
At

Barringtons Hospital, Limerick
September 2003 to August 2007

For

Mr. Denis Cahalane, Chief Executive Officer, Barringtons Hospital

By

Dr. Henrietta Campbell

March 2008
Acknowledgements

I would like to acknowledge all the effort, diligence, professionalism and patience of my colleagues on the review team. Their priority was that of ensuring the confidence and well-being of the patients who entrusted their medical records to our scrutiny. I would also wish to acknowledge the openness and engagement of all the staff at Barringtons Hospital.

My thanks go to all the patients who consented to this review, particularly for their patience throughout these past months. A special word of acknowledgement must go to those patients who took the time to meet with us. We were immensely touched by their courage, good humour, inner strength and graciousness. Our thoughts are with them.
Report on the Independent Review of Symptomatic Breast Care Services at Barringtons Hospital

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References
1. Executive Summary

This independent review was established by Barringtons Hospital and the Department of Health and Children following concerns which had been raised about the standard of symptomatic breast care including cancer services at the Hospital. The terms of reference for the review are included at Appendix 1.

An independent review team was established under the chairmanship of Dr Henrietta Campbell. The membership is listed at Appendix 2.

The objective was to review the medical charts, diagnostic tests and reports of all patients presenting at Barringtons Hospital with symptomatic breast disease during the period 1 September 2003 to 10 August 2007 to identify those women needing further diagnostic or therapeutic interventions. This included 8 of the 10 index cases specifically referred to in the terms of reference. Of these 10 patients, one was deceased and a further patient had never been treated at Barringtons Hospital.

Hospital records identified 331 patients falling within the remit of the review. Each patient was written to with an invitation to participate in the review of their records. Following a second letter to non responders, 285 patients consented to the review.

Following assessment of all available records, the review team concluded that, in their opinion, the diagnosis and treatment of 139 patients was entirely appropriate and there was no need for further assessment.

In a further 118 cases, it was the clinical and professional judgement of the review team that the level of clinical care was not always what they considered as appropriate. However, in none of these cases was a diagnosis of cancer missed or delayed, and in no case was a diagnosis of cancer wrongly given. Whilst it is not considered that any of these patients have come to lasting harm, the review team is of the opinion that many of these patients could have been managed differently. In some women with benign disease, operative intervention would not have been required if appropriate investigations had been undertaken prior to surgery. In other cases where cancer was
present, definitive surgery should have been undertaken as one procedure rather than in two stages.

In 26 cases it was concluded that these patients should be referred for further investigations in order to exclude the possibility of breast cancer. In most of these cases the referral was regarded as a precautionary measure.

At the time of finalising this report further investigations were satisfactory in 22 patients with no evidence of any previously missed or interval diagnosis of cancer. One patient had recently moved abroad and is being followed up satisfactorily, one patient has not taken up the offer of a referral, one patient is awaiting confirmation of investigation results and one is expected to be seen shortly at a time of her choice.

In two patients, a diagnosis of cancer was delayed for a significant period from initial presentation, potentially causing serious harm. The review team followed up these women and were content that they are now receiving appropriate treatment and did not require clinical reassessment.

In reaching these conclusions, the review team exerted its clinical and professional judgement and expertise with multidisciplinary agreement. In summarising the reasons for their conclusions on the appropriateness of care for the patients under review, the following points emerged:

- Under usage of imaging as part of diagnosis. Mammography was not used in some cases where this would normally be expected and ultrasound was not available in all cases.

- Image guided biopsy was not available. Ultrasound and x-ray guided biopsy are considered routine and neither was available at the hospital. Many patients underwent surgical excision biopsy and therapy without prior appropriate image guided biopsy. Specimen radiography was not used to assess whether impalpable breast lesions had been excised completely.

- As a result some patients may have undergone unnecessary surgery and others did not receive definitive surgery based on the results of normally expected pre-operative diagnosis.
2. Introduction

Background

Concerns were raised regarding the clinical management of 10 patients receiving care at Barringtons Hospital between September 2003 and July 2007. Barringtons Hospital was advised by the Department of Health and Children (DoHC) to cease provision of breast care services on 10 August 2007. It was then agreed by Barringtons and DoHC that an independent review should be undertaken of all symptomatic breast care services delivered at the hospital between 1 September 2003 and 10 August 2007.

Review Team

With the agreement of Minister for Health and Children, Mary Harney, TD, an independent review team was appointed to carry out the review into symptomatic breast care services at Barringtons Hospital between September 2003 and August 2007 (Appendix 1).

Indemnity and Funding for the Review

The DoHC indemnified and funded the review process. Barringtons Hospital agreed to provide local administrative assistance to ensure that the review process could proceed efficiently.

Terms of Reference

These were finally agreed at the end of October 2007 (Appendix 2).
3. Background Information on Care of Symptomatic Breast Disease

The review team reached agreement on what they would expect to see in a service to ensure that appropriate care was being delivered to women with symptomatic breast disease. This framework provided a benchmark against which to make a clinical judgement on the effectiveness of diagnosis and care from each medical record; it also provided an agreed basis on which to make a clinical judgement on the need for referral for further diagnostic or therapeutic intervention.

Modern breast care requires a multidisciplinary team (MDT), which should include surgeons, radiologists, pathologists, oncologists and breast nurses to ensure effective and safe assessment and management of patients with symptomatic breast disease.

This ensures prompt access to clinical surgical assessment, mammography and ultrasound scanning and thereafter fine needle and core biopsy. Facilities need to be in place to support patients with counselling throughout the process of investigation, diagnosis and treatment.

Breast imaging has been used routinely for screening and symptomatic breast assessment for at least 25 years. Mammography is the technique of choice for asymptomatic breast screening in women over 40 years of age. Screening is not recommended in women under this age unless they have been formally assessed to have a high genetic risk of breast cancer. A combination of mammography and breast ultrasound is used for symptomatic breast assessment. In symptomatic younger women ultrasound is the first line imaging method. Ultrasound is used in combination with mammography in the assessment of symptomatic women over the age of 35 – 40 years. All patients with significant symptoms or signs should undergo clinical assessment by a breast clinician before imaging assessment.

Mammography and ultrasound form part of what is known as the ‘triple test’ – the combination of clinical assessment and imaging with needle sampling carried out in those cases where either clinical assessment or imaging suggest a significant abnormality may be present. The triple test is applied to achieve high accuracy in
diagnosis without resort to surgery. When applied effectively the triple test will ensure that women with benign problems do not undergo unnecessary surgery for diagnosis while those with significant disease have a diagnosis made in advance of surgery allowing for informed treatment planning. This triple test has been considered the expected standard of care for symptomatic breast assessment and assessment of screen-detected abnormalities for at least 10 years.

Needle sampling of palpable breast abnormalities can be carried out either free-hand or under image guidance while impalpable abnormalities require image guided biopsy. A breast radiologist is expected to have the skills required to interpret mammography, carry out breast ultrasound and to carry out both x-ray guided and ultrasound needle sampling. Where surgery is being carried out on impalpable lesions a radiologist with skills in pre-operative localisation techniques is required. For wide local excision of impalpable breast cancer or surgery for excision of tissue containing mammographic micro calcifications the facility for specimen radiography is considered standard.

The multidisciplinary discussion is central to the effective diagnosis and treatment of breast disease and should take place prior to surgery. It is required to determine the optimum treatment plan for each patient, or to discuss those cases where investigations have been inconclusive. A consensus treatment plan should be reached for patients with cancer, or those with difficult benign disease.

No patient should undergo surgery, except under the rarest circumstances, without a precise diagnosis. Women with a benign lump should be given the option of not having surgery, as a significant proportion of these disappear spontaneously. With proper counselling, many will opt not to have surgery, though the patient will have the right to opt for surgery if they have a high level of anxiety.

With effective triple assessment, the vast majority of patients with cancer will have been given their diagnosis before proceeding to surgery. Definitive surgery will then be scheduled, with partial or total mastectomy together with appropriate axillary surgery being undertaken in a single operative procedure.
Axillary surgery is still a controversial area. Some surgeons remove only a sample of the glands (four glands being removed) and others still opt to undertake a full axillary clearance.
4. Review Process

Inclusion Criteria

Women who attended symptomatic breast care services in Barringtons Hospital between September 1 2003 and August 10 2007 were included in the review process. In line with advice by the Attorney General each patient received a letter inviting her consent into a review of her medical documentation by members of the review team.

A total of 331 patients who had attended the hospital with symptomatic breast disease within the review period were identified from theatre and outpatient records at the hospital.

Due to the necessary time taken to obtain consent, there was an inevitable delay in beginning the review of the patient records.

By 26 November 2007, 204 consents had been received. A follow up letter requesting consent again was sent to those patients who had not responded to the initial letter.

By 10 December 2007 consent had been received from 279 patients. A small number of patients subsequently consented, bringing the total number of women included in the review to 285. No further returned consents were accepted for inclusion in the review after 11 January 2008.

Review Process, Protocols and Proformas

The review team examined each patient record against standards of care which would be expected in modern breast care practice to determine whether any patient needed to be recalled for further investigations (Appendix 3). Proformas were developed to allow a systematic appraisal of the medical records of each patient, covering the clinical pathway through surgery, pathology and radiology (Appendix 4). The review of the medical records of each patient included an assessment of the clinical pathway by each
discipline, highlighted the need for further comprehensive multidisciplinary review and ultimately any recommendation to offer further clinical reassessment.

The completed proformas were classified, in the opinion of the review team, to indicate:

- Satisfactory management, no further action,
- Potentially inappropriate clinical practice, but no need for multidisciplinary patient documentation review or clinical patient reassessment,
- Inappropriate clinical practice and need for multidisciplinary patient documentation review and possible clinical reassessment and
- Recall for clinical reassessment and possibly further investigations and treatment.

Co-ordination with Concurrent Reviews

Following earlier reports of concerns regarding pathology reporting at University Hospital College Galway, 87 patients contacted Barringtons Hospital and were offered a review of their pathology specimens. Barringtons Hospital and University College Hospital Galway co operated to facilitate prompt review of these women’s pathology samples independently of this review, and pathology samples reviewed in this manner were subsequently reported as in keeping with the original diagnosis.

In the meantime, separate reviews were set up, led by the Health Information and Quality Authority (HIQA) into pathology services provided at University College Hospital Galway. These were under way at the time of this review, and some women eligible for the independent Barringtons Hospital review were also included in the HIQA pathology review. In line with the terms of reference for the Barringtons Hospital review, the review team decided to undertake an independent review of all available pathology samples of women consenting to the review.
The Faculty of Pathology nominated two of the expert pathology reviewers already working on the HIQA review to undertake the Barringtons Hospital review pathology work. This process was delayed until 26 November 2007.

The subsequent organisation of the pathology review proved complex because other reviews were taking place in parallel and/or sequentially of the same pathology material as follows:

- Quality assurance of pathology specimen and report reviews already undertaken in University College Hospital Galway at the request of Barringtons Hospital since August 2007 on behalf of and requested by women attending services at Barringtons,

- Obtaining and reviewing specimens and reports which had already been referred to the HIQA review team members and were therefore not easily accessible.

- Undertaking the review of all remaining cyto- and histopathology specimens and reports included under the terms of reference for the Barringtons Hospital review.

**Information Management**

An excel spreadsheet was developed to record patient demographic and clinical care details, track patient communication and collate review results. This was maintained by Barringtons Hospital with quality checks from the review team.

**Communication with Patients included in the Review**

All patients who had consented to be included in the review received personalised letters appropriate to the findings of the independent review team in their individual case, offering an opportunity to discuss findings further, either on the telephone or in person. This process commenced in early February 2008 as soon as the results from all aspects of the review had been collated.
Women who needed to be referred for further clinical assessment were advised of this in person by telephone in late December 2007 due to the short time frame between availability of review findings and provision of review appointments in University College Hospital Cork. Women were offered appointments over the following month.

A summary report was offered to women undergoing further clinical assessment. Those women where concerns about adequacy of care had originally led to the review being undertaken were offered the opportunity to meet with members of the independent review team to discuss their findings. Six women accepted this invitation.
5. Review Results

Patient Access to Symptomatic Breast Care Services at Barringtons Hospital

Patients accessed breast care services at Barringtons Hospital as follows:

- Direct self referral to the hospital either for screening or for symptomatic breast care,
- Referral by another medical practitioner, usually a General Practitioner (GP), for investigation of symptomatic breast disease and
- Referral for breast screening imaging services by a GP (this practice ended in August 2006).

Breast Care Services at Barringtons Hospital

Symptomatic breast care services had been provided in Barringtons Hospital since 1991. Mammography equipment was installed in November 2003.

There was no multidisciplinary team approach in existence at the hospital and therefore no opportunity for triple assessment in the context of multidisciplinary meetings.

Due to limited secretarial support, communication with GPs mostly took place via photocopied surgical outpatient, theatre and pathology reports. GPs therefore received very limited information in formats not easily accessible or understood by non specialist medical practitioners.

Oncology services are not available at Barringtons Hospital, but are accessible on referral of patients to Limerick General Hospital. There was prompt and consistent referral of women with breast cancer to these off-site oncological services.
Imaging

A breast imaging service was introduced at Barringtons Hospital in November 2003. Initially both mammography and breast ultrasound were offered. Breast ultrasound was withdrawn in 2004 as the ultrasound equipment was not considered to be suitable for breast imaging. The equipment used for mammography was to the highest standard and reading facilities were satisfactory. The quality of mammography imaging during the period of the mammography review is assessed as being to a high standard.

Contrary to this, there was no engagement of the consultant radiologist in multidisciplinary assessment or in systematic continuous professional development.

Prior to July 2006 mammography referrals were accepted for patients with symptomatic breast disease from general practitioners and from clinicians at the Hospital. There was no formal written breast imaging protocol. Reports on mammograms performed on both symptomatic and screening referrals were sent to GPs and hospital clinicians with recommendation for ultrasound or further referral where considered appropriate. There was no mechanism to follow up whether recommended actions had been carried out. Breast ultrasound service was provided independently at another private imaging facility, but there was neither image-guided breast biopsy (mammographic or ultrasound guided) nor pre-operative localisation procedures. There was a lack of coordination and correlation of breast imaging done for individual women at various sites.

Following the appointment of a new senior radiographer in July 2006 more formal mechanisms for accepting and recording mammography referrals were introduced. Referrals from GPs were restricted to asymptomatic screening only and a lower age limit of 40 years introduced for screening. Referral clinical details were recorded and the radiographer completed a patient questionnaire prior to imaging. GPs making symptomatic referrals were contacted and referral for initial clinical assessment recommended. Mammography was not performed in symptomatic women under the age of 35 after July 2006. The referral details, questionnaires and reports for
mammograms have been kept on file. The digital mammograms are kept on CD and are available for all examinations back to November 2003.

Reports were produced and stored electronically and printed for filing or at patients’ and clinicians’ request.

**Surgery**

There were no waiting lists at Barringtons Hospital and the atmosphere was pleasant.

Patients were assessed in Barringtons Hospital and investigated either on the day of first appointment, depending on availability of practitioners and services in the required discipline like radiography, urgency of the case and patient preference, or at a later date, sometimes on the day of surgery.

The review of medical notes was complicated by inadequate surgical note keeping and documentation of decision making processes.

Preoperative investigations were frequently found to be inconclusive or incomplete, leading to some patients undergoing surgery without clear indication. This over reliance on surgery can be attributed to preference of the surgeon at the hospital but also in some instances to patient choice, leading to the excision of breast lumps which may not have required removal and therefore exposing some women unnecessarily to the risks of an operative procedure. In women with breast cancer, the lack of comprehensive preoperative assessment often led to the need for two stage surgery where otherwise all necessary surgery may have been undertaken in a single procedure. Frequently an initial lumpectomy was followed after a four week period by further breast tissue excision and/or axillary clearance.

Even in benign disease the predominant surgical technique practiced appeared to be that of wide excision. There also seemed to be an unconventional approach to axillary surgery with number of excised lymph nodes often too large for diagnostic and at other times too small for clearance.
Intra operative anaesthesia was given intravenously in combination with local anaesthetic. Surgery did not always take place as a day case and complex surgery was more often done on an inpatient basis. Occasionally women left the hospital with drains in situ. This is in keeping with modern practice.

Pathology specimens obtained surgically were often divided in several pieces and not consistently marked with sutures to allow accurate pathological examination of the microscopic extent of the breast disease process.

There was no facility for x-ray of specimens obtained during surgery. Therefore, the localisation of abnormal areas of breast tissue such as micro calcifications and an assessment of whether surgery had accurately removed these areas of concern was not possible intraoperatively or immediately postoperatively.

Postoperative care was provided directly by the surgeon in the absence of a specialised breast care nurse or domiciliary care team. All patients were advised on discharge to telephone the hospital immediately with any concerns during their recovery.

**Pathology**

Pathology services were provided externally by University College Hospital Galway and since May 2007 also by Bon Secours Hospital Cork.

Delays in receiving pathology reports processed externally in University College Hospital Galway extended to several weeks on many occasions.

**Outcomes for Women consenting to the Review**

**Imaging**

A total of 148 patients’ mammograms were reviewed.
• In 117 cases the mammogram request was reasonable and the mammograms report satisfactory.

• In 31 cases initial review suggested that there may have been inappropriate referral or inappropriate clinic management following imaging or a reporting error.
  - Following multidisciplinary review 20 of these were considered satisfactory, giving a total of 137 women with satisfactory imaging.
  - The remaining 11 were judged to have received inappropriate levels of care.
    - In one of these cases, imaging findings had been incorrectly reported at the time of initial assessment and further investigations had not been initiated by the referring GP as recommended. This woman was diagnosed with breast cancer a year later.
    - In another case the imaging findings, not reported at the time, were sufficient to recommend urgent reassessment. After multidisciplinary discussion, it emerged that this woman had in fact undergone further investigations elsewhere and did not need to be recalled as a result of the independent review findings.
    - 9 women were deemed to have received inappropriate imaging, but were not considered as having come to material harm in terms of diagnosis and long term management.

**Figure 1** Imaging Review Results
Pathology

The overall standard of cytology and histology reporting carried out at University College Hospital Galway for the Barringtons Hospital Breast Care Service was found to be acceptable, but results were not analysed in the context of multidisciplinary care and investigations. Consultation with external colleagues was appropriate with one case being sent to the United States for a second opinion.

Pathology samples of 234 women were independently reviewed. There were no new major discrepant findings on review of either cytology or histology cases at University College Hospital Galway. In other words, no benign diagnosis was changed to malignant and no malignant diagnosis changed to benign as a result of this independent review. A small number of discrepancies were identified but this is considered to be consistent with any review process.

Cytopathology
Review of pathology samples from fine needle aspirates identified the following:

- Minor discrepancies were identified in samples from three women.
- 19 cytology cases required clinical correlation in discussion with other members of the multidisciplinary independent review team. In many of these cases the original pathology reporting had used the terminology for classification of cytopathology inconsistently and sometimes inappropriately. Following discussion, the review team concluded that none of these patients required to be reviewed for pathology reasons, but seven of them were identified for clinical reassessment through the imaging and surgical review.

Histopathology
Pathology samples including core needle biopsies, diagnostic open breast biopsies, wide local excisions and mastectomies were reviewed. The macroscopic descriptions and sampling of large specimens particularly cancer specimens was appropriate. Sampling of tissue was appropriate. Microscopic reporting was appropriate and
detailed particularly in cancer specimens and all the parameters required for staging patients were present.

- There was one major discrepant diagnosis, which had already been identified by the surgeon at Barringtons and led to the HIQA review at University College Hospital Galway. A multidisciplinary meeting where the discrepancy between pathology and radiology findings would have become apparent would likely have led to a review of the initial pathological misdiagnosis and the correct diagnosis made.

A small number of cytology and histology samples, which form part of the separate HIQA reviews, had not been made available for Barringtons Hospital pathology review, however it is noted that the HIQA reviews have robust procedures in place for the follow up of patients in whom discrepant diagnoses are identified on pathology review.

Figure 2 Pathology Review Results

Review of Medical Records

All 285 consented patients’ clinical records were surgically reviewed. This provided the basis of the summary findings for all women included in the review below:
• 139 patients were found to have been investigated and treated satisfactorily.

• 118 patients were considered to have received inappropriate care, but were not considered as having come to material harm in terms of diagnosis and long term management. While these patients did not require to be recalled for reassessment, the review team concluded that their care did not meet the standards which would have been considered as acceptable at their time of treatment.

• 2 patients had their diagnosis of cancer delayed for a significant period. These delays were avoidable and may potentially have caused harm.

• 26 further patients’ medical records contained insufficient information to allow the review team to determine whether or not a recall was needed. These cases were followed up through enquiries to GPs regarding other follow up arrangements such as repeat mammography. Four of these women had been referred into the public sector for follow up. On further enquiry, these women were on a waiting list for public services extending to two years and the decision was taken to invite them for early review at Cork University Hospital. One further patient had moved abroad and reassured the review team that she was being followed up in a specialist breast care clinic.

  o In summary, 26 women were identified by the review team as requiring recall and clinical reassessment to exclude significant breast disease. Of these, 1 woman had moved abroad and was being appropriately followed up, 4 women were awaiting follow up in the public sector but, due to the length of time they were being expected to wait, the review team took the clinical decision that they should be fast-tracked for reassessment.
Figure 3  Medical Records Review Results

MEDICAL RECORDS REVIEW

285 women with consent

285 women with records for review

139 women with satisfactory care on records review

120 women with inappropriate care on records review

26 women for multidisciplinary review

26 women for reassessment

END
6. Reassessment Process

Arrangements to offer services to patients identified by the review process as needing clinical reassessment were put in place by 18 December 2007. Patients requiring recall were contacted by phone prior to the Christmas holiday period and offered appointments in University College Hospital Cork. Many of the patients were seen between 19 December and the end of January. One woman did not accept the invitation for reassessment.

The four women also initially identified for recall and found to be awaiting symptomatic breast care services on public waiting lists were referred for triple assessment in University College Hospital Cork in February 2008. The review team was of the opinion that the length of time they were required to wait for review was clinically unacceptable and that they should be fast-tracked for review.
7. Reassessment Results

At the time of writing this report, of the 24 women who accepted the invitation to be reassessed, 22 women have already been fully and appropriately investigated and no new cases of cancer have been found. One woman is awaiting the result of one aspect of her follow up investigations. One woman has chosen to schedule her appointment later in the next month.

Figure 4    Reassessment Results
8. Conclusions

Appropriate standards of breast cancer care are based upon multidisciplinary team work. A multidisciplinary approach requires an environment where specialised breast surgeons and breast radiologists work in conjunction with breast pathologists to undertake and discuss comprehensive pre-, intra- and postoperative investigations, diagnostic procedures, treatment and follow up. The mainstay of the accurate diagnosis of breast cancer is based upon triple assessment, which includes clinical examination, imaging (mammography and ultrasound), and biopsy.

To maintain excellence in the treatment and care of breast cancer patients it is now recognised that there needs to be a sufficient throughput of patients and effective clinical governance arrangements. This inevitably demands an increased centralisation of breast cancer care. These basic principles are recognised in the strategic approach to the future delivery of cancer services throughout Ireland as set out in the Strategy for Cancer Control in Ireland.

 Whilst there is a clear direction for the delivery of breast cancer services in Ireland, this review of breast cancer treatment at Barringtons Hospital needs to be seen in the context of cancer care as it prevailed throughout Ireland during the period 2003 to 2007.

 Of 331 patients who were invited to consent to the review of their records, 285 patients gave their consent. The review team conducted a thorough review of all available records. A small number of cytology and histology samples from women who are also included in separate HIQA reviews had not been made available for the Barringtons Hospital pathology review.

 The review team concluded that in only two patients was there a significant and avoidable delay in the diagnosis of cancer, and that this delay may potentially have caused harm.

 The review team was further of the view that the diagnosis and treatment of 139 patients was entirely satisfactory.
In the remainder of patients, the independent review team concluded that there were indications of inappropriate care. It must be emphasised that the review team is of the opinion that no lasting harm will have been caused in the vast majority of these patients. Many of the shortcomings were due to the lack of a multi-disciplinary team approach, the absence of on-site pathology expertise and the non-availability of essential diagnostic capability such as image-guided biopsy.

In a number of patients the lack of effective triple assessment prior to surgery may have led to unnecessary surgical intervention, with its associated risks. In other patients with cancer two surgical procedures were undertaken where, with triple assessment prior to surgery, one definitive intervention could have been undertaken.

Of 26 women who were identified through the independent review for clinical reassessment, one has not accepted the invitation for reassessment, one has moved abroad and is being appropriately followed up, and one has chosen to be reassessed later in April. Of the 23 already assessed, laboratory results are expected imminently on one woman. In the 22 women where investigations are complete, no new cases of cancer have been found.

The independent review process did not lead to the identification of any missed diagnoses of breast cancer, but it did find evidence of inappropriate clinical care in more than half of the women who had consented to have their records reviewed.
Appendix 1

Terms of Reference for review of patients’ files who presented to Barringtons Hospital and Medical Centre in the period 1 September 2003 to 10 August 2007 with symptomatic breast disease

The Review Team to:-

1. Conduct a review of the medical charts, diagnostic tests and diagnostic reports of women seen at Barringtons Hospital for the investigation, diagnosis and/or treatment of symptomatic breast disease during the period September 2003 to 10 August, 2007 in order to identify and prioritise which, if any, of these women may need further diagnostic or therapeutic interventions. Consent must be obtained from all women whose files will be reviewed.

2. Without prejudice to paragraph 1, the review team may offer to arrange clinical assessment and/or diagnostic investigations for a woman in order to assist in determining whether that woman may need further diagnostic or therapeutic interventions.

3. In the case of any women identified as needing further diagnostic or therapeutic interventions, the Hospital to make this information available to the women concerned and/or their GPs and to use it to facilitate the rapid provision of any service that such women need through a facility of their choice, be this in the public or the private sector.

4. Provide an interim report by 31 October, 2007 and complete the review by 30 November, 2007. In the event that the review team forms a view that it will not be possible to complete the task at paragraph 1 by the 30 November, 2007, it will report this immediately on forming that view to the Hospital and to the Minister.

5. Present a draft report on completion of the review to Barringtons Hospital, and to any doctor whose professional reputation may be affected by its contents, for their views. Provide the final report to the Hospital and to the Minister. The report to the Minister will be anonymised.

6. Report immediately to the Hospital and to the Minister in the event of the withholding or withdrawal of co-operation from the review team by any person (other than a patient).

7. Include the 10 patients, subject to their consent, identified by Professor Gupta and referred to in the correspondence from the Health Information and Quality Authority to the Chief Medical Officer of the Department and Children, in this review.
Appendix 2

Membership of Review Team

Dr Henrietta Campbell (Chair),

Dr Robin Wilson, Radiologist, University College, London, United Kingdom,

Prof Roy Spence, Breast Surgeon, Belfast City Hospital, Northern Ireland,

Dr Christine McMaster, Specialist Registrar in Public Health Medicine, Eastern Health and Social Services Board, Northern Ireland,

Dr Conor O'Keane, Consultant Pathologist, Mater Hospital, Dublin, Ireland (joined 26 November 2007),

Dr Tom Crotty, Consultant Pathologist, St Vincent’s Hospital, Dublin, Ireland (joined 26 November 2007).
Appendix 3a

Review Process (Section A)

Process for Chart Review (Section A)

1. Patient attending Barringtons Hospital for Breast Care
   01/09/2003 - 10/08/2007

2. Symptomatic Breast Disease?
   - NO
   - YES

3. Enter patient details on database
   Collate patient notes / imaging
   Advise patient using Letter of Consent A

4. Patient consent received within 14 days?
   - NO
   - YES

5. Patient consent refused?
   - NO
   - YES

6. Trace patient
   Request consent again using Letter B
   Attach Chart/Imaging/Pathology Review Proforma
   Enter Consent Given on database
   Green Sticker
   Review completed
   No Multidisciplinary Patient Documentation Review required
   Enter Chart/Imaging/Pathology Review on database
   Advise patient using Letter D
   Copy Chart/Imaging/Pathology Review Proforma for Review Team records
   Insert proformas in patient notes
   Return notes and images

7. Unable to contact patient?
   - NO
   - YES

8. Red Sticker
   Patient Reassessment required
   Enter Chart/Imaging/Pathology Review on database
   Advise patient using Letter F
   Proceed to Multidisciplinary Patient Documentation Review
   (Section B)
   Proceed to Patient Reassessment

9. Blue Sticker
   Clinical Practice Concern, but no patient documentation review or reassessment required
   Enter Chart/Imaging/Pathology Review on database
   Advise patient using Letter E
   Copy Chart/Imaging/Pathology Review Proforma for Review Team records
   Insert proformas in patient notes
   Return notes and images

END
Appendix 3b

Multidisciplinary Patient Documentation Review Process (Section B)

Process for Multidisciplinary Patient Documentation Review (Section B)

Retain notes and imaging
Attach *Multidisciplinary Patient Documentation Review Proforma*

Review Team carry out *Multidisciplinary Patient Documentation Review* and produce *Review Report*

**Green/ Blue Sticker**
Review completed
Advise patient using *Letter D/ E*
Enter details on database

**Red Sticker**
Patient Reassessment required
Advise patient using *Letter F*
Enter details on database

**Copy Multidisciplinary Patient Documentation Review Report** for Review Team records
Insert proforma and report into patient notes

**Copy Multidisciplinary Patient Review Report** for Review Team records
Insert proforma and report in patient notes
Retain notes and imaging for reassessment

Patient requests report?

NO

YES

Send patient copy of report with cover *Letter G*
Enter on database
Return notes and imaging

Enter into *Reassessment Arrangements*

END
Appendix 4a

Barringtons Hospital Imaging Review Proforma

Patient Name:       DOB: 
Clinical information:     DOD: 

<table>
<thead>
<tr>
<th>Mammography</th>
<th>No □</th>
<th>Yes □</th>
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<td>Request reasonable:</td>
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Report:    Satisfactory □ Not satisfactory □

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<td>Request reasonable:</td>
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<td>Yes □</td>
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Is MULTIDISCIPLINARY PATIENT DOCUMENTATION REVIEW required?    Y □ N □  
Comment:_____________________________________________________________

Is PATIENT REASSESSMENT required?      Y □ N □  
Comment:_____________________________________________________________

Reviewer name:_______________Signature:________________Date:_______________
**ADMINISTRATION**

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<tr>
<td>Blue Sticker</td>
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- **Database updated**: [Y] Signature/Date: __________________________
- **Chart review completed**: [Y] Signature/Date: __________________________
- **Pathology review completed**: [Y] Signature/Date: __________________________
- **Patient letter sent**: [Y] Signature/Date: __________________________
Appendix 4b

BARRINGTONS HOSPITAL CHART REVIEW PROFORMA

Patient Name:      DOB:
Clinical presentation:      DOD:

INVESTIGATION

Was breast imaging carried out appropriately?   Y □  N □  N/A □
Comment: ________________________________________________________

Was percutaneous needle sampling carried out appropriately?  Y □  N □  N/A □
Comment: ________________________________________________________

Was follow up appropriate?  Y □  N □  N/A □
Comment: ________________________________________________________

In summary, were investigations satisfactory?   Y □  N □  N/A □
Comment: ________________________________________________________

SURGICAL TREATMENT

Was surgery carried out appropriately?  Y □  N □  N/A □
Was axillary surgery carried out appropriately?  Y □  N □  N/A □
Comment: ________________________________________________________

Were specimens orientated to allow assessment of margins?  Y □  N □  N/A □
Were margins assessed?  Y □  N □  N/A □
Were pathology results acted on appropriately?  Y □  N □  N/A □
Comment: ________________________________________________________

In summary, was treatment satisfactory?   Y □  N □  N/A □
Comment: ________________________________________________________
### ONCOLOGICAL MANAGEMENT AND FOLLOW UP

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<th>Question</th>
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<td>Were follow up arrangements appropriate?</td>
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<tr>
<td>Was referral for oncology assessment made appropriately?</td>
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<tr>
<td>Is the quality of note keeping adequate?</td>
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**In summary, was oncological and follow up care appropriate?**

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**Comment:**

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### Is MULTIDISCIPLINARY PATIENT DOCUMENTATION REVIEW required?

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**Comment:**

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### Is Patient Reassessment required?

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**Comment:**

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### ADMINISTRATION

- **Green Sticker**: Chart Review completed
- **Red Sticker**: Patient Reassessment required
- **Amber Sticker**: Multidisciplinary Patient Documentation Review required
- **Blue Sticker**: Clinical Practice Review required

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<th>Task</th>
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<tbody>
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<tr>
<td>Patient letter sent</td>
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**Signature/ Date:**

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References

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