Report on a clinical review of mammography service at Midland Regional Hospital Portlaoise for the Health Services Executive Dublin Mid-Leinster

Dr. Ann O'Doherty,
Consultant Radiologist, St. Vincent's Health Care Group and Clinical Director, BreastCheck, Merrion Unit, Dublin.

29th February 2008

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Appendices

1. Introduction and Background

29th August 2007 I was asked by Dr. Mary Hynes, Assistant Director of Quality, Risk and Customer Care, HSE, by telephone to carry out a clinical review of ultrasounds and mammograms at the Midland Regional Hospital Portlaoise between November 2003 and August 2007. I advised Dr. Hynes that it was not possible to review hard copy of ultrasound examinations and an alternative method would have to be identified for the review of ultrasounds. I asked that a small group of local people be set up to assist me with the clinical review of mammography services.

31st August 2007 I received a letter dated 31st August 2007 from Mr. John Bulfin, Network Director, HSE Dublin Mid-Leinster Area confirming the request to carry out the clinical review on behalf of the HSE Dublin Mid-Leinster Area and confirming that funding for that review would be made available. (Appendix 1)

Early September 2007 A review facilitation group was established by the HSE Dublin Mid-Leinster Area. Membership of the group is set out in Appendix II.

13th September 2007 The first meeting of the Review Facilitation Group took place in the Midland Regional Hospital Portlaoise. I attended this first meeting and Mr. Moss McCormack, HSE, again requested that there should be a review of mammograms and ultrasounds taken between November 2003 and August 2007. I again advised the HSE that it was not possible to review hard copy ultrasounds and that if they wished to do such a review an alternative method would have to be identified. I advised that a chart review by a surgeon followed by a repeat ultrasound, if deemed necessary, was the approach which in my view should be utilised. This evaluation should be informed by the Guidelines for Breast Imaging utilised in St. Vincent's Hospital, Dublin, a copy of which I supplied. These guidelines have been set out in Appendix III. The Review Facilitation Group decided that a Consultant Surgeon in the Midland Regional Hospital Portlaoise, should review the charts. I then outlined to them the methodology I proposed to adopt in relation to the proposed clinical review of the mammograms (see below). The Group agreed that they would facilitate me in that process. I further advised that patients whose imaging was reviewed as part of this process should be informed of the result of their review, when the process was complete.

In addition, and prior to the preparation of this report, I was asked by Mr. John Bulfin, Network Director, HSE Dublin Mid-Leinster Area in a letter dated 20th November 2007 to prepare a written report outlining the results of the clinical review of the breast radiology service referred to above and to draw conclusions and make recommendations.(Appendix IV)

2. Methodology under which the clinical review of mammograms was carried out

- Three Consultant Radiologists carried out a review of films: Dr. Ann O'Doherty, Consultant Radiologist, St. Vincent's Health Care Group and Clinical Director Merrion Unit BreastCheck, Dr. Louise Coffey, Consultant Radiologist BreastCheck and St. Michael's Hospital Dun Laoghaire and Dr. Susan Pender, Consultant Radiologist, BreastCheck and St. Columcille's Hospital, Loughlinstown.

- The review was carried out at short notice, on behalf of the HSE, at the Merrion BreastCheck Unit, and the staff there facilitated this review. (This decision had been made following consultation with the CEO of the National Cancer Screening Service, Mr. Tony O'Brien.)

- Films were couriered over a period of six weeks from Portlaoise to the BreastCheck building in batches. A log was established to record the receipt of films.

- Films were then loaded on multiviewers and examined, reviewed and reported on by one of the three Consultant Radiologists.

- At the end of each report an "R" code was assigned to the examination.

  R1 = normal, fatty breast tissue
  R2 = benign nodularity
  R3 = indeterminate, probably benign
  R4 = indeterminate, probably malignant
  R5 = almost certainly malignant.

- Patients with technically inadequate mammograms were coded R3 for the purpose of this review so they could be identified as requiring further evaluation by repeat mammography.

- All normal mammograms were then returned to the Midland Regional Hospital Portlaoise with reports, as soon as the reporting process was complete. The return of the films was again logged.

- All patients with codes R3 – R5 were deemed abnormal and required further assessment. Films of such patients were held at BreastCheck pending subsequent clarification of the abnormality and chart review.

3. Results of clinical review of mammography services and further assessment of patients with abnormal findings

- 3037 mammograms were reviewed.

- A number of women whose mammograms were reviewed as part of this process and did not appear to have clinical symptoms were in the age range that would have rendered them eligible to attend for breast screening in the National Breast Screening Programme.

- 235 patients with R3-R5 results were included in the further assessment.

- Formal chart reviews of any patients with R3 – R5 codes were carried out by a Consultant Surgeon and the Director of Nursing in the Midland Regional Hospital Portlaoise to determine and correlate the mammographic and clinical findings. Patients who required further assessment following chart review were contacted by staff at the Midland Regional Hospital Portlaoise and advised of arrangements to attend Dublin.

- A number of patients whose images were reviewed were identified as having had a new diagnosis of breast cancer as a result of investigations carried out in Portlaoise following the reviewed mammograms. These women either had or were having treatment for breast cancer and this group of patients were excluded from requiring further review.

- 76 patients were identified by the Surgeon and Director of Nursing who had either had subsequent imaging or surgery for benign disease following their initial mammogram. Therefore abnormalities identified at the time of the review had already been addressed. Some of the subsequent imaging referred to had taken place at St. Vincent's Health Care Group.

- 29 patients had mammograms coded R3 due to poor image quality of such a serious nature to deem them unsafe rather than specific mammographic abnormalities. It was felt that the appropriate action was to give those women (including those with low risk lesions) who were in the eligible age group, appointments with the National Breast Screening Programme (NBSP). Those outside the age group were invited to attend an assessment clinic in Dublin for a repeat bilateral mammogram (see following paragraph).

- 101 patients were identified as requiring further assessment. These patients were contacted by the Midland Regional Hospital Portlaoise and given appointments to attend an assessment clinic in Dublin.

- 2 patients did not attend their invitation to assessment. Both the patients and their General Practitioners have been contacted.

- 2 patients in this group are deceased. There is no evidence that their deaths are attributable to a delay in diagnosis of breast cancer.

- There were 18 patients who had had mammograms in the Midland Regional Hospital Portlaoise but whose films could not be located for the purpose of the review. These patients have been contacted and have had repeat mammograms as appropriate.

- All patients who attended for assessment had their imaging reported during the clinic and patients with normal results were given these results orally, prior to leaving the clinic. A formal report was also subsequently issued to the Midland Regional Hospital Portlaoise.

- 14 patients were identified as requiring biopsy. These biopsies were carried out at the initial visit. Arrangements were made with the patients to receive their biopsy results following discussion of those results by the consultant team at a multidisciplinary meeting.

- 4 patients had concordant benign (i.e. with radiology and histopathology results) biopsy results and were discharged.

- 1 patient had an indeterminate abnormality which though benign, required surgical excision.

- 9 patients had histologically proven breast cancer.

- 2 of the patients diagnosed with breast cancer had a previous personal history of breast cancer.

A flowchart summarising these results has been set out in Appendix V.

4. Findings

I have set out in Appendix VI a short synopsis on best breast imaging practice in a symptomatic breast unit in accordance with published evidence. In order to evaluate the safety, quality and standard of the Breast Imaging Service at the Midland Regional Hospital Portlaoise over the period between November 2003 and August 2007, I now propose to outline the manner, which demonstrates, in my opinion, a failure to adhere to best practice in the breast imaging service.

Image quality

Analysis of the quality of the mammograms presented for review revealed that their quality was patchy, mostly for technical reasons. As set out above, 29 were of insufficient technical quality to allow diagnosis and repeat mammograms had to be performed. In particular, the technical quality of the mammography was variable. The poor quality mammograms were not confined to a particular period but rather were scattered over the review period. This suggests to me that many of the issues with regard to quality were related to the processing of the images rather than to the mammography machine. As the machine had been decommissioned before I was asked to do this review, I was advised by Mr. Niall Phelan, Chief Physicist, National Breast Screening Programme, that a full report on the equipment would not be possible. Therefore, I asked Mr. Phelan to review the available documentation. His report is set out in full in Appendix VII.

Although the image quality was sub-optimal, the cancers diagnosed as part of this review were diagnosed on the same mammograms that were reported by the Consultant Radiologists in the Midland Regional Hospital, Portlaoise.

Reporting on mammograms and breast ultrasounds

Quality of reporting

Many of the reports issued on mammography and breast ultrasound in the Midland Regional Hospital Portlaoise over the period under review, were in my opinion difficult to interpret. They lacked clarity, specificity, and helpful conclusions that could have directed clinical management. Abnormalities were not reported in concise terms and reports did not suggest image guided biopsy. On occasion, open surgical biopsy was suggested on normal mammograms.

Missed malignancies

The team of 3 Consultant Radiologists reviewed 3037 mammograms carried out in the Midland Regional Hospital in Portlaoise over the period requested. Those 3037 mammograms had been carried out by 7 different Radiologists. For the purpose of this report, they will be identified as Radiologist A, Radiologist B, and so on.

Number of mammograms reported

Radiologist A reported 1924 mammograms.
Radiologist B reported 861 mammograms.
Radiologist C reported 41 mammograms.
The remaining 211 mammograms were reported by four other Radiologists, D, E, F and G.

Malignancies not detected on the initial mammograms

Radiologist A	4
Radiologist B	3
Radiologist C	1

During the course of the clinical review referred to above no undetected malignancies were identified in the 211 mammograms reported by Radiologists, D, E, F and G.

Radiologists A and B have permanent consultant appointments at the hospital. Radiologist C is no longer working at the hospital.

As will be seen below, one of the nine patients now found to have breast cancer was identified by reporting Radiologist A as having an abnormality suggestive of malignancy but was not subsequently biopsied.

Time from Portlaoise mammogram to confirmed diagnosis on review.

The time between the reviewed mammogram at the Midland Regional Hospital Portlaoise to diagnosis of the patients identified in this review as having cancer was between 4 ½ months and 2 years and 9 months.

Patient 1	4 1/2 months
Patient 2	5 months
Patient 3	6 months
Patient 4	7 months
Patient 5	9 months
Patient 6	1 year
Patient 7	1 year and 5 months
Patient 8	2 years and 9 months
Patient 9	2 years and 9 months

Triple assessment

Triple assessment by means of clinical, radiological and pathological evaluation is a cornerstone of symptomatic breast care. It is an important component in achieving high standards of care, particularly in patients who have a palpable mass or other high risk clinical findings. Such triple assessment can be used to reduce the rate of misdiagnosis of breast cancer. I was advised by the Consultant Surgeon and the Director of Nursing that triple assessments were not utilised in the Midland Regional Hospital Portlaoise during the period under review.

Image guided biopsy

Many patients attending symptomatic breast clinics require image guided biopsy for diagnosis of both benign and malignant conditions. Such biopsies are usually guided with ultrasound but may require x-ray guidance. The use of such techniques is an important component of good practice and can reduce the number of open surgical operations. It also facilitates efficient

diagnosis and reduces the time between patient presentation and definitive diagnosis. I was unable to establish that the Consultant Radiologists performed imaged guided biopsies at the Midland Regional Hospital Portlaoise during the period under review, which may have resulted in avoidable surgical procedures.

Multidisciplinary team review

Following the initial presentation and assessment of patients with abnormality, multidisciplinary team review is an essential and effective mechanism for ensuring that patients receive the highest standard of care. It would be in accordance with best practice that all patients who had an imaging and/or clinical abnormality would have a needle biopsy to ascertain diagnosis. Such patients should then be discussed at a multidisciplinary meeting to ensure that the results of the triple assessment matched.

I was informed by clinical staff that no such *diagnostic* multidisciplinary meetings took place at the Midland Regional Hospital Portlaoise during the period under review. In addition, one of the nine women identified in this review as having cancer was having annual follow up for family history of breast cancer. Radiologist A reported an abnormality in 2006. A subsequent review of this patient, also in 2006, at the St Vincent's Health Care Group, (see appendix VI), did not concur with this finding. Radiologist A also reported an abnormality in February 2007 with which this clinical review agreed. Had a multidisciplinary meeting taken place in February 2007 it is my opinion that a decision would have been made at that stage to carry out a biopsy and a diagnosis would have been made.

Patients with breast cancer should also be discussed at a multidisciplinary meeting *following surgery*. I was informed by a Consultant Surgeon that fortnightly multidisciplinary meetings attended by Consultant Surgeons, Pathologists, Medical Oncologists and Breast Care Nurses took place following surgery for breast cancer, to discuss further management of patients.

Pre-operative needle localisation of abnormalities

I was unable to establish that any pre-operative image guided localisation was performed to assist the Surgeon to excise abnormalities identified on imaging at Midland Regional Hospital Portlaoise during the period under review.

5. Conclusions

Breast Imaging Service

There is, in my opinion, clear evidence that the safety, quality and standard of many aspects of the Breast Imaging Service at the Midland Regional Hospital Portlaoise, over the period between November 2003 and August 2007, fell well below achievable best breast imaging practice and that this has resulted in a significant and avoidable delay in the diagnosis of breast cancer.

Analysis of misdiagnosis in symptomatic breast cancer

There is no evidence base to determine an acceptable mis-diagnosis rate in high quality symptomatic breast cancer services; though it is well recognised that even in the centres operating to the highest standards some women with breast cancer will have a delayed diagnosis. In general, such failures can be attributable to poor image quality, poor technique, errors in interpretation or particular lesion characteristics, which are difficult to interpret radiologically. The false negative rate in this review on aggregate falls within the false negative rates published within similar reviews. In this review, it would appear that all the factors discussed earlier in this report, which relate to service organisation contributed to this outcome (Appendix IX).

Quality of reporting

In my opinion, the quality of some of the reporting resulted in significant difficulty for clinicians delivering the service.

Impact of this review on the women involved

Whilst every effort has been made to complete this review in an expedient fashion, I am conscious that this review has led to significant anxiety for the women involved and their families. This review was completed over an 8-week period and all efforts were made to keep women informed, where possible. It is recognised that women who were identified as having breast cancer and many who did not have breast cancer, have had a stressful time while waiting for results.

6. Recommendations

- In the light of the recent Government policy announcement that symptomatic breast services will only be located in eight centres, an immediate decision on the future location of services needs to be made by the HSE Dublin Mid-Leinster Area. It is essential that women in this region have access to the highest quality of breast care. It is also important that this decision be made, as uncertainty of the future location of breast services seems to be having a detrimental effect on staff morale. In my view, unless there is put in place a breast imaging service run to the standards set out in the National Quality Assurance Standards for Breast Disease completed in 2006 and announced by the Minister of Health & Children (see Appendix IX), no further breast imaging should be carried out in the Midland Regional Hospital Portlaoise.

- Patients who have been diagnosed with breast cancer as a result of this review should be fully informed about the circumstances surrounding their initial misdiagnosis.

- Women who are *asymptomatic* between the ages of 50 and 64 should be encouraged to take up their invitation to attend for breast screening as part of the National Breast Screening Cancer Programme, rather than having regular mammography in their local hospital.

- It is my view that the National Quality Assurance Standards for Breast Disease referred to above should be implemented with immediate effect throughout the country. This document outlines the key performance indicators that must be met to attain high standards of care for women attending symptomatic breast centres. In addition, a mechanism for measuring standards in each centre and comparing practice between centres should be devised rapidly so that women can be reassured that the standard of care they receive is optimal. Implementation of these standards would, in my view, significantly reduce the likelihood of such an occurrence of sub-standard care in the future.

7. Acknowledgements

I would like to acknowledge the enormous extra workload for staff both at the Midland Regional Hospital Portlaoise and at BreastCheck. This was a complex process and involved many different staff from a variety of sections in the healthcare service. It was carried out in a spirit of great cooperation between the two units. Staff at both units showed a caring ethos at all times and were conscious of the stress involved for women and their families. The speed and efficiency of the review was important in minimising anxiety for patients. Much of the work was done by staff who frequently worked late into the night during the period of this review. They continued to deliver normal services to their patients.

Appendix I

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Midlands Area
Limistéar Lár Tíre
Network Manager's Office,
HSE Area Office,
Ardan Road
Tullamore

Telephone: 05793--59775
Fax: 05793-52663

Dr. Anne O'Doherty,
Clinical Director,
Breastcheck,
Merrion Screening Unit,
Merrion Road,
Dublin 4.

31 August 2007

Re: Review of Mammograms – MRH at Portlaoise.

Dear Dr. O'Doherty,

I refer to your discussion with Dr. Mary Hynes, Assistant National Director, Quality, Risk and Customer Care, Health Service Executive, regarding the above.

In this connection, I wish to request that you would carry out a review of the mammograms reported on by Dr. X, Consultant Radiologist, since her appointment to MRH at Portlaoise. This review is being requested as a result of a significant number of false positive results detected in Dr. X's reports as part of an in-house quality assurance process.

I wish to confirm the full co-operation of staff in Portlaoise with this review and also my commitment to paying appropriate costs for the review. The hospital is in a position to commence the review immediately.

I look forward to hearing from you on the matter as soon as possible.

Yours sincerely,

Mr John Bulfin, Network Manager,
HSE Dublin Mid-Leinstser,
HSE Area Office, Ardan Road, Tullamore

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Appendix II

Members of the Review Facilitation Group

Mr. John Bulfin, Network Manager, HSE Dublin Mid-Leinster Area

Dr. Mary Hynes, Assistant Director of Quality, Risk and Customer Care, HSE

Mr. Joe Martin, General Manager, Acute Hospital Services, HSE Dublin Mid-Leinster Area

Mr. Moss McCormack, Manager, Strategic Planning and Performance Management, Acute Hospital Services, HSE Dublin Mid-Leinster Area

Ms. Maureen Nolan, Director of Nursing, Midland Regional Hospital Portlaoise

Mr. Peter Naughton, Consultant Surgeon, Midland Regional Hospital Portlaoise

Appendix III GUIDELINES FOR BREAST IMAGING

Guidelines for symptomatic breast imaging are divided into two categories:

- Women under the age of 35 who should only have mammography at the specific request of a Consultant Surgeon and
- Women over the age of 35 for whom mammography is usually indicated.

WOMEN OVER THE AGE OF 35

Women over the age of 35 referred with a focal clinical mass
Women in this category should have a full imaging work up including a bilateral mammogram, a targeted breast ultra sound and if there is an imaging abnormality an image-guided biopsy (either ultra sound or x-ray). If no imaging abnormality is identified the woman should be referred back to the breast clinic for consideration of a clinical core biopsy.

Women over the age of 35 referred with breast pain
These women should have a bilateral mammogram.

Women over the age of 35 with a positive family history
These women should have a bilateral mammogram.

Women over the age of 35 who have nipple discharge (not bloody)
These women should have a bilateral mammogram.

Women over the age of 35 with bloody nipple discharge
These women should have a bilateral mammogram and an ultra sound of the retroareolar region of the relevant breast.

Women over the age of 35 with nipple changes
These women should have a bilateral mammogram and an ipsilateral breast ultra sound.

Women over the age of 35 with generalised nodularity
These women should have bilateral mammogram.

WOMEN UNDER THE AGE OF 35

Women under the age of 35 with a definite clinical lump
These women should have a targeted breast ultra sound. If there are any worrying sonographic features an ultrasound guided core biopsy should be performed so that there will be a definitive pathological diagnosis.

Women under the age of 35 with pain and tenderness
These women do not require imaging.

Women under the age of 35 with bilateral nodularity
These women do not require imaging.

Women under the age of 35 with family history
These women should not be routinely imaged. If there is a greater than ten times risk the case should be discussed with a Consultant Radiologist.

Women under the age of 35 with clear nipple discharge
These women do not require any imaging.

Women under the age of 35 with bloody nipple discharge
An ultra sound examination of retroareolar ducts of the relevant breast is appropriate.

Women under the age of 35 with thickening rather than discrete nodularity
These women do not usually require any imaging. If there is concern clinically they should be reviewed by a Consultant Surgeon and an ultra sound examination may be required.

Appendix IV

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

FSS Baile Átha Cliath & Lár-Laighin
HSE Dublin Mid-Leinster

HSE Area Office,
Arden Road,
Tullamore,
Co. Offaly.
Tel. (057) 9359787
Fax. (057) 9352663

20th November, 2007

Dr. Ann O'Doherty,
Clinical Director,
Breast Check,
Merrion Unit,
Merrion Rd.,
Dublin 4.

Review of Symptomatic Breast Radiology Services
The Midland Hospital Portlaoise, County Laois

Dear Dr O'Doherty

Thank you for your letter dated 16 November.

I confirm firstly that you should treat this letter as a formal request to issue your draft report which will include the conclusions drawn by the Review group following their review of the breast imaging service of the Midland Regional Hospital, Portlaoise.

In relation to the matters set out in your letter I am grateful to you for bringing these to our attention. I understand that your report will refer to these matters so that there is no suggestion of any conflict of interest or lack of objectivity in relation to the report to be issued in this matter. I do not believe that these matters suggest any such conflict or lack of objectivity but, for the sake of completeness and to ensure no possible argument on the matter I agree it is prudent to include reference to these matters in the report.

I will forward to you under separate cover further clarification on the extent of the proposed indemnity for consideration both in relation to you and also the other members of the review team.

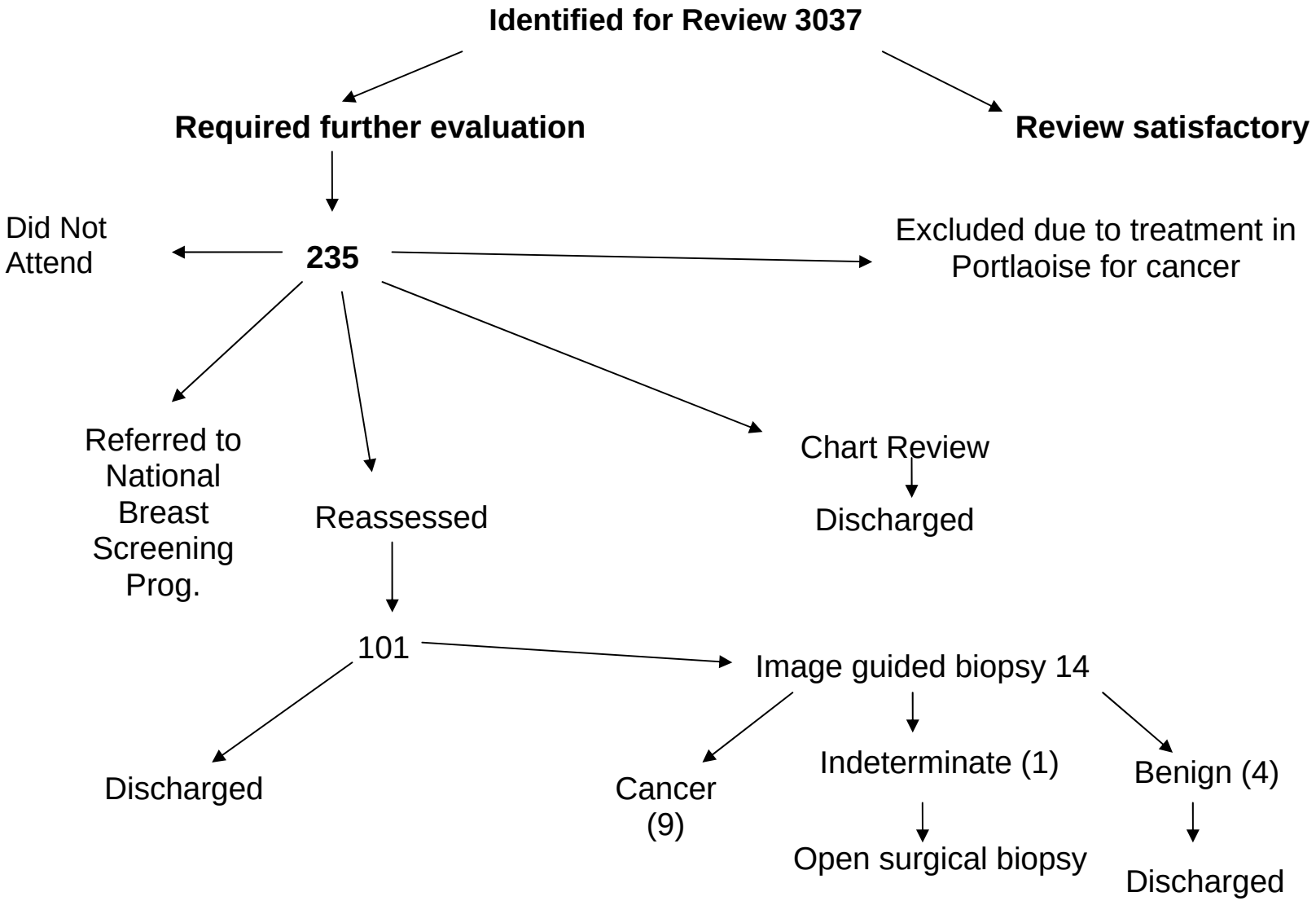
Yours sincerely,

John Bulfin
Network Manager

M-4533486-1

Appendix V

Flowchart of the results



Appendix VI Breast Imaging: a synopsis of expected best practice

This is a brief synopsis of current best practice in breast imaging clinical practice. This synopsis has been drawn from two main sources:

1. *Development of Services for Symptomatic Breast Disease*. Report of the Sub Group of the National Cancer Forum (March 2000), Department of Health and Children.

2. *European Guidelines for Breast Cancer Screening and diagnosis*. 4th Edition European Breast Cancer Network Co-ordination office, January 2006, Office for official publications of the European Communities.

Image quality

Mammography equipment should meet internationally accepted quality assurance standards and should undergo appropriate daily, weekly and monthly testing to ensure optimal image quality.

Reporting on mammograms and breast ultrasounds

Reports on breast imaging should include site, size (mm) extent and nature of abnormality together with a description of associated features and an opinion as to the most likely diagnosis. The reports should also on occasion direct clinical management – e.g., by suggesting image guided biopsy.

It goes without saying that the primary function of the Radiologist is to identify and report on abnormalities that may be malignant.

Triple assessment

Triple assessment is utilised to assess patients attending with a discrete lump, skin ulceration, distortion of the breast or nipple, or bloody nipple discharge or a suspicious mammogram. Some patients who attend symptomatic breast clinics with non urgent symptoms may not require full triple assessment.

Triple assessment involves a clinical examination by a Surgeon coupled with an imaging examination by a Radiologist which will usually include mammography and ultrasound. If an abnormality is identified either clinically or on imaging, the third component of the triple assessment is required, which is either a core biopsy or fine needle aspiration for cytology.

Image guided biopsy

The Radiologist must have sufficient expertise and experience to perform image guided procedures to achieve a high non-surgical diagnosis rate of cancer and a low open surgical excision rate of benign abnormalities.

Image guided biopsy involves a Radiologist guiding a needle into an abnormality using image guidance and taking a sample of tissue for analysis by the Pathologist. Most image guided biopsies are performed under ultrasound guidance. Some image guided biopsies are performed under x ray control. Occasionally patients with breast cancer do not have an abnormality on imaging but have other symptoms and in this situation a clinical core biopsy is performed.

Multidisciplinary team review

Patients who have had a needle biopsy should be discussed at a multidisciplinary meeting. Multidisciplinary team review involves the discussion of a patient by a Consultant Surgeon, Radiologist, Pathologist, Medical and Radiation Oncologist and Breast Care Nurses. Following the clinical examination a code S1 – S5 is assigned to each patient by the Surgeon. The Radiologist assigns codes R1 – R5 following radiological examination and the Pathologist, following examination of the pathology slides, also assigns a "B" code 1 - 5 to the examination. The codes surgical, radiological and pathological reflect the degree of abnormality.

1 = normal fatty tissue
2 = normal benign nodularity
3 = indeterminate, probably benign
4 = indeterminate, probably malignant
5 = indeterminate, has the appearances of malignancy

The purpose of the multidisciplinary meeting is to ensure that all disciplines are in agreement and therefore the outcome of the patient, whether benign or malignant, is concordant.

At the multidisciplinary meeting patients who have benign results are identified as appropriate for discharge.

Patients who have results on any one of the three sub specialty areas that do not match are then deemed to have discordant results. Patients who have discordant results require further evaluation and sometimes require surgical excision for final diagnosis.

Patients with breast cancer are discussed and an assessment is made of their optimum surgical management. Patients are identified who may require imaging insertion of a wire prior to surgery (see below). Following the surgical treatment for breast cancer a further multidisciplinary discussion should take place to ensure that the tumour has been adequately removed. At this time discussions with the Medical and Radiation Oncologist take place to optimise further management.

Pre-operative needle localisation of abnormalities

In patients who are having a diagnostic biopsy or who are having breast conserving treatment for breast cancer a wire may be required to locate an abnormality that is impalpable or difficult to palpate. The Radiologist inserts a wire to enable the Surgeon to operate on the abnormal area identified on imaging.

In addition, in patients who are having breast conserving surgery for cancer, wires may be required on either side of the cancer to enable the Surgeon to completely remove the tumour.

The Radiologist has a central role in the above outlined triple assessment, multidisciplinary meeting and image guided biopsy. It would be expected that Radiologists involved in symptomatic breast practice would be centrally involved in all of these areas.

Appendix VII

Review of Quality Assurance Documentation on the physical / technical aspect of the equipment

Documentation received:

1. Copy of notebook containing routine QC measurements in respect of the x-ray system from 2003 to present.
2. Copy of film processor QC charts from 2003 to present.
3. Copy of various mammography phantom and consistency tests performed during 2006 and 2007.
4. Copy of annual medical physics quality assurance report for May 2006.
5. Copy of x-ray unit engineers routine inspection report for May 2006.

Introduction:

Given the nature of the information and documentation available, it is difficult to provide a definitive report in respect of the technical quality of the system over the period of interest and therefore I present my findings by way of observations and comment.
A comprehensive review would necessitate a visit to the unit, inspection and quality assurance measurements of the x-ray and film processing equipment and an interview with relevant staff.

Equipment:

The x-ray equipment used was a Picker Sureview mammography system. There is no indication of the age of this machine from the documentation received but based on the availability of this model; it is probably in the region of 15 years old. Whilst equipment of this type is capable of performing adequate breast imaging, particularly if operated in an optimised, well maintained and quality assured framework, there has been at least two generations of technical development in mammography x-ray equipment since this model. A service engineering report of May 2006 suggests the unit was operating satisfactorily within specification.
There is no information in relation to the model of film processing system. There is no specific information about the films/screen utilised. There is no information in relation to age of the film processing system, whether it was a dedicated system for mammography or whether it was operating in an optimised way.
There is no information provided in relation to the x-ray film viewing equipment or conditions. Inadequate viewing conditions associated with low or non-uniform viewer light intensity, poor masking of glare and high background illumination can have a significant impact on the detection of low contrast image features in mammography.

Routine Quality Control:

There was no written protocol for quality control in the received documentation but it appears that there was a level of routine quality control performed.

These tests appear to consist of daily measurement of the consistency of x-ray exposure and film optical density. Additionally, there appears to be twice weekly sensitometry measurements of the film and processor.
A review of the results for target film density over the period 2003-2007 suggest there was considerable variability as a result of the film processing system throughout the entire period. Correlation of these results with the sensitomery charts also confirms this. There are many occasions and several prolonged periods when the system was operating with a target film density and film contrast significantly lower than would be considered acceptable according to established standards for optimal imaging and lesion detection.
There is no evidence, based on the documentation received, that the quality control results were subject to routine or periodic critical review in order to feedback to necessary interventions and adjustments to maintain consistent and optimal technical image quality.

Annual Technical Quality Assurance:

Medical Physics QA is provided by contract with an external service and reports are included for 2006 only. However, the equipment appears to have been subject to annual quality assurance visits as required in order to satisfy RPII licence conditions.
Annual Medical physics QA is adequate to satisfy regulatory requirements for radiation safety but more medical physics support would be necessary to ensure consistent and optimised image quality for mammography and support for the routine QC programme.
A significant finding was made in the 2006 report relating to a low breast glandular dose which raises concerns about the adequacy of image quality. This is likely to be related to optimisation of film processing which would be consistent also with the routine QC data but there is no evidence that this finding resulted in any appropriate intervention to optimise image quality.

Summary:

- The x-ray unit appears to have been performing in a satisfactory way and within specification. The film processing system performance appears to have been inconsistent and variable. Achieving consistency of film processing is difficult and a number of factors can inhibit it, including the use of a system which is not dedicated for mammography, low film throughput and inconsistent or sporadic use of the film processor.
- For imaging equipment of this type, ten years would be generally considered an upper limit for useful clinical lifetime and replacement.
- The overall imaging system appears not to have been adequately optimised to produce consistently high quality films.
- Additionally, there is no evidence that the x-ray film viewing conditions were optimised or satisfactory.
- While routine quality control was performed, there appears to have been inadequate feedback of outcomes to appropriate interventions. Without this feedback, there is marginal benefit in the operation of such a quality control system and this is not an uncommon failure of such systems.

Mr. Niall Phelan, Chief Physicist, National Breast Screening Programme

Appendix VIII

Declaration of interest

In my capacity as Consultant Radiologist with St. Vincents Health Care Group specialising in breast imaging I am regularly requested to give an additional opinion on cases. The request usually comes from radiology colleagues but not infrequently from surgical colleagues. In the last six months of 2006 an average of 8 such referrals a month came from the Midland Regional Hospital Portlaoise. In the first six months of 2007 approximately 5 such referrals per month came from the Midland Regional Hospital Portlaoise. Similar level of referrals are received from other hospitals.

I was a member of the appointment panel for one of the Consultant Radiologists referred to in this report.

16th November 2007.

Mr. John Bulfin,
Network Manager
Health Service Executive
Midlands Area
HSE Area Office,
Ardan Road,
Tullamore
Co. Offaly

Re: Enquiry into Radiology Services
Midland Hospital, Portlaoise, Co. Laois

Dear Mr. Bulfin,

I refer to your request to conduct a review of the breast imaging service of the Midland Regional Hospital Portlaoise and report on the findings.

At the outset, I believe that certain matters should be highlighted that have come to my attention during the preparation of this report to ensure that neither the HSE or I are compromised by any suggestion of conflict or objectivity. These matters are:-

a. I sat on the interview panel for one of the Radiologists referred to in this report. I requested notes of the deliberation and recommendations of the interview panel but have been advised that same are only available to the applicant and not to me as a member of the panel.

b. In January, 2006 Mr. Peter Naughton advised that you had authorised that patients could be referred to St. Vincent's Hospital for which I am responsible. There were an increasing number of referrals to me in 2007

c. One of the patients who is included in the nine who have breast cancer was imaged in Portlaoise and reported as abnormal in February of 2006 and was subsequently referred to St. Vincent's Hospital where it was not considered to be a malignancy. This patient due to the strong family history had a further mammogram a year later, which was called abnormal in Portlaoise but not biopsied and was eventually diagnosed with cancer as part of this review.

The other outstanding issues are:-

a. I still await the Indemnity as agreed and have been advised that same should be reviewed by my legal advisors.

b. Please confirm that the report has been prepared for the Midland area of the HSE. If it has been prepared for the HSE itself please feel at liberty to copy this letter to Dr. Mary Hynes.

Could you confirm you still wish me to furnish this report?

Yours sincerely,

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Dr. Ann O'Doherty
Clinical Director

Appendix IX

References

a) *Development of Services for Symptomatic Breast Disease*. Report of the Sub Group of the National Cancer Forum, March 2000. Department of Health and Children, Ireland.
http://www.dohc.ie/publications/pdf/symptomatic_breastdisease.pdf?direct=1

b) *European guidelines for quality assurance in breast cancer screening and diagnosis*. Fourth edition. European Breast Cancer Network Co-ordination office, January 2006, Office for official publications of the European Communities. IBSN 92-79-01258-4
http://ec.europa.eu/health/ph_projects/2002/cancer/fp_cancer_2002_ext_guid_01.pdf

c) *Developing Quality Care for Breast Services in Ireland. National Quality Assurance Standards for Symptomatic Breast Disease Services,* October 2006, Department of Health and Children, Ireland.
http://www.dohc.ie/publications/pdf/qa_standards_symptomatic_breast_disease.pdf?direct=1

d) *Review of Breast Cancer Services in Trafford and North Manchester*. Prof. Mark Baker. February 2007.
http://www.northwest.nhs.uk/document_uploads/baker/baker_report.pdf

e) *NHS Greater Glasgow and Clyde External clinical review*. Thompson and George. September 2007.
http://library.nhsgg.org.uk/mediaAssets/library/nhsggc_irh_breast_servicer_external_report_2007-10-31.pdf

f) *Report on a review of breast imaging at Altnagelvin, Belfast City Hospital and Antrim Area Hospital for the Permanent Secretary, DHSSPS Northern Ireland*. R. Wilson January 2006.
http://www.dhsspsni.gov.uk/review-brimaging-jan06.pdf

ADDENDUM

The draft report has been furnished by the HSE Dublin Mid-Leinster Region to parties identified by them as being entitled to receive same. As a result of this I have received correspondence from a number of people:

a) I have received a letter from Mr. Peter Naughton, Consultant Surgeon, Portlaoise working in the Midland Regional Hospital. This correspondence has been emphatic in showing that he consistently and repeatedly wrote to Senior Health Board Officials, Ministers for Health and the Department of Health and Children requesting an improvement in facilities and seeking specialist medical staff. My report is a clinical one and does not address what action was taken by the Authorities.

b) The Solicitors representing one of the parties has sought to highlight that in their opinion there was a lack of medical resources and specialist training in breast imaging. Whilst these comments were noted. The clinical findings identified were on the same mammograms that were initially reported in Portlaoise.

c) Two of the Consultants who were identified as having reported a very small number of cases have written to me stating that they did not read any of the mammogram's notwithstanding the fact they were attributed to them in the records as furnished to me. This represented a very small number of mammograms and there were no malignancies identified in this group.