- 5.2 The issue of Dr X's contractual and professional accountability for the poor diagnostic practice that resulted in the missed cancers is the subject of a separate process of investigation being undertaken by his employers (East Lancashire Hospital NHS Trust) and the General Medical Council. For the purposes of this report however it is necessary to record the bare facts relating to Dr X's role
- 5.3 Dr X was appointed as a consultant with an interest in Breast Diseases in 1992 and was also appointed directly into the post of Director of the East Lancashire Breast Screening Unit. At the time of his appointment the assessment of screen detected breast disease did not routinely involve the use, within the assessment clinic, of ultrasound guided core biopsy although the use of ultrasound for additional imaging was already the practice in some units. The biopsy technique in use in assessment clinics at the time of Dr X's appointment was FNA (fine needle aspiration) where the needle was guided stereotactically (using the mammogram equipment).
- 5.4 The use of core biopsies (which retrieve a sample of tissue) was increasingly introduced into assessment clinics throughout the 1990's. In 2001 the NHSBSP published the first formal *Clinical Guidelines for Breast cancer Screening Assessment* which is described in the introduction to the document as
- "..... the minimum standards required for satisfactory breast screening assessment"*
- This document sets out very clearly the clinical indications for the use of ultrasound examination and needle biopsy. For most indications ultrasound examination is recommended and in regard to needle biopsy the document is clear that core biopsy is a preferred investigation over FNA for 3 of the 4 types of abnormality normally being investigated. The document is also clear that for other than 1 particular indication the ultrasound guided technique is the preferred method for taking a core biopsy.
- 5.5 The major benefits of ultrasound guided biopsy of the breast is that the test itself takes considerably less time than stereotactic (X-ray) guided biopsy and is a much less unpleasant experience for the woman. Fainting episodes are not an uncommon problem where the stereotactic method is being used.
- 5.6 The 2001 guidelines were re issued and strengthened in 2005.
- 5.7 It follows therefore that extensive use of ultrasound examination in the assessment of screen detected breast abnormalities coupled with very clear indications for the use of ultrasound (or stereo) guided core needle biopsy have been incorporated in explicit breast assessment guidelines since 2001. It is against these guidelines that Dr X's practice was audited during the Incident Review and as recorded in section 4 it was found that over the 28 month period of the review

- 276 patients (out of 390 patients originally assessed by Dr X) did not get an ultrasound examination as indicated by the guidelines
- 49 patients were not biopsied as indicated by the guidelines
- Dr X used Stereotactic guided biopsy for almost all patients where a biopsy was undertaken despite the recommended option of ultrasound guided biopsy for a large number of these patients

5.8 The Incident Review Team properly and successfully focussed their attention on the identification of women who may still have had an undiagnosed cancer as a result of a wrong diagnosis by Dr X. The terms of reference of this review require however that the ‘root causes’ of the incident and associated failures of governance should be identified. To do this properly requires that the origins of the problem should be as accurately pinpointed as possible so that a judgement can be made about what, if any, opportunities existed over what period of time for management and governance processes to prevent or mitigate the errors that occurred.

5.9 There is strong evidence to suggest that over many years prior to the period reviewed by the incident team a number of other women have experienced delays in the diagnosis of their cancer as a result of Dr X’s incomplete assessments. The evidence for this is as follows

5.9.1 The deficiencies in Dr X’s assessment practice are evident throughout the 28 months (94 clinics) that were reviewed by the Incident Team. The first missed cancer was identified in the second month of the review period (September 2006) with the remainder spread fairly evenly throughout the whole period of the review up to December 2008. It is highly improbable that the origins of Dr X’s poor assessment practice will have coincided with beginning of the 2006 – 2009 Screening round. Whilst it is the case that the beginning of the review period roughly coincides with the ‘stressful incident’ affecting Dr X ( referred to earlier) it must be observed that Dr X’s practice in screening film reading, symptomatic breast radiology and general radiology does not appear to have suffered a sudden deterioration from the time of the ‘stressful incident’

5.9.2 It will be shown later in this report that Dr X has never become personally proficient in a diagnostic technique (ultrasound guided core biopsy) that was shown by the review to be one of the key areas of non compliance with the national assessment pathway. This deficiency in personal skill dates back at least as far as 2001 when ultrasound guided core biopsy was becoming common practice in the assessment of screen detected abnormalities

5.9.3 There is evidence of one case that was missed by Dr X at an assessment in 2003 and again at an assessment in 2006.

5.9.4 Analysis of interval cancers linked to the ELHT Breast Screening Unit has identified 10 women with category 3 interval cancers in the period 1995 to 2006 that had been previously assessed and discharged as cancer free by Dr X.

A category 3 interval cancer is defined as a cancer occurring after a routine screening or assessment where “..... *there are signs suspicious of malignancy on the original screening films*”. Category 3 is the highest (or most serious) category of interval cancer – category 2 interval cancers have ‘minimal signs’ on the original films and category 1 have no signs of abnormality on the original mammogram. For this number of category 3 interval cancers to occur after a clinical assessment and in relation to one consultant is highly suspicious of sub optimal assessment practice.

5.9.5 A detailed audit of Dr X’s assessment practice for the 3 years prior to the Incident Team Review has demonstrated a very similar pattern of significant underutilisation of both ultrasound and ultrasound guided core biopsy as was evident in the period of the Incident Team review.

**5.10 This additional scrutiny of Dr X’s earlier practice has confirmed that in addition to the 20 cancers missed by him between August 2006 and December 2008 an additional 41 women have suffered a delayed diagnosis of cancer as a consequence of an incorrect assessment by Dr X in the period 2000 through to 2006.**

5.11 As intimated previously, consideration of Dr X’s contractual and professional accountability for his practice is the subject of separate enquiries by the Trust and the General Medical Council. For the purposes of this review however it is necessary to record such facts as are known and agreed (by Dr X) in relation to why Dr X did not follow the NBSA assessment guidelines. This is important because it is necessary to establish in this review not only what the fundamental cause of the missed cancers was, also but the extent to which the events might have been prevented or mitigated by the myriad of governance and management processes which exist in the NHS and which have the self evident objective of ensuring the safety, well being and high quality care of patients.

5.12 For the record there can be no doubt that Dr X was aware of the existence and content of the national guidelines. He does not claim to be unaware of the guidelines and, moreover, as Director for the Breast Screening Unit it was his responsibility to ensure full dissemination of these and other guidelines to his colleagues in the unit.



5.13 Dr X's account of why he hadn't followed the national assessment guidelines can be summarised as follows

- Although he acknowledges that he has been trained and is competent in the use of breast ultrasound he has never been formally trained or assessed in undertaking ultrasound guided biopsy as this technique emerged after he had taken up post as a consultant.
- Pressure of work has prevented him from taking the necessary time off from his duties to undertake this training.
- His use of Stereotactic guided biopsy for all biopsies was a result of his concern to do the best for his patients by not subjecting them to a procedure (ultrasound guided biopsy) he wasn't sufficiently competent to perform.

(As is the case in many Breast Screening Units, stereotactic biopsy is carried out in East Lancs by advanced radiography practitioners, rather than by the consultant radiologist, which means that by use of this method for all his biopsies Dr X was not himself required to undertake any biopsies at the assessment clinics)

- It is his opinion that Stereotactic guided biopsies are at least as accurate ultrasound guided biopsy in assisting with diagnosis
- He is of the view that guidelines are for 'guidance' and are not a replacement for an individual's clinical judgement.
- Although he was clearly aware that he was not following the guidelines in relation to indications for Ultrasound Guided biopsy, he says he was not aware of the extent to which his use of ultrasound was so much less than his peers.
- Even in the light of the knowledge he now has about the scale of the difference between his assessment practice and that of his peers he continues to defend his own approach on the basis that "..... it doesn't matter what methods you rely on as long as you get the right result"
- He initiated a discussion with his Clinical Director at his 2005 annual appraisal concerning his need for further training but this was not followed up.

5.14 Dr X maintains that the missed cancers in the period 2006 to 2008 were not a result of his lack of compliance with the assessment pathway but a direct consequence of illness and stress caused by an unrelated matter in the autumn of 2006. Dr X maintains that as a consequence of this illness and personal stress his judgement and concentration at assessment clinics was impaired.

## MAIN CONCLUSIONS IN REGARD TO WHY THE CANCERS WERE MISSED

5.15 Dr X is a breast radiologist of 18 years standing and for most of that time was the Director of the ELHT screening unit. The fact that he has never developed the skills to undertake ultrasound guided breast biopsy and undertakes so few ultrasound examinations at breast clinics is regarded with some incredulity by all the experienced breast radiologists whose advice had been sought during the preparation of this report.

5.16 The Guidelines issued by the NBSP *Quality Assurance Guidelines for Breast Cancer Screening Radiology* which set out the ‘responsibilities’ of breast radiologists are explicit about the skills required of a breast specialist as the following extract confirms

*“A radiologist involved in breast cancer screening has the following responsibilities.*

*To ensure that he or she acquires and maintains a comprehensive knowledge of breast disease and the necessary skills to conduct the full diagnostic process, including:*

- *reading and interpretation of mammograms*
- *use of ultrasound and its application to breast assessment*
- *assessment of suspected abnormalities*
- *performing fine needle aspirations, wide bore needle biopsies and localisation by palpation, ultrasound and x-ray (stereotactic) control.*

*This will involve attendance at the Royal College of Radiologists (RCR) approved breast screening training courses and subsequently regular reading of appropriate articles/journals and attendance at scientific meetings that include breast imaging. The screening radiologist is expected to participate in the college’s continuing medical education (CME) credit scheme and ensure continuing accreditation by the college. It is suggested that at least 25% of a screening radiologist’s CME time should be spent specifically in breast screening education (12.5 hours per year at present).”*

5.17 Notwithstanding Dr X’s view that “guidelines are for guidance and should not over-ride individual clinical judgment” he acknowledges that his practice of defaulting to Stereotactic guided biopsy is a response to his lack of skills in ultrasound guided biopsy and not because he disagrees with the pathway. He has

confirmed that if he had been competent to undertake ultrasound guided biopsy he would have done so.

- 5.18 Dr X's assertion that the missed cancers were a result of stress affecting his judgement after the unrelated investigation in the autumn of 2006 is not supported by the fact that additional enquiries initiated by this review have shown that 41 additional cancers were also missed in the period 2000 – 2006.
- 5.19 The issue of appraisal, identification of training needs, study leave etc. will be dealt with in detail in later sections of this report covering governance processes within ELHT. It can be recorded here however that there is no evidence that Dr X has ever been prevented from taking his full allocation of study leave throughout the period of his employment with East Lancs NHS Trust (and its forbears). Furthermore there is no evidence that, despite the discussion at the 2005 appraisal meeting, Dr X himself subsequently made any serious enquiries of his managers or to the identified training institution about undertaking the specific training he required in relation to ultrasound guided biopsy.
- 5.20 Whilst the Breast Screening Unit was undeniably busy and under pressure to fulfil national waiting time targets Dr X was always able to take his full allocation of study leave (30 days in each 3 year period) and had at least one half day per week specifically built into his weekly timetable for clinical audit, teaching, research etc which, in the circumstances, could have and should have been used to facilitate the extra training he knew he required.
- 5.21 The GMC publication *Good Medical Practice* is unambiguous on the issue of maintaining relevant skills. The relevant section says the following

*“Keeping up to date*

*You must keep your knowledge and skills up to date throughout your working life. You should be familiar with relevant guidelines and developments that affect your work. You should regularly take part in educational activities that maintain and further develop your competence and performance”*

In the introductory paragraphs to *Good Medical Practice* it is explained that the term ‘you must’ is used *“for an overriding duty or principle”*

- 5.22 The evidence of this review (building on the conclusions of the QA team review which preceded it) has established that the single fundamental reason for the cancers missed at Dr X's assessment clinics was the failure of Dr X to follow the nationally recommended assessment guidelines from the time of the first introduction of these guidelines in 2001.

## **6. FAILURES WITHIN THE ELHT BREAST SCREENING UNIT**

- 6.1 The East Lancashire Breast Screening Unit (ELBSU) was established in 1990 at the time the NBSP was implemented following publication of the Forrest Report. The service is delivered to the populations covered by 2 Primary Care Trusts – NHS East Lancashire (Burnley and its environs) and NHS Blackburn with Darwen. The full population of women eligible for screening is currently 66,000. Take up of the service is 70% and as such 15,000 women per annum are screened in a 3 yearly cycle.
- 6.2 The managing Trust at the time the unit was established was Blackburn, Hyndburn and Ribble Valley NHS Trust which became East Lancashire NHS Trust (through a merger with Burnley Healthcare NHS Trust) in 2003.
- 6.3 The 4 most senior clinical staff in the East Lancashire Screening Unit screening unit have been in post together since 2005
- Dr X was appointed as Consultant Radiologist and Director of Screening in 1992
  - Consultant Radiologist 2 was appointed in 2000
  - Consultant Radiologist 3 was appointed in 2004 ( a consultant since 1999)
  - The Superintendent Radiographer and Programme Manager has been in post since 1990
- 6.4 The main screening unit was located, from the time of its establishment in 1990 in the Accrington Victoria Community Hospital and moved to substantially more spacious accommodation in Burnley General Hospital in May 2010.
- 6.5 Throughout the whole period of its existence up until the discovery of Dr X's assessment errors in December 2008 the East Lancashire Breast Screening Unit has achieved acceptable overall clinical outcomes when measured against the standards set by the NBSP. Radiology standards (i.e. the work of the radiologists) were described in very positive terms in the 2003, 2006 and 2009 reports following the triennial visits of the Regional QA team. (A much fuller account of the work of the regional QA team in relation to ELBSU will be provided in a later section of this report)
- 6.6 The unit has been affected by a number of operational issues since it was established including
- A 30% increase in workload associated with the extension of the programme in 2003 to women between the ages of 50 and 70.

- Inability to recruit to 4 additional radiology consultant sessions (approved in relation to the programme extension)
  - A chronic shortage of space in the main base at Accrington (where the assessment clinics were undertaken ) which was inevitably and seriously exacerbated by the workload increase in 2003
  - A variety of clerical and radiography staffing pressures arising from vacancies, sickness, recruitment freezes, maternity leave etc. (of the kind that affect all clinical services in the NHS).
- 6.7 A combination of these problems following the programme extension in 2003 resulted in a situation where the unit was, for a number of years, failing to achieve national standards for screening times which requires that 90% of women should be screened within 3 years of their previous screen. The 2009 QA visit noted that a recovery plan had been put in place which had, by the end of 2008, achieved the screening interval target but that more recent problems had developed in relation to targets for results after screening and appointment for assessment.
- 6.8 The main problem solving focus of senior clinical staff in the East Lancs BSU in the period since 2003 has been directed to workload and capacity issues. This has been a necessary response to the (perfectly proper) performance management pressure exerted by the QA team, the PCTs and the Trust Managers for achievement of national targets. The consistent achievement by the unit of minimum and expected national standards for clinical outcomes appears to have resulted in a situation where ongoing critical appraisal of the clinical processes and outcomes within the unit were not a priority for the senior clinical staff, the Trust management or the Regional QA team. Having said this it is clear that the leadership style of Dr X as Director of Screening was such that robust processes of clinical governance within the unit were not in place and it is probable that had a less complacent, laissez faire approach to clinical governance been in place the poor assessment practice of Dr X may have been identified at a much earlier stage than it was and this is examined in more detail in the following paragraphs

### **Clinical leadership within the East Lancs BSU**

- 6.9 Everybody interviewed for this review who was in a position to observe Dr X's leadership of the ELBSU as Director of Screening between the period 1992 and 2008 expresses the view that he was not proactive in any aspect of this responsibility. This view was not only held by all his senior colleagues within the unit but was shared by the Director of the Regional QA team. His lack of external commitment to his role as Director of the unit is graphically illustrated by the fact of his regular non attendance at the twice yearly meeting of the Directors of all NHS Northwest Screening Units with the Regional QA Director and the QA Team. Of the 11 meetings of this group between 2003 and 2008 when Dr X was

Director of the ELBSU he failed to attend on 9 occasions (leaving the ELBSU completely unrepresented on 7 occasions).

- 6.10 Dr X says his failure to attend meetings was due to “pressure of work” and describes the role of Director of the Screening unit as a “clinical figurehead”.
- 6.11 Within the unit it is clear that for the greater part of his tenure as Director Dr X did not provide active clinical leadership and that the burden of delivering the service, coping with operational pressures and major programme-related initiatives fell on the Superintendent Radiographer in her role as Programme Manager. Whilst it is reasonable that the Programme Manager should carry the burden of day to day delivery of the service it is evident from discussions with her that the drive, determination and enthusiasm to excel in service quality which should emanate from the Director of the unit simply wasn’t on offer. By way of example it is a fact that the unit struggled in very inadequate facilities for the whole 16 year period of Dr X’s tenure as Director but there is very little evidence in the record that Dr X pressed this case forcibly with the Hospital Managers. Most of the pressure on Hospital Managers to do something about the poor accommodation came from the Programme Manager and the Regional QA team both in their reports and directly with the Trust management. In response to this specific point Dr X expresses the view that “it was in the QA report and it was up to the managers to deal with it”
- 6.12 Dr X’s lack of managerial leadership of the unit was equally (and crucially) present in relation to clinical leadership. According to his 2 consultant colleagues there was very little, if any, systematic collective multidisciplinary appraisal of clinical performance within the unit itself. Monitoring of clinical process and outcomes relied exclusively on the work and output of the Regional QA team and the national outcome statistics. There appears to have been no recognition that good clinical governance is not simply about achieving a minimum standard but also about establishing a culture where clinical staff are motivated individually and collectively to be constructively self critical in the pursuit of improved standards of service and outcomes for patients. Virtually none of the processes that would establish such a culture were evident in the East Lancs BSU during Dr X’s tenure as Director viz:-
- No regular consultant and/or multidisciplinary team meetings of unit staff to discuss clinical processes
  - No internal programme of clinical audit
  - No routine audit or multidisciplinary discussion of compliance with national clinical guidance

- No multidisciplinary discussion of the impact on unit protocols of new national guidance ( e.g. the revised assessment guidelines issued in 2005)
  - No systematic approach to the review and classification of interval cancers.
- 6.13 National guidance suggests that reviewing Interval Cancers “..... will ensure that radiologists and film readers continue to learn from interval cancer film review”. In an exemplar unit elsewhere in the country interval cancers are reviewed and classified once a month by every film reader in the unit (consultants and advanced radiography practitioners). In East Lancs a backlog of interval cancers would be reviewed and classified by the Director and a colleague just before they were due to be presented for review by the QA radiologist at the triennial visit. The present Director of the unit confirms that there was a backlog of unclassified interval cancers at the time of the 2009 QA visit.
- 6.14 It is clear that the absence of any systematic approach to reviewing or discussing clinical processes within the East Lancs Breast Screening Unit and particularly the absence of a programme of routine clinical audit within the unit (which ought, at some stage, to have included the assessment process) was a factor in allowing Dr X’s poor assessment practice to go ‘undiscovered’ for so many years. It must be recognised, of course, that the fact that the consultant with poor assessment practice was the unit’s Director and, as such, was himself responsible for implementing robust clinical governance policies within the unit, was unfortunate.

**Were Dr X’s colleagues aware of his poor assessment practice?**

- 6.15 Dr X’s consultant colleagues within the unit, the Programme Manager and the advanced practitioners (who undertook the stereotactic biopsies) were all aware that Dr X did not perform ultrasound guided core biopsy and all were aware that this was an important limitation in his assessment practice.
- 6.16 All these colleagues suggest that they became more concerned about his practice and more aware of his limitations after the deterioration in his morale following the non clinical investigation in which he was involved in the early part of 2007. Whilst it is certainly likely that colleagues will have become more concerned about Dr X’s manner in the period since early 2007 it is also the case that they must all have been aware of his limitations in regard to assessment practice prior to this. At the very least it would have been known that that he was requesting advanced practitioners to undertake stereotactic biopsy for women who, the practitioners will have known, should have been having an ultrasound guided core biopsy.
- 6.17 Exactly when each of these colleagues became aware of the problem to the point of being concerned remains unclear but it is probable that there were some concerns prior to the period beginning August 2006 to December 2008 which is the period covered by the incident review and where 20 cancers were missed.

Bearing in mind this is a relatively small clinical unit with good knowledge amongst very experienced radiology and radiography staff of the full assessment pathway options it seems highly likely that most of the senior clinical staff will have known of Dr X's idiosyncratic assessment practice going back many years. This is almost certainly the case in relation to his inability to undertake ultrasound guided biopsy himself and is probably the case in relation to his practice of discharging patients without either ultrasound examination or biopsy. This is evidenced by the fact that one of the advanced practitioners acknowledged that she had queried directly with him Dr X's decision not to do an ultrasound examination on a number of occasions.

6.18 This raises the question of whether these colleagues should have taken action in relation to the concerns which they have all acknowledged were present to varying degrees within the unit. Their decisions collectively and individually not to 'raise' the issue outside the unit were based on a number of key factors as follows

- They were of the view that there was no evidence that the unit's performance in detecting cancers was less than it should have been. The external QA report consistently praised radiological performance based on the unit's performance against national standards. **All staff who acknowledge awareness of Dr X's problem insist that they had no reason to believe any patients were coming to harm.**
- Consultants 2 and 3 believed that when, prior to September 2008, Dr X worked with another consultant present in the assessment clinics he was able as the senior consultant and unit Director to allocate cases likely to require a biopsy to the other consultant. This they believed was helping to mitigate any potential problems.
- Dr X was both the senior consultant and the Director of the unit. His colleagues were inhibited in 'complaining' about his practice (and questioning his competence) given the favourable outcome statistics for the unit and the consistently favourable external QA reports.
- It is also possible that a lack of confidence in the ability of senior Trust managers to confidently and sensitively handle the 'fall out' of a challenge to Dr X's competence in a way that ensured avoidance of personal or career 'damage' to the complainant could have been an inhibiting factor.

6.19 As will be seen later in this report, throughout the period over which concerns amongst Dr X's colleagues may have intensified there was perpetual reorganisation at Trust level and frequent turnover of Executive Directors and the CEO. Notwithstanding the availability of a comprehensive 'Whistle blowing Policy' within the Trust, a pre requisite for its use is that any consultant or other senior member of staff contemplating the possibility of raising serious concerns



about the clinical practice of a senior colleague will need to have complete trust in the process. In particular they will need to have complete confidence that the CE and the relevant executives have the experience and wisdom to ensure the process followed is careful, sensitive, proportionate and assiduously protective of all the individuals who will get drawn into the enquiries that must be made. Such trust depends on a degree of senior management stability in the organisation that has been manifestly absent at ELHT for the last decade.

## **MAIN CONCLUSIONS IN REGARD TO FAILURES WITHIN THE EAST LANCBS BREAST SCREENING UNIT**

- 6.20 The radiological performance of this unit has been judged within the unit almost exclusively on the basis of the achievement of national standards for minimum/expected clinic outcomes. Since the establishment of ELBSU in 1990 the national cancer detection statistics have never been interpreted as giving any direct indication in any particular year that there were ever serious problems in relation to cancer detection results in the unit. The positive view of the Unit's staff regarding radiological performance was reinforced and endorsed by the consistent and equally positive view taken by the QA Radiologists at QA visits in 2003, 2006 and 2009. National guidance does contain a clear warning that unit level statistics are not sensitive enough to 'pick up' failings by an individual practitioner but, as will be seen later in this report, there is strong evidence from this case that achievement of national clinical standards is assumed to provide adequate assurance on its own that all radiologists are individually performing to the required standards. Stronger mechanisms than currently exist need to be put into place to provide a greater level of assurance about the competence of individual radiologists and this is discussed in more detail in the section of this report dealing with the role of the Regional QA team.
- 6.21 The senior unit staff (both clinical and management) have tended in recent years to focus their energies on the achievement of service access targets (screening interval, waiting time for screening results and waiting time for assessment appointments). This is entirely reasonable given the justifiable degree of importance attached to these targets nationally and the fact that they were being properly pressurised by the Primary Care Trusts and Regional QA team to achieve these targets. There is no implied criticism intended here in relation to the focus given to access and waiting targets – these are especially justifiable in a programme relating to a disease that arouses such great levels of anxiety in the patients.
- 6.22 The ambivalent attitude of Dr X to his responsibilities as the Director of Screening was both tolerated and uncommented on over many years by his senior colleagues and the Regional Director for Quality assurance. It was because of Dr X's lack of active leadership within the unit that the robust clinical governance processes that might have picked up his own poor assessment practice were not in

place. It is unfortunate that someone can be regarded as ineffectual in his role (both by senior colleagues within his department and by an external QA organisation) for such a long period without being replaced. If the Regional QA team were not directly aware of the fact that Dr X's lack of interest in attending Regional QA meetings was reflective of his approach within the unit then the question must be asked as to why this was not exposed through more searching enquiry in the wider QA process. It is reasonable to assume that if Dr X had been replaced as Director of the unit on the basis of a more systematic critical appraisal of his performance in this role, a more dynamic Director may have instituted a clinical governance regime that would have picked up Dr X's poor assessment practice.

- 6.23 The quality of clinical leadership is known to be of fundamental importance to the clinical quality of patient care. This case illustrates the importance of ensuring that clinical leadership roles do not default to the senior clinician (or the only volunteer) without any regard for their abilities as a manager and leader.
- 6.24 As noted earlier in this report the role of Director of Screening at a Breast Screening unit is self evidently of critical importance to the success of the national breast screening programme. The extent to which this is a fact is evidenced by the list of responsibilities attached to the role in the publication *Organising a Breast Cancer Screening Programme* which was issued by the NBSF in December 2002. Surprisingly there appears to be no policy relating to the method of appointment of Screening Directors, no formal assessment by any representative of the national Programme as to the suitability of candidates for the role, no requirement for formal induction and training and no arrangements for the formal appraisal of the incumbents.
- 6.25 Dr X's limitations in relation to the assessment pathway were known to his consultant colleagues, the programme manager and the advanced radiography practitioners to a greater or lesser extent going back many years. In the absence of any evidence that cancers were being missed and taking account of the fact that Dr X was the senior radiologist and Director of the unit their reluctance to raise concerns formally is understandable but not defensible. It is clear that all were genuinely of the view that cancers were not being missed so they can not be criticised on the basis that they knowingly failed to act in relation to known or assumed serious clinical failings. What they did know however was the fact that Dr X was not undertaking at the assessment clinics a procedure (ultrasound guided biopsy) that is a mainstream diagnostic tool and which is fundamental to accurate diagnosis for many women. It was also known that as a consequence women were being sent for stereotactically guided breast biopsies who should have had a much quicker and less unpleasant ultrasound guided biopsy. Stereoractic biopsies also subject the women to ionising radiation (as is the case with all X rays) which ultrasound does not and although in itself this does not represent a particular danger to the women it is in direct contradiction of a

requirement on the NHS to minimise the exposure of patients to ionising radiation.

- 6.26 For any of the individuals concerned to openly challenge the competence of the senior radiologist and Director of the Unit (with no evidence to offer of missed cancers) would have been extraordinarily difficult. Commentators will no doubt point to the *Duties of a Doctor* as set out in the GMC publication *Good Medical Practice* which sets out a specific duty to

*“Act without delay if you have good reason to believe that you or a colleague may be putting patients at risk”*

The same document also carries a stern warning about making unfounded criticisms of colleagues.

- 6.27 Notwithstanding the very clear and simple moral imperative on all medical staff to ‘raise the alarm’ about what they believe to be a colleague’s poor practice there remains a complex and unresolved question within the NHS about the relative primacy of national or local clinical guidelines against the judgement of (often very senior and very experienced) individual clinicians who may choose to stick with their old approach with equal success. This is not to suggest that clinicians are routinely ‘allowed’ to ignore clinical guidelines to the obvious and evident detriment of patients but, as in this case, the detriment to patients wasn’t obvious to colleagues and they were confronted with a very senior colleague continuing to do things in what he regarded as his own tried and trusted way . These comments are not made with the intention to condone, justify or support a failure to raise a concern about a doctor but to remove the benefit of hindsight from the analysis.

- 6.28 There was, however a non confrontational avenue through which the colleagues could have raised their concern. Unlike many clinical services provided by the NHS the NBSB does have a systematic Quality Assurance process based on expert peer review which includes actual review of the work of the practitioners engaged in the service. There is no reason why the consultants could not have privately expressed their concerns to the QA radiologist who would then have had a more detailed look at Dr X’s assessment practice during a QA visit or devised a pretext to do so if a concern was raised between visits. Similarly the Programme Manager and advanced practitioner radiographers could have expressed concerns privately to the QA radiographer who would then have referred the issue to the QA radiologist. This would have ensured a proper examination of Dr X’s practice through the mechanism that exists for this purpose and would have avoided the staff concerned having to make an ‘open’ challenge to the competence of a senior colleague (with the very difficult personal consequences for them if they were either mistaken or not supported). They should have taken this option.

- 6.29 In its report *Review of early warning systems in the NHS* published in February 2010 the National Quality Board for the NHS makes a specific recommendation

that the Medical Royal Colleges and the Department of Health should review the options for encouraging a culture of openness about poor practice within the medical community and specifically in regard to providing a supportive environment in which doctors will feel able to raise concerns at an early stage. This case provides further evidence of the importance and urgency of this proposed review.

## **RECOMMENDATIONS REGARDING FAILURES WITHIN THE ELHT BREAST UNIT**

**It should be noted that on completion of the Incident Team Review in August 2009 an immediate programme of improvement was implemented in relation to the management and governance processes within the East Lancashire Trust Breast Screening unit. These changes, which have addressed all the governance weaknesses in the unit present throughout the tenure of Dr X, will be described in full in the final section of this report. The following recommendations relate to wider national learning points arising from the failings identified and now rectified at East Lancs.**

*R6.1 The NBSP should undertake a fundamental review of current quality assurance processes with a view to ensuring a culture of ongoing clinical audit is embedded at the local level.(further recommendations in relation to the QA process are made in a later section of this report)*

*R6.2 The NBSP should agree with Trusts a more formal process for the appointment of Directors of Screening involving*

- Regional Directors of QA acting as external assessors*
- A minimum allocation of 1 PA in the Directors Job Plan*
- A minimum period of initial training for newly appointed directors including secondment to a leading Screening Unit. This recommendation should be applied retrospectively for Directors appointed within the last 2 years*
- Appointments should be subject to renewal on a 3 yearly basis*
- Renewal of appointments should be dependent on a full and formal appraisal of Screening Directors by the Regional Director of QA and the Regional QA Radiologist as part of the triennial QA visit.*

*R6.3 The possibility of a confidential (but not anonymous) national arrangement through which concerns about the practice of another consultant can be raised should be considered in the discussions initiated by the National Quality Board between the Department of Health and The Medical Royal Colleges*

## **7. WEAKNESSES IN RELEVANT GOVERNANCE PROCESSES WITHIN EAST LANCASHIRE NHS TRUST**

### **Overall Context**

- 7.1 To give a fair account of the extent to which governance processes within ELHT may have failed to detect the problems in the Screening Unit requires a degree of context setting.
- 7.2 The communities of Blackburn and Burnley each have their own distinct identity and the fact that they are near neighbours has over many years generated a significant degree of civic and population ‘rivalry’ between the two communities with each fiercely valuing their independence and self sufficiency in all things important to the identity of a major town or city.
- 7.3 Having their own fully fledged hospital has always been at or near the top of the list of civic ‘crown jewels’ that define the independence and self sufficiency of these two communities.
- 7.4 Against this background the pressure from Lancashire and Cumbria Health Authority in the early part of the current decade to merge the Management of the Burnley Healthcare NHS Trust and the Blackburn, Hyndburn and Ribble Valley NHS Trust into a single organisation was greeted with considerable suspicion and hostility by the two communities and by staff in the two hospitals. Initially the merger was proposed as a ‘merged management’ arrangement to reduce the costs of bureaucracy and which would not affect the existence of, or the facilities at either hospital. On this basis the merger went ahead with effect from April 2003 and precipitated a long period of management upheaval in both organisations.
- 7.5 East Lancashire NHS Trust was created as a result of this merger which transformed two small and relatively compact Trusts, with separate management teams largely focussed on a local District General Hospital, into a large ‘two centred’ conglomerate organisation. The Trust has a current annual budget of £323 million and employs 5,600 staff. The various hospitals in the Trust treat 60,000 emergencies and 60,000 people as inpatients or day cases each year and see a total of over 500,000 people each year as outpatients.
- 7.6 By any standard or comparison this is a large and complex organisation
- 7.7 A combination of financial pressures inherited by the merged Trust (a deficit which eventually peaked at £20 million) and clinical pressures (imposed reductions in junior doctors hours etc.) quickly triggered serious consideration by the new Trust of clinical service rationalisation between the 2 hospitals which resulted in a consultation regarding major service reconfiguration in 2006. There followed a prolonged period of highly contentious dialogue with clinicians in the two hospitals and with local community leaders. Given that the proposed changes

had the effect of moving some services from Blackburn to Burnley and vice versa it is hard to imagine a more challenging strategic agenda. Some of the more controversial changes already made remain the focus of national level political interest. For good measure the management of the new Trust was fully engaged with the closure of the old Blackburn Royal Infirmary and the transfer of all BRI services to a brand new £113 million PFI facility in 2006 (to become the new Royal Blackburn Hospital). At the same time the Trust was opening a £31 million development on the Burnley Site. Even by itself the complete transfer of services from an old site to a complete new hospital is exceptionally complex and will consume every second of senior management time available. To do so in the teeth of a political storm around a major service reconfiguration affecting two such fiercely independent communities and against the backdrop of a severe financial crisis is as challenging a set of high level organisational objectives as could be faced.

- 7.8 Inevitably the pressures of the agenda resulted in a very high turnover of CEO's and Executive Directors but even allowing for the scale of the pressures the level of senior management turnover has been exceptional.

Since the Trust was formed in 2003 there have been

4 Chairs  
7 CEOs (including Exec Directors in the role on an acting basis)  
2 deputy CEO's  
3 Directors of Operations  
2 HR Directors  
3 Directors of Nursing  
4 Finance Directors

- 7.9 Even in a Trust with a stable environment and stable management the task for the Board of being assured that every clinical process (of which there are hundreds) is carried out on every occasion exactly as it should be, is at the highest end of challenges faced by NHS managers. The size, scale and complexity of East Lancashire Trust's agenda needed at the very least a long period of stability and continuity at the top of the organisation. In the end the size of the management task was such that the very opposite occurred. With so much large scale change to deliver accompanied by such damaging levels of senior management turbulence it is not surprising that at some point the process of scrutiny of day to day service delivery would be compromised.

### **Direct Board knowledge of the Breast Screening Unit**

- 7.10 There isn't much in the way of evidence to suggest that the day to day operations of the East Lancashire Breast Screening Unit was ever 'on the radar' at Trust Board level. It is only relatively recently (since 2007) there has been serious

consideration at Executive Board level of the need to find more suitable accommodation for the unit despite this being the single most consistent negative finding of the triennial external QA report over the last 10 years. Moreover there is no record or minute to show that the QA reports of 2003 and 2006 were ever considered by the main Board or a major Board sub committee (as mandated in the Executive Letter EL(97)67 issued following the review of Breast Screening services at Exeter in 1997).

- 7.11 By itself however Board consideration of the QA reports of 2003 and 2006 (despite the very clear concerns expressed about the cramped and unsuitable accommodation) would not have generated any alarm about clinical standards in the unit given the largely positive conclusions reached by the QA team about the service being delivered. Bearing in mind the wider strategic agenda being tackled by this Board over this period it would be facile to criticise it for not paying more attention to a unit that was regularly given a relatively clean bill of health as far as clinical standards were concerned by an independent Regional QA process.
- 7.12 Another potential source of direct information to the Board concerning the Breast Unit is the local 'annual report' to the Trust Board that is recommended in guidance issued by the NBSP. This guidance reflects another requirement stipulated in EL(97)67 that 'Health Authorities should receive a report provided annually by the Director of Breast Screening with a contribution from the Regional Director of QA'. Such annual reports have never been submitted to the Board of East Lancashire Trust and it has been suggested that for NHS Northwest this requirement is now fulfilled by the preparation of an aggregated annual report presented to the Strategic Health Authority by the Regional Director of QA which is made available to all Primary Care Trusts and NHS Trusts. Again there is no evidence that this report has ever been seen by the Board of ELHT and again it must be observed that these reports, based as they are on the findings of the QA visits will not have provided any indication to the Board of ELHT that there were serious problems in the unit.

### **Broader Governance and Assurance Processes**

- 7.13 Given the Board has ultimate responsibility for service quality and patient safety it must accept responsibility for what occurred. The legal fact of the Board being responsible is a given – what really matters is how and why the Board failed to discharge its responsibility and how processes can be strengthened for the future. The sheer complexity of hospitals presents a daunting challenge to Boards in fulfilling their overall responsibility for ensuring the patients are kept safe and treated well. Any large hospital has thousands of patients coming for treatment every week for hundreds of different conditions and who are treated by thousands of different individual members of staff employed in dozens of different professions. In formal terms the Board of ELHT has a collective legal responsibility to ensure that 5600 staff always deliver care to patients according to current best practice and never compromise the safety of patients by failing to

follow prescribed procedures or accepted good practice. Professional staff are making individual decisions or carrying out aspects of the treatment of individual patients every minute of every day somewhere in a hospital. The practicalities for a Board of having in place processes that provide them the assurance they need to have, that at all times all staff deliver care optimally and safely, can not be underestimated – but neither should the importance of having such effective assurance processes in place.

## **Incident Reporting**

- 7.14 As dealt with in an earlier section of the report describing how the incident came to light there was a failure to initiate an incident report on a ‘false negative’ assessment by Dr X which came to light in 2007. For convenience the relevant paragraphs are duplicated below

*(3.10)The false negative assessment that came to light in 2007 should have been the subject of an internal incident report in accordance with the very comprehensive and very detailed Incident Reporting policy of the Trust. Had the incident been reported in accordance with the reporting policy in force at the time it would have been necessary for the person reporting the incident to ‘grade’ the incident in line with a standard frequency/impact matrix. This particular incident is likely to have fallen within the grading band that would prompt an internal Root Cause Analysis.*

*(3.11)A Root Cause Analysis would have been undertaken by staff not directly involved in the incident and if conducted according to its literal title may have discovered the actual root cause of the incident was not ‘isolated’ to this one incident . . . . .*

*(3.12)A full and proper internal response to the false negative assessment which came to light in November 2007 could, in theory, have exposed the degree to which Dr X’s assessment practice was deficient. This incident serves to illustrate for Trust Boards the need for them to have in place robust assurance processes that go well beyond the knowledge that a good policy exists. Boards need to be sure that their good policies on ‘paper’ are properly and consistently implemented. The case also serves to illustrate the considerable potential for incident reporting systems to point Trusts in the direction of a serious patient safety concern.*

## **Consultant appraisal process**

- 7.15 In an acute hospital the principal decision makers about the care of patients are the consultants (and other professionally independent practitioners such as midwives and nurse consultants). Not only do consultants make the vast majority of the important decisions about treatment but they have a unique responsibility



for being assured themselves that other professional staff caring for their patients do so carefully and conscientiously. It follows therefore that one of the most critical governance processes in a hospital is the annual appraisal of consultants where the competence and performance of every consultant is reviewed by a senior colleague. This process is so important to the overall quality of patient care and safety in the NHS that it forms the bedrock component of plans by the Government and the GMC to introduce (now delayed until 2012) quinquennial formal revalidation of all NHS consultants (a process which will determine every 5 years that every consultant in the NHS has the knowledge and skills to continue to practise in the area of medicine in which he or she specialises).

- 7.16 A Trust Board that can be genuinely certain that it has in place a well developed, well managed and constructively challenging process of annual appraisal for its consultants will have in place a vital (arguably the most vital) clinical governance process to assist in the challenge it faces in assuring the overall quality of patient care. This is not only because the best consultant appraisal processes help to sustain a commitment to the highest quality standards amongst consultants but also because consultants who themselves are committed to quality and safety have an authoritative influence on the quality of care delivered by all other clinical professionals
- 7.17 Compulsory Annual appraisal of consultant staff was introduced to the NHS in 2001 and became a contractual requirement in 2003 (for the vast majority of consultants who accepted the new consultant contract introduced in 2003). **Since its inception in 2001, consultant appraisal in East Lancashire Hospital Trust has been poorly and only partially implemented (and at the time of this review remains an area of considerable weakness).** The failure by the Trust Board to ensure the implementation of robust annual appraisal of consultants has made a direct contribution to the circumstances that led to the missed cancers that are the subject of this report. While there are clear failures in this regard on the part of the Trust Board there are also potential weaknesses inherent in the national process of consultant appraisal that are indicated by the events at East Lancs.
- 7.18 The detailed process requirements for consultant appraisal were set out by the Department of Health in advance letter (MD) 6/100. ELHT have consistently failed to fulfil the core requirements of the process including all of the following specific responsibilities set out in the advance letter
- Chief Executives are required to ensure that all consultants are appraised annually and that any follow up action is completed
  - Chief Executives should see and review appraisal summaries for all consultants
  - The Chief Executive and the Medical Director must review the Personal Development Plan agreed for each consultant at their appraisal

- Chief Executives should submit an annual report to the Board on the process and operation of the appraisal scheme.
- The Clinical Director is responsible for ensuring that any necessary action arising from appraisal is taken
- Chief Executives should ensure that the necessary links are made between the consultant appraisal process and other clinical governance processes (*e.g. consultant requests for study leave*)

7.19 In his 18 years of employment as a consultant at East Lancashire NHS Trust Dr X has had only 3 formal appraisals and records of only 2 of these (2005 and 2008) have been retained. Crucially, he was formally appraised by his Clinical Director in 2005 and **at this meeting he himself raised a personal training need relating to undertaking core biopsies.** It was agreed at this meeting that Dr X should make arrangements to undertake this training at the Nightingale Centre in South Manchester (the main training unit for the Breast Specialists in the North West). This discussion was at least 12 months prior to the beginning of the period during which the 20 cancers were missed.

7.20 The agreement to undertake this additional training was never carried out and a number of factors contributed to this

7.20.1 The Clinical Director undertaking the appraisal, although a radiologist was not himself a breast specialist and did not appreciate the immediate significance of the training need identified by Dr X to his day to day work as a breast specialist. Dr X acknowledges that he conveyed neither any particular urgency nor significance to his Clinical Director when raising the issue.

7.20.2 The Clinical Director was advised (accurately) by Dr X that the Royal College of Radiology had recently issued a certificate confirming that Dr X had achieved the required number of credits under the College scheme for *Continuing Professional Education* for the years 2000 through to 2005 and as such was 'accredited' by the College in relation to his CPD status for a further 5 years through to 2009.

7.20.3 The Clinical Director was aware that Dr X had been the Director of the ELHT Screening Unit for 13 years at the time of this appraisal and that external QA reports were consistently complimentary about the standard of Radiology in the unit.

7.20.4 At the time there was no effective central management and coordination of consultant appraisal which was left largely in the hands of the Clinical Directors. A copy of the letter confirming the outcome of the appraisal

- 7.20.5 The Medical Director in place at the time of the 2005 appraisal asserts that a 'light touch' and informality of process in regard to consultant appraisal was an explicit policy within the Trust given the extent of consultant concerns about the lack of reliable and objective data by which their performance as consultants could be fairly measured ( a view that would have found an echo right across the NHS at the time and which still provokes much debate)
- 7.20.6 Such was the 'lightness of touch' at East Lancashire Trust that Dr X was not appraised again in either 2006 or 2007 (nor were any of the other radiologists in the Trust ) despite the fact that annual appraisal is a national contractual requirement for all consultants. The significance of this in relation to Dr X is that had he been appraised again in 2006 as he should have been it is probable (but by no means certain) that he would have been challenged as to why he had not undertaken the extra training agreed at the 2005 appraisal.
- 7.20.7 Shortly after Dr X's 2005 appraisal there was a change of Clinical Director in the Radiology Unit. The outgoing Clinical Director did not pass on the appraisal documentation he had concerning the radiologists nor did the incoming Clinical Director ask for it. The new Clinical Director says he simply did not have time to undertake appraisal on his colleagues in either 2006 or 2007 as this was the period which coincided with the intense activity relating to the opening of the new Blackburn Hospital and as he was never 'chased' by the Trust management team he assumed it was not a priority.
- 7.20.8 At the time of the 2005 appraisal of Dr X there was no formal process for ensuring requests for study leave by consultants (who are entitled to 30 days study leave in a rolling 3 year period) were checked against training needs identified at annual appraisal. This has since been rectified but, had such a process been in place at the time, each one of the numerous requests made by Dr X for study leave after the 2005 appraisal may have prompted a question as to why he had not undertaken the extra training identified in the 2005 appraisal. Even though the cross reference between appraisal outcomes and study leave was formally established by the Trust with a new policy in 2006 the lack of rigour in ensuring appraisal actually

- 7.20.9 There is some evidence that the Medical Staffing Department within the Trust was assigned a support role in the early days for the consultant appraisal process. Whatever support this may have evolved into as the process became more established was, it seems, prevented by a reorganisation of the Medical Staffing process (linked to the 2003 Trust merger) which removed functions and staff from the department and left it without the resources to support the consultant appraisal process.
- 7.20.10 Dr X himself claims that he did not make any attempt to arrange the additional training agreed because it would probably have involved attending the training centre for a half day a week for as long as 6 months and in his opinion the pressure in his department to achieve national targets was such that he was of the view that he ‘couldn’t be spared’.

## **MAIN CONCLUSIONS IN REGARD TO RELEVANT GOVERNANCE PROCESSES WITHIN THE TRUST**

- 7.21 Notwithstanding the fact that Boards are mandated in EL(97)67 to consider and act on the findings of QA visits it should be a general rule for NHS Boards that a credible external peer review of any service should always be considered by a Board Committee. This is because external peer reviews of specific clinical services are not commonly undertaken in the NHS and when they are available they provide a level of assurance to a Board that cannot be obtained from internal governance processes. Independent assurance mechanisms also provide Boards with a perspective on different approaches to assist in the judgement they must make about the rigour of their own internal processes. The fact that the external QA process in this particular instance was not as rigorous as it might have been (as will be seen later in this report) does not invalidate the general point that for NHS Boards, independent assessment of service quality and safety will usually provide a greater level of assurance than internal governance processes
- 7.22 Whilst it is certainly the case that the external QA reports of 2003 and 2006 should have been reviewed by the Board (or its Governance subcommittee) it is unlikely, in this case, that these reports would have prompted any action by the Board that would have mitigated or prevented the missed cancers. There was nothing in the QA reports that indicated deep rooted problems within the unit other than a consistent call for better accommodation.

- 7.23 The Exeter related guidance relating to annual reports should be reviewed in the light of the many changes in NHS structure since 1997. Given the burden of governance that falls on NHS Trust Boards these days it may be reasonable to confine mandatory Board review of reports to the triennial QA report. The need for Boards to consider an annual report in addition to the triennial QA report is debatable.
- 7.24 In relation to the issue of accommodation it is neither possible nor necessary to comment on the priority given to this need by the Board as this would require a review of relative priorities across the Trust going back many years. As there is no evidence that accommodation problems were in any way a factor in the missed cancers there no substantive grounds to review the decisions of the Board with regard to capital development priorities.
- 7.25 The Trust has a well developed incident reporting procedure and there is no doubt as to the priority attached to the process by the organization. Both Incident Reporting and the 'Being Open' policy (issued in 2006 by the National Patient Safety Agency) are part of the Trust's Mandatory Training Programme. The failure to submit an incident report relating to the 'false negative' assessment that was identified in 2007 is an indication, however, that understanding of and compliance with the process is not well enough established across the workforce. This statement could of course be made about many Trusts in the NHS as it would be wrong to suggest that the NHS as a whole has yet achieved the culture of complete openness about errors and 'near misses' that has been a key goal for the service - particularly since the publication of the landmark report of the Chief Medical Officer *An organization with a memory in 2000*. The reference in paragraph 6.29 to the recent recommendation of the National Quality Board concerning the need to encourage and support a culture of openness within the NHS is relevant here.
- 7.26 Most NHS professionals understand full well the contribution to improved patient care that will arise from incident reviews but there is an undeniable tension between their desire to comply with incident reporting and their concerns about consequences when they are themselves responsible for, or directly associated with, mistakes or near misses. An essential prerequisite for a more compliant approach by staff to incident reporting is complete trust by the staff that the local management team will properly apply the principles of 'fair blame' to incident reporting and place the emphasis in their response on learning and support rather than on blame and retribution. The fact that this approach is documented in the policy will not of itself build the necessary trust – managers win the trust of staff through their behaviors across a range of issues over many years. Since the time of the merger in 2003 both the turnover of senior managers and the controversial merger of the clinical processes at Burnley and Blackburn (however rational this will have been) must have affected to a significant extent the building of a confident and trusting relationship between clinical staff of ELHT and the procession of different senior managers they have had to work with.

- 7.27 Against this difficult background it is to the credit of the Trust that statistics issued by the National Patient Safety Agency show that a reporting rate of 5.0 incidents per 100 admissions is only slightly below the median figure for similar Trusts (5.4) and places the Trust within the middle 50% for incident reporting. The conclusion that the Trust has near average levels of compliance with incident reporting and average levels of understanding among staff of incident reporting objectives is reinforced by the findings of the 2009 national staff survey.
- 7.28 The most significant and serious failure of Governance processes within the Trust relating to the missed cancers is the unsatisfactory implementation of the consultant appraisal process from its introduction as a compulsory requirement in April 2001(advance letter MD 6/00) right through to the present day. As in many other Trusts, ELHT will have been hampered initially by strong resistance to the introduction of annual appraisal arising from concerns amongst consultants about the absence of objective measures of their performance as clinicians. Consultants were also concerned about the practical difficulties of appraisal by Clinical Directors who in most cases would not be in the same subspecialty. Many Trusts will have adopted the same ‘light touch’ in the early years as was the case at ELHT but it is to be hoped that few Trusts will have failed to evolve and strengthen the process over time to the extent that it has been neglected at ELHT.
- 7.29 ‘Light touch’ in relation to the robustness of individual appraisals in the early years is perfectly reasonable given the time needed to develop the skills of appraisers and to increase consultants confidence in the quality of information used to underpin appraisal. In the case of ELHT ‘light touch’ appears to have extended to whether or not consultants were appraised at all and this situation (whether deliberate or as a consequence of poor record keeping) is unacceptable given the critical role of good consultant appraisal in the clinical governance process. The failure by the Trust to properly implement the consultant appraisal process resulted in the fact that Dr X has been appraised on only 3 occasions in the 8 years between the date appraisal was first introduced in 2001 and the emergence of the missed cancers in early 2009. The absence of any effective system to follow up Dr X’s training needs identified in the 2005 appraisal and the failure to ensure he was appraised in 2006 and 2007 must be regarded as a significant missed opportunity to mitigate or prevent the cancers missed at assessment by Dr X in the period covered by the incident review from August 2006 through to December 2008. Notwithstanding Dr X’s inclination to use his own clinical judgment rather than follow consensus guidelines, had he attended a leading unit over a period of months to be trained in ultrasound guided biopsy he will doubtless have observed the extent to which, in modern practice, the extensive use of ultrasound at assessment has become indispensable. It is reasonable to conclude, therefore, that had Dr X attended a training course for ultrasound guided biopsy his assessment practice subsequent to this training will have more closely followed the national guidelines.

- 7.30 Whatever the failings of the Trust in relation to implementing Consultant appraisal there is no mitigation to be found here for Dr X's personal failure to act on the agreement in the 2005 appraisal meeting that he should attend a specialist centre for training. Neither should Dr X have waited until his 2005 appraisal before raising this issue and acting on it. The 2001 assessment guidelines were clear enough about the preferred use of Ultrasound and Ultrasound Guided biopsies for particular indications and Dr X should have taken steps to get the necessary training at this time. His assertion that he could not have been spared is not credible. He was able to take all his study leave regularly and had specific time for audit and personal development built into his weekly timetable that he could have used for a weekly training session at the local training centre. It is also inconceivable that the Trust would not have allowed him release from clinical duties to get this training if this had been necessary.
- 7.31 The Trust Board was seriously hampered in relation to monitoring implementation of the appraisal process by the failure of the Executives to submit the required annual report on the process. It is also relevant to record that the poor implementation of the process was compounded in no small way by the failure to recognize and resource the considerable additional workload generated by the process for those with the key roles (Medical Director and Clinical Directors). The logistics, training requirements, information gathering, record keeping and follow up processes associated with a formal appraisal of 240 consultants every year is a significant management and administrative undertaking. Busy clinicians will always find it practically difficult to prioritize paper driven, information dependent 'admin' processes – even one as important as annual appraisal. Leaving the implementation of the process largely to the Clinical Directors with no obvious additional admin resources to assist in coordinating the arrangements suggests that CEOs at the time the process was set up (and in the years since) either did not accord consultant appraisal the high priority it warranted or misjudged the management effort that successful implementation required.
- 7.32 In addition to the weakness of the consultant appraisal process at ELHT there are a number of issues relating to the robustness of the national appraisal process as revealed by the appraisal of Dr X which did occur in 2005. It is recognized of course that this is a review of a particular issue at a particular Trust and that the terms of reference do not extend to reviewing major national governance processes. There were, however, weaknesses evident in the appraisal process at ELHT that may be present in the national process and given this process is the basic building block for the proposed GMC revalidation system they are noted here for the attention of interested parties
- 7.32.1 The fact that the Clinical Director who appraised Dr X in 2005 was not of the same radiological subspecialty was a crucial limiting factor in the appraisal given he did not appreciate the significance or urgency of the training requirement that was raised. In this particular case the Clinical

Director will doubtless have been mindful that there is a separate peer review process for Breast Screening. Where such processes are not in place it does raise a question about the extent to which appraisal processes should be reliant on Clinical Directors (or Divisional Directors) who can not have a detailed appreciation about the practical skills and knowledge base required for all subspecialties. Advanced letter MD 6/100 does offer advice on the need for peer review for 'the more specialist aspects of a consultant's clinical work' and that this 'should be planned into the timetable in advance of the appraisal interview'. If carried out faithfully this advice would involve making separate arrangements for a preliminary peer review ahead of the main annual appraisal for many consultants. This may prove to be logistically impractical in some Trusts.

7.32.2 In the absence of personal detailed knowledge of a consultant's sub specialty the Clinical Director may place a certain amount of reliance on Royal College accreditation of the CPD record for confirmation that a consultant is 'keeping up to date' with developments and knowledge in the specialty. In this case Dr X's CPD for the 2005 appraisal had been accredited by the Royal College of Radiologists but only on the basis of a written assurance from Dr X that he had acquired the necessary credits and that his CPD diary was available for audit. In the case of the RCR only 10% of CPD diaries are audited. Moreover RCR accreditation of CPD is not related to the consultant's subspecialty interest as credit can be obtained for any radiology approved education. Based on the practice of the RCR the accreditation of CPD may provide only very limited assurance as to a consultants competence at a subspecialty level. The RCR makes no claim that CPD accreditation is anything more than confirmation that a consultant is attending events and undertaking education that are relevant to the wider specialty of radiology. If this is the case with other College CPD accreditation it is important that CEOs and Boards who are ultimately accountable for the competence of consultants in their employment are fully cognizant of the limitations of College input to the annual appraisal process.

7.32.3 The above may be affected by the outcome of the recent GMC consultation on the detailed approach to the revalidation of consultants. Of particular relevance here is the recommendation of the GMC (in paragraph 78 of the document) that the Royal Colleges should not have any direct responsibility for validating evidence relating to the competence of individual consultants in the portfolio of information to be submitted by consultants as part of the appraisal process. The GMC proposes that the College role should be focused on setting standards and stipulating the requirements of appraisers for specialty level support information. Whether or not this will provide the sort of detail about the practice of a sub specialist to allow an informed appraisal by a non specialist appraiser and the subsequent recommendation of the 'Responsible Officer'



regarding revalidation will doubtless be carefully monitored by the relevant authorities.

7.32.4 Where consultant appraisals do not have a direct peer review element and the College input does not extend to confirming subspecialty competence, a great deal of reliance must be placed on internal governance processes for confirmation of continuing clinical competence as in

- The fullest possible organizational compliance with clinical incident reporting and root cause analysis
- A willingness of colleagues to raise concerns
- Good evidence from recent clinical audit of the standard of the consultant's own clinical work (as opposed to participation in departmental or specialty level audit)

7.33 These comments on the potential weakness of the national consultant appraisal system may be beyond the scope of this enquiry but it has to be said that in this particular Trust a more informed approach to the appraisal of Dr X in 2005 might have prevented 20 missed cancers.

7.34 ELHT has recently completed the AQMAR (*Assuring the Quality of Medical Appraisal for Revalidation*) self assessment. The summary of responses from all the NW trusts that responded does not suggest that ELHT is an outlier in relation to the number of replies in the self assessment that were red rated. On this basis the assertion in the national summary of AQMAR responses that “..... *there is a strong foundation of organizational appraisal and clinical governance systems to build upon*” (for the GMC revalidation process) may be somewhat complacent.

## **RECOMMENDATIONS RELATING TO TRUST LEVEL GOVERNANCE ISSUES**

*R7.1 All Trust Boards hosting Breast Screening Units should be reminded that the full report of the triennial Quality Assurance visits must be considered at the Governance Committee of the Trust Board in the presence of the Director of Screening and the Director of the Regional QA team.*

*R7.2 Previous advice concerning the production of formal annual reports for mandatory presentation to Trust Boards should be reviewed*

*R3.1 The Board of East Lancashire NHS Trust should take immediate action to be fully assured that all staff employed by the Trust are fully cognizant with the content of the Trust policy on incident reporting and how to properly fulfill their individual responsibilities for implementation of the requirement of this policy.*

- R7.3 *The Board of East Lancashire NHS Trust should take urgent action to ensure that a fully robust and comprehensive consultant appraisal process is put in place which covers 100% of consultant staff during the year 2010/2011 and for every year thereafter.*
- R7.4 *The Trust should urgently identify designated management and administrative resources to support and coordinate the consultant appraisal process*
- R7.5 *The Board should receive a report setting out what steps have been taken to implement the recommendations (R7.3 and R7.4) above concerning consultant appraisal by no later than 31<sup>st</sup> December 2010. The first annual report on consultant appraisal covering the year 2010/2011 should be submitted to the Board no later than 31<sup>st</sup> May 2011.*
- R7.6 *NHS Northwest and Monitor should commission a joint independent regional review of consultant appraisal processes for the purpose of identifying and sharing best practice (along the lines recommended by the Revalidation Support Team in its AQMAR report of May 2009)*
- R7.7 *The Department of Health in conjunction with the GMC and the Medical Royal Colleges should consider the practicalities of introducing a greater degree of direct peer review into consultant appraisal.*
- R7.8 *The specialty specific ‘standards for revalidation’ recently produced by the various Medical Royal Colleges may eventually be refined to sub specialty level. In the meantime interim advice should be urgently issued to Chief Executives and Medical Directors about the minimum requirements for information in consultant appraisal portfolios which can be produced locally to more thoroughly establish the competence of consultants in their own designated subspecialty.*
- R7.9 *In relation to the specifics of this review the relevant National Coordinating Committee of the NBSP should agree an ‘appraisal guidance note’ for the use of non expert (i.e. not of the same specialty) Clinical Directors appraising breast specialists. This guidance note should provide a summary of the knowledge, training requirements, CPD priorities and practical competencies required by a breast specialist. Whilst this would not be an alternative to full peer review it would ensure non- expert CDs appraising breast specialists are not ignorant of the key skills and competencies required.*
- R7.10 *The Care Quality Commission and the NHS Litigation Authority should require 100% achievement of consultant appraisal (with exclusions allowed only for illness) as a minimum requirement for compliance in the relevant sections of their external assessments*

## 8. WEAKNESSES IN THE EXTERNAL QUALITY ASSURANCE PROCESS

### How the QA Programme is organized

- 8.1 The North West Breast Screening Quality Assurance Reference Centre (referred to in this report as the Regional QA team) was established in 1998 when responsibility for the Quality Assurance function relating to the NBSP was transferred to NHS regions. This change was made in line with the recommendations of a review of Breast Cancer services in Exeter published in 1997 in Executive Letter (97)67.
- 8.2 The QA team for the NW Region is responsible for assuring the quality of Breast Screening services at 12 Breast Screening units across the North West of England as follows:-

PROGRAMME	SCREENING POPULATION	TOTAL WOMEN SCREENED	ANNUAL
BOLTON	78000	21262	
CHESTER	23901	6846	
CREWE	39283	10404	
EAST LANCS	65855	16574	
GTR MANCHESTER	150000	34408	
LIVERPOOL	105930	24565	
EAST CHESHIRE AND STOCKPORT	62545	15869	
NORTH CUMBRIA	46274	12124	
NORTH LANCASHIRE	105000	29860	
WARRINGTON	72982	16137	
WIGAN	85762	22672	
WIRRAL	44991	11733	

Source: Programme and 2008-09 KC62

The NW QA team comprises:-

A Regional Director                      Employed in this role since 1999 – originally for 2 half days per week increasing to 3 half days a week since 2006.

QA coordinator                              A full time managerial position

Information Manager                      Full time statistician/analyst

Information Officer

Office Manager

- Specialist advisors    2 x Consultant Radiologists (1 half day per week each)  
                                  2 x Consultant Pathologists (1 half day per week each)  
                                  2 x Consultant surgeons (1 half day per week each)  
                                  2 x senior radiographers (2 half days per week each)  
                                  2 x Admin advisors (2 half days per week each)  
                                  2 x Technical (Physics) specialists (1 half day per week each)  
                                  1 x Nursing Advisor(1 half day per week)
- 8.3    In broad terms the role of the QA Team is to monitor and report on the quality of service provided at all the Breast screening units in the Region (as listed above) against a range of national standards determined by the National Breast Screening Programme.
- 8.4    The regional QA Team discharges its role in a number of ways
- By coordinating and facilitating collective discussion on service delivery and improvement between the senior professional staff engaged in providing breast screening services across the Region
  - By monitoring the performance at each of the units as reflected in detailed statistical reports of the achievement of each unit against the national quality and performance standards
  - Through an on site quality assurance visit to each unit in a rolling programme of 3 yearly visits
- 8.5    For practical reasons to do with the dispersed geography of the region the time of the specialist advisors (where there are 2 advisors) is devoted to either the Merseyside/Cheshire area or the Manchester/Lancashire area. The unit at East Lancashire is served by the Manchester/Lancashire advisors.
- 8.6    The Programme is coordinated at National level by a National Director. Regional quality assurance directors and professional coordinators meet regularly in a series of national coordinating committees. Representatives of relevant professional organisations such as the Royal Colleges are also represented on these committees. The national coordinating committees produce guidance on good practice and set standards and targets for staff working in the breast screening programme and for the technical performance of equipment. National standards and targets for the performance and outcomes of the programme are also published. These are published in a series of NHS Breast Screening Publications. Although this report does identify some gaps and issues in relation to national guidance and programme management the overall impression is of a programme that is exceptionally well managed. There is a comprehensive range of detailed and up to date guidance covering every aspect of the service.

- 8.7 For the majority of problems identified in this report (and in particular the root cause) it is compliance with the guidance rather than the guidance itself that has been the problem.
- 8.8 There is a long list of standards and sub standards against which the performance of each breast unit is routinely monitored. For many of these standards there are minimum achievement levels and expected achievement levels. Some of the standards and the underpinning assumptions for them are technical in nature and for the purpose of this report will be described in more simplistic lay terms. The full and detailed explanation of all the national standards can be found in the publication *Consolidated guidance on standards for the NHS Breast Screening Programme* issued by the NBSB in April 2005. For the purposes of this report the relevant standards include

***Coverage, uptake and round length***

The number of eligible women who are invited and who accept the invitation to be screened and the proportion of women who are screened within 3 years of their previous screen

***Recall rates***

The proportion of women who are referred from screening for a full assessment of a possible abnormality

***Cancer detection rates***

The number and type of cancers detected

***Waiting times***

The time it takes for a screened patient to get the results of her screening visit and, for those referred for assessment, the waiting time for their clinic visit and subsequent results.

***Interval cancers***

The number of women who have breast cancer diagnosed by referral to a symptomatic breast clinic in the 3 year interval between screening appointments

**Weaknesses identified in the Quality Assurance process which may have contributed to the missed cancers at East Lancashire**

- 8.9 Relatively few clinical services in the NHS are externally quality assured through a dedicated national process and with dedicated resources on the scale devoted to

the National Breast Screening Programme. It follows therefore that where, as in this case, there has been a serious failure of service quality to a degree that has jeopardized the proper treatment of patients it is imperative for maintaining public confidence in the programme that any weakness in the external QA process are quickly identified and corrected.

- 8.10 Although there are some specific weaknesses in the national assurance process identified, the main conclusion reached is that the Regional QA team was not sufficiently assertive (and in some specific respects not sufficiently thorough) in relation to the radiology component of the QA process at the East Lancashire Unit.
- 8.11 The missed cancers at the East Lancs unit were a direct result of the poor practice of a consultant radiologist. It follows that in this report the focus will be on the external Quality Assurance process as it relates to radiology. Apart from making some reference to the role of the QA radiographer other aspects of the QA process (surgery, pathology, medical physics, nursing and admin) have not been looked at and are not commented on.
- 8.12 In the national guidance document *Quality Assurance Guidelines for Breast Cancer Screening Radiology* published in 2005 the following statement is made

*“..... 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”*

Notwithstanding this warning that the QA process must not be over reliant on global performance statistics it is evident that in the QA visit reports of 2003, 2006 and 2009 a great deal of the judgment, made on each occasion, that the East Lancs unit was performing well, related to the fact that overall cancer detection rates were at or above the nationally specified detection rates on a year by year basis. The QA radiologist for the 2006 and 2009 QA visits has stated that this unit was “never on the QA team radar”. In other words the QA team had no serious concerns about the unit prior to the 2009 revelations concerning the missed cancers.

- 8.13 A number of concerns were identified by the QA team over this period and these were pursued as a matter of course with the Breast Screening Unit and with the Trust. A recurring theme in the 2003, 2006 and 2009 QA reports was the serious and justifiable concerns of the QA team about the cramped and inadequate accommodation for the Breast Screening Unit’s clinical and administrative base at Accrington Victoria Hospital. It is evident however, that at no stage did the 2 key people in the QA Team (the Director and the Radiology advisor) ever feel that the issues of concern that they did have about the unit were such as to shake the confidence they had in the overall strength of the clinical radiology component of the service as indicated by the overall cancer detection rates. There is also some

evidence that the reassurance provided to the QA team by national statistics for this unit resulted in an uncritical approach to the radiology component of the QA visits.

- 8.14 A more critical and objective assessment of the range of evidence and information available to the QA team and a more rigorous approach to the Radiology component of the QA visit could well have sounded alarm bells about this unit some time before the discovery of the missed cancers.

The evidence for this conclusion is as follows

### **Leadership of the East Lancs Breast Screening Unit**

- 8.15 This topic is covered in detail in section 6 of this report and the comments which are relevant to the weaknesses of the external QA process is reproduced below

*“6.9 Everybody interviewed for this review who was in a position to observe Dr X’s leadership of the ELBSU as Director of Screening between the period 1992 and 2008 expresses the view that he was not proactive in any aspect of this responsibility. This view was not only held by all his senior colleagues within the unit but was shared by the Director of the Regional QA team. Dr X’s lack of external commitment to his role as Director of the unit is graphically illustrated by the fact of his regular non attendance at the twice yearly meeting of the Directors of all NHS Northwest Screening Units with the Regional QA Director and the QA Team. Of the 11 meetings of this group between 2003 and 2008 when Dr X was Director of the ELBSU he failed to attend on 9 occasions (leaving the ELBSU completely unrepresented on 7 occasions).*

*.....6.22. The ambivalent attitude of Dr X to his responsibilities as the Director of Screening was both tolerated and uncommented on over many years by senior colleagues and the Regional Director for Quality Assurance. It was because of Dr X’s lack of active leadership within the unit that the robust clinical governance processes that might have picked up his own poor assessment practice were not in place. It is unfortunate that someone can be regarded as ineffectual in his role (both by senior colleagues within his department and by an external QA organisation) for such a long period without being replaced. If the Regional QA team were not directly aware of the fact that Dr X’s lack of interest in attending Regional QA meetings was reflective of his approach within the unit then the question must be asked as to why this was not exposed through more searching enquiry in the wider QA process. It is reasonable to assume that if Dr X had been replaced as Director of the unit on the basis of a more systematic critical appraisal of his performance in this role, a more dynamic Director may have instituted a clinical governance regime that would have picked up Dr X’s poor assessment practice.”*

## Performance Analysis

- 8.16 The table below summarises the performance of the breast Screening Unit at East Lancashire in relation to just 2 of the national standards over the ten year period 1998/99 to 2008/09.

The 2 measures shown in the table below are

**Standardised Detection Rates (SDR)** which takes some account of the differential characteristics of the population

**Referral to assessment (RR)** rates (%) for patients attending screening for the first time (prevalent round)

In each case the national minimum target and expected target is shown at the head of the relevant columns and the ranking position on the measure for ELHT out of all Trusts is also shown for each year. For each measure there is a column that records the 50<sup>th</sup> percentile value for all breast screening units in the country to give an idea for comparison of the value at the mid point of the range of results recorded for all Trusts.

Year	RR (P)	rank	50 <sup>th</sup> %	SDR	rank	50 <sup>th</sup> %
<b>Min</b>	<b>&lt;10%</b>			<b>&gt;0.85</b>		
<b>Exp</b>	<b>&lt;7%</b>			<b>&gt;1.00</b>		
98/99	5.47	14/95	7.88	1.01	69/95	1.11
99/00	5.70	14/95	8.19	1.14	40/95	1.10
00/01	6.83	22/95	8.25	1.40	15/95	1.21
01/02	7.46	30/94	8.91	1.26	38/94	1.20
02/03	6.11	13/95	8.63	1.50	19/95	1.33
03/04	3.25	1/95	8.84	1.25	69/94	1.36
04/05	1.72	1/95	8.66	1.03	92/95	1.34
05/06	2.02	1/93	8.54	1.33	51/93	1.34
06/07	3.72	1/93	8.66	1.28	56/93	1.30
07/08	4.13	2/92	9.32	1.20	77/92	1.38

- 8.17 As will be seen in each individual year the Unit ‘achieves’ the national minimum and the national expected rate for these two measures and this is reflected in the very positive description of the standards of radiology in each of the QA visit reports in 2003, 2006 and 2009.

There is however a very striking change in the % of patients referred to assessment from 2003/04 onwards. This is referred to in the 2006 QA findings as follows:-



*“The programme has a very low recall rate when compared with other programmes and a reasonable Standardised Detection Rate ..... It was suggested that if this were raised, then this might well affect the SDR”*

The need for any action in relation to the low recall rate is not, however, included in the summary of ‘key challenges and recommendations’ at the head of the report

There is no reference at all to the sudden and striking change to the recall rate in the separate report of the QA radiologist within the 2006 visit report. In this section of the 2006 report the QA radiologist concludes

*“..... this is a very highly performing unit”*

8.18 It is a specific goal of the Breast Screening Programme to minimize the anxiety for women of being recalled for further tests by ensuring that recall rates are as low as is consistent with ensuring all potential cancers are referred for assessment. The national target rate for recall is a rate of less than 7% with a maximum rate of 10%. There is no national figure for the minimum recall rate but the Regional Director’s reference to the “very low recall rate” in the 2006 QA report will reflect his concern at the time that a recall rate of under 2% (compared with the 50<sup>th</sup> percentile value of 8.8% and the highest rate in the country of 18%) raised the possibility that too few women were being recalled and that screen detected cancers might be missed. The brief reference to this issue in the 2006 QA report findings and its exclusion from the ‘recommendations’ does not, however, convey to the reader that this is a matter of any great concern. (The change in recall rates is reflected to an almost identical extent in the recall rate for women attending for a second and subsequent screen.)

8.19 In the 2006 QA report the section of the ‘overview’ dealing with screening outcomes (para 6.5) the report concludes

*“Performance figures for the last 5 years i.e. 2000- 2005 indicate that the East Lancs Breast unit is performing well with consistently good cancer detection rates .....*”

8.20 A more critical and more complete commentary of the stats for the years immediately preceding the 2006 QA visit might have mentioned

- The ELHT recall rate was the lowest of all 95 breast screening units in the country in both 2003/04 and 2004/05
- The standardized detection rate had fallen significantly in both these years and in 2004/05, while still (just) at the national performance threshold, was the third lowest in the country whereas in 2002/03 it had the 19<sup>th</sup> best SDR in the country.

- The fact that the year when the reduction in the recall rate first occurred (2003/04) coincided exactly with the significant (30%) additional workload for the unit associated with the extension of the age range for eligible women from 65 to 70.

8.21 The Regional Director did pursue his concerns about the change in the recall rate in separate correspondence either side of the 2006 QA visit. He raised in July 2005 a concern with Dr X (Unit Director at the time) that in the national comparison of PPV statistics (*Positive Predictive Value measures the proportion of assessed women diagnosed with a cancer*) the unit at East Lancs was an extreme outlier (the unit was in fact almost literally ‘off the graph’). The implied concern here was that the unit’s unusually high ‘success’ rate in detecting cancers at the assessment clinics may reflect the fact that too few women were being referred for assessment. Dr X replied to the effect that this would be ‘investigated’ but suggested that “with a reasonable Standardized Detection Rate it may well be just a statistical quirk”

8.22 The Regional Director wrote again in December 2006 when the provisional national stats for 2005/06 were released and the following is an extract from his letter

*“The provisional KC62 return shows some worrying results for the EL Breast Programme. The prevalent (first screens) round SDR is 0.6 (below the national minimum) and the recall rate is only 2.2%. Whilst the incident round (subsequent screens) SDR of 1.6 offers some comfort that the prevalent SDR statistic might be a small number statistic, further investigation is merited.*

*As you know there is a shared concern that the lack of space in the assessment centre is leading to longer waiting times and the ‘reactive’ low recall rate may account for the low SDR.”*

8.23 This letter was copied to the Trust CEO in post at the time. The Director specifically refers in this letter to the possibility that the low recall rate reflects a recall threshold which is inappropriately influenced by the inadequate accommodation in the assessment clinics. This is an entirely legitimate concern but he does not also make the point that the recall rate he is concerned about has been at this same low level for 3 years and has only become an ‘issue’ since the increase in workload associated with the age extension in 2003. The combination of very inadequate accommodation with a sudden 30% increase in the workload which is followed by an immediate and very substantial reduction in the recall rate for assessment amount to very strong grounds for the concerns of the QA Director.

8.24 In the event, however, the Regional Director was assured by the Unit’s radiologists (by letter) that the below target cancer detection rate for the prevalent screen in 2005/06 was a statistical quirk attributable to ‘low numbers’. He was

- further reassured by the unit consultants, after raising the matter again in 2008, that the low recall rate was not related to any non clinical impediments to recalling patients but was simply a reflection of the robust regime that was in place for double reading and arbitration of screening films.
- 8.25 Beyond expressing concern and receiving assurances the Regional Director initiated no more searching enquiries or reviews to assuage his concerns. Although the 2009 QA radiologist report notes that there had been a recent increase in the recall rate “which had been advised” it does not record that despite this increase the recall rate for the East Lancs unit continued to be at or near the lowest rate in the country for a patient’s first screen right through from 2003/04 to 2008/09 with similar results for patients attending for subsequent screens.
- 8.26 The message delivered to Trust Managers on radiology standards in the 2006 QA report was that the recall rate was low but not a major concern as “results were good”. In fact the 2006 report could have been much less upbeat about radiology performance and posed more serious and challenging questions about why the East Lancs unit should have the lowest recall rate in the country and whether or not this was connected to the increased workload arising from the age extension and the deterioration in the cancer detection rate over the period.
- 8.27 It is not suggested that the missed cancers which are the subject of this review had anything to do with the low recall rate. We know the missed cancers were missed in the women who were recalled for assessment and we know why. The point of this discussion about the low recall rate is to evidence the conclusion that the Regional Director and the QA radiologist have not been critical enough in their assessment of the strengths and practices of the radiology team at East Lancs. It is clear that despite the generally favourable outcome statistics, the Regional Director had a longstanding concern about the exceptionally low recall rate at the unit but did not take any steps in conjunction with the QA radiologist to independently audit screening practice at the unit. Neither did the QA team provide in the published reports of the regional QA visits a full enough analysis of performance to include an account of comparative and trend performance as opposed to simply recording the fact that the unit had achieved the national ‘pass mark’ for the service.
- 8.28 Beset as they were by an extremely challenging strategic and financial agenda, the senior management of the Trust would not have seen in the 2006 QA report any cause to take a closer interest in standards of radiology practice in the Breast Screening Unit. Had the report been more explicit about the Trust having the lowest recall rate in the country (and the reasons why the Regional Director was concerned about this) and the deteriorating performance on cancer detection rates, the Medical Director and other senior clinical managers in the Trust might have taken a keener interest in clinical practices within the unit. This might have exposed the fact for instance that of the three consultants, Dr X was in fact the one with the most strikingly low recall rate. As it was the ‘Key challenges and

recommendations' in the 2006 QA report related exclusively to tackling the resource issues (accommodation and staffing) that were perceived to be hampering achievement of national access and waiting time targets.

- 8.29 The unit's performance in relation to the achievement of the national target (that for 90% of women the time interval between screenings should be no longer than 36 months) had deteriorated dramatically since the extension of the age range in 2003. Prior to 2003 the unit regularly exceeded the target whereas at the time of the 2006 QA visit only 63% of women were screened within the required 3 year period. Achievement of the national access and waiting times targets deteriorated further in 2007 and 2008 to such an extent that a 'Recovery Plan' was agreed between the Trust, the Regional QA team and the local Primary Care Trusts which produced an improved position by the time of the 2009 QA visit.
- 8.30 It is clear that the unit at East Lancs was struggling from the outset to cope with the additional workload generated by the age extension in 2003. That the unit's failure to achieve waiting time targets should be a focus of the QA visits is neither surprising nor inappropriate. As intimated in an earlier section of this report the levels of anxiety generated for patients by breast screening is such that undue delay in appointments for results and appointments for assessment cannot be tolerated. What is surprising is the apparent acceptance by the Regional Director and the QA radiologist of the assertion by the unit consultants that this small provincial Breast Screening Unit (that was clearly under enormous pressure to manage its workload), was able to safely function with recall rates that, for 4 years, were the lowest in the country.. This may have been the case but it should have been looked at more closely.

### **Performance Reporting differences between QA Teams**

- 8.31 On the basis of the papers produced relating to the visits of NW QA team, the team has relied largely on the (KC62) data produced nationally to measure the performance of screening units against national standards and targets. These national statistics provide information on comparative 'unit level' performance where the measurement of radiology quality is based on overall, unit level, cancer detection rates. As has been noted previously the guidance published by the NBSP on assuring radiology quality is clear that overall unit statistics can mask poor individual performance.

A different approach is adopted by the West Midlands QARC which produces for each visit a very comprehensive booklet which includes a much more complete picture of performance in a single document which focuses on detailed comparison on a wider range of measures between the units in the region and which includes data on the performance of individual radiologists. The information in the West Midlands pre-visit booklet includes, in addition to overall cancer detection rates :-

- A report on the performance of individual film readers in the unit visited which includes comparative individual recall rates and missed cancers. (Missed cancers are where the first reader does not recall the woman to assessment but the second reader does and a cancer is found at assessment).
- Positive predictive values for both film reading and assessment
- Comparative interval cancer rates for all the units in the region using historically complete data. Rates are compared within the region and with the national 'standard' rate of 1.2 per 1000 women screened
- Interval cancers following assessment, by unit and by individuals within the unit visited.

Many of these additional measures are presented in control chart form which is helpful in separating results that are statistically significant from those due to normal statistical variation.

The North West QARC has a competent, committed and hard working team (based on the evidence of their support to this review). Although the raw data which is used to create these additional analyses will be available to them it has been suggested that the ability of the West Midlands QARC to produce these more detailed and sophisticated reports relates to differences in resources and greater experience in exploiting the potential of the NBSS computer system.

It is probable that the level of comparative Regional analysis produced by the West Midlands QARC has only been possible since the standardization of Screening Unit databases based on NBSS and, as such, no claim is made in this report that the NW QARC was in a position prior to 2006 to produce routine statistics that might have exposed Dr X's poor assessment practice. What is clear, however, is that, had it been available in the past, this more detailed comparative analysis (specifically relating to false negative assessments and comparative interval cancer rates) may have flagged up some concerns at East Lancs. The important point to emphasise here is the need, going forward, for all QA teams to make maximum use of statistics that should now be available to all Regions to provide a layer of detail in relation to unit and individual radiology performance that isn't provided by statistics reporting performance against the national standards.

The importance of the additional analysis provided by the West Midlands QARC is that it includes a focus on cancers being potentially missed at both unit and individual level which provides an important alternative view of performance to that provided by the overall measurement of cancers detected which is the focus of the national standard stats. After all, the programme exists to detect cancers and as such it may be reasonable for the performance management regime to increase the focus on the cancers that were not (but should have been) detected.

## **QA visits and the role of the QA radiologist**

- 8.32 The key individual in regard to assessing radiology practice during the triennial QA visit is the QA radiologist. The same individual acted as QA radiologist for the 2006 and 2009 QA visit.

The National Programme has issued detailed guidance on the QA visits in *Guidelines on Quality Assurance Visits* issued in October 2000.

- 8.33 For convenience some key extracts concerning the tasks of the QA radiologists are set out below

### ***Routine measurement of radiological performance***

*Radiological performance should be measured as a matter of routine as part of the NHSBSP QA programme. This document describes the key steps to be followed by the regional QA radiologist together with the regional QA team in:*

- 1. Measuring radiological performance in breast screening*
- 2. Identifying underperformance by radiologists and acting to rectify such underperformance constructively and effectively to ensure that high standards of radiological practice within the NHSBSP are maintained.*

*This document should be read in conjunction with the Quality Assurance Guidelines for Radiologists.*

*(Extract from QA Guidelines for Radiologists – “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”.*

### ***Documentation and examination of figures***

*The QA radiologist will document and examine figures related to:*

- core radiological quality standards*
- general radiological standards*
- general screening standards*
- interval cancer rates*
- screening intervals*
- quality measures recommended for regular audit*

*The QA radiologist should discuss the audit figures with the local radiologists and compare the figures with both the published standards and the national*

*average performance set out in the annual breast cancer screening radiology audit figures produced for the national radiologists coordinating group.*

### ***Peer review of screening cases***

*As part of routine practice during a QA visit, the QA radiologist should undertake a case review with the screening programme radiologists. Case selection for review should be decided by the QA radiologist as indicated from analysis of screening results.*

*The QA radiologist should ensure that there is an appropriate system with documentation for identification and review of interval cancers.*

*It is suggested that the following are appropriate groups of cases for review:*

- *films, records and review results for all minimal sign and possible false negative cancers identified during the previous year*
- *films and records of women seen at an assessment clinic – one clinic to be selected from the previous 6 months*
- *films and records of the last 20 women placed on early recall during the last screening year*
- *films and records of all women placed on early recall for a second Time*
- *films and records of women diagnosed with cancer on early recall*
- *films and records of the last five women who have undergone image guided localisation followed by surgical excision*

### ***Radiology training***

*The local radiologists' previous training and records of continuing medical education (CME) should be reviewed. If the radiologists have not previously attended a Royal College of Radiologists (RCR) accredited breast screening training programme, then they should do so immediately. The recommended syllabus is that all radiologists should have attended a multidisciplinary and specialist theoretical course at a recognised breast screening training centre, followed by a period of secondment for practical training. Attendance at regular update meetings should also be reviewed (these include RCR breast group meetings, Symposium Mammographicum, etc). It is suggested that around 25% of a screening radiologist's CME time (currently 12.5 hours per year) should be spent specifically in breast screening education. If there is evidence of poor training, then this should be rectified immediately.*

***Identifying underperformance and acting to ensure that satisfactory radiology standards are achieved***

*There are two main areas of possible radiological underperformance:*

- 1. repeated failure to recognise or interpret signs of malignancy at screen reading*
- 2. failure at assessment to carry out the appropriate investigation to establish a definitive diagnosis or to determine further management of the case.*

*The QA radiologist, in conjunction with the QA director and the local radiologists and clinical director of the screening programme, should decide on a clearly defined plan of action to address the problem. The plan of action should be related to the area of underperformance identified by the QA radiologist. In most cases, the problem should be effectively addressed at local/regional level and may involve a period of problem specific training at one of the national breast screening training centres.*

- 8.34 It is evident from these guidelines that review of national performance statistics is only one element of the process by which the QA radiologist should assess the quality of radiology practice. Given the specific advice that “aggregated data can mask individual underperformance” it is reasonable to suppose that the key focus of the Radiology QA at the triennial visit should be direct review of the work of the individual local radiologists through the review of films, records and cases suggested in the visit guidance and the review of the training of individual radiologists.
- 8.35 In regard to the QA radiologist’s involvement in the visits to the East Lancashire Breast unit in 2003, 2006 and 2009 there were some clear weaknesses which in some cases were compounded by gaps and ambiguities in the national guidance. These weaknesses are discussed in the following paragraphs

**QA radiologist role at Triennial Visits**

**Review of assessment clinics**

- 8.36 The national guidelines on QA visits suggest that the films, investigations and decisions at one assessment clinic undertaken in the 6 months prior to the QA visit should be reviewed by the QA radiologist. All Breast screening units will employ more than one radiologist undertaking assessment clinics which means that compliance with this guidance in the case of East Lancs would mean that the assessment clinic practices and standards of 2 out of the 3 radiologists would not



be audited at the QA visit. In fact the practice of the QA radiologist who undertook the 2006 and 2009 visits at East Lancs was to review 2 assessment clinics. No records exist of what clinics or patients were reviewed in either year but we do know that the two clinics were for different consultants. What we don't know is which of the 3 consultants were looked at so it is possible that Dr X's assessment clinics were not audited by the QA radiologist at any of the 2003, 2006 and 2009 QA visits.

If the purpose of the review of assessment clinics is to check compliance with assessment pathway guidelines the absolute minimum requirement should be that at the very least one clinic from each consultant should be audited. Even then it is debatable if this would generate a sufficiently large sample of each consultants work for the QA radiologist to make a confident judgment as to whether the assessment guidelines were being followed by all consultants.

- 8.37 This of course is a crucial issue as it is directly due to Dr X's non compliance with national guidance on assessment of screen detected abnormalities that cancers have been missed. Notwithstanding the issue of sample size discussed above, such was the extent to which Dr X made decisions without the aid of ultrasound and ultrasound guided biopsy there is at least the possibility that had one of his clinics been looked at in one or other of the 2003, 2006 and 2009 QA visits his idiosyncratic practice may have been picked up.
- 8.38 Bearing in mind the critical function of the assessment clinic in the Breast Screening pathway, it is subject to very little in the way of a 'failsafe' process such as in the double reading and arbitration of screening films or in the multidisciplinary team discussions to agree treatment options for individual patients after cancer is diagnosed. The reliability of decisions at assessment clinics (if the service in East Lancs is typical) is exclusively dependent on the judgment of a single consultant whose compliance with guidelines may never be audited if his/her clinics are not selected for the triennial review by the QA radiologist. It is, therefore, surprising that a more robust approach to auditing assessment clinics either locally or through the QA process was not introduced or recommended by the NBSP after the review of the Breast Screening Programme at Altnegavin Hospital in Northern Ireland in 2006 where missed cancers were also caused by an individual radiologist not following the national assessment guidelines. This very similar and equally serious failure of assessment processes within a breast screening programme does not appear to have produced any new guidance or advice for the English Screening programme.
- 8.39 The QA incident team which undertook the 'look back' exercise at ELHT considered and rejected the notion that the films of patients discharged from the assessment clinics without a biopsy should be 'checked' by a second radiologist. This seems to be an entirely reasonable conclusion bearing in mind that full compliance with the national pathway should minimize, if not eliminate, the scope for error and routine double checking by a second radiologist would entail

- an unjustifiable additional cost and impact on the overall efficiency of the programme. What is required is a more robust audit mechanism in relation to compliance with the assessment pathway by individual radiologists and there are 2 complementary new approaches that may be considered
- 8.40 Firstly, every Breast Screening Unit is on a national IT system (NBSS - National Breast Screening System) which collects data from every assessment clinic on the components of the national pathway which were deployed for every patient seen. It should be possible to devise a standard report using the data on the system to produce for every consultant an individual and comparative analysis of their practice against the requirements of the national pathway. This should provide a reliable indicator of potential problems in relation to consultants elsewhere in the country whose practice appears to be at odds with the majority interpretation of the national assessment pathway. Given the problem that has now been identified at East Lancashire the National Programme should consider devising an interim report for an immediate analysis of this sort to identify if there are any other radiologists in the national programme who are major outliers in the use of ultrasound and ultrasound guided biopsy.
- 8.41 It should be pointed out that this option was not available prior to 2006 when many Screening units were on local, less sophisticated IT systems.
- 8.42 To balance the 'top down' statistical audit suggested above there should be a mandatory requirement for all Breast Screening Units to conduct a local audit of compliance with the national assessment pathway by each consultant. This local audit should be undertaken periodically to a timescale that will allow it to be used by the QA team as key source of information ahead of and during the triennial QA visit. The national assessment pathway lends itself to a straightforward compliance audit of this sort which would need to be undertaken strictly in accordance with a national protocol devised by the National Committee of Radiology QA coordinators.
- 8.43 Notwithstanding the importance and effectiveness of the external QA mechanism deployed by the NBSP, the quality of service and the safety of the patients will depend more in the long run on the ongoing commitment to good clinical governance within each unit - at the centre of which is a programme of regular and robust clinical audit.
- 8.44 Subject to the discussion below about the need for a more consistent national approach to the review of interval cancers, the introduction of continuous statistical and clinical audit of assessment clinic practice for all consultants may eventually make it possible to review the need to continue with the current, more cursory, audit of sample clinics at the triennial QA visit.

## Review of Radiologists Training

8.45 The relevant section of the national guidance on QA visits states

*“The local radiologists’ previous training and records of continuing medical education (CME) should be reviewed. If the radiologists have not previously attended a Royal College of Radiologists (RCR) accredited breast screening training programme, then they should do so immediately. The recommended syllabus is that all radiologists should have attended a multidisciplinary and specialist theoretical course at a recognised breast screening training centre, followed by a period of secondment for practical training. Attendance at regular update meetings should also be reviewed (these include RCR breast group meetings, Symposium Mammographicum, etc). It is suggested that around 25% of a screening radiologist’s CME time (currently 12.5 hours per year) should be spent specifically in breast screening education. If there is evidence of poor training, then this should be rectified immediately.”*

8.46 Despite this very clear guidance all the radiologists working at the East Lancs Unit have stated that they have never been involved in ‘one to one’ discussions about their training with the QA radiologist either at the QA visits or in any other forum, other than providing assurances that they have been able to obtain their Royal College CPD credits. The QA radiologist at the 2006 and 2009 QA visits has confirmed that this is the case. This means that Dr X in particular has never been asked about his training history (and any training needs) as specifically suggested by the QA visit guidelines.

8.47 Dr X says he would ‘probably’ have discussed his need to be trained in Ultrasound Guided biopsy had he been asked a direct question about training needs by the QA radiologists at either the 2003 or 2006 QA visits. The fact he wasn’t asked does not, of course, excuse his own failure over many years to make arrangements to get the additional training he needed. Nonetheless, and in the light of the fact that Dr X had ‘put on the record’ his training needs with his Clinical Director at the 2005 appraisal, it is possible that if he had been asked about training needs during the 2006 QA visit he might have felt compelled to admit his ‘problem’ with breast biopsies. Had he done so the QA radiologist would have appreciated the significance of this skills gap (unlike the Clinical Director) and would doubtless have taken robust action to ensure the training was undertaken.

8.48 Had the QA visit guidelines with regard to the training history of the unit radiologists been fully complied with by the QA radiologists at the 2003 and 2006 visits it is possible that Dr X’s need for additional training would have been identified and remedied. As discussed earlier the attendance by Dr X at a leading unit to undertake the additional training he needed might have improved more generally his compliance with the Breast assessment pathway and as such might have improved the accuracy of his diagnosis in subsequent years.

8.49 Although the QA radiologists sought assurances from the unit radiologists that they had obtained their required CPD credits for the Royal College of Radiology CPD scheme there was no examination of CPD diaries. The QA radiologist would not, therefore, have been able to verify that 25% of annual CPD related to Breast radiology as is required. The Clinical Directors undertaking annual appraisal were not aware of this requirement (and in any event didn't check CPD diaries) and as noted previously the Royal College only checks 10% of diaries and does not check for the sub specialty component of CPD. The consequence of this is that despite the existence of 3 separate mechanisms to review the CPD of the breast radiologists at East Lancs their compliance with the requirement to devote 25% of CPD to Breast radiology has probably never been verified. Whether or not this situation applies at other units in the country is something the NBSP may wish to investigate.

### **QA visit review of Interval Cancers**

8.50 The QA visit guidance states that the QA radiologist should review at the Triennial QA visit

*“films, records and review results for all minimal sign and possible false negative cancers identified during the previous year”*

For convenience some facts included in an earlier section of this report are repeated to provide a reminder of the context for this requirement at East Lancs

*(5.9.4) Analysis of interval cancers linked to the ELHT Breast Unit has identified 10 women with category 3 interval cancers in the period 1995 – 2006 that had been previously assessed and discharged as cancer free by Dr X.*

*A category 3 interval cancer is defined as a cancer occurring after a routine screening where “..... there are signs suspicious of malignancy on the original screening films”. Category 3 is the highest (or most serious) category of interval cancer – category 2 interval cancers have ‘minimal signs’ on the original films and category 1 have no signs of abnormality on the original mammogram. For this number of category 3 interval cancers to occur after a clinical assessment and in relation to one consultant is highly suspicious of sub optimal assessment practice.*

8.51 For the purposes of this section it should also be noted that in addition to the 10 category 3 interval cancers referred to in the preceding paragraph, over the same period an additional 19 interval cancers in women previously assessed by Dr X for screen detected abnormalities were also identified. These had been originally graded as category 0, 1 or 2 but on re-examination 4 of these have been reclassified as ‘false negative’ (category 3) cases

- 8.52 The review of interval cancers within the screening units is primarily to facilitate ongoing education and skills in film reading through constructive, collective discussion on the interpretation of the original screening films. As has already been discussed earlier in this report there was no systematic process for review of interval cancers with the East Lancs Unit.
- 8.53 It is assumed that the review of Interval Cancers which is carried out by the QA radiologist at the triennial visit is intended primarily to facilitate constructive discussion with the local Radiologists about the interpretation of the original screening films (and especially so in the case of category 3 interval cancers). It is therefore, something of a mystery as to why none of the 14 category 3 false negative assessments and 15 other (cat 0, 1, 2) assessed interval cancers (all of which were assessed by Dr X) do not appear to have been picked up by the QA radiologist at either the 2003, 2006 or 2009 visits. Interval cancers following assessment should be a relatively rare event compared with false negative interpretations of original mammograms and would inevitably have provoked discussion had they been in the batch of cases reviewed at the QA visits.
- 8.54 It must be assumed that these cases were not reviewed at the QA visit because either
- The Unit had not classified and reported the cases to the Regional QA office
  - The cases had not been notified to the screening unit (and therefore had not been classified as Interval cancers) when they were diagnosed symptomatically
  - The cases were in the backlog of cancer registry cases yet to be reviewed by the Regional QA analysts for unreported interval cancers
  - The cases were always in the 2 years of interval cancers not looked at the QA visits (only the most recent year is looked at)
- 8.55 The QA radiologist at the 2006 and 2009 visit has commented that the number of interval cancer cases presented was less than might be expected and the present Director has confirmed that a backlog of cases had not been classified (and therefore were not presented) at the time of the 2009 visit. The small number of cases available to review at the visit was not raised with the Unit Director by the QA radiologist at the time of the visit and was not mentioned in the report of the visit.
- 8.56 There are no records of the actual Interval cancers reviewed at the QA visits of 2003, 2006 and 2009 and it must be presumed that for one or other of the reasons mentioned above none of the false negative assessments were ever reviewed by the QA radiologist. The *National Quality Assurance Guidelines for Breast Cancer Screening Radiology* has a specific section on false negative assessments which states

*“For cases when a woman has been recalled following screening and has undergone assessment for an abnormality that is shown to correspond to the breast cancer, the case should be reviewed within a multidisciplinary forum. These should be separately reported to the QARC in aggregated reports as a subcategory of interval cancer”*

8.57 There is no evidence that this procedure has ever been followed in relation to any of the 29 interval cancers linked to assessments by Dr X and because of this the Regional QA team were not alerted through routine interval cancer reports that Dr X was associated with a potentially unusual number of assessed interval cancers. Bearing in mind the importance of assessed interval cancers as an indicator of possible problems with individual clinical practice the NBSP may wish to reaffirm to all units its current advice on the need for these to be separately reported.

8.58 As has previously been recorded there was no systematic process in place for collective classification and discussion of interval cancers by the Radiologists and Radiography film readers in the East Lancs unit. The QA visit guidelines requires the QA radiologist to

*“ensure that there is an appropriate system with documentation for identification and review of interval cancers”*

Presumably this requirement relates to the importance of a systematic approach in which all staff who read films participate in interval cancer classification and that the documentation referred to would demonstrate this was the case.

It appears that the QA radiologist at the 2006 and 2009 visits reviewed the cases presented but did not take any specific steps to review the robustness of the local process

8.59 It is recognized that classification and review of interval cancers is primarily for the purpose of learning and education. Even so it is possible that, had the system for reporting, classifying and reviewing interval cancers been robust enough both locally and at regional level to ensure Dr X’s false negative assessment cases were picked up in the QA review of interval cancers at successive QA visits since 1998, his poor assessment practice may have been identified and remedied many years ago. This conclusion is supported by the fact that variation in assessment practice (albeit not on the scale evident at East Lancs) has been picked up by a different QA radiologist elsewhere in the North West through the review of interval cancers at a QA visit. It is the practice of this particular QA Radiologist to review for the smaller units all interval cancers reported since the previous QA visit and a minimum of 2 years cases for the larger units.

8.60 The NBSP may wish to reconsider whether Interval Cancer review has an important role (or not) in the identification of poor individual practice and if this is the case then the current reporting and review arrangements may need to be strengthened. Possible options may include

- Stipulating a minimum number of interval cancers to be reviewed at the QA visit and including cases in all of the 3 years between visits.
- Ensuring that outcome documentation for Breast Cancer Multidisciplinary Team meetings requires positive confirmation that the local Regional Breast Cancer QARC has been notified of every Interval Cancer where the patients screening history is known.
- Introducing a requirement that all false negative assessments producing category 3 interval cancers are reported as a 'serious untoward incident' requiring immediate investigation by the host Trust with the involvement of the Regional QA radiologist
- Issuing fuller guidance to all units on the minimum process requirements and documentation for local review and classification of interval cancers

#### **Other Professional Review activities**

8.61 QA visit guidelines suggest a variety of activities that may be initiated and coordinated by the regional QA team in general and the QA radiologist in particular. These include

- The various QA specialists convening regular meetings with professional colleagues in a Region
- The QA specialist visiting units on an annual basis between formal QA visits
- Arranging a multi disciplinary case review to coincide with the QA visit at which the QA team and the Unit team ( including all relevant clinical disciplines) jointly discuss a selection of "interesting or discordant cases"

8.62 None of these additional QA/ professional activities for radiologists are in place in relation to the Screening Units covered by the Greater Manchester and Lancashire QA Radiologist. The QA radiologist says this is because it has been difficult to persuade the breast radiologists in the area that these additional professional meetings yield sufficient benefit to justify the time they take.

In contrast Radiologists in the breast units covered by the Cheshire and Merseyside QA Radiologist meet as a group twice a year to discuss clinical and other issues arising from the biennial national meeting of QA radiologists. In the West Midlands Region the breast radiologists from every screening unit meet on 3

occasions during each year where a sample selection of interval cancer classifications from each unit are peer reviewed by consultants from other units. This serves the dual purpose of stimulating debate and learning for all participants as well as moderating and externally validating the objectivity of Interval Cancer Classification across the region. It seems that a similar arrangement once existed for reviewing interval cancers in the North West Region but was discontinued some years ago.

- 8.63 In itself the absence of regular professional meetings in Manchester and Lancashire does not constitute any sort of direct contribution to the missed cancers at East Lancashire but it does raise a question about the potential danger of professional isolation of radiologists employed in the smaller screening units in the region if opportunities for professional interaction with other breast specialists are limited to annual or bi annual national events.

### **QA visit process**

- 8.64 There is some evidence that in the case of the Radiologists and the Radiographers most of the direct interaction and discussion before, during and after the QA visits was between the relevant QA specialist and the local heads of service (Unit Director, Programme Manager/Senior Radiographer and the QA Radiographer). Whilst it is inevitable that these individuals will have a major input into the QA process it is also the case that, as the senior managers of the local service, they will have a perfectly natural tendency to promote the strengths of the unit. They will do so not because they are intent on concealing problems (although this may be a temptation in some circumstances) but because they are proud of their service and will want as positive an outcome as possible for the unit.
- 8.65 Whilst it is perfectly proper for the QA team to adopt a supportive, advisory and helpful stance in their approach it should always be uppermost in their minds that their purpose is to provide expert independent assurance to the Trust Board, the PCT, the SHA and the National Programme which are all in one way or another accountable to the wider public for the quality and safety of the service in each Breast Unit. This means that as well as being helpful, friendly and constructive, the QA team needs to avoid over reliance on what they already know of the unit and what they are told by the local managers of the unit. The QA team must make specific and determined efforts to probe 'beneath the surface' during their visit. In particular there should be an opportunity for all unit staff (radiologists, radiographers and admin staff) to meet QA team members either individually or in groups without their managers present as it is often the case that the 'rank and file' is more objective and open about problems where these exist.



## **The role of the local Primary Care Trusts**

8.66 At the time from which the problems in the East Lancashire Breast Screening service have been identified (2000) the service covered populations which were the responsibility of 3 Primary Care Trusts viz:-

Blackburn with Darwen  
Hyndburn and Ribble Valley  
Burnley, Pendle and Rossendale

In 2006 the 2 PCTs of Hyndburn & Ribble Valley and Burnley, Pendle & Rossendale were amalgamated to form NHS East Lancashire (PCT)

Changes in organisation and senior management personnel over this period have made it difficult to establish the extent to which the PCTs took any independent steps either singly or collectively to monitor clinical standards at the East Lancashire Breast Screening Unit. PCTs do have an overall responsibility for being assured about the quality for services they commission for their populations but in the case of the Breast Screening Service this responsibility was specifically removed from local 'commissioners' and transferred in 1997 (under EL97/67) to regional offices of the NHS Executive -the regional tier of the NHS at the time. Regional Offices were required to discharge responsibility for the QA function in relation to breast screening services through the Director of the Regional Quality Assurance Unit.

There is clear evidence that in more recent years local Primary Care Trusts have been active in monitoring access targets (uptake and waiting times for assessment appointments and results etc.) but it appears to be the case that in regard to the quality of the service local PCTs have relied on the reports of the Regional QA service. This is an entirely reasonable position for the PCTs to take given the fact that the Regional QA team was established with a specific responsibility to assure the quality of the breast screening service and has specific resources and specialist staff to undertake this task. Further informal reassurance for the local PCTs would be derived from the fact that for most of the relevant period the Director of the Regional QA service was also the Director of Public Health for Burnley, Pendle and Rossendale and subsequently East Lancashire PCT."

## **RECOMMENDATIONS RELATING TO THE EXTERNAL QUALITY ASSURANCE PROCESS**

*R8.1 Statistical assessment of radiological performance should not be limited to year on year achievement of the national 'pass marks'. Significant changes in performance should attract scrutiny, comment and independent investigation where unit explanations are not convincing.*

- R8.2 *The NBSP should review the range and quality of statistical information produced for QA advisors by the different regional QARCs and develop or facilitate a standardized approach based on best current practice. Wherever practical standard reports should be produced at national level to avoid duplicated effort at regional level and to help mitigate the differences caused by differential analytical resource in the different regions.*
- R8.3 *The current advice that QA radiologists review only 1 assessment clinic at the QA visit should be urgently reconsidered. A minimum sample size for the work of each radiologist in the unit should be agreed.*
- R8.4 *A standard national report should be devised which utilizes data already collected by the NBSS system to generate regular reports on the diagnostic options used by all radiologists undertaking assessment clinics. An early interim version of this report should be used by the NBSP for an urgent baseline check on the current assessment practice of all radiologists*
- R8.5 *The national committee of QA radiologists should devise a standard protocol for a full local audit of compliance with the national breast assessment guidelines to be undertaken by the local unit on a cycle which would allow the report to be presented for discussion at Triennial QA visits*
- R8.6 *Consideration should be given as to whether the adoption of the preceding 2 recommendations would eventually allow the Triennial review of sample clinics to be dropped from the QA visit (with the time saved devoted to review of specified cases – interval cancers etc.)*
- R8.7 *All QA radiologists should be reminded of the requirement to engage in detailed ‘one to one’ discussions with all radiologists on their ‘patch’ about their training history and outstanding training needs (as currently recommended in the QA visit guidelines). QA radiologists should take responsibility for ensuring, by review of CPD diaries, that breast radiologists comply with the requirement that 25% of their accredited CPD should relate to Breast Radiology. The 3 year cycle of the QA visit should be sufficient for these discussions bearing in mind radiologists should be having similar discussions on an annual basis with their local Clinical Directors. The QA radiologist should confirm the outcome of their training and development discussions with Radiologists in a letter which should be copied to the Local Clinical Director who, together with the radiologist, will be accountable for ensuring any identified training needs are met within the timescale stipulated by the QA radiologist.*
- R8.8 *The National Programme should consider whether or not events at East Lancashire have exposed more general weaknesses in the process for reporting, classifying, recording and reviewing interval cancers. This is a complex matter and it is not amenable to informed recommendation by a lay reviewer. The following are suggestions rather than firm recommendations*

- R8.8.1 Coordinators for Breast MDTs should be made responsible for ensuring the screening histories of symptomatic breast referrals are recorded and for notifying their local QARC (irrespective of where screening was performed) of the interval cancer after the MDT meeting has confirmed the diagnosis.*
- R8.8.2 A performance management regime should be initiated by which Regional QARCs ensure classification by the local unit of interval cancers within a specified period after notification*
- R8.8.3 National guidance concerning the process and documentation for local (Breast unit) classification and review of interval cancers should be produced. The documentation specified should facilitate the triennial check by the QA radiologist of compliance by local units with the recommended process.*
- R8.8.4 The review of Interval Cancers at the triennial QA visit should be undertaken jointly by the QA radiologist and all the Breast Radiologist/film readers in the unit.*
- R8.8.5 Agreement is necessary on a manageable sample size of Interval Cancers (and the spread of categories and cases across the 3 years) that should be reviewed at the triennial visit.*
- R8.8.6 If all Regions were to institute regular interval cancer peer review meetings similar to those in the West Midlands with a full record of which units attended, the number of cases reviewed for each unit and the degree of concurrence with the local classification, this could allow for a very detailed multi disciplinary focus on fewer, more recent interval cancers, at the triennial visit.*
- R8.9 There needs to be an urgent review of the extent to which the separate reporting and multi disciplinary review of assessed interval cancers is complied with (or not) on a national basis.*
- R8.10 Consideration should be given to the designation of false negative assessments which produce a category 3 interval cancer as a Serious Untoward Incident (SUI) requiring a Root Cause Analysis by the host Trust with the active involvement of the Regional QA radiologist.*
- R8.11 The current arrangements for regular professional meetings in the different regions should be discussed by the QA radiologist' coordinating committee with a view to agreeing a common approach that makes best use of time.*

*R8.12 QA radiologists (and other QA specialists) should undertake at least two visits each year in a different (geographically distant) region where they will need to rely more on their ability to analyse data, to ask more questions and to probe more fully than is the case when they visit local units they know well and where they may have preconceived ideas regarding the quality of the unit. This occasional involvement of a non local specialist in a QA visit may also serve as an antidote to over familiarity amongst the rest of the QA team on that visit and as a mechanism for sharing good practice.*

**9. ASSESSMENT AS TO WHETHER THE BREAST SCREENING UNIT AT EAST LANCASHIRE HOSPITAL IS NOW SAFE AND ‘FIT FOR PURPOSE’**

9.1 Notwithstanding the very serious nature of the individual and organizational failings that resulted in the failure to diagnose so many breast cancers it is clear that the other staff in the unit are highly competent, dedicated and conscientious individuals who have been both shocked and deeply upset about the consequences for their patients of Dr X’s failings. As with so many staff associated with the breast screening programme nationally they are deeply committed to the objectives of the service and have been naturally concerned that the damage to the unit’s reputation may adversely affect the uptake of invitations to screening. For this reason there has been the fullest possible cooperation from all the staff of the unit to the initial Incident Team Review (and to this more detailed review) and to the rapid implementation of the many changes and improvements that have been identified as necessary to improve the clinical safety of the service.

9.2 Before detailing the management and organizational changes that have been made it is important for public confidence in the current standards of care at the unit to reiterate two key points about competence of the consultant staff of the unit.

- Dr X has been relieved of his duties within the breast Unit
- The two expert radiologists on the Incident Review Team have provided independent assurance that there are no grounds for concern about the clinical practice of the 2 other consultant radiologists (or indeed any other staff) working in the unit.

9.3 A number of changes have been made relation to the running of the Breast Screening Unit which reflect the findings of the Incident Team Review and which anticipate the relevant findings of this report. These changes include

9.3.1 A Chief Executive who has successfully managed a neighbouring Foundation Trust for 20 years is now providing the quality of experienced leadership to the East Lancashire Hospital Trust which is essential to the

strengthening of governance processes required to assist the Trust in managing the challenging agendas it is dealing with.

- 9.3.2 The new Director of Screening at the East Lancashire Breast Screening Unit is a highly competent, very experienced and enthusiastic champion for the development of a service of the very highest standards of safety and clinical excellence.
- 9.3.3 A full time Consultant Radiographer has been appointed who will provide increased senior clinical capacity for the unit
- 9.3.4 The Director of Screening now has a formal job description which sets out clearly and unambiguously the responsibility of the post holder for the safety of patients and for ensuring compliance of all staff with all national consensus guidelines for diagnosis, care and treatment.
- 9.3.5 The Director of Screening has a formal session identified within his consultant Job Plan which creates the time needed for the important management and governance activities that the Director is required to undertake.
- 9.3.6 The Director of Screening has taken effective steps to be personally assured that all relevant staff are fully aware of and are complying with national and local clinical guidelines.
- 9.3.7 A formal clinical governance process has been implemented within the unit led by a designated consultant. The new clinical governance process involves regular (bi monthly) review meetings at which all film readers review and discuss interval cancers and any other decisions on screening films that warrant collective reappraisal and discussion.
- 9.3.8 Incorporation of Breast Unit clinical governance issues in the wider clinical governance process for the Radiology Directorate
- 9.3.9 A formal mechanism has been instituted to annually audit the compliance of individual consultants with the National Guidelines for breast assessment and to regularly audit and discuss other important aspects of the clinical work of the unit
- 9.3.10 There are regular (monthly) meetings of the senior clinical team for open discussion on the day to day operational issues that need collective discussion and agreement. These are the same operational issues faced by all Breast Units and will include such things as:-
- Meeting access and waiting time targets
  - Discussing incident reports and complaints

- Dealing with staff shortages as caused by vacancies, sickness and Maternity leave
  - Discussing the implications of new national and local policy initiatives
- 9.3.11 Quarterly meetings between the Director of Screening and the Programme Manager with the Divisional General Manager and Clinical Director for Radiology to discuss the overall performance of the Screening Unit against agreed objectives
- 9.3.12 Full participation by the Director and other senior staff in the regular programme of Regional meetings arranged by the Regional QA team
- 9.3.13 A local Breast Screening Programme Board is being established through which the 2 Primary Care Trusts served by the unit will directly monitor and influence the achievement of service, safety and quality standards.
- 9.3.14 In April 2010 the unit moved into new accommodation on the site of Burnley General Hospital. This new accommodation fully meets the current needs of the unit for clinical and ancillary space until such time as the unit is fully integrated with the symptomatic breast care service.
- 9.4 As would be expected following the discovery of a clinical practice problem on the scale and over the period which it occurred there has been an immediate and effective response by the Unit, The Trust and the Regional QA team such that **the women of Blackburn and Burnley can now be fully confident about the quality and safety of the Breast Screening Service at East Lancashire.**
- 9.5 For anybody who has had the opportunity to spend time in the unit since the missed cancers came to light there can be no doubt about the commitment of the staff of the unit to make sure that such a thing never occurs again and about the fact that they will succeed in making sure this is the case.
- 9.6 The women of Blackburn and Burnley are not, of course, able to have the opportunity themselves to be personally assured that everything that needs to be changed has been changed and some residual public nervousness about the reliability of the unit is both natural and inevitable. In this case therefore it is reasonable that the public is provided with some additional, independent and ongoing reassurance that the improvements detailed above and recommended in this report have been made in practice, are sustained and then embedded in the processes of the Unit. This would be best and most straightforwardly achieved if an independent, highly experienced Breast Radiologist with experience as the Director of a Breast Screening Unit attended the key clinical governance meeting of the Unit on a monthly basis at least until the time of the next triennial QA visit in January 2012.

- 9.7 The Director of the Unit and the independent Radiologist should personally present a report on progress direct to a public meeting of the Trust Board within 3 months of the publication of this report and every 6 months thereafter until the time of the next Triennial QA visit at which time a decision on the need to continue with the assistance of the independent radiologist will be taken.
- 9.8 Whilst it can be confidently said that for the present workload the unit at East Lancs is now safe and 'fit for purpose' there are stresses and strains on the service similar to those experienced by all operational services across the whole of the NHS. Over the years the Breast Screening service at East Lancs has struggled in one way or another with staff shortages including:-
- A long term inability to recruit to 2 vacant radiology sessions
  - Sickness, Maternity leave and turnover affecting radiography staff and clerical staff
- 9.9 Like all small, specialist units in the NHS, the BSU at East Lancs is dependent on a relatively small number of staff and is disproportionately affected by staffing difficulties because it doesn't have the 'slack' and flexibility in staffing available to other much larger NHS services. There is no evidence that these persistent staffing pressures were in any way connected with the problem of the missed cancers between 2006 and 2009 but the terms of reference require a view in this report of the quality and reliability of service going forward into the future.
- 9.10 There must be a concern therefore about the implication for the service at East Lancashire of the further extension to the age eligibility ceiling from 47 to 73 in 2011. This will generate a significant additional workload for which the unit will need to be funded for the additional staffing required. The unit would ideally prefer to be staffed to a level that would enable them to cope with the expected loss of staff to sickness and maternity leave whereas the Primary Care Trust may wish to offset new investment against disinvestment and/or increased efficiency expectations in other areas. What is absolutely certain is that discussions regarding the additional resources required for the further age extension will in some way be affected by the increasingly difficult financial climate for the NHS as a whole. The Breast Unit at East Lancashire is not in a position to claim some form of 'immunity' from the efficiency challenge faced by the remainder of the NHS and it would not be sensible to propose this.
- 9.11 The situation does require, however, that in the light of recent history (and again to provide an additional layer of public reassurance) the Regional QA team should provide independent assurance that the Unit does have adequate funding for the numbers of staff it requires to absorb the additional workload associated with the age extension in 2011. Moreover there should be an agreed contingency plan in place agreed by all the key stakeholders (Breast Unit, Trust management, PCT, QA team) which is explicitly clear about high and low priority service targets for

times of exceptional and unavoidable staffing pressure, with some thresholds agreed for when these revised priorities can be triggered.

## **RELATED RECOMMENDATIONS**

- R9.1 An independent senior radiologist should monitor the implementation of the service and governance improvements at the East Lancashire Breast Screening Unit at least until the time of the next triennial QA visit*
- R9.2 The Director of the unit accompanied by the independent radiologist and the Regional QA Director should personally present a report on progress direct to a public meeting of the Trust Board every 6 months until the next triennial QA visit in January 2012*
- R9.3 The Regional QA team should be independently assured that the unit has adequate funding for the staffing levels it requires to manage the additional workload arising from the next age extension.*
- R9.4 All the key stakeholders should agree the ‘triggers’ for a contingency plan that allows the unit to focus on agreed high level priorities (related to maintaining a safe clinical service) when staffing pressures exceed the level that the unit should be able to absorb without any impact on delivery of the required service targets.*

## **10. FULL LIST OF RECOMMENDATIONS**

- R3.1 The Board of East Lancashire NHS Trust should take immediate action to be fully assured that all staff employed by the Trust are fully cognizant with the content of the Trust policy on incident reporting and how to properly fulfill their individual responsibilities for implementation of the requirement of this policy.*
- R3.2 The Board of East Lancashire NHS Trust should take immediate action to be fully assured that all Board members, Executive Directors, Divisional Managers, Directorate Managers and all consultant staff are fully cognizant with the content of the current Trust policy for dealing with concerns about handling clinical performance and how to properly fulfill their individual and collective responsibilities when concerns come to light.*
- R3.3 The National Director of the Breast Screening Programme should take steps to remind all Directors of Screening Units that the Regional Director of Quality Assurance must be notified immediately in the event of any concerns about the clinical performance of a Breast Radiologist.*
- R3.4 A number of recommendations will be made about the appointment, tenure, training and appraisal of Directors of Screening in a later section of this report.*



- R4.1 The NHS Breast screening programme should mandate that all clinical staff involved in reading mammograms participate in the external PERFORMS QA process. Individual results should be available to the Director of the Screening Unit and be presented as a mandatory component of the individuals appraisal portfolio.*
- R6.1 The NBSP should undertake a fundamental review of current quality assurance processes with a view to ensuring a culture of ongoing clinical audit is embedded at the local level.(further recommendations in relation to the QA process are made in a later section of this report)*
- R6.2 The NBSP should agree with Trusts a more formal process for the appointment of Directors of Screening involving*
- Regional Directors of QA acting as external assessors*
  - A minimum allocation of 1 PA in the Directors Job Plan*
  - A minimum period of initial training for newly appointed directors including secondment to a leading Screening Unit. This recommendation should be applied retrospectively for Directors appointed within the last 2 years*
  - Appointments should be subject to renewal on a 3 yearly basis*
  - Renewal of appointments should be dependent on a full and formal appraisal of Screening Directors by the Regional Director of QA and the Regional QA Radiologist as part of the triennial QA visit.*
- R6.3 The possibility of a confidential (but not anonymous) national arrangement through which concerns about the practice of another consultant can be raised should be considered in the discussions initiated by the National Quality Board between the Department of Health and The Medical Royal Colleges*
- R7.1 All Trust Boards hosting Breast Screening Units should be reminded that the full report of the triennial Quality Assurance visits must be considered at the Governance Committee of the Trust Board in the presence of the Director of Screening and the Director of the Regional QA team.*
- R7.2 Previous advice concerning the production of formal annual reports for mandatory presentation to Trust Boards should be reviewed*
- R3.1 The Board of East Lancashire NHS Trust should take immediate action to be fully assured that all staff employed by the Trust are fully cognizant with the content of the Trust policy on incident reporting and how to properly fulfill their individual responsibilities for implementation of the requirement of this policy.*

- R7.3 *The Board of East Lancashire NHS Trust should take urgent action to ensure that a fully robust and comprehensive consultant appraisal process is put in place which covers 100% of consultant staff during the year 2010/2011 and for every year thereafter.*
- R7.4 *The Trust should urgently identify designated management and administrative resources to support and coordinate the consultant appraisal process*
- R7.5 *The Board should receive a report setting out what steps have been taken to implement the recommendations (R7.3 and R7.4) above concerning consultant appraisal by no later than 31<sup>st</sup> December 2010. The first annual report on consultant appraisal covering the year 2010/2011 should be submitted to the Board no later than 31<sup>st</sup> May 2011.*
- R7.6 *NHS Northwest and Monitor should commission a joint independent regional review of consultant appraisal processes for the purpose of identifying and sharing best practice (along the lines recommended by the Revalidation Support Team in its AQMAR report of May 2009)*
- R7.7 *The Department of Health in conjunction with the GMC and the Medical Royal Colleges should consider the practicalities of introducing a greater degree of direct peer review into consultant appraisal.*
- R7.8 *The specialty specific ‘standards for revalidation’ recently produced by the various Medical Royal Colleges may eventually be refined to sub specialty level. In the meantime interim advice should be urgently issued to Chief Executives and Medical Directors about the minimum requirements for information in consultant appraisal portfolios to more thoroughly establish the competence of consultants in their own designated subspecialty.*
- R7.9 *In relation to the specifics of this review the relevant National Coordinating Committee of the NBSP should agree an ‘appraisal guidance note’ for the use of non expert (i.e. not of the same specialty) Clinical Directors appraising breast specialists. This guidance note should provide a summary of the knowledge, training requirements, CPD priorities and practical competencies required by a breast specialist. Whilst this would not be an alternative to full peer review it would ensure non- expert CDs appraising breast specialists are not ignorant of the key skills and competencies required.*
- R7.10 *The Care Quality Commission and the NHS Litigation Authority should require 100% achievement of consultant appraisal (with exclusions allowed only for illness) as a minimum requirement for compliance in the relevant sections of their external assessments*

- R8.1 *Statistical assessment of radiological performance should not be limited to year on year achievement of the national ‘pass marks’. Significant changes in performance should attract scrutiny, comment and independent investigation where unit explanations are not convincing.*
- R8.2 *The NBSP should review the range and quality of statistical information produced for QA advisors by the different regional QARCs and develop or facilitate a standardized approach based on best current practice. Wherever practical standard reports should be produced at national level to avoid duplicated effort at regional level and to help mitigate the differences caused by differential analytical resource in the different regions.*
- R8.3 *The current advice that QA radiologists review only 1 assessment clinic at the QA visit should be urgently reconsidered. A minimum sample size for the work of each radiologist in the unit should be agreed.*
- R8.4 *A standard national report should be devised which utilizes data already collected by the NBSS system to generate regular reports on the diagnostic options used by all radiologists undertaking assessment clinics. An early interim version of this report should be used by the NBSP for an urgent baseline check on the current assessment practice of all radiologists*
- R8.5 *The national committee of QA radiologists should devise a standard protocol for a full local audit of compliance with the national breast assessment guidelines to be undertaken by the local unit on a cycle which would allow the report to be presented for discussion at Triennial QA visits*
- R8.6 *Consideration should be given as to whether the adoption of the preceding 2 recommendations would eventually allow the Triennial review of sample clinics to be dropped from the QA visit (with the time saved devoted to review of specified cases – interval cancers etc.)*
- R8.7 *All QA radiologists should be reminded of the requirement to engage in detailed ‘one to one’ discussions with all radiologists on their ‘patch’ about their training history and outstanding training needs (as currently recommended in the QA visit guidelines). QA radiologists should take responsibility for ensuring, by review of CPD diaries, that breast radiologists comply with the requirement that 25% of their accredited CPD should relate to Breast Radiology. The 3 year cycle of the QA visit should be sufficient for these discussions bearing in mind radiologists should be having similar discussions on an annual basis with their local Clinical Directors. The QA radiologist should confirm the outcome of their training and development discussions with Radiologists in a letter which should be copied to the Local Clinical Director who, together with the radiologist, will be accountable for ensuring any identified training needs are met within the timescale stipulated by the QA radiologist.*

R8.8 *The National Programme should consider whether or not events at East Lancashire have exposed more general weaknesses in the process for reporting, classifying, recording and reviewing interval cancers. This is a complex matter and it is not amenable to informed recommendation by a lay reviewer. The following are suggestions rather than firm recommendations*

R8.8.1 *Coordinators for Breast MDTs should be made responsible for ensuring the screening histories of symptomatic breast referrals are recorded and for notifying their local QARC (irrespective of where screening was performed) of the interval cancer after the MDT meeting has confirmed the diagnosis.*

R8.8.2 *A performance management regime should be initiated by which Regional QARCs ensure classification by the local unit of interval cancers within a specified period after notification*

R8.8.3 *National guidance concerning the process and documentation for local (Breast unit) classification and review of interval cancers should be produced. The documentation specified should facilitate the triennial check by the QA radiologist of compliance by local units with the recommended process.*

R8.8.4 *The review of Interval Cancers at the triennial QA visit should be undertaken jointly by the QA radiologist and all the Breast Radiologist/film readers in the unit.*

R8.8.5 *Agreement is necessary on a manageable sample size of Interval Cancers (and the spread of categories and cases across the 3 years) that should be reviewed at the triennial visit.*

R8.8.6 *If all Regions were to institute regular interval cancer peer review meetings similar to those in the West Midlands with a full record of which units attended, the number of cases reviewed for each unit and the degree of concurrence with the local classification this could allow for a very detailed multi disciplinary focus on fewer, more recent interval cancers, at the triennial visit.*

R8.9 *There needs to be an urgent review of the extent to which the separate reporting and multi disciplinary review of assessed interval cancers is complied with (or not) on a national basis.*

R8.10 *Consideration should be given to the designation of false negative assessments which produce a category 3 interval cancer as a Serious Untoward Incident (SUI) requiring a Root Cause Analysis by the host Trust with the active involvement of the Regional QA radiologist.*

- R8.11 The current arrangements for regular professional meetings in the different regions should be discussed by the QA radiologist' coordinating committee with a view to agreeing a common approach that makes best use of time.*
- R8.12 QA radiologists (and other QA specialists) should undertake at least two visits each year in a different (geographically distant) region where they will need to rely more on their ability to analyse data, to ask more questions and to probe more fully than is the case when they visit local units they know well and where they may have preconceived ideas regarding the quality of the unit. This occasional involvement of a non local specialist in a QA visit may also serve as an antidote to over familiarity amongst the rest of the QA team on that visit and as a mechanism for sharing good practice.*
- R9.1 An independent senior radiologist should monitor the implementation of the service and governance improvements at the East Lancashire Breast Screening Unit at least until the time of the next triennial QA visit*
- R9.2 The Director of the unit accompanied by the independent radiologist and the Regional QA Director should personally present a report on progress direct to a public meeting of the Trust Board every 6 months until the next triennial QA visit in January 2012*
- R9.3 The Regional QA team should be independently assured that the unit has adequate funding for the staffing levels it requires to manage the additional workload arising from the next age extension.*
- R9.4 All the key stakeholders should agree the 'triggers' for a contingency plan that allows the unit to focus on agreed high level priorities (related to maintaining a safe clinical service) when staffing pressures exceed the level that the unit should be able to absorb without any impact on delivery of the required service targets.*

## **APPENDIX 1**

### **Terms of Reference for an Independent review of the management of the breast screening incident in East Lancashire**

#### **Purpose of the Independent Review**

Following the delayed diagnosis of breast cancer in 19 patients, an independent review has been commissioned by East Lancashire Hospitals NHS Trust, into the adequacy of the management and governance systems and processes in place, at the time of the incident and the subsequent management of this incident.

This will include:

- Making recommendations as to any patient safety lessons that can be applied in the future by the trust and the wider NHS
- Providing explanations to the patients and their families of what happened.
- And providing reassurance to the public and local community on the effectiveness and adequacy of the breast screening service

#### **Terms of Reference**

- To provide a chronology of the events leading up to the incident over the whole 3 year screening cycle; starting from the time of the QA visit in January 2006
- To review the robustness of the process applied to identify, engage, treat and counsel the women affected by this incident
- To examine the decision regarding the necessity for further investigation into symptomatic services and the length of the look-back period.

- To identifying care or service delivery issues, along with the factors that might have contributed to the issues identified:
  - management of the breast screening service at a local level
  - the process for monitoring and maintaining clinical standards of performance and practice of individual consultant radiologists to minimise the risk of a recurrent incident of this nature
  - the management of patients within East Lancashire Hospitals NHS Trust undergoing breast screening compared to practice in those Trusts identified as centres of excellence in the provision of this service
  - the management of this incident by the Trust and the Incident Team
  
- To review the role of the organisations (Trust, PCTs, Regional Quality Assurance team, SHA) involved in the management of this incident
- To identify Root Cause and Contributory factors leading to the incident
- To provide a final report with recommendations for any changes in operational methods, policy, practice or management arrangements locally , regionally or nationally would help prevent a recurrence

## **Methodology**

- The review will be conducted by an independent external reviewer agreed by all parties
- The reviewer will receive all relevant reports to determine any areas for further investigation and advise ELHT and the SHA of any proposed changes to the terms of reference

- Interviews will be held with relevant stakeholders
- The individuals and organisations taking part in the review will keep confidential all data or other information he/ she acquires in co-operating with this review pending publication of the final agreed report
- The draft final report will be submitted to ELHT and to the SHA. The draft will be anonymised and all parties will have an opportunity to clarify issues of factual accuracy and interpretation, prior to publication.
- In undertaking their obligations under the terms of this review all parties will comply with all relevant legal requirements including the Data Protection Act 1998, Information Governance and Caldecott Guardian.
- The East Lancashire Hospitals NHS Trust will indemnify the reviewer in relation to work undertaken within the agreed terms of reference