



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte

Report of the investigation into the circumstances surrounding the provision of care to Rebecca O'Malley, in relation to her symptomatic breast disease, the Pathology Services at Cork University Hospital and Symptomatic Breast Disease Services at the Mid Western Regional Hospital, Limerick.

21st March 2008

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# About the Health Information and Quality Authority

The Health Information and Quality Authority is the independent Authority which has been established to drive continuous improvement in Ireland's health and social care services. The Authority was established as part of the Government's overall Health Service Reform Programme.

The Authority's mandate extends across the quality and safety of the public, private (within our social care function) and voluntary sectors. Reporting directly to the Minister for Health and Children, the Health Information and Quality Authority has statutory responsibility for:

- **Setting Standards for Health and Social Services** - *Developing the quality and safety standards, based on evidence and best international practice, for health and social care services in Ireland (except mental health services).*
- **Monitoring Healthcare Quality** - *Monitoring standards of quality and safety in our health services, implementing continuous quality assurance programmes and accrediting service providers towards excellence.*
- **Health Technology Assessment** - *Ensuring the best outcome for the service user by evaluating the clinical and economic effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.*
- **Health Information** - *Advising on the collection and sharing of information across the services, evaluating information and publishing information about the delivery and performance of Ireland's health and social care services.*
- **Social Services Inspectorate** - *Registration and inspection of residential homes for children, older people and people with disabilities. Monitoring day and pre-school facilities and children's detention centres; inspecting foster care services.*

# 1 Executive Summary

## 1.1 Background

This report outlines the findings of an investigation into the care received by Rebecca O'Malley following her presentation to the Mid Western Regional Hospital (MWRH) Limerick in 2005 with symptomatic breast disease. It also includes her pathway following re-presentation to the MWRH and subsequent diagnosis of breast cancer and treatment in 2006 and 2007.

As a result of the concerns raised by Rebecca O'Malley, in May 2007 the Health Service Executive (HSE) requested the Health Information and Quality Authority (the Authority) to consider undertaking an investigation. Subsequently, the Board of the Authority decided to instigate an investigation under Section 9(1) of the Health Act 2007. The scope of the investigation was to consider all aspects of Rebecca O'Malley's care. This incorporated the symptomatic breast disease service at the MWRH and the pathology service as it related to breast disease at Cork University Hospital (CUH). As permitted by the terms of reference certain other aspects of pathology services of CUH were also considered. CUH was included because the missed diagnosis of cancer arose from an error made in the interpretation of her breast cytology in the pathology laboratory at CUH.

An additional significant concern to Rebecca O'Malley was the delay in communication by the HSE and its directly managed hospitals (MWRH and CUH) with her during 2006 and 2007. Rebecca O'Malley felt this failure of communication was most evident following her discovery that an initial error had been made and her wish to understand how and why this had happened.

The Authority's investigation entailed a review of documentation including relevant strategic plans, policies and procedures and evaluations at the MWRH and CUH and correspondence relevant to Rebecca O'Malley's experience. It also involved site visits and interviews with clinical and non-clinical staff, Rebecca O'Malley, her husband and a lady identified by the investigation team and referred to in this report as Ms X. It carried out reviews of patient records, imaging material and pathological specimens.

During the course of this investigation, key themes consistently emerged from all these methods that support the findings of this report. The investigation team recognises that there may be materials that it was not possible to review and that some individuals will place a different interpretation on the events under investigation, particularly those discussed at interview. It is satisfied, however, that it has tried to present a fair, balanced, objective and accurate account of the circumstances surrounding the care of Rebecca O'Malley, in line with the investigation's terms of reference.

The investigation also included a review of the anonymised files of 24 patients who had been identified by the MWRH as having followed a similar pathway of care around the same period as Rebecca O'Malley. These latter case reviews included images and pathology specimens.

An extensive review was undertaken of the work of Consultant Pathologist A who was employed at CUH and who made the initial interpretive error. This review included all breast cytology and histopathology specimens reported by Consultant Pathologist A during their period of employment at CUH (see section 6.3, page 36).

Following these clinical and pathology reviews, two further audits were undertaken:

1. All breast cytopathology for the year 2005 reported at CUH by consultants with cytopathology subspecialty
2. All non-breast diagnostic cytopathology reported by Consultant Pathologist A during their entire employment period, July 2004 to August 2005

## 1.2 Findings

The main findings of the investigation team are outlined below.

### Rebecca O'Malley's Diagnosis

*In Rebecca O'Malley's case there was an error in diagnosis made by Consultant Pathologist A at CUH. This in itself may not have led to a delay in treatment for Rebecca O'Malley, had a fully functioning multi-disciplinary team meeting to discuss her case taken place.*

According to best practice, the assessment of patients with symptomatic breast disease involves triple assessment which includes: clinical examination; radiological imaging with mammography, plus or minus ultrasound; and pathological assessment using either fine needle aspiration (FNA) cytology or core biopsy. The results of all three assessments should be reviewed and discussed at a multi-disciplinary team meeting. At this meeting the surgeon, radiologist and pathologist who have carried out the review in preparation for the meeting should be present. Following this review and discussion of relevant findings, a management plan should be agreed for each patient that is dependent on the results of the triple assessment. In particular, where there is discordance between any of the triple assessment<sup>1</sup> results, further diagnostic evaluation tests ought to be carried out.

This was not the case for patients with symptomatic breast disease who presented to the MWRH and who had their cytopathology reported at CUH, including Rebecca O'Malley. The cytopathology specimen was not reviewed in preparation for the multi-disciplinary team meeting and no arrangements were made for the pathologist who had reported or reviewed the slides, or a different pathologist, to be present at that meeting. Consequently, a potential opportunity to correct the interpretative error was missed.

Consultant Pathologist A identified fibroadenoma, a benign condition. However, there was no imaging or clinical evidence to suggest a fibroadenoma and therefore this was a discordant element. This was not identified at the team meeting and consequently appropriate further diagnostic evaluation was not performed, resulting in another missed opportunity to correct the interpretative error.

<sup>1</sup> O'Higgins N. *Development of services for symptomatic breast disease. Report of the sub-group to the national forum. Dublin: Department of Health and Children; 2000.*

The lack of cytopathology review and the failure to identify and therefore investigate the discordant triple assessment, both contributed to the misdiagnosis and delay in diagnosis of Rebecca O'Malley's case.

## Pathology Review

The entire breast workload of Consultant Pathologist A from July 2004 to August 2005 was reviewed.

*The team found that Consultant Pathologist A had made one mistake resulting in the misdiagnosis of Rebecca O'Malley. There was no evidence identified of a wider concern about their practice.*

It is important to note that a small number of such interpretative errors is a recognised feature of histopathology and cytopathology and hence the need for triple assessment for patient management. The practice of triple assessment is a mechanism for reducing the risk of an error occurring but does not totally eradicate this risk.

The audit of breast cytopathology reported by all consultants reporting cytopathology at CUH for the year 2005 showed an overall non-diagnostic rate of 54%, this figure increasing to 75% when cysts were excluded. Of these, cancers accounted for only 0.4%. The acceptable range is between 10 and 25%.<sup>2</sup> The figures are similar for FNA specimens from both the MWRH and CUH. This audit highlights two areas of concern: first, the high non-diagnostic rate and second, the low number of cancers diagnosed using this diagnostic technique.

The poor quality of FNA cytology specimens relates to the technique of clinicians, for example surgeons, obtaining the samples when inserting a needle into a lump, as well as the technical process of slide preparation. The low number of cancers diagnosed relates to the practice of selectively using FNA breast cytology for lesions clinically thought to be benign and performing core biopsies for clinically suspicious lesions. This practice is not recommended as the cytopathologists will not be reviewing the entire spectrum of breast cytopathology.

Clear recommendations are made in this report about the use of FNA as a diagnostic technique and the absolute requirement for quality assurance of the service.

The audit of non-breast diagnostic cytopathology reported by Consultant Pathologist A showed the expected reporting profiles for all systems.

## Case Reviews and Ms X

The case reviews of the 24 patients who had followed a similar pathway of care to Rebecca O'Malley identified seven patients requiring precautionary follow-up of ultrasound imaging. This was recommended by the Authority to the MWRH, on the advice of the investigation team.

<sup>2</sup> Cytology Subgroup of the National Coordinating Committee for Breast Screening Pathology. *Guidelines for cytology procedures and reporting in breast cancer screening. Sheffield: NHS Breast Screening Programme (BSP); 1997.*

Ms X was a patient within this group of seven patients and the expert cytology team reviewed her cytology sample. The team agreed with the original slide diagnosis that no malignancy was present. However, during the period of the investigation Ms X re-presented to Consultant Surgeon A and was diagnosed with breast cancer.

As a result of further enquiry into Ms X's experience, which included delays and instances of poor communication, the investigation team concluded that these were a further indication of the requirement for systems and processes to be focused more clearly on the needs of patients.

## **Leadership, Governance, Communication and Management**

Effective leadership is critically important in any enterprise. This is especially so in healthcare organisations where there is a duty of care to vulnerable patients and their families. From the interviews conducted, the investigation team did not find sufficient evidence of a sense of common purpose, particularly between senior management and clinical staff. Nor was the team satisfied that there was robust evidence of coherence across systems and processes or clarity of accountability for achieving this.

The term governance is used to describe the overarching framework which should be in place to provide the necessary assurance to those charged with responsibility for delivering safe services. The investigation team found that formal risk management policies were not being effectively implemented and that the management of risk was not fully embedded or consistently applied across both organisations.

The team also found significant shortcomings in the system of communication within and between the MWRH, CUH and the corporate HSE. These failings undoubtedly led to a disjointed and delayed response to Rebecca O'Malley's concerns. The team also consider them a symptom of systemic problems arising from under-developed and ineffective management systems within these hospitals.

The core purpose of management in a healthcare organisation is to facilitate, through an appropriate balance of clinical and management staff, the delivery of safe, high quality, responsive services, whilst ensuring effective use of resources. This requires the ability to achieve informed consensus about difficult choices and priorities. It can only be achieved with effective team work between clinicians, managers and administrative staff.

The investigation team recognised that there was a dedicated and hard working clinical and non-clinical workforce in both hospitals. A consistent theme from the interviews was that the availability of key resources presented significant challenges. Furthermore, it was apparent that many of those interviewed identified that there were shortcomings in leadership, governance including risk management, communications and management.



## 1.3 Conclusion

In conclusion, a single error was made by the Consultant Pathologist A. The clinical systems in place within and between CUH and the MWRH at the time did not detect this error and, as a consequence, a further delay took place prior to her diagnosis of breast cancer being made.

The management of Rebecca O'Malley's concerns about the accuracy of her original diagnosis was hampered by there being no effective system wide approach initiated involving both clinical and managerial staff and no single nominated lead to manage the response.

A series of recommendations are made as a result of these findings. The majority of these recommendations are linked to standards in the National Quality Assurance Standards for Symptomatic Breast Disease Services, 2007<sup>3</sup>. The investigation team recognises these standards were not in place at the time covered by the investigation. However in 2000 the 'Development of Services for Symptomatic Breast Disease,' report had been published and should have been the basis of planning.<sup>1</sup>

The investigation team would like to thank Rebecca O'Malley for the courageous and clear way in which she has told her story. The team would also like to thank Ms X for recounting her story at a particularly difficult time. Finally the team would like to thank the many clinicians, managers and administrative staff who participated so openly and cooperatively in this investigation.

1 *O'Higgins N. Development of services for symptomatic breast disease. Report of the sub-group to the national forum. Dublin: Department of Health and Children; 2000.*

3 *Health Information and Quality Authority. National quality assurance standards for symptomatic breast disease services: developing quality care for breast services in Ireland. Dublin: Health Information and Quality Authority; 2007.*

## 2 Summary of Recommendations

### Recommendation 1

A pathologist, together with a surgeon and a radiologist, all of whom should have a specific interest in breast disease, must always be present at a multi-disciplinary team meeting of triple assessment clinics. A discordant set of triple assessment results should trigger further discussion within the clinical team into the cause of such discordance.

### Recommendation 2

Any patient who has a suspected delayed diagnosis of breast cancer should have immediate recourse to a multi-disciplinary team assessment with a formal response from a lead clinician. A delayed diagnosis should trigger a formal incident response including an internal root cause analysis, and the relevant senior management should be notified. The patient should be informed of the findings and outcome as a priority.

### Recommendation 3

The HSE should urgently review the formal communications processes, policies and procedures which its hospitals uses to respond to patients when there is a serious incident, including communications within and between its hospitals.

### Recommendation 4

Appropriate psychosocial support should be available to patients and their families at any stage during care for symptomatic breast diseases as recommended in the National Quality Assurance Standards for Symptomatic Breast Disease Services.<sup>3 (p.56)</sup>

### Recommendation 5

When breast tissue sampling is required, a core biopsy should be performed under imaging guidance to ensure optimal targeting, for all women with radiological abnormalities. Breast fine needle aspiration cytology should only be used when quality-assured with on-site cytopathology expertise.

3 Health Information and Quality Authority. *National quality assurance standards for symptomatic breast disease services: developing quality care for breast services in Ireland*. Dublin: Health Information and Quality Authority; 2007.

## Recommendation 6

To ensure the effective management and review of patients, a functioning multi-disciplinary team meeting must be held at least weekly, as part of the normal working day. One representative from surgery, radiology and pathology must be available with patient information, including imaging, pathology and copies of relevant clinical reports.<sup>3</sup> (pp15-16)

## Recommendation 7

Breast fine needle aspiration cytology must be quality assured. This should include:

- *Units using breast fine needle aspiration as a diagnostic modality must audit the service and achieve the minimum standards set by the United Kingdom NHS Breast Screening Programme (BSP). Audit should calculate sensitivity, specificity, positive predictive value of C5, false negative rate, false positive rate, inadequate rate, inadequate rate from cancers and suspicious rates<sup>2</sup>*
- *Any units not achieving the minimum standards should introduce initiatives to improve the diagnostic performance of the technique. If the minimum standards are not achieved, fine needle aspiration should not be used as a diagnostic modality*
- *Reports must be clear and unambiguous and use the C1–C5 classification system<sup>2</sup>*
- *Any units using fine needle aspiration solely for breast lesions clinically thought to be benign, create a difficulty for pathologists to maintain diagnostic expertise for the entire spectrum of breast cytopathology and is therefore not recommended*

## Recommendation 8

Core biopsies should be reported using the B1–B5 system with classification of cancer type and grade.<sup>4</sup>

Pathology reports of breast cancer resection specimens should use:

- *Template reporting with a minimum dataset for breast cancer specimens*
- *Microscopic confirmation of invasive tumour size*

2 *Cytology Subgroup of the National Coordinating Committee for Breast Screening Pathology. Guidelines for cytology procedures and reporting in breast cancer screening. Sheffield: NHS Breast Screening Programme (BSP); 1997.*

3 *Health Information and Quality Authority. National quality assurance standards for symptomatic breast disease services: developing quality care for breast services in Ireland. Dublin: Health Information and Quality Authority; 2007.*

4 *Ellis IO, Humphreys S, Michell M, Pinder SE, Wells CA, Zakhour HD. Guidelines for breast needle core biopsy handling and reporting in breast screening assessment. J Clin Pathol 2004;57:897–902. See also Appendix 7, page 71.*

## Recommendation 9

Clinical requirements at first attendance require triple assessment diagnostic procedures of clinical examination, imaging by mammography and/or ultrasound and pathology sampling.<sup>3</sup> Prior to having invasive tests such as FNA or core-biopsy, all non-invasive tests should be considered and if relevant performed.

## Recommendation 10

Senior management, together with clinicians in both organisations, should introduce new arrangements for the effective delivery of patient centred services. This should be measured, monitored and published in an annual report.

## Recommendation 11

A robust clinical governance framework should be adopted at local, regional and national level. It should include as a minimum:

- *At National and Hospital level, a named individual at senior management level should be responsible and accountable for clinical governance*
- *A quality and safety framework that includes a schedule of internal and external audits. This framework needs to focus on both organisational and speciality specific standards, including the National Quality Assurance Standards for Symptomatic Breast Disease Services and The Faculty of Pathology's Histopathology Quality Assurance Programme<sup>5</sup>*
- *Laboratories should engage in a recognised accreditation programme in order to assure robust clinical governance at the laboratory level*
- *A patient liaison programme, which involves access to an independent advocate and a hospital appointed dedicated patient liaison person, as part of a complaints structure. This patient liaison person, who should be at a senior level, will be the principal point of contact with the patient and/or family. They must be kept appraised of all developments in the case and have the responsibility to brief the patient and/or family in a timely fashion of these developments. Protocols should be established to implement such arrangements*

<sup>3</sup> Health Information and Quality Authority. *National quality assurance standards for symptomatic breast disease services: developing quality care for breast services in Ireland*. Dublin: Health Information and Quality Authority; 2007.

<sup>5</sup> Faculty of Pathology Histopathology QA programme. Dublin: Faculty of Pathology, Royal College of Physicians of Ireland; 2007.

## Recommendation 12

Risk management arrangements at both hospitals should be reviewed to ensure they demonstrate clarity of purpose, transparency in decision making and accountability in order to safeguard high standards of treatment and care. This should include a review of their arrangements for managing risk.

Specifically they should:

- *Ensure that structures, roles and lines of accountability are clearly defined and reviewed on a regular basis to ensure consistency and clarity of purpose*
- *Identify areas where there may be gaps in controls and/or assurances and put in place corrective action as required*
- *Ensure monitoring and reporting systems are timely and effective*
- *Ensure that all staff involved in the risk management process are appropriately qualified, trained and supported with adequate resources available to them to fulfil their role effectively*
- *Review arrangements for communicating risk management policies to all staff*
- *Ensure that risks associated with working with other organisations or partners are explicitly assessed and managed*

## Recommendation 13

The hospitals should establish an effective, patient focused communication strategy that addresses the needs of internal and external audiences. This should include:

- *Ensuring that the views and perspectives of patients, service users and front line staff are taken into account*
- *Supplementing the formal communication process with regular visits to the 'shop floor' and face to face dialogue*

The effectiveness of this strategy should be reviewed on a regular basis.

## Recommendation 14

Governance arrangements need to be strengthened to ensure:

- *Clarity of delegated levels of authority, reporting relationships and accountability at local, regional and national levels*
- *Transparent business planning and decision making processes*
- *Effective engagement and involvement of clinicians in the executive management process*

## Recommendation 15

The corporate HSE executive management team should nominate a specific director accountable for ensuring the development of an implementation plan for these recommendations. This should include a clear timeframe and milestones. Progress against the plan should be made public and reported to the Board of the HSE.

## 3 Introduction

In accordance with Section 9(1) of the Health Act 2007, (the Act), the Health Information and Quality Authority (the Authority) instigated an investigation into the circumstances surrounding the care of Rebecca O'Malley. In conducting this investigation the Authority had particular regard to the provisions of Section 9(3) of the Act which states that in carrying out an investigation such as this one, the Authority must ensure that it does not interfere or conflict with the functions of other statutory bodies.

The investigation included a review of the provision of symptomatic breast disease services at the Mid Western Regional Hospital (MWRH), Limerick, and pathology services provided by Cork University Hospital (CUH). The focus of the investigation was on relevant aspects of the safety, quality and standards, including the governance arrangements, of those services.

It sought to ensure that best practice is being carried out and aimed to identify any serious risk to the health or welfare of a person receiving these services. In addition, it sought to make recommendations with a view to eliminating or reducing risks for current and future patients.

The investigation was carried out within the following terms of reference.

### Terms of Reference

#### 1. Introduction

In accordance with Section 9(1) of the Health Act 2007 the Health Information and Quality Authority (the Authority) will undertake an investigation into the circumstances surrounding the care of Rebecca O'Malley in relation to her symptomatic breast disease, and the provision of the symptomatic breast disease services provided by the Health Service Executive (the Executive) at the Mid Western Regional Hospital and pathology services provided by the Executive at Cork University Hospital.

Accordingly, the focus of the Investigation by the Authority will be on relevant aspects of the safety, quality and standards, including the governance arrangements, of symptomatic breast disease and pathology services provided by the Executive to Ms O'Malley and other patients, to ensure that best practice has been carried out and, if this is not the case, to ensure that where there may be serious risk to the health or welfare of a person receiving such services from the Executive, these risks shall be identified and recommendations can be made with a view to eliminating or ameliorating these risks for current and future patients. The Investigation shall be carried out within the following terms:

## 2. Terms

- 2.1. In respect of the period January 1st 2005 to 31st May 2007, the persons authorised to carry out the Investigation (“Investigation Team”) will:
  - 2.1.1. Investigate the safety, quality and standards (including but not limited to the governance arrangements) of the services provided, and investigation undertaken, by the Executive to Rebecca O’Malley. The means of Investigation shall include (but not be limited to) inspection of medical records, imaging and slides.
  - 2.1.2. Investigate the safety, quality and standards (including but not limited to the governance arrangements) of pathology services provided by the Executive at Cork University Hospital with a view to identifying any circumstances which may give rise to a serious risk to the health or welfare of any person receiving or having received such services and further to make such recommendations as the Investigation Team see fit in relation to this.
  - 2.1.3. Investigate the safety, quality and standards (including but not limited to the governance arrangements) of symptomatic breast disease services provided by the Executive at (including but not limited to) the Mid Western Regional Hospital, Limerick with a view to identifying any circumstances which may give rise to a serious risk to the health or welfare of any person receiving or having received such services and further to make such recommendations as the Investigation Team see fit in relation to this.
- 2.2. If necessary the Investigation Team will carry out an investigation into one or more of the matters mentioned at 1.1, 1.2 and 1.3 above for such other period that the Investigation Team deems necessary if this becomes apparent during the course of the Investigation.
- 2.3. The Investigation shall be carried out in whatever manner and with whatever methodology the Investigation team believes is the most appropriate, having regard, in particular, to the clinical judgment of the Investigation Team. The scope of the Investigation will be limited to those patients and to those aspects of safety, quality, standards, and governance that the Investigation Team considers are most relevant and material to the Investigation.
- 2.4. The Investigation Team shall prepare a report outlining the Investigation, its findings, conclusions and any recommendations that the Investigation Team see fit to make.
- 2.5. If, in the course of the Investigation, it becomes apparent that there are reasonable grounds to believe that there is a serious risk to the health or welfare of any person and that further investigation is necessary beyond the scope of these terms of reference, the Investigation Team may in the interests of investigating all relevant matters, and with the formal approval of the Authority, extend these terms to include such further investigation within their scope or recommend to the Authority that a new investigation should be commenced as appropriate.



The investigation entailed a review of relevant documentation (including strategic plans, policies and procedures and evaluations), case records, pathology specimens and imaging materials; site visits of CUH and the MWRH and interviews with Rebecca O'Malley, members of staff from the MWRH, CUH, the HSE, and other key individuals.

This report outlines the:

- *Chronology of events*
- *Methodology of the investigation*
- *Findings of the investigation*
- *Conclusions and recommendations*

The report is supported by a number of appendices to provide the reader with technical explanations and background information.

Throughout the investigation importance was given to Rebecca O'Malley's wish that apportionment of blame should not be seen as an end in itself but that the healthcare system within Ireland should learn from her experience.

## 4 Chronology of Events

The following outlines the chronology of events for Rebecca O'Malley from the point at which she presented to her GP and includes the key steps in her care.

**1st March 2005:** Rebecca O'Malley attended a General Practitioner (GP) at her regular practice. During the consultation it was observed that there was an abnormality in her left breast. This was referred to as a 2cm abnormal area in the left upper quadrant. She was referred to the MWRH Breast Clinic.

**15th March 2005:** Rebecca O'Malley attended the Breast Clinic and was examined by Consultant Surgeon A. It was recorded that there was a large firm area (5–6cm) in her left breast. She had a mammogram x-ray and ultrasound scan performed that day and both were reported as normal. Consultant Surgeon A then performed a fine needle aspiration (FNA) of the tissue in this area. This FNA cytology specimen was sent to CUH, which was the practice at that time.

**22nd March 2005:** The report on this FNA cytology specimen was authorised. Two fixed slides were received and it identified that no malignant cells were seen. It was further reported that the appearance of the cellular aspiration (specimen of the FNA) was consistent with a fibroadenoma, which is a benign condition.

**8th April 2005:** Rebecca O'Malley was seen in the MWRH Breast Clinic and was informed that the results of her mammogram, ultrasound and cytology specimen were normal. It was recorded that an area of thickening remained in her left breast but had reduced. Consultant Surgeon A arranged for a final clinical assessment to take place in June 2005. Rebecca O'Malley's GP was advised of these findings by letter from Consultant Surgeon A.

**7th June 2005:** Consultant Surgeon A discharged Rebecca O'Malley back to the care of her GP after a further clinical assessment.

**29th March 2006:** Rebecca O'Malley attended her regular GP on a different matter. Her GP referred her back to the MWRH Breast Clinic because, on examination, the area of thickening was still present in her left breast.

**20th April 2006:** Rebecca O'Malley was seen by Consultant Surgeon A at the MWRH Breast Clinic. During this consultation, it was noted there was a thickened area in her left breast and a further mammogram was requested.

**27th April 2006:** The mammogram was performed.

**11th May 2006:** A biopsy (which obtains a larger sample than FNA) was performed on Rebecca O'Malley by a member of the surgical team.

**18th May 2006:** The report on this biopsy was available and revealed atypical ductal hyperplasia; this is indicative of premalignant breast disease. Rebecca O'Malley's GP was updated on this by letter from Consultant Surgeon A.

**22nd May 2006:** A wire guided surgical biopsy was performed on Rebecca O'Malley.

**8th June 2006:** The result of this biopsy was discussed with Rebecca O'Malley. It confirmed the presence of an invasive breast cancer. It was recommended that, because of the location of the tumour, a left mastectomy should be undertaken with axillary evaluation (to determine whether there were affected lymph nodes in the left armpit). During this consultation Rebecca O'Malley asked whether a second opinion could be sought. Consultant Surgeon A suggested that this could be obtained at University Hospital Galway (UHG). Rebecca O'Malley agreed to this referral and immediately made the necessary arrangements.

Consultant Surgeon A wrote the following letters:

- *To Rebecca O'Malley's GP outlining the diagnosis and that Rebecca O'Malley wanted a second opinion*
- *To UHG setting out the facts and seeking a second opinion on behalf of Rebecca O'Malley*
- *To a hospital in the United Kingdom setting out the facts and seeking a second opinion on behalf of Rebecca O'Malley*

**9th June 2006:** Rebecca O'Malley discussed her diagnosis with her regular GP who also provided her with a referral letter for a consultation at UHG.

**10th June 2006:** Rebecca O'Malley was contacted by Consultant Surgeon A who confirmed an appointment for her on 12th June at UHG. This followed a telephone conversation between Consultant Surgeon A and Consultant Surgeon B in Galway.

**12th June 2006:** The second opinion was obtained in UHG. It was recommended that she should have a left mastectomy together with a sentinel node biopsy (see glossary) and an immediate breast reconstruction. It was confirmed this could be carried out within the following week. Later that evening Rebecca O'Malley had a further consultation with Consultant Surgeon C in London.

**13th June 2006:** Rebecca O'Malley underwent staging scans to assess any spread of the cancer and returned to Ireland.

**17th June 2006:** Rebecca O'Malley underwent a left mastectomy and sentinel node biopsy in London.

**4th July 2006:** Rebecca O'Malley commenced chemotherapy in London. Tony O'Malley, (Rebecca's husband), wrote to their regular GP advising of the current treatment plan for Rebecca O'Malley. He expressed his concern about the failure to detect his wife's cancer.

**25th July 2006:** Rebecca O'Malley was advised from London that analysis of the sentinel node tissue, removed at operation had revealed "sub-micrometastases" (evidence that the cancer had spread).

**5th September 2006:** Rebecca O'Malley was advised by Consultant Surgeon C that a further evaluation of her histology confirmed "micrometastases (3mm)" and a full axillary clearance (removal of lymph nodes in armpit area) was recommended.

**27th October 2006:** Rebecca O'Malley wrote to Consultant Surgeon A at the MWRH requesting information as to how the diagnosis of the cancer had been missed in 2005.

**3rd November 2006:** A member of the Risk Management Department in the MWRH acknowledged receipt of Rebecca O'Malley's letter and stated that the matters raised in the letter of 27th October 2006 were being investigated.

**16th November 2006:** A meeting took place at the MWRH between Rebecca and Tony O'Malley, Consultant Surgeon A and a member of the risk management team. At this meeting Rebecca and Tony O'Malley requested that her 2005 cytology specimens, mammograms and ultrasound be re-examined. It was agreed that the cytology specimen would be reviewed in the first instance in CUH and the MWRH respectively. It was further agreed that an external opinion would be sought from a hospital in Dublin. It was agreed that a further meeting would take place with Rebecca and Tony O'Malley when Consultant Surgeon A had received the results of the Dublin hospital review.

At this time Consultant Surgeon A wrote a letter to the Cytopathology Department at CUH seeking an independent review of Rebecca O'Malley's cytology specimen.

**2nd December 2006:** Following completion of her chemotherapy Rebecca O'Malley underwent a left axillary clearance in London.

**7/8th January 2007:** Consultant Surgeon A states that they contacted CUH to find out the progress of the requested review of Rebecca O'Malley's cytology specimen.

**22nd January 2007:** A letter was issued from CUH to Consultant Surgeon A with the results of the review of Rebecca O'Malley's March 2005 cytology specimens by two pathologists from CUH. This stated that the specimen was found to contain cells which suggested malignancy.

**24th January 2007:** A member of the risk management team at the MWRH sent a letter to Rebecca O'Malley, stating that the results of the cytology and mammogram review were not available but that Consultant Surgeon A had been in contact with both CUH and the hospital in Dublin and that a meeting would be arranged to discuss these results as soon as they became available.

**24/25th January 2007:** Dates when Consultant Surgeon A states that the results of the review of Rebecca O'Malley's cytology specimens from CUH were received by Consultant Surgeon A. This confirmed that the specimens were "highly suspicious of malignancy"

**26th January 2007:** Rebecca O'Malley's cytology specimens were received in the Dublin hospital from CUH.

**31st January 2007:** A report dated 31st January was received shortly after this date by the pathology department in CUH with the external review of Rebecca O'Malley's cytopathology slides carried out by the Dublin hospital. This review confirmed the findings of the internal review, that the specimen was found to contain cells which suggested malignancy. No contact was made by the pathology staff of CUH with the staff of the MWRH at this point as it was assumed by them that this report had been sent to Consultant Surgeon A.

**16th February 2007:** Consultant Surgeon A was on leave for 4-5 weeks after this date.

**15th March 2007:** Rebecca and Tony O'Malley sent a letter to the MWRH seeking information on the reviews that had been promised at the meeting in November 2006.

**20th March 2007:** Consultant Surgeon A returned from leave.

**21st March 2007:** Consultant Surgeon A contacted the Dublin hospital which had carried out the external review of Rebecca O'Malley's cytopathology slides to find out the progress on this review. The Dublin hospital was unaware that Consultant Surgeon A had not seen the copy of their report and sent it by fax to Consultant Surgeon A.

**4th April 2007:** As agreed at the meeting on 16th November, a meeting took place between Rebecca and Tony O'Malley, Consultant Surgeon A and a member of the risk management team to inform them of the reviews of her cytology specimen. Rebecca and Tony O'Malley were informed that the reviews confirmed that a misdiagnosis had occurred and the original cytology specimen from March 2005 was found to contain cells which suggested malignancy. At this meeting Consultant Surgeon A and the member of the risk management team apologised to Rebecca O'Malley for the error which had occurred.

It was explained to Rebecca O'Malley that Consultant Surgeon A was carrying out an audit of patient files in order to identify if any other patients could be affected by a similar error. It was also explained that the MWRH would write to CUH to request that they carry out a review of the cytology department to ensure that no other incidents such as this had occurred. Rebecca and Tony O'Malley asked that an external independent review be carried out as they felt this would be more beneficial than an internal review. They explained that if an independent investigation did not happen quickly then they would make public their concerns in order to help protect other patients. They were discouraged from making the matter public: they understood this discouragement originated in genuinely held concerns that publicity might cause unnecessary anxiety or panic amongst people who may not be affected by any errors.

It was agreed that Rebecca O'Malley's mammograms would be sent to a hospital in the United Kingdom for review.

**3rd/4th April 2007:** Senior management in the MWRH wrote to senior management in CUH outlining the history of Rebecca O'Malley's care and stating that Rebecca O'Malley was concerned to find out why there was a misdiagnosis in her case and what was being done to ensure that it did not happen to other patients.

**11th April 2007:** A senior manager in CUH wrote to a senior manager in the MWRH acknowledging receipt of the letter of 4th April 2007 and stating that the matter had been passed to Risk Management Department in CUH.

**14th April 2007:** A senior manager in the MWRH wrote to CUH explaining that Rebecca and Tony O'Malley had requested an external independent review and seeking confirmation whether any action was proposed by CUH in relation to the matter.

**19th April 2007:** Rebecca O'Malley sent a letter to a member of the risk management team at the MWRH seeking written notes of the meeting of 4th April 2007. She expressed concern that she had not been contacted by senior management in the MWRH or by CUH to apologise for what had happened. She expressed surprise that she had not received copy correspondence between the MWRH and CUH. She expressed her view that an independent review should be undertaken of CUH laboratory and of her individual case. She expressed dissatisfaction with the slow pace of events since the meeting of 16th November 2006 and stated that if she did not receive adequate assurances that matters were being addressed within 10 days she would make public her serious concerns.

**24th April 2007:** Senior management in the MWRH wrote to senior management in CUH outlining the content of Rebecca O'Malley's letter of 19th April 2007 and seeking confirmation as to what action had been undertaken or proposed by CUH in respect of this matter.

**25th April 2007:** A member of the risk management team at the MWRH sent a letter to Rebecca O'Malley enclosing notes of the meetings of 16th November 2006 and 4th April 2007. This letter explained that senior management in the MWRH had written to CUH to outline that Rebecca and Tony O'Malley wanted an independent investigation to take place and had written again to CUH to outline the content of Rebecca O'Malley's letter of 19th April 2007. This letter also stated that the report of the review of the mammograms by the hospital in the United Kingdom (UK) was awaited, and concluded by assuring Rebecca O'Malley that she would be updated on developments as they occurred.

**8th May 2007:** Rebecca O'Malley wrote to Consultant Surgeon A expressing her disappointment that she had not received any response to her letter of 19th April 2007 and stating that if she did not receive a response in 7 days she would make the matter public.

**8th May 2007:** Senior management in CUH wrote to the Chief Executive's office in the HSE stating that their understanding of the HSE National Complaints Policy was that when a complaint was made the initial step is for an internal review to be conducted and advising that this was currently being done in CUH. The letter also sought advice on whether Rebecca O'Malley's requests should be escalated to the next stage in the National Complaints Policy and noted that Rebecca O'Malley had not corresponded directly with CUH.

**11th May 2007:** Rebecca O'Malley wrote to a member of the risk management team and acknowledged that she was written to on 25th April 2007. She expressed concern that she had not been communicated with directly by senior management in the MWRH or CUH.

**11th May 2007:** Senior management in the MWRH wrote to senior management in CUH enclosing Rebecca O'Malley's letter of that date, noting that no further responses had been received from CUH and seeking an urgent response to the concerns raised by Rebecca O'Malley.

**15th May 2007:** Senior management in the MWRH wrote to Rebecca O'Malley providing a full response to the issues raised in her letter of the 11th May, which included an expression of their sincere regret for the error in her cytology test.

**15th May 2007:** Rebecca O'Malley wrote to a member of the risk management team enclosing comments in respect of the notes of the meetings of 16th November 2006 and 4th April 2007, copies of which had been sent to her.

**16th May 2007:** Rebecca O'Malley wrote to senior management in the MWRH stating that she appreciated the concern shown for her by everyone at the MWRH and that a press release would be issued that day.

**16th May 2007:** Senior management at the MWRH wrote to senior management in CUH outlining details of Consultant Surgeon A's audit and identifying the cases where cytology needed to be re-assessed.

**17th May 2007:** The Minister for Health and Children requested a report on the circumstances surrounding the misdiagnosis from the HSE by 18th May.

**17th May 2007:** A member of the risk management team wrote to Rebecca O'Malley enclosing amended notes of the meetings of 16th November 2006 and 4th April 2007.

**17th May 2007:** Rebecca O'Malley wrote to the member of the risk management team about what occurred in both meetings.

**17th May 2007:** A letter was written from the laboratory in CUH to The Faculty of Pathology (the Faculty) of the Royal College of Physicians of Ireland (RCPI) seeking external audit of certain cytology specimens.

**18th May 2007:** A report was issued from CUH indicating that the misdiagnosis was as a result of interpretive human error.

**18th May 2007:** Senior management in CUH wrote to Rebecca O'Malley apologising for the error in diagnosis in 2005 and enclosing a copy of the CUH investigation into events in the intervening time.

## 5 Methodology

### 5.1 Introduction

The Authority's investigation entailed a documentation review of the strategic plans and relevant policies, procedures and evaluations at the MWRH and CUH. It also involved site visits and interviews with clinical and non-clinical staff, Rebecca O'Malley, her husband and a lady identified by the investigation team and referred to in this report as Ms X. It carried out reviews of case records, imaging material and pathological specimens. It also had access to correspondence between Rebecca O'Malley and senior members of staff from the MWRH and CUH which it reviewed. The review of all the above material enabled it to verify the above chronology and its subsequent findings.

A diagrammatic representation of the review methodology can be seen in Diagram 1 page 27.

### 5.2 The Investigation Team

The Authority identified a team of experts, led by Dr Michael Durkin, Medical Director, South West Strategic Health Authority, United Kingdom, to carry out the investigation according to the terms of reference. The members of the team were authorised in keeping with Section 70 of The Health Act 2007. The membership of the team is detailed in Appendix 1.

### 5.3 Documentation Review

The HSE, including the MWRH and CUH, provided documentation to the investigation team. A list of documentation requested by the investigation team is attached in Appendix 2. In addition, a comprehensive set of clinical case notes, images, pathology reports and specimens and correspondence relating to Rebecca O'Malley and other patients were reviewed.

### 5.4 Site Visits

Members of the investigation team visited the MWRH and CUH and visited a range of clinical and non-clinical areas.

### 5.5 Interviews

In total 38 interviews (of 35 individuals) took place. Many of those interviewed held other appointments relating to the organisation of cancer care and specifically breast disease.

Core to the investigation was the experience of Rebecca O'Malley. She was interviewed twice during the investigation. A further patient who was identified during the course of the investigation (Ms X) was also interviewed. Further details relating to her case can be found in section 6.4, page 38.



Interviews were carried out in a style and format that fostered an accurate and supportive exchange whereby learning from this experience was deemed to be central to the process.

Both hospitals were provided with guidance on the interview process and interviewees were allowed to be accompanied by another person.

The interviews were conducted by at least two members of the investigation team, one of whom was a designated note taker. Notes of each interview were kept by the investigation team. These notes were used for subsequent corroboration between all material gathered at interview and provided by documentation. It was agreed prior to each interview that these notes would be shared with the interviewee for verification of their factual accuracy.

A coding system was used to structure findings of the investigation team. These codes are outlined in Appendix 3b. This coding system enabled the interview notes to be categorised into structured themes, for example, "Use of information to audit services".

## **5.6 Pathology Review**

The Faculty of Pathology (the Faculty) of the Royal College of Physicians of Ireland (RCPI) was requested by the HSE to undertake an independent review of a cohort of specimens, identified as a result of Consultant Surgeon A's audit. In light of the fact that the Authority would be undertaking a full investigation into the care of Rebecca O'Malley, it was agreed between the Faculty and the Authority that the pathology review would be undertaken as part of the Authority's investigation. The Authority then engaged the Faculty, which developed a series of protocols in order to assess the pathology standards and capability of the systems in place at the MWRH and CUH. These protocols were informed by national and international best practice and are included in Appendix 5.

### **5.6.1 Initial Case Review**

Following the identification of the misdiagnosis of Rebecca O'Malley, Consultant Surgeon A initiated an audit of 333 patients who had presented from 1st March 2005 to 31st May 2005, (the period during which Rebecca O'Malley had initially presented). This audit, which was conducted outside of Consultant Surgeon A's normal working hours, identified 80 patients for whom cytology sampling was a key component. Of these patients, 24 were identified as having their cytology review at CUH and no related histopathology sampling to confirm diagnosis. These 24 patients, in addition to Rebecca O'Malley, were recommended by the investigation team for a further clinical case review.

It was decided by the clinical experts of the investigation team to review this cohort. It was further identified that as a result of the initial review that it may be necessary to carry out an in-depth review of the work of Consultant Pathologist A and the quality of the cytology service at CUH.

The review of the slides for the 24 patients (see methodology in Appendix 5) was performed by three expert pathologists on the investigation team. Each pathologist reviewed the slides independently and recorded their diagnosis. On completion of the review by all three pathologists, the review diagnosis was compared with the original diagnosis. No change in diagnosis was found to be necessary for these 24 patients. This was not the case for Rebecca O'Malley.

Rebecca O'Malley's cytology slides were originally reported as consistent with fibroadenoma, a benign condition. All three reviewers on the investigation team interpreted this case as malignant. One of the reviewers thought that the FNA was diagnostically challenging and showed a superficial resemblance to fibroadenoma, in that there were some benign cells present as flat sheets. These were admixed with malignant cells arranged in crowded groups and singly.

Rebecca O'Malley's FNA specimen was noted by the reviewers to be of good quality and suitable for diagnosis. However, there was a large number of non-diagnostic specimens in this cohort. It was decided therefore to conduct a further review of Consultant Pathologist A's work as the small sample in the original review did not allow for comprehensive assessment of the diagnostic accuracy of Consultant Pathologist A.

A broader review of the quality of the cytology service would also inform the investigation as to percentage of non-diagnostic specimens overall.

### **5.6.2 Review of Pathology Reports**

The investigation team decided to extend the scope of the review to include a full review of all work conducted by Consultant Pathologist A during their employment at CUH.\*

The following pathology reports prepared by Consultant Pathologist A were requested from CUH:

*(a) breast histopathology*

*(b) all other histopathology reports*

*(c) breast cytopathology from the MWRH*

*(d) breast cytopathology from CUH*

*(e) all other diagnostic cytopathology from the MWRH*

*(f) all other diagnostic cytopathology from CUH*

All breast cytopathology reports for the year 2005 reported at CUH separated into the following categories were also requested for comparison purposes:

*(a) breast cytopathology from the MWRH*

*(b) breast cytopathology from CUH*

\* As permitted under 2.2 of the Investigation's Terms of Reference.

### **5.6.3 Review of Slides**

The investigation team also reviewed all diagnostic breast specimens reported by Consultant Pathologist A.

### **5.6.4 Cytopathology Review**

The investigation team reviewed all 170 breast cytology cases, which had been reported by Consultant Pathologist A, between July 2004 and August 2005.

### **5.6.5 Histopathology Review**

The investigation team also reviewed all 60 breast histology specimens reported by Consultant Pathologist A, between July 2004 and August 2005. These included:

- *27 core biopsies*
- *33 surgically obtained specimens*

### **5.6.6 Review of Rebecca O'Malley's slides**

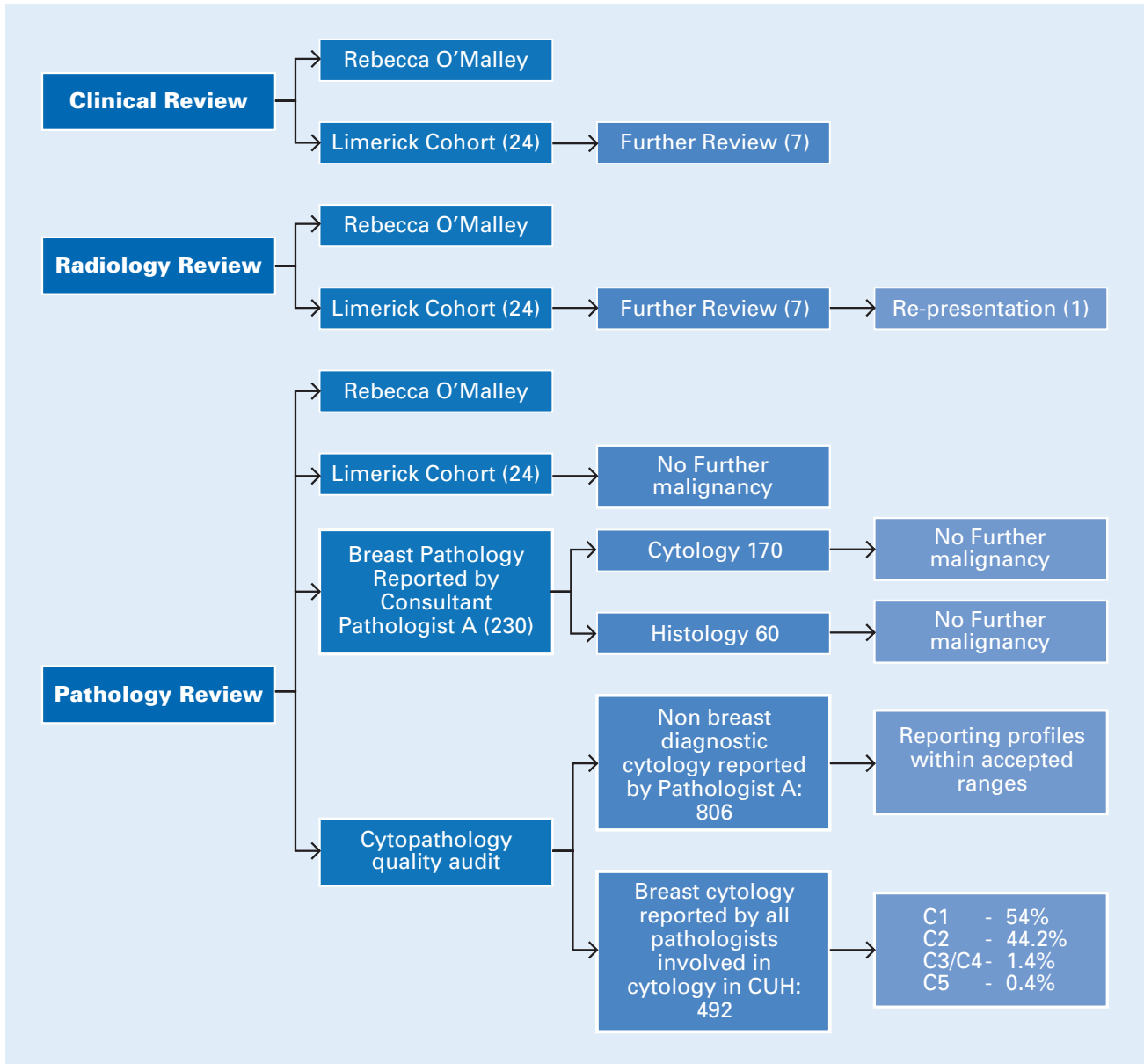
In addition the team reviewed all Rebecca O'Malley's histopathological specimens from the MWRH, London Clinic and the Royal Marsden Hospital.

## **5.7 Radiology and Clinical Review**

The investigation team decided that the 25 cases identified by Consultant Surgeon A should also undergo further radiological and clinical review. This included the case of Rebecca O'Malley.

The clinical notes and imaging findings were reviewed by the clinical experts on the investigation team. A further and subsequent review then took place which allowed for further integration of the pathology, surgery and radiology opinion. A conclusive statement was then made by the investigation team based on the combined pathology, clinical and imaging findings.

**Diagram 1: Diagrammatic representation of review methodology**



See Appendix 7 for explanation of C1-C5 Classifications.

## 6 Findings

The following section of the report outlines the findings of the investigation team regarding Rebecca O'Malley's pathway of care. The team has also made findings relating to the wider aspects of organisational competence. In particular it has commented on the leadership culture, governance capability, use of clinical audit and risk management approach, communication within and between organisations, and management effectiveness. All of these are fundamental in the provision of safe, high quality care.

This section also outlines the recommendations for improvement as a result of the findings of this investigation. Many of the recommendations can be applied to any centre providing initial diagnosis and treatment of symptomatic breast disease.

In parallel with these recommendations, it is expected by the Authority that the MWRH and CUH will implement the requirements of the standards contained within the National Quality Assurance Standards for Symptomatic Breast Disease Services 2007,<sup>3</sup> and recognise the implications of the National Cancer Control Strategy. Consequently, the recommendations do not intend to duplicate the entirety of these standards within this report.

### 6.1 Pathway of Care for Rebecca O'Malley

#### 6.1.1 Clinical Management

##### 2005

Rebecca O'Malley first attended a GP on 1st March 2005 and was given an appointment to be seen at the MWRH Breast Clinic, on 15th March 2005. On examination, Rebecca O'Malley was noted to have a large firm area (5-6cm) in her left breast and a 1.5cm soft node in her left axilla. This was described also, in different documents, as a thickened area or lump.

Based on their review it was the view of the investigation team that the approach taken to Rebecca O'Malley's care on this occasion was appropriate. She was offered a triple assessment: she had a mammogram, ultrasound and FNA at that visit.

Triple assessment is an assessment constituting clinical examination, imaging and pathology. Following the triple assessment, a multi-disciplinary team meeting should be held where the results of all three assessments are presented and discussed. When all three results are in agreement, this is known as a concordant triplet. When there is a difference between the results, this is known as a discordant triplet. In Rebecca O'Malley's case, the multi-disciplinary team review was compromised by the fact that although the report of the FNA was discussed at the meeting, no review of the slide took place nor was the reporting pathologist present. It should be noted that there was no arrangement in place for either the reporting pathologist, another pathologist or the cytology slides to be present at this meeting.

<sup>3</sup> Health Information and Quality Authority. National quality assurance standards for symptomatic breast disease services. Dublin: Health Information and Quality Authority; 2007.

The report on the FNA suggested that there was no malignancy and that the findings were consistent with a fibroadenoma. It is the view of the investigation team that because there was nothing to suggest a fibroadenoma either clinically or on imaging, the multi-disciplinary review was discordant. This was not identified as a discordant set of results and therefore another opportunity to correct the interpretive error was lost.

If the slides had been reviewed at the meeting it may have highlighted the fact that the result was discordant. Where there is a discordant result it is appropriate for the patient to have a subsequent core biopsy.

The investigation team believes that this discordant triple assessment was a key factor leading to Rebecca O'Malley's misdiagnosis.

The practice of using fine needle aspiration of tissue samples in the diagnosis of symptomatic breast disease is discussed below; in 2005 it was normal practice in the MWRH to send these tissue samples to CUH for analysis and reporting.

Rebecca O'Malley's subsequent clinical review and discharge were based on the fact that the findings appear to have been non-specific or benign.

In summary, Rebecca O'Malley was seen at an assessment clinic in a timely fashion on 15th March 2005. The investigation team believes that the absence of the cytology slides coupled with the absence of the reporting consultant pathologist at the multi-disciplinary meeting probably resulted in the failure to alert the team to the fact that this was a discordant result.

The view of the investigation team is that Rebecca O'Malley should have had a core biopsy in May 2005 when she had a discordant triple assessment which identified her cytology as suggesting a fibroadenoma with a normal clinical examination and a normal reported mammogram. Senior clinical staff at the MWRH, (including Consultant Surgeon A), have expressed the view that there was no discrepancy, i.e. no discordance, because the pathology, the radiology and the clinical examination clearly indicated a benign process in each case. However the investigation team disagrees with this view because fibroadenoma was indicated only in the pathology and not in the other two methods of assessment. This was a discordant result and should have been investigated further.

## 2006

Rebecca O'Malley re-presented to her regular GP in March 2006 on a different health matter. Her GP re-referred her to the MWRH because of her continuing breast signs and symptoms. She was offered an appointment in an appropriate timeframe.

A mammogram performed on 27th April 2006 (reported on 9th May 2006) indicated that there was "suspicious micro calcification with a stellate mass in the upper outer aspect of the left breast" - appearances possibly indicative of malignancy. A clinical core biopsy was performed on 11th May 2006 and a wire guided diagnostic excision biopsy was performed on 22nd May. The diagnosis was communicated to Rebecca O'Malley on 8th June 2006.

It is the view of the investigation team that because of the suspicious mammographic findings, rather than a clinical core biopsy being taken, a more appropriate course would have been a repeat ultrasound and ultrasound guided biopsy in early May.

The subsequent meeting with Consultant Surgeon A and request for a second opinion was handled in an efficient and reasonable manner. At this time, sentinel node biopsy was not available in the MWRH but only in the major teaching hospitals. Subsequent second opinions and transfer to the care of Consultant Surgeon C in London were handled in an efficient, co-operative manner with a prompt disclosure of all clinical and pathological information.

### Recommendation 1

A pathologist, together with a surgeon and a radiologist, all of whom should have a specific interest in breast disease, must always be present at a multi-disciplinary team meeting of triple assessment clinics. A discordant set of triple assessment results should trigger further discussion within the clinical team into the cause of such discordance.

#### 6.1.2 Response to the Error

It is of concern to the investigation team that it was left to Rebecca O'Malley to raise questions regarding a serious error in her care in 2005. When a patient who had been assessed or seen within the previous year is subsequently diagnosed with cancer, a full and further evaluation should take place with a formal response from a lead clinician. The investigation team found that although a policy was in place in the MWRH to manage adverse clinical incidents, in this case no root cause analysis had been undertaken. While it is acknowledged that an incident report form was completed in November 2006, it did not trigger an effectively managed action plan on the part of the MWRH. There was no integrated system wide approach involving both managerial and clinical input and no single nominated lead to manage the overall response. The opportunity for the system to respond to Rebecca O'Malley was lost because this was not in place. An audit system should have been in place that allowed these issues to be discussed and lessons learned.

### Recommendation 2

Any patient who has a suspected delayed diagnosis of breast cancer should have immediate recourse to a multi-disciplinary team assessment with a formal response from a lead clinician. A delayed diagnosis should trigger a formal incident response including an internal root cause analysis, and the relevant senior management should be notified. The patient should be informed of the findings and outcome as a priority.

Rebecca O'Malley's concerns regarding the accuracy of her original diagnosis were raised by her in her letter dated 27th October 2006. That letter was passed to Risk Management in the MWRH who issued a holding letter outlining the complaints policy. The investigation team, through interviews, learned that the functions relating to complaints management and risk management operated separately. Consultant Surgeon A, on their own initiative, invited a separate senior risk manager to become involved in the management of this response. However, despite this intervention, there was no effective process with clear delineation of roles, which meant that the management of response was not followed through conclusively.

The investigation team found that several attempts were made by members of staff at the MWRH to resolve Rebecca O'Malley's concerns. However, the failure to make explicit the assignment of specific responsibility for each element of the process to named post holders - including the triggering of the adverse clinical incident reporting system with an agreed action plan, meant that the opportunity to resolve matters speedily was lost. This confusion created an impression that the suspected delay in diagnosis was not being accorded the attention it required and that there was an absence of an effective patient-centred ethos.

A patient concerned with a suspected delay in diagnosis requires as much personal and sensitive care as when first receiving the diagnosis. When Rebecca O'Malley was communicating her concern regarding her possible misdiagnosis and seeking information, the presence of a breast care nurse would have been helpful. It is important to provide a prompt and personal response from a senior representative of the hospital, which should include both managerial and clinical input.

During the November 2006 meeting with Rebecca O'Malley she was given a commitment that another meeting would be held to inform her of the results of the proposed internal CUH review of her cytology from 2005 as well as the external review of the Dublin hospital. After the MWRH asked CUH to carry out this review of Rebecca O'Malley's original cytology in November 2006 it was some two months later that this review was actually carried out. Consultant Surgeon A has stated that they telephoned CUH pathology laboratory on around 7th or 8th January 2007 to enquire as to whether the review had been carried out. The review was conducted and a report issued on 22nd January 2007. This report was received by Consultant Surgeon A on 24th/25th January 2007.

CUH then sent the cytology slide to the hospital in Dublin for an external review and this review was carried out on 31st January 2007. It is clear that this report was received by CUH shortly after this date but it was not sent by them to Consultant Surgeon A as CUH assumed that this had already been done by the Dublin hospital. Consultant Surgeon A did not receive the report until 21st March when they requested it directly from the hospital in Dublin (after returning to work on the 20th March, following 4-5 weeks leave).

The investigation team has no knowledge of any communication from CUH to the MWRH about this report in the period up to 21st March 2007.



As agreed with Rebecca O'Malley in November 2006 a meeting was held on 4th April 2007 to discuss the two reviews. All in all it took 5 months for Rebecca O'Malley to have the results of the two reviews of her cytology communicated to her, as agreed at the meeting the previous November.

Rebecca O'Malley wrote five letters between October 2006 and May 2007 in which she sought responses to her concerns. There were attempts by staff in the MWRH to get answers for Rebecca O'Malley and they did respond to her letters. However, it was only after her fifth letter that she received a full response to her questions. This response came from the senior management of the MWRH. Rebecca O'Malley's first contact from CUH senior management was only after she had issued a deadline of 16th May 2007 in previous correspondence.

These delays are unacceptable for someone who has received a delayed diagnosis. It caused Rebecca O'Malley a great deal of anguish and concern for others who might be in a similar situation, on top of having to deal personally with her misdiagnosis.

Given the seriousness of the delays in responding to Rebecca O'Malley, the investigation team believes that an urgent review should be conducted by Corporate HSE of communications within its hospitals to ensure that effective communications policies and procedures are in place to provide an efficient and co-ordinated response to the patient when a serious incident arises.

The opportunity exists for all hospitals to learn from the experiences of Rebecca O'Malley and the manner in which the MWRH and CUH responded to her concerns. The findings of this investigation should inform the review undertaken by the HSE.

This review should also examine how individual hospitals communicate internally, with other hospitals and with corporate HSE when a serious incident arises.

### Recommendation 3

The HSE should urgently review the formal communications processes, policies and procedures which its hospitals uses to respond to patients when there is a serious incident, including communications within and between its hospitals.

Breast cancer is a distressing and complex journey for women and their families. The purpose of an effective symptomatic breast cancer service is to harness the collective, multi-disciplinary, specialist expertise and support to produce the best possible results in diagnosis, treatment and recovery for women with breast cancer. The fact that Rebecca O'Malley had to initiate action to get a response, coupled with the unacceptable delays in addressing all her concerns, demonstrates the gap that existed between her experience and the best practice in patient support expected of symptomatic breast centres.

## Recommendation 4

Appropriate psychosocial support should be available to patients and their families at any stage during care for symptomatic breast diseases as recommended in the National Quality Assurance Standards for Symptomatic Breast Disease Services.<sup>3</sup> (p56)

It says an enormous amount for Rebecca O'Malley that during treatment she chose to focus on getting answers to her concerns not only for herself but for others who might be in a similar situation.

### 6.2 Symptomatic Breast Disease Services, including Pathology, at the MWRH

Specific services for the management of patients with symptomatic breast disease were established at the MWRH in 1998 and provide out-patient, day case and in-patient services. This directorate is led by a clinical director with the support of a business manager, breast services coordinator and an assistant director of nursing. In 2006 the service had 3,457 attendances and 197 new cases of breast cancer were diagnosed.

It was obvious to the investigation team that there is a committed multi-disciplinary team at the MWRH working hard to provide the best possible service in an extremely busy environment where consultant time is at a premium.

The organisation of the out-patient rapid access clinic has been given some considerable thought and effort. It works well, given the number of consultant staff available to provide the service. It would however be desirable to have better access to imaging and image guided biopsies. It is the view of the investigation team that in the context of a general department with a high workload, radiology consultant capacity is a limiting factor.

#### 6.2.1 Surgical Service

This multi-disciplinary service consists of three consultant general surgeons who, since 2005, include one with a special interest in breast disease and reconstruction. This is a committed team of professionals, who have experienced an excessive increase in workload without an apparent commensurate increase in personnel.

Consultant Surgeon A has part-time support from a second consultant surgeon. Matching resources to increasing demands has been a challenge and there was reported to be significant competition for access to theatre time and beds at the MWRH. Consultants working alone in such a busy service have little time to plan for the development of the required resources. An allocation of time within a clinical directorate system would support the business and service planning process of the department and hospital. Strategic service development for cancer services will be most effectively addressed by national planning and commissioning to ensure resources are matched to demand and a clearly defined output.

3 Health Information and Quality Authority. *National quality assurance standards for symptomatic breast disease services*. Dublin: Health Information and Quality Authority; 2007.

The widespread use of clinical fine needle aspiration (FNA) as a diagnostic tool in symptomatic breast disease should be reduced; and should only be used under clearly defined circumstances.

### **6.2.2 Radiology Service**

There are three consultant radiologists and a specialist radiographer providing the symptomatic breast disease service at the MWRH. There was a skilled team of radiographers performing the mammograms. The consultant radiologists provide a highly valued service in the context of intense work pressures indicated by reporting backlogs and difficulties in securing locum cover. In 2006, 3,114 mammograms and 951 ultrasounds were performed. The investigation team believes a review of the radiology department's workforce should be undertaken to ensure clinical staff can undertake an increased number of image guided biopsies, which would further develop the efficiency and quality of the service.

### **6.2.3 Radiology and Clinical Case Review**

The radiology and clinical case review of the 24 patients (excluding Rebecca O'Malley) considered that the majority of the patients had been adequately evaluated.

There was concern however that some patients had undergone FNA with inadequate indication. In particular, there was concern that seven patients had FNA in the absence of ultrasound examination. For completeness, as there was no evidence that these seven patients had ultrasound, the investigation team recommended to the Authority that these seven patients should have further ultrasound examination to confirm that all sonographic appearances were normal.\* Subsequently the Authority wrote to the MWRH on the 3rd of September 2007 recommending this measure.

It subsequently came to the attention of the investigation team that one of these seven patients, referred to within this report as Ms X, had re-presented with symptomatic breast disease to her GP and had been referred to Consultant Surgeon A at the MWRH during the investigation. The chronology and findings of Ms X's care are outlined in section 6.4.

### **6.2.4 Pathology Service at MWRH**

There are three pathologists providing this service. From 1st June 1997 to 30th June 2005, cytology specimens were transferred to CUH through an outsourced arrangement.

The histopathology service at the MWRH was found to be of a good clinical standard, in that reports are generated in a timely fashion and those on major specimens follow a relevant and protocol driven system.

There is however a significant issue in terms of staffing in the pathology department. It was reported to the investigation team that a consultant histopathologist with special interest in cytopathology has been unable to establish a cytology service due

\* As permitted under 2.2 of the Investigation's Terms of Reference.

to the lack of technical staff and other resources. The investigation team believes that the outsourcing of cytology services is not an optimal arrangement. The current arrangements allow for minimal or complete lack of input into the cytology element at the multi-disciplinary team meetings. In the absence of appropriate in-house cytology services, interim arrangements should be put in place for the necessary pathology input, via either effective technology, for example video conferencing, or the physical presence of a pathologist with the relevant slides. The relative costs and quality implications of out-sourcing, compared to providing an appropriately planned and resourced in-house service, should be reviewed with a view to moving towards in-house provision.

With the current arrangements and staffing, when breast tissue sampling is required, a core biopsy should be performed, preferably under imaging guidance to ensure optimal targeting, for all women with radiological abnormalities. Breast fine needle aspiration cytology should only be used when quality assured with on-site cytopathology expertise.

As the work is outsourced, it was difficult for the investigation team to understand why a practice had evolved that relied on FNA cytology, in the absence of appropriate technological facilities to support distant review. Furthermore, the precise indication for cytology was not clear, nor was it clear who makes the decision to perform an FNA.

### Recommendation 5

When breast tissue sampling is required, a core biopsy should be performed under imaging guidance to ensure optimal targeting, for all women with radiological abnormalities. Breast fine needle aspiration cytology should only be used when quality-assured with on-site cytopathology expertise.

#### 6.2.5 Multi-Disciplinary Review

The practice of multi-disciplinary meetings is well established and they were well attended. At these meetings, a multi-disciplinary discussion takes place on patients who have had fine needle aspiration cytology. However, in the absence of cytology slide review and pathological input (as for those patients whose cytology was reviewed externally) this practice is not truly multi-disciplinary.

The multi-disciplinary meeting takes place at six o'clock on a Tuesday evening after the rapid access clinic. The investigation team believes this is not appropriate. To ensure high quality output from such a meeting it should be part of the normal working day rather than following a full day's busy clinical workload.

The breast services at the MWRH have many of the attributes of a well run service. The investigation team observed a clinical workload that appeared to be out-stripping the number of clinical staff available. The total activity of this service has increased by 142% between 2001 and 2006 with further increases projected. The clinical staff reported that they spent a lot of time engaged in activity aimed at securing the resources they need to deliver their service. This is not a good use of their time or energy and may detract from their ability to practise effectively.

## Recommendation 6

To ensure the effective management and review of patients, a functioning multi-disciplinary team meeting must be held at least weekly, as part of the normal working day. One representative from surgery, radiology and pathology must be available with patient information, including imaging, pathology and copies of relevant clinical reports.<sup>3</sup> (pp15-16)

### 6.3 Breast Pathology Services at CUH

The investigation team identified a number of factors that it believes affected the quality of the breast cytopathology service provided at CUH, during the period under review. These included:

- *Poor quality of the fine needle aspirates, both qualitatively and quantitatively*
- *Lack of quality audits in CUH laboratory*
- *Absence of standardised reporting, giving rise to ambiguous language in reports*
- *The lack of a quality assured service level agreement between CUH and the MWRH*
- *The informal arrangement from laboratory to laboratory*

The quality of the FNA material submitted to the pathologist for interpretation was poor, both quantitative and qualitative, with an overall 50% non diagnostic rate (i.e. not suitable for diagnosis). The non-diagnostic rate for solid masses was as high as 75%.

Despite the discomfort that was felt and reported by staff in the cytology laboratory about the unsafe practice of reporting breast cytology in isolation, it did not cease until July 2005.

The NHS Breast Screening Programme (BSP) Guidelines for quality assurance in breast cytology recommend evaluation of sensitivity, specificity, positive predictive value of C5, false negative rate, false positive rate, inadequate rate and suspicious rate.<sup>2</sup> The information management and technology facilities with dedicated staff to support the recording of all data required was not in place in CUH laboratory.

However, the investigation team notes that the breast pathology department at CUH has subsequently initiated a number of policies to quality assure services, including a weekly multi-disciplinary meeting, standard operating procedures for specimen handling and reporting, standardised terminology and ongoing audit. In addition, the investigation team was informed that the department of histopathology at CUH applied for external laboratory accreditation in March 2007.

<sup>2</sup> *Cytology Subgroup of the National Coordinating Committee for Breast Screening Pathology. Guidelines for cytology procedures and reporting in breast cancer screening. Sheffield: NHS Breast Screening Programme (BSP); 1997.*

<sup>3</sup> *Health Information and Quality Authority. National quality assurance standards for symptomatic breast disease services. Dublin: Health Information and Quality Authority; 2007.*

## Consultant Pathologist A - Cytopathology

A significant diagnostic error was identified, this being Rebecca O'Malley's cytopathology case.

The review of the breast cytopathology workload of Consultant Pathologist A revealed 170 breast cytopathology specimens reported during their period of employment.

A comparison of the investigation team's review findings with the original diagnosis by Consultant Pathologist A showed no significant diagnostic discrepancies or errors.

Some original reports used conflicting terminology, for example, "no malignant cells seen, no epithelial cells seen." The original reports are descriptive and in many cases do not use the standardised "C" classification system, a recognised pathology reporting system).<sup>2</sup> During this period, there was no operational policy in CUH for using this standard classification system.

## Consultant Pathologist A - Histopathology

A total of 60 breast histopathology cases were reviewed. This was made up of 27 core biopsies and 33 excision biopsy, lumpectomy or mastectomy specimens.

The investigation team found that the diagnosis agreed with the original report in all cases. There was a minimum prognostic data set included in the breast cancer reports. There were a small number of minor discrepancies, each of which could be explained on the basis of acceptable variations in reporting terminology or practice and in the view of the investigation team did not affect the reported diagnosis.

The reporting of tumour size (as invasive and/or whole) was incomplete and did not clearly define distinctions between macroscopic and microscopic, and evaluation of invasive and whole tumour size. The investigation team believed that this is a matter for the pathology department protocols rather than an individual reporting pathologist.

Core biopsies were not reported using the "B" classification system<sup>4</sup> and breast cancer in the core biopsies were not typed or graded in all cases.

All the breast diagnostic work for Consultant Pathologist A was reviewed. On the basis of this review there is no evidence of a significant diagnostic error rate in breast histopathology or breast cytopathology for this pathologist. One significant diagnostic error was identified, this being the Rebecca O'Malley cytopathology case.

2 *Cytology Subgroup of the National Coordinating Committee for Breast Screening Pathology. Guidelines for cytology procedures and reporting in breast cancer screening. Sheffield: NHS Breast Screening Programme (BSP); 1997.*

4 *Ellis IO, Humphreys S, Michell M, Pinder SE, Wells CA, Zakhour HD. Guidelines for breast needle core biopsy handling and reporting in breast screening assessment. J Clin Pathol 2004;57:897-902. See also Appendix 7, below.*

## Recommendation 7

Breast fine needle aspiration cytology must be quality assured. This should include:

- *Units using breast fine needle aspiration as a diagnostic modality must audit the service and achieve the minimum standards set by the United Kingdom NHS Breast Screening Programme (BSP). Audit should calculate sensitivity, specificity, positive predictive value of C5, false negative rate, false positive rate, inadequate rate, inadequate rate from cancers and suspicious rates<sup>2</sup>*
- *Any units not achieving the minimum standards should introduce initiatives to improve the diagnostic performance of the technique. If the minimum standards are not achieved, fine needle aspiration should not be used as a diagnostic modality*
- *Reports must be clear and unambiguous and use the C1–C5 classification system<sup>2</sup>*
- *Any units using fine needle aspiration solely for breast lesions clinically thought to be benign, create a difficulty for pathologists to maintain diagnostic expertise for the entire spectrum of breast cytopathology and is therefore not recommended*

## Recommendation 8

Core biopsies should be reported using the B1–B5 system with classification of cancer type and grade.<sup>4</sup>

Pathology reports of breast cancer resection specimens should use:

- *Template reporting with a minimum dataset for breast cancer specimens*
- *Microscopic confirmation of invasive tumour size*

### 6.4 Pathway of Care for Ms X

During the course of the investigation, the investigation team identified seven women who required further ultrasound imaging. These further tests were recommended to the MWRH on 3rd September 2007. As outlined previously, Ms X was one of these seven women.

The chronology and findings for the care of Ms X are outlined below.

**16th March 2005:** Ms X went to her GP having felt an irregular swelling in her right breast. Ms X had a family history of breast cancer for which she had previously received mammograms.

2 *Cytology Subgroup of the National Coordinating Committee for Breast Screening Pathology. Guidelines for cytology procedures and reporting in breast cancer screening. Sheffield: NHS Breast Screening Programme (BSP); 1997.*

4 *Ellis IO, Humphreys S, Michell M, Pinder SE, Wells CA, Zakhour HD. Guidelines for breast needle core biopsy handling and reporting in breast screening assessment. J Clin Pathol 2004;57:897–902. See also Appendix 7, below.*

**29th March 2005:** Ms X was seen by Consultant Surgeon A. She underwent a mammogram and had a FNA in the area of the irregular swelling.

She subsequently saw Consultant Surgeon A for a follow-up appointment and was told that all her tests were normal.

**30th July 2007:** Ms X experienced discomfort in her right breast. She saw her GP who, although unable to detect a lump, referred Ms X to the MWRH. The referral was sent by Ms X's GP to the MWRH. An appointment was arranged by the MWRH for 15th August 2008 but Ms X was unable to attend because she was out of the country until the 2nd of September.

**2nd September 2007:** Ms X contacted the MWRH to request an appointment by phone having missed the appointment allocated whilst on holiday. Ms X was told to await an appointment by post. Ms X states that she informed the MWRH that she would be away from 20th to 25th September 2007 and requested that an appointment was not booked for that time. An appointment was made for the day of her return but Ms X missed the appointment because she was out of the country.

**3rd September 2007:** A letter was issued to the MWRH from the Authority recommending that Ms X and a further six women receive ultrasound examination.

**9th October 2007:** Ms X attended a clinic with Consultant Surgeon A for her appointment to evaluate a tender swelling in her right breast.

**24th October 2007:** A mammogram was performed. The results of the mammogram report lesions in the upper inner aspect of the right breast and an ultrasound was recommended.

**1st November 2007:** Ms X was seen at the MWRH breast clinic for follow up.

**6th November 2007:** An ultrasound examination and a guided biopsy were performed.

**13th November 2007:** At a multi-disciplinary review, the findings of this case were discussed and it was recommended that Ms X should await the return of Consultant Surgeon A, who was on leave at this time.

**16th November 2007:** The written report of the findings of the ultrasound guided biopsy detail an invasive lobular carcinoma, moderately differentiated.

**20th November 2007:** Ms X was seen by Consultant Surgeon A and informed that she had breast cancer. Ms X was offered a date for her operation on 3rd December 2007. She was informed that she required a pre-operative Magnetic Resonance Imaging (MRI) scan.

**27th November 2007:** A further multi-disciplinary review of Ms X's care took place. There were difficulties in obtaining the MRI scan at the MWRH and Consultant Surgeon A arranged for an MRI scan to be performed in Dublin.

**28th November 2007:** Ms X had an MRI in Dublin which reported an abnormal area of 53mm containing two defined lesions, one measuring 19mm and the second 11mm. Consultant Surgeon A was informed by phone that evening.

**30th November 2007:** Ms X was informed of the results of her MRI.



**7th December 2007:** A second ultrasound was performed.

**10th December 2007:** Ms X underwent a right mastectomy.

**18th January 2008:** The MWRH received a letter of complaint from Ms X.

**20th February 2008:** The MWRH replied to the letter of complaint from Ms X.

Ms X had initially presented to the symptomatic breast disease service in Limerick in 2005. At that time she had tissue sampling with FNA and this was reported as benign. The technique employed in 2005 did not utilise an ultrasound guided FNA of breast tissue. Ms X's slide was reviewed by the investigation team and this review concurred that it was benign.

The investigation team reviewed the case notes and radiological images for Ms X during her 2005 presentation and her 2007 presentation. The investigation team agreed with the interpretation of the cytology specimen in 2005. However, despite the investigation team finding a consistent finding of benign cytology in Ms X's 2005 specimens, and the mammogram being normal at that time, Ms X was one of the seven patients identified by the investigation team as requiring further ultrasound imaging. This was communicated to the MWRH on 3rd September 2007 and Ms X received her ultrasound on 6th November 2007. The remaining 6 women had ultrasound examination and no further treatment was required.

As in the case of Rebecca O'Malley, Ms X did not undergo a full multi-disciplinary team review in 2005. This is because during this period, while multi-disciplinary meetings were held, no review of the slide took place nor were arrangements made for the reporting pathologist to be present at these meetings.

Ms X was interviewed by the investigation team. She expressed concerns and frustrations regarding her care since the time of her referral on 30th July 2007. These related to ongoing problems in communication, access to tests and the underpinning systems and processes to support effective communication between Ms X and the MWRH. Ms X wrote to the MWRH on 16th January 2008 expressing similar concerns, and the MWRH responded on the 20th February 2008.

Ms X was referred by her GP on 30th July 2007 to the MWRH but did not have an appointment in the MWRH until 9th October 2007. Delays occurred in arranging this appointment due to several factors including poor communication and Ms X being out of the country on two occasions. Contributing factors to the delays experienced by Ms X in her treatment included the need for her to return on different occasions for different tests and treatment. These assessments should take place on a single visit and clinicians should have access to appropriately trained radiology staff.

## Recommendation 9

Clinical requirements at first attendance require triple assessment diagnostic procedures of clinical examination, imaging by mammography and/or ultrasound and pathology sampling.<sup>3</sup> Prior to having invasive tests such as FNA or core-biopsy, all non-invasive tests should be considered and if relevant performed.

## 6.5 Leadership and Clinical Engagement

Successful organisations demonstrate effective leadership at all levels and within all teams. This is especially important in healthcare where a multi-disciplinary approach is necessary to ensure seamless care for patients. Leadership is essential in the search for safety and quality improvement.

Similarly, for clinical practice to be effective, structures should be in place and adequate resources provided to facilitate research, audit, a focus on health outcomes and a multi-disciplinary team approach to the total patient experience.

All staff must feel empowered to take the initiative and, in turn, this requires significant levels of discretion and delegated authority.

Throughout the course of this investigation it became apparent from interviews conducted that shortfalls in leadership at different stages and at various levels had contributed to an environment which was not conducive to the successful delivery of high quality services.

This consistent feedback included the:

- *Ineffective engagement between clinicians and managers*
- *Poor focus and lack of personal responsibility for the total patient experience*
- *Limited evidence of effective arrangements for patient and public involvement in the design and delivery of services*
- *Reliance on individual commitment and professional values, rather than as a result of a systematic and coherent organisational framework*
- *Unclear lines of accountability*

Sufficient evidence could not be found of a true congruence of purpose between the managerial and clinical agendas and where this is the case, the potential for safety problems to arise in the pathway of care for patients is significant.

At both hospitals, the limited nature of the arrangements for effective engagement between clinicians and management, in the investigation team's view, represents a major weakness.

It should be recognised that this investigation is a snapshot at a particular point in time. It is also important to set any shortcomings in the context which prevailed at the time of Rebecca O'Malley's initial contact with services at the MWRH and CUH. Significant organisational restructuring on a national basis had taken place in the recent past and according to many of the managers that the investigation team interviewed, the knock-on effect of the 'bedding in' process was still being felt. This is not necessarily a reflection on those charged with managing the system, but a feature of the scale and complexity of the change process. This process can however result in very different perspectives between front-line staff and management.

Views were also expressed to the investigation team that effective engagement between management and clinicians may have been hampered by national negotiations on key issues and the lack of opportunity for local management to speed up the process. Equally important, managerial turnover had occurred at a local level and acting arrangements were in place; this may have contributed to a lack of continuity and possibly a lack of focus at crucial times. To compound matters, major financial pressures undoubtedly required significant investment of management time and energy, creating the potential for other priorities to be given less attention.

It should be noted that, prior to this investigation senior management in CUH had taken steps to try and address some of these issues.

The members of the investigation team were consistently impressed with the calibre of staff and their motivation to provide the best service possible to patients and their families. However, there was a lack of visibility of senior management and there was a front line view of an insufficient focus on the things that matter to patients. There was a lack of recognition of where leadership lay within the structure, and consequently little confidence that the day to day realities faced by staff and the patients they serve were fully understood.

### Recommendation 10

Senior management, together with clinicians in both organisations, should introduce new arrangements for the effective delivery of patient centred services. This should be measured, monitored and published in an annual report.

## 6.6 Governance

Good and effective governance is a fundamental requirement in the delivery of high quality safe care. An organisation that has effective governance and control arrangements will be in a strong position to address the risks and opportunities associated with the challenging nature of changing healthcare.

As all forms of healthcare entail some degree of risk, it is essential that an effective assurance framework is in place. The purpose of an assurance framework should be to provide an organisation with a consistent, focused and iterative process which provides evidence that appropriate controls are in place and are operating effectively, to reduce the likelihood of risks occurring, particularly in regard to patient safety and that learning takes place within an open and transparent culture.

Major investment of management time and energy had taken place in developing risk management policies and procedures during the last five or six years. From a comparatively low baseline significant progress had been made in certain areas.

In addition, an extensive programme of risk management education and workshops had been undertaken. However it was clear that, at both hospitals, weaknesses in the operation of the reporting systems remained and the risk management system could not be described as 'joined up'.

The investigation team found that the necessary policies and procedures for effective clinical governance were not fully owned. Similarly, they had not been fully implemented or evaluated and the management of risk is not fully embedded or consistently applied across the organisations. Moreover, the risks associated with working with other organisations and across boundaries had not been explicitly assessed and managed.

Neither hospital had an effective framework in place which allowed them to deal with Rebecca O'Malley's concerns. Roles and responsibilities in relation to risk management were not sufficiently understood or appreciated, despite efforts to achieve ownership throughout the organisations.

The team could not assert with confidence that either organisation had a satisfactory assurance framework in place, although it is recognised that, both at a national and local level, a systematic review of the processes is being undertaken.

The investigation team noted that CUH had taken the initiative in 2006 to request that an external review of key aspects of clinical governance activity in the organisation be undertaken. This review was carried out in February 2007 and the investigation team has been provided with the report of the review. Among other things, the report stated that "the pathway of accountability and reporting at senior management level was not clear with no easily identified designated team to lead and co-ordinate hospital wide clinical governance activities and developments". It was recommended in the report that CUH urgently address its risk management and patient complaints systems and processes.

The investigation team's findings in relation to the manner in which CUH dealt with Rebecca O'Malley's concerns are consistent with the findings of the above report.

There was insufficient evidence of an organisational culture that supports understanding and ownership of risk management at all levels. For example an incident reporting form relating to Rebecca O'Malley's misdiagnosis was completed but no root cause analysis was initiated.

Rebecca O'Malley's concerns did not trigger any risk reviews in either hospital, apart from Consultant Surgeon A's self initiated audit of women that had presented during a similar time period to Rebecca O'Malley.

The weaknesses in the management of risk was to prove a fundamental shortcoming in the overall pathway of care for Rebecca O'Malley.

The most disconcerting aspect of the overall governance arrangements was a failure to initiate a speedy response once shortcomings had been identified and to use these as an opportunity to learn and improve. Clinical governance has a major role to play in the development of a culture that is patient-focused, fosters openness and accountability and recognises the value of learning.

The word 'audit' in clinical medicine means more than the accurate recording of data. Specifically it involves the analysis of data in the context of current good practice, proposals for improvement arising from the analysis, the implementation of these

proposals and a repeat of the process in the light of new developments. Thus clinical audit is a 'continuous process in an upward spiral of improving care'.<sup>3</sup> (p2)

Minimising undetected errors requires good cohesive teamwork between clinical staff, management and risk management staff working together to develop a supportive culture through learning and continuous improvement for when things go wrong. However at both hospitals the investigation team found evidence of ineffective engagement between management and clinicians.

In November 2006, the MWRH asked the pathologists in CUH to review Rebecca O'Malley's March 2005 cytology specimen. Senior management in CUH were not informed of this request. During April and May 2007 the senior management in CUH were made aware of Rebecca O'Malley's concerns about her misdiagnosis and what was being done to prevent a repeat error by the senior management in the MWRH. It is the view of the investigation team that they failed to recognise the significance of the complaint. Furthermore, staff in CUH required clarification on the New National Complaints Protocol from the corporate HSE.

Weaknesses in quality assurance systems, clinical audit, multi-disciplinary team working and workload review mechanisms were highlighted consistently during the interviews conducted by the investigation team.

## Recommendation 11

A robust clinical governance framework should be adopted at local, regional and national level. It should include as a minimum:

- *At National and Hospital level, a named individual at senior management level should be responsible and accountable for clinical governance*
- *A quality and safety framework that includes a schedule of internal and external audits. This framework needs to focus on both organisational and speciality specific standards, including the National Quality Assurance Standards for Symptomatic Breast Disease Services and The Faculty of Pathology's Histopathology Quality Assurance Programme<sup>5</sup>*
- *Laboratories should engage in a recognised accreditation programme in order to assure robust clinical governance at the laboratory level*
- *A patient liaison programme, which involves access to an independent advocate and a hospital appointed dedicated patient liaison person, as part of a complaints structure. This patient liaison person, who should be at a senior level, will be the principal point of contact with the patient and/or family. They must be kept apprised of all developments in the case and have the responsibility to brief the patient and/or family in a timely fashion of these developments. Protocols should be established to implement such arrangements*

3 Health Information and Quality Authority. National quality assurance standards for symptomatic breast disease services. Dublin: Health Information and Quality Authority; 2007.

5 Faculty of Pathology Histopathology QA programme. Dublin: Faculty of Pathology, Royal College of Physicians of Ireland; 2007.

## Recommendation 12

Risk management arrangements at both hospitals should be reviewed to ensure they demonstrate clarity of purpose, transparency in decision making and accountability in order to safeguard high standards of treatment and care. This should include a review of their arrangements for managing risk.

Specifically they should:

- *Ensure structures, roles and lines of accountability are clearly defined and reviewed on a regular basis to ensure consistency and clarity of purpose*
- *Identify areas where there may be gaps in controls and/or assurances and put in place corrective action as required*
- *Ensure monitoring and reporting systems are timely and effective*
- *Ensure that all staff involved in the risk management process are appropriately qualified, trained and supported with adequate resources available to them to fulfil their role effectively*
- *Review arrangements for communicating risk management policies to all staff*
- *Ensure that risks associated with working with other organisations or partners are explicitly assessed and managed*

## 6.7 Communication

There is considerable evidence, across all healthcare systems, that shortfalls in communication are a major cause of patient dissatisfaction and compromising of patient safety. The investigation team recognises that there were examples of good communication and teamwork at front line services within CUH and the MWRH, however, the interviews demonstrated that communications between senior management and front line staff were not perceived as effective. It is clear from the investigation that poor communication was a significant factor in the difficulties which Rebecca O'Malley and her family faced. The shortcomings in communication were unacceptable and exacerbated the levels of anxiety and distress that Rebecca O'Malley and her family were already experiencing.

The first letter that Rebecca O'Malley wrote to Consultant Surgeon A at the MWRH was acknowledged promptly by a member of staff in the Risk Management Department. As discussed earlier, this department appears to deal with only limited aspects of risk management and is entirely separate from any aspects of risk management entailing adverse clinical incidents – for which there is a discrete structure. The investigation team can find no logical explanation for this artificial separation of responsibilities and in the team's view this gives rise to the potential for confusion. The letter of acknowledgement was followed some two weeks later by a meeting involving Rebecca and Tony O'Malley, Consultant Surgeon A and a senior member of the risk management team.

Given the nature of her concerns, it could reasonably be expected by Rebecca O'Malley and her family that those initial contacts would serve as a catalyst for an efficient and effective investigation into the matters she had raised and would result in a comprehensive and speedy response from the healthcare organisations involved. It is the view of the team that it should have been possible to investigate these concerns and provide a full response in a matter of several weeks. While attempts were made by the MWRH to coordinate a response, the two organisations failed to act in harmony, and Rebecca O'Malley's concerns effectively 'fell between two stools' for an unacceptable period of time.

Both organisations made assumptions about who should take lead responsibility and senior hospital staff did not take personal control of the situation at an early stage. As a result the onus for bringing matters to a resolution fell to Rebecca O'Malley and her family.

Notwithstanding the weaknesses in communication, the investigation team are cognisant of the genuine concern expressed by the interviewees in regard to the way Rebecca O'Malley was dealt with. It should also be acknowledged that an apology was made to Rebecca O'Malley and her husband by Consultant Surgeon A and the Risk Management Department at the MWRH when they communicated the misdiagnosis to her on the 4th April 2007.

During the course of the investigation, it became apparent that communication systems generally were not satisfactory, both within and across the two organisations and also between the HSE corporately and with local organisations. Common themes which emerged from the interviews undertaken by the investigation team included:

- *Lengthy delays or often a failure to receive any response to formal letters sent within the management system*
- *Inconsistent messages about resources and priorities*
- *Ineffective mechanisms for communicating and engaging with staff*
- *A general lack of confidence in the integrity of the communication process*

### Recommendation 13

The hospitals should establish an effective, patient focused communication strategy that addresses the needs of internal and external audiences. This should include:

- *Ensuring that the views and perspectives of patients, service users and front line staff are taken into account*
- *Supplementing the formal communication process with regular visits to the 'shop floor' and face to face dialogue*

The effectiveness of this strategy should be reviewed on a regular basis.

## 6.8 Management

At this time, there was significant organisational change in the health system that included the merger of 11 Health Boards into one national organisation - the HSE. The consequences of organisational change on the productivity, efficiency and safety of participant and merging organisations are well documented. It is also apparent that these changes led to a loss of organisational memory in terms of governance. In addition, disillusionment with the role of the HSE was a consistent feature in most of the interviews.

Patient-centred care should be at the core of every healthcare organisation. This maxim applies equally to management processes as it does to clinical services. Therefore it is essential that management have a clear understanding of their patients' health needs and their patients' experiences of healthcare. From this starting point, the organisation should articulate clearly its purpose, its vision and its values in such a way that the public can understand them and the staff can take ownership of them. This, in turn, should inform the way in which the organisation conducts its business.

During the course of this investigation no evidence was found to suggest that this ethos was sufficiently embedded in the management process. The impression gained was of a system that delayed or avoided difficult decisions and gave priority to listening to those at a national level rather than to their patients and front line staff.

At times of significant pressure, it is even more important that management should engage with clinicians and other stakeholders to discuss how best to reconcile conflicting demands which may divert attention away from quality and safety.

The team found no evidence of such an approach during this investigation. Local managers did not appear to have sufficient authority vested in them to make decisions about priorities and thus their credibility was undermined. Engagement in the business planning process was widely regarded as a futile exercise as priorities were decided at another level.

Similarly, the team did not find evidence of an appropriate balance of clinical and other professional staff effectively engaged in the management process.

### Recommendation 14

Governance arrangements need to be strengthened to ensure:

- *Clarity of delegated levels of authority, reporting relationships and accountability at local, regional and national levels*
- *Transparent business planning and decision making processes*
- *Effective engagement and involvement of clinicians in the executive management process*



The HSE's network management system did not appear to have the confidence of staff and many commented that the new system delayed the decision making process rather than facilitating it. Support offered to managers appeared to be minimal and the selection, induction and development process may well need strengthening.

Significant improvements in clinical services in both hospitals since March 2005 were evident. However, there was a disconnection between both management and clinical staff at a local level as well as between the hospitals and the National Hospitals Office. In addition, consistent themes from our interviews included significantly increasing workloads not matched by resources and recurring difficulties and delays in securing additional staff, as well as disillusionment with the role of the HSE.

It was also apparent from interviews that there was a need to drive for more significant engagement of senior clinical leaders in the management of hospitals and where this engagement is effective the lessons should be transferred to other hospitals within the HSE. It was acknowledged that much work was needed to develop effective succession planning for the general management of the HSE and its constituent hospitals.

## 7 Conclusions

The investigation team has reached the following conclusions.

### **Rebecca O'Malley's Misdiagnosis**

This investigation has concluded that in respect of Rebecca O'Malley's misdiagnosis, the primary error was made by a consultant pathologist at CUH who interpreted a cytology tissue sample as suggestive of a fibroadenoma (a benign condition). Subsequent review - confirmed by this investigation - concluded that this slide showed malignant cells.

A wider review of this pathologist's work indicated this to be an isolated error in their tenure at CUH. A small number of such interpretive errors is a recognised feature of histopathology and cytopathology and hence the need for triple assessment for patient management.

Subsequent to the initial error, a multi-disciplinary meeting at the MWRH reviewing Rebecca O'Malley's case did not include a review of the relevant slides or a contribution from the reporting pathologist, as would be regarded as good practice. This was because the cytology reviews were conducted at another hospital, CUH, as part of an out-sourcing agreement. In these circumstances, arrangements should have been put in place to ensure pathology input at the multi-disciplinary team meeting. However, because there was nothing to suggest a fibroadenoma either by imaging or clinical test, the result was discordant. This discordance or disagreement between the clinical, imaging and pathology findings were not identified at this meeting. As a result, the opportunity to correct for the initial interpretive error was missed.

### **Quality Assurance of Cytology**

The investigation identified that the quality of the cytology samples routinely presented for interpretation in CUH was poor. This indicates the need for a comprehensive quality assurance programme for FNA cytology.

There is also a need to reduce the reliance on fine needle aspiration (FNA) as a diagnostic tool in symptomatic breast disease except under clearly defined conditions.

### **Ms X's Experience**

Taking a wider perspective, whilst the symptomatic breast disease service at the MWRH exhibited many aspects of a good quality service in terms of organisation, the experience of Ms X (including potentially sub-optimal diagnostic processes, delays and poor communication) further reinforces the need for greater emphasis on patient centred systems and processes.

## Decision Making and Resources

In both services under review (symptomatic breast disease incorporating surgery and radiology at the MWRH and cytopathology at CUH) frontline clinicians raised concerns about the resources available to meet demand. Addressing these issues was not helped by what was reported as an inability for decisions to be made locally about resourcing priorities.

Linked to the concerns surrounding resources, the impact of the transition to the new HSE structures was cited as having an influence on the overall management environment. The investigation also identified examples of ineffective engagement between clinicians and managers.

The investigation team understands that since it concluded its work the National Cancer Control Plan directorate of the HSE has conducted a benchmarking exercise to assess the need for additional resources at the MWRH and CUH to move towards meeting the Symptomatic Breast Disease Standards. The team understands that the necessary funding has been allocated recently to allow key appointments to proceed.

## Accountability

A recurrent message from interviews indicated a lack of clarity about roles, responsibilities, accountability and leadership within the system which had been accentuated by recent management changes and ongoing national negotiations.

Taken together, the hospitals managed by the HSE did not respond adequately to Rebecca and Tony O'Malley when they wanted to find out more about the mistake in diagnosis. Whilst individual managers and clinicians made efforts to resolve Rebecca O'Malley's concerns, there was a collective lack of accountability, cohesion and focus on the needs of the patient.

Despite being part of the same organisation, the hospitals were not able to coordinate an investigation and credible explanation of Rebecca O'Malley's misdiagnosis. This left Rebecca O'Malley feeling that her experience was not regarded as a priority and that she had to make the running in obtaining information. In addition, there was a disjointed, incomplete clinical and managerial response to the discovery of what was an adverse clinical incident with no root cause analysis being conducted.

In keeping with Rebecca O'Malley's wishes, this investigation has not sought to apportion blame. However, it is seeking to highlight the importance of clinical and managerial accountability and that this can never be diluted or abdicated by transitory organisational change. The effort of both should be integrated to promote high quality safe care. This implies the need for clear systems of governance that support decision making at every level but also challenge those making decisions to ensure they are always focused on the best interests of patients.

## The Future

The findings have led the investigation team to make a number of recommendations which it believes will improve the quality of care offered to all women who present with symptomatic breast disease not only to Limerick and Cork but to all hospitals in Ireland where such services are provided.

The Authority will expect the HSE to performance manage the respective hospitals against the implementation of these action plans and consider at a corporate level where the recommendations should be applied nationally – for example as part of the National Cancer Control Plan. The Authority will agree with the HSE a time frame for the Authority to periodically monitor that the recommendations are being implemented.

### Recommendation 15

The corporate HSE executive management team should nominate a specific director accountable for ensuring the development of an implementation plan for these recommendations. This should include a clear timeframe and milestones. Progress against the plan should be made public and reported to the Board of the HSE.

This active and visible demonstration of change and progress will be necessary in order to rebuild the confidence and trust of past and current patients and their families.

The investigation team strongly recommends that the senior management and clinical teams of all hospitals in Ireland who are providing symptomatic breast disease services should read this report, undertake their own baseline assessment against these specific recommendations and make the necessary changes in addressing where gaps exist.

## Concluding Remarks

This investigation into the quality of care offered to Rebecca O'Malley and the management of her concerns by the clinicians, managers and institutions of the HSE, including the Mid Western Regional Hospital, Limerick and Cork University Hospital, would not have taken place without the extraordinary efforts of the patient and her husband.

These efforts were made to try and understand what had gone wrong, why it had gone wrong and what would be put in place, by the various responsible members of the clinical and managerial staff, to ensure that this would not happen again and that no other patients would suffer as a result of a similar error.

It is a salutary lesson to all involved in the pathway of care offered to Rebecca O'Malley that the system did not recognise that an error had been made, that the system did not protect her from a delay in diagnosis and treatment for her breast cancer and that when she was at her most vulnerable, the system did not respond in a way that recognised she was the most important person within her pathway of care.

Rebecca O'Malley has demonstrated, through her personal experience, that the system was inadequate and was not able to respond to her needs. Every effort must be made to ensure this cannot happen again and those involved in leading and developing the health service in Ireland must learn from her experience and recognise that they are in her debt for having the courage and resilience to bring her experience to their attention.

## 8 References

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## 9 Glossary of Terms and Abbreviations

- Aspirate:** sample of cells taken from a tumour.
- Atypical Ductal Hyperplasia:** unusually excessive growth of cells in a duct.
- Axillary:** relating to the armpit area.
- Benign:** non-cancerous.
- Calcification:** hardening of tissue because of calcium deposits.
- Carcinoma:** cancer of the cells covering the internal or external surfaces of the body.
- Clinical Governance:** the framework through which all the components of quality, including patient and public involvement, are brought together and placed high on the agenda of each organisation.
- CUH:** Cork University Hospital.
- Cytopathology:** the study of diseased cells.
- Epithelial cells:** cells covering over the internal and external surfaces of the body.
- Fibroadenoma:** a benign lump in the breast.
- Fine Needle Aspiration:** use of a needle attached to a syringe to withdraw cells from a tumour.
- HIQA:** Health Information and Quality Authority.
- Histopathology:** the study of diseased tissue.
- HSE:** Health Service Executive.
- Multi-disciplinary team review:** The results of all three results are presented and discussed. Where all three results agree, this is a concordant triplet. When there is a variance in results, this is known as a discordant triplet.
- MWRH:** Mid Western Regional Hospital.
- NHO:** National Hospitals Office.
- Patient Advocacy:** an individual acts independently on behalf of, and in the interests of a patient/service user, who may feel unable to represent themselves in their contact with staff.
- Risk Assurance Framework:** a process which provides feedback on the efficiency, effectiveness, integrity and quality of an organisation's operations.
- Risk Management:** the systematic identification, evaluation and treatment of risk. A continuous process with the aim of reducing risk to organisations and individuals alike.
- Sentinel Node Biopsy:** removal and examination of one or a few lymph nodes to which cancer cells are likely to spread from a primary tumour; used to predict nodal stage of disease.
- Stellate:** star-shaped.
- Triple Assessment:** An assessment which includes clinical examination, imaging and pathology tests.

# 10 Appendices

## Appendix 1: The Investigation Team

**Dr. Michael Durkin** is Medical Director of the South West Strategic Health Authority having been appointed in 2006; he has particular responsibility for clinical governance across the NHS South West which serves a population of 5 million.

He has held research and teaching appointments and for three years was on the faculty at Yale University School of Medicine, USA where he was also Attending Anaesthesiologist.

In 2001 he became Advisor to the National Leadership Development Programme for Clinical and Medical Directors and supports the delivery of these programmes across Trusts and Strategic Health Authorities in England. He has introduced mentoring training programmes for NHS Trusts and Medical Directors.

He has led clinical performance and governance reviews for Royal Colleges and in NHS and Independent hospitals in the UK, for other SHAs in England and in 2003/04 for a Ministerial Review in Gibraltar. In 2006 he was appointed to act as the External Medical Advisor to the Regulatory and Quality Improvement Authority in Northern Ireland.

**Dr. Gerard Boran**, is a graduate of Trinity College Dublin and is Consultant Chemical Pathologist at the Adelaide and Meath Hospital Dublin, incorporating the National Children's Hospital. Dr. Boran has over 10 years experience as a consultant in Ireland and 4 years as a consultant at the Royal Hull Hospitals, UK (1993-1997). Dr. Boran is currently Dean of the Faculty of Pathology of the Royal College of Physicians of Ireland. He is also a Steering Board Member of the Irish External Quality Assurance Scheme (IEQAS). He is course co-ordinator for the Trinity College Dublin Master of Science course in Clinical Chemistry.

**Dr Mairead Griffin** is Consultant Histopathologist and Lecturer in Histopathology at St James's Hospital and Trinity College Dublin. Her areas of sub-specialty expertise include cytopathology, breast and gynaecologic pathology. Mairead Griffin was previously Quality Assurance Pathologist for the Irish Cervical Screening Programme. She is a member of Irish Association of Clinical Cytology, the British Society of Clinical Cytology and the International Academy of Pathology. She is a member of the editorial board for "Cytopathology." Her research interests include automation in cervical screening.



**Professor Arnold Hill** is Professor of Surgery and Chairman of the Department of Surgery at The Royal College of Surgeons in Ireland and at Beaumont Hospital, Dublin. He did a two year basic research fellowship with Dr John Daly at The Hospital of the University of Pennsylvania and The New York Hospital / Cornell Medical Center in the United States. He returned to Ireland to do his Senior Registrar training on the National Training Programme in Ireland. He also did a clinical fellowship in Surgical Oncology at Memorial Sloan Kettering Cancer Center in New York. His clinical interests are in the area of breast cancer and melanoma. In January 2006, Professor Hill took up Chair of Surgery at The Royal College of Surgeons of Ireland and transferred his clinical practice to Beaumont Hospital, Dublin, the principal teaching hospital of the RCS Ireland.

**Edward Kinsella** is an independent healthcare consultant, specialising in effective corporate governance, patient safety and quality. He has extensive leadership experience, having served as a Chief Executive at both Hospital and Health Authority level, and works closely with the NHS Clinical Governance Support Team and the Healthcare Standards Unit at Keele University.

**Christine Murphy-Whyte** holds an honours degree in Social Science and a Masters in Social Administration from UCD. She has over 33 years full-time employment experience mainly in state sponsored agencies including 20 years management experience, mostly at senior management level. She has worked with and on behalf of people with disabilities in the fields of education/training and employment, disability services, advocacy, and national policy development and has extensive experience at both practitioner and management levels in the fields of research, training and development, standards, certification and quality assurance. Formerly, Head of Policy and Public Affairs with the National Disability Authority, she took early retirement in 2005, following diagnosis and treatment for breast cancer, and currently is Chairperson of Europa Donna Ireland -The Irish Breast Cancer Campaign, a volunteer-based patient advocacy organisation.

**Sheila O'Connor** is a non-executive member of the Board of the Health Information and Quality Authority. She is a founding member of Patient Focus a national patient advocacy charity. Patient Focus' niche in the system is helping people damaged by the Health Care System achieve resolution in a constructive way. She holds Bachelors and Masters Degrees in Social Science and Sociology from UCD as well as a Bachelors Degree in Civil Law also from UCD. She holds a Certificate in Counselling Skills from Maynooth University.

**Dr. Ann O'Doherty** is Clinical Director, National Breast Screening Programme Merrion Unit and Consultant Radiologist, St. Vincent's Group Hospitals. In 2005 Dr. Ann O'Doherty was appointed to the Department of Health and Children's Committee to establish National Quality Assurance Guidelines for Symptomatic Breast Cancer. She is a member of the Sub-Group to The National Cancer Forum, reported on the Development of Services for Symptomatic Breast Disease in 2000. She was previously, Clinical Director, Eastern Board Breast Screening Service and Quality Assurance Director, Quality Assurance Radiologist Northern Ireland Breast Screening Programme.

### **Investigation Project Manager**

**Triona Fortune**, the Health Information and Quality Authority.

## Appendix 2: Documents Requested

The following documents were requested and used to inform this investigation into the circumstances surrounding the care of Rebecca O'Malley and the related services provided by CUH, the MWRH Limerick and the HSE.

### Mid Western Regional Hospital Limerick

#### Corporate Arrangements

- *Organisational structure.*
- *Clinical governance, accountability and line management structure within the MWRH.*
- *Board minutes in relation to the Rebecca O'Malley case and the symptomatic breast disease services.*
- *Minutes of clinical governance and or risk management committee for the last year.*
- *Copies of correspondence between CUH and the MWRH relating to the symptomatic breast disease service at the MWRH, pathology service at CUH and the Rebecca O'Malley case.*
- *Contract between the MWRH and CUH for pathology services and between the MWRH and the UK laboratories.*

#### Symptomatic Breast Disease Service - structures and minutes

- *Organisational and clinical governance structure within the surgical, radiological and pathology department.*
- *Regional/national networked symptomatic breast disease meetings participation over the last three years.*
- *Number of staff working, and respective roles, within the departments providing the symptomatic breast disease services since the time of the case.*
- *Quality assurance arrangements over the last 3 years for the symptomatic breast disease service – surgery, radiology and pathology.*
- *Adverse incident and near miss reporting procedure.*
- *Minutes of multi-disciplinary meetings for symptomatic breast disease service around March 2005 and since that time.*
- *Minutes of meetings outlining any actions taken regarding the case, learning and changing practice.*

- *Credentialing procedures for permanent and temporary staff.*
- *Staff supervision policy.*
- *Probationary arrangements for new staff.*
- *Minutes of multi-disciplinary meetings with other disciplines and hospitals relating to the symptomatic breast disease service.*
- *Previous serious adverse events in relation to the pathology department for the last three years and any actions or developmental support taken.*

### **Symptomatic Breast Disease Service - Activity**

- *Activity breakdown for the symptomatic breast disease service over the last three years by:*
  - type*
  - new referral and follow-up*
  - assessments performed*
  - diagnosis by type*

### **Symptomatic Breast Disease Service - Clinical audit**

- *Clinical audit activity for the symptomatic breast disease service over the last three years.*

### **Organisational Policies and Procedures**

- *Healthcare risk management incident reporting policy and procedure. 2004. HSE Mid Western Area.*
- *Healthcare risk management strategy. 2005. HSE Mid Western Area.*
- *Disclosure policy. 2006. HSE Mid Western Area.*
- *Complaints policy.*
- *Credentialing, recruitment, induction and appraisal policies for permanent, temporary, locum and agency staff.*
- *Performance development review procedure.*
- *Staff supervision policy.*

## Cork University Hospital

### Corporate Arrangements

- *Organisational structure.*
- *Clinical governance, accountability and line management structure within CUH.*
- *Board minutes in relation to the Rebecca O'Malley case and the pathology services.*
- *Minutes of clinical governance and or risk management committee for the last year.*
- *Copies of correspondence between CUH and the MWRH relating to the symptomatic breast disease service at the MWRH, pathology service at CUH and the Rebecca O'Malley case.*
- *Contract between the MWRH and CUH for pathology services.*

### Pathology Service – structures and minutes

- *Organisational and clinical governance structure within the pathology department.*
- *Regional/national networked pathology meetings participation over the last three years.*
- *Number of staff working, and respective roles within pathology services, since the time of the case.*
- *Quality assurance arrangements over the last three years for the pathology service.*
- *Adverse incident and near miss reporting procedure.*
- *Minutes of multi-disciplinary meetings for pathology services around March 2005 and since that time.*
- *Minutes of meetings outlining any actions taken regarding the case, learning and changing practice.*
- *Credentialing procedures for permanent and temporary staff.*
- *Staff supervision policy.*
- *Probationary arrangements for new staff.*
- *Minutes of multi-disciplinary meetings with other disciplines and hospitals relating to the pathology service.*
- *Previous serious adverse events in relation to the pathology department for the last three years and any actions or developmental support taken.*

### **Pathology Service – Activity**

- *Activity breakdown for the pathology service over the last 3 years by:*
  - specimen type*
  - histopathologist*
  - referring hospital*

### **Pathology Service – Clinical audit**

- *Clinical audit activity for the pathology service over the last 3 years.*

### **Organisational Policies and Procedures**

- *Adverse incident and near miss reporting procedure.*
- *Complaints policy.*
- *Credentialing, recruitment, induction and appraisal policies for permanent, temporary, locum and agency staff.*
- *Performance development review procedure.*
- *Staff supervision policy.*

## Appendix 3a: Interview Methodology

A total of 35 people were interviewed over thirteen separate sessions in Limerick, Cork and Dublin. The format for the interviews generally followed this style although the content reflected the issue to be addressed.

- *Timing up to 45 minutes.*
- *Interviewee may be accompanied by a colleague.*
- *Two interviewers and one observer from the investigation team.*
- *All parties present will be identified.*
- *Contemporaneous notes will be taken.*
- *Tape recording will not be used.*
- *All exchanges are non-attributable to any party.*
- *A second interview may be requested at a later stage.*
- *The draft record of the interview will be shared with the interviewee to confirm accuracy of fact.*
- *No individuals other than members of the investigation team will be identified in the draft report.*
- *Refer to the agreed Terms of Reference in explaining the purpose.*

# Appendix 3b: Interview Codes

All interviews were coded to structure the findings of the investigation team. This coding system enabled the interview notes to be categorised into structured themes.

## **SC Strategic Capacity and Capability**

**SC1** Strategic planning

**SC2** Business planning

**SC3** Involvement of staff in planning

**SC4** Involvement of stakeholders, patients and the community in planning

**SC5** Evidence of using priorities and risks to inform decision-making

**SC6** Evidence of informed decision-making in planning

**SC7** Connectivity in planning

## **OC Organisation of Care - General**

**OC1** Systems and processes, policies and procedures

**OC2** Evidence of provision of services based on need

**OC3** Monitoring of quality and safety of the services at departmental, senior management, regional and national level

**OC4** Networked arrangements with other centres

**OC5** Meetings with external stakeholders

## **OCC Organisation of Clinical Oncology Services**

**OCC1** Systems and processes, policies and procedures

**OCC2** Quality assurance arrangements in oncology department

**OCC3** Supervision of new and existing staff

**OCC4** Communication between services and sites (including results)

**OCC5** Internal audit activity

**OCC6** Monitoring of activity and reporting

**OCC7** Demonstration of learning from reporting trends

**OCC8** Multi-professional review meetings – internal

**OCC9** Multi-professional review meetings - with external services

**OCC10** Implementation of evidence-based best practice

**OCC11** Meetings with external stakeholders

**OP Organisation of Pathology Services**

**OP1** Systems and processes, policies and procedures

**OP2** Quality assurance arrangements in pathology department

**OP3** Supervision of new and existing staff

**OP4** Communication between services and sites (including results)

**OP5** Internal audit activity

**OP6** Monitoring of activity and reporting

**OP7** Demonstration of learning from reporting trends

**OP8** Multi-professional review meetings - internal

**OP9** Multi-professional review meetings with external services

**OP10** Implementation of evidence-based best practice

**OP11** Meetings with external stakeholders

**OR Organisation of Radiology Services**

**OR1** Systems and processes, policies and procedures

**OR2** Quality assurance arrangements in radiology department

**OR3** Supervision of new and existing staff

**OR4** Communication between services and sites (including results)

**OR5** Internal audit activity

**OR6** Monitoring of activity and reporting

**OR7** Demonstration of learning from reporting trends

**OR8** Multi-professional review meetings - internal

**OR9** Multi-professional review meetings with external services

**OR10** Implementation of evidence-based best practice

**OR11** Meetings with external stakeholders

**OSB Organisation of Symptomatic Breast Disease Services**

**OSB1** Systems and processes, policies and procedures

**OSB2** Quality assurance arrangements in breast disease services



- OSB3** Supervision of new and existing staff
- OSB4** Communication between services and sites (including results)
- OSB5** Internal audit activity
- OSB6** Monitoring of activity and reporting
- OSB7** Demonstration of learning from reporting trends
- OSB8** Multi-professional review meetings - internal
- OSB9** Multi-professional review meetings with external services
- OSB10** Contractual arrangements with outsourced providers, including pathology
- OSB11** Implementation of evidence-based best practice
- OSB12** Meetings with external stakeholders

**RM Risk Management**

- RM1** Systems and processes, policies and procedures
- RM2** Risk register
- RM3** Management of adverse events, near misses, complaints, claims, including reporting procedures
- RM4** Feedback to staff following reporting of incidents
- RM5** Infection control and health and safety
- RM6** Training in risk management
- RM7** Evidence of learning following adverse incidents, near misses, complaints, claims

**CE Clinical Effectiveness**

- CE1** Systems and processes, policies and procedures
- CE2** Application of evidence based practice, standards and guidelines
- CE3** Clinical audit activity - individuals, teams, organisation.
- CE4** Evidence of learning from clinical audit
- CE5** Multi-disciplinary audits
- CE6** Patients involved in audits

**SM Staff Management and Performance**

- SM1** Systems and processes, policies and procedures
- SM2** Recruitment - credentialing, references for permanent, locum, bank, agency staff

<b>SM3</b>	Accountability arrangements with agencies
<b>SM4</b>	Induction programme
<b>SM5</b>	Appraisal/performance development reviews for staff
<b>SM6</b>	Grievance, disciplinary, sickness / absence procedures
<b>SM7</b>	Supporting staff and staff welfare

### **ETD Education, Training and Development**

<b>ETD1</b>	Systems and processes, policies and procedures
<b>ETD2</b>	Mandatory training
<b>ETD3</b>	Continuous professional development
<b>ETD4</b>	Implementation of training priorities
<b>ETD5</b>	Service plans for training needs

### **PPI Patient and Public Involvement**

<b>PPI1</b>	Systems and processes, policies and procedures
<b>PPI2</b>	Patient involvement in their individual care planning
<b>PPI3</b>	Patient and public involvement in the planning of their services
<b>PPI4</b>	Patient experience - evidence of monitoring
<b>PPI5</b>	Arrangements for patient feedback at service and hospital level
<b>PPI6</b>	Patient groups

### **IM Information Management**

<b>IM1</b>	Systems and processes, policies and procedures
<b>IM2</b>	Management of medical records
<b>IM3</b>	Data protection and confidentiality
<b>IM4</b>	Use of information to plan and improve services
<b>IM5</b>	Use of information to audit services

### **RE Research Effectiveness**

<b>RE1</b>	Systems and processes, policies and procedures
<b>RE2</b>	Planning research activity
<b>RE3</b>	Implementing research to inform practice
<b>RE4</b>	Access to library, internet, journals

**LE Leadership**

- LE1 Strategic capacity and capability of senior management team/board
- LE2 Board/non-executive directors
- LE3 Senior management team
- LE4 General manager
- LE5 Lead clinicians and senior managers
- LE7 Departmental leads
- LE8 Network management arrangements
- LE9 Clarity of accountability arrangements
- LE10 Organisation of governance within organisation—meetings
- LE11 Demonstration of senior management team/board in receiving, addressing and acting on concerns
- LE12 Culture

**CO Communications**

- CO1 Systems and processes, policies and procedures
- CO2 Communications within and between organization and stakeholders, public, patients
- CO4 Communications between and within services, clinicians and managers

**TW Team working**

- TW1 Systems and processes, policies and procedures
- TW2 Team working between and within services
- TW3 Team working between clinical teams

## Appendix 4: Case Review Methodology

25 cases were reviewed from Limerick.

The clinical notes were reviewed by a consultant breast surgeon. A surgical code "S1–S5" was allocated to each patient.

The imaging was then reviewed by a consultant radiologist. An "R" classification was allocated to the mammogram findings. A "U" classification was allocated to the ultrasound findings. A conclusion was then made based on the clinical and imaging findings. It is only possible to have a full multi-disciplinary review after the cytological review was complete. A further and subsequent review took place which allowed for further integration of the pathology, surgery and radiology opinion.

# Appendix 5: Slide Review Methodology

## Phase 1: **Cytopathology Review of the case of Rebecca O'Malley and 24 further cases**

### Background

The Faculty of Pathology has been requested by the Authority to work with them as part of this investigation. The Faculty of Pathology can be consulted as an authoritative body by national, international and government agencies and it has an important role in safeguarding the quality of the pathology service in Ireland.

The Authority's investigation team has requested a case review of an identified number of patients who had cytopathology interpreted at Cork University Hospital. Currently there have been 24 cases plus Rebecca O'Malley (making 25 in total) identified by the Mid Western Regional hospital as requiring a cytopathology, and or, case review.

This document outlines the specific terms of reference in relation to the cytopathology review of these 25 patients.

### Terms of Reference

1. The Dean (or another Officer) of the Faculty of Pathology will chair and facilitate the review panel.
2. The objective of this review will be to determine whether errors have occurred, to provide a commentary on their nature and extent, and to produce a Statement of Findings which will be the deliverable and will form an input into the Authority's overall investigation.
3. Three reviewers will be selected. The criteria for selection of reviewers will be as follows:
  - a. Reviewers will be consultant histopathologists with a special interest and actively reporting breast cytology.
  - b. Reviewers will not be connected with any of the hospitals or laboratories in Ireland or the United Kingdom that have been identified in the cases.
  - c. Reviewers should be on the Histopathology division of the appropriate register of medical specialists and have good communication skills .

4. The materials required for the review will be made available to the Faculty and will include:
  - a. All slides made including special stains
  - b. Clinical request forms (where available)
  - c. Copy of the original pathology report
  - d. Slides and reports of any follow-up biopsies or resections where applicable
  - e. The basis and criteria on which each case has been selected for review by Limerick
  - f. Written summary of the context in which breast cytology is undertaken (where aspiration is performed, by whom (surgeon/ pathologist/ radiologist), criteria for referral for core biopsy, multi-disciplinary case discussion protocol)
5. Each member of the review panel will conduct a blind review of slides from the cases, using only the slides and clinical request form (if available).
6. When each review panel member has completed their blind review, the panel will meet to review the findings and prepare a Statement of Findings. Cases where there is discrepancy in interpretation between reviewers and/or between reviewers and original pathologist will be discussed at multi-observer microscopy.
7. The Statement of Findings will give for each of the cases the findings of each review panel member. The original pathologist's report will also be tabulated for each case.
8. Every effort will be made to deliver the Statement of Findings to the Authority's investigation team within two weeks of commencement of the review.
9. Once completed and delivered to the Authority's investigation team, the Statement of Findings will input into a case review process by the multi-disciplinary investigation panel being established by the Authority's investigation team for the purposes of conducting the overall investigation.
10. The Rebecca O'Malley case will be included in the review process as the nature of the original error may inform the review process. The Rebecca O'Malley case will, however, be the subject of a further review coordinated by the Authority's investigation team, which will examine all aspects of the case including the pathology.

## Phase 2: Further Review

A further review of the pathology service will be organised to verify the quality of other pathology work conducted by the pathologist who originally reported on the Rebecca O'Malley case.

### General principles

In order to assist with determining the scope of the work involved, a two stage process will be used for the main audit methodology:

1. initially computer printouts of all pathology reports will be reviewed
2. based on this review, a decision will then be taken on which cases (if any) require further scrutiny, e.g. a slide review.

### Materials Requested

#### *(1) Audit of pathology reports (computer reprints)*

Pathology reports will be requested to be obtained from CUH computer as described below, sorted into requesting consultant order.

- (i) copies of all pathology (histology and cytology) reports reported by the Consultant Pathologist A between July 2004 and August 2005 separated into the following categories:
  - (a) breast histopathology
  - (b) all other histopathology reports
  - (c) breast cytopathology from Limerick
  - (d) breast cytopathology from CUH
  - (e) all other diagnostic cytopathology from Limerick
  - (f) all other diagnostic cytopathology from CUH
- (ii) all breast cytopathology reports for year 2005 reported at CUH separated into the following categories will also be requested for comparison purposes:
  - (a) breast cytopathology from Limerick hospital
  - (b) breast cytopathology from CUH

#### *(2) Review of all slides for Rebecca O'Malley*

For completeness the team also decided to review all the histopathology on Rebecca O'Malley from Limerick, the London Clinic and Royal Marsden Hospital. All slides were requested, not just a representative section.

#### *(3) Review of Slides following the audit of pathology reports (described in (1) above)*

- (i) Following from the audit of pathology reports (described under (1) above), the Authority's investigation team decided to obtain all the slides and request forms for the remaining breast cytology cases reported by Consultant Pathologist A.

The Health Information and Quality Authority investigation team also requested a review of all breast histology specimens reported by Consultant Pathologist A between July 2004 and August 2005.

### **Procedure – general terms**

1. The Dean (or another Officer) of the Faculty of Pathology will facilitate the review panel.
2. The objective of this review will be to determine whether errors have occurred, to provide a commentary on their nature and extent, and to produce a Statement of Findings which will be the deliverable and will form an input into The Authority's overall investigation.
3. The Faculty will recommend three reviewers, including one reviewer from another jurisdiction. The criteria for selection of reviewers will be as follows:
  - a. Reviewers will be consultant histopathologists with a special interest and actively reporting breast cytology
  - b. Reviewers will not be connected with any of the hospitals or laboratories in Ireland or the UK that have been identified in the cases
  - c. Reviewers should be on the Histopathology division of the appropriate register of medical specialists and have good communication skills
4. The materials required for the review will be made available to the Faculty as stated above.
5. Every effort will be made to deliver the Statement of Findings to the Authority's investigation team within two weeks of completion of the review, and within the timescale of the overall Authority review.
6. The Statement of Findings will input into the overall review process as determined by the Authority's investigation team and will not be published as a separate report.

### **Procedure – specific terms**

1. The audit of pathology reports (from computer printouts) will be conducted by one or more pathologists on the team and the findings will be documented in the Statement of Findings.
2. There are 4 components in the audit of pathology reports:
  - (1) breast cytology reported by Consultant Pathologist A
  - (2) breast cytology reported by all pathologists (in order to compare reporting profiles)
  - (3) non-breast diagnostic cytology reported by Consultant Pathologist A
  - (4) breast histology reported by Consultant Pathologist A



3. Components (1) and (4) above will be the subject of a further slide review, i.e. breast cytology and histology reported by Consultant Pathologist A
4. For the slide review, two of the pathologists will separately review the slides (without blinding).
5. Any discrepancies will be resolved by sending the appropriate slides to the third (international) pathologist for examination in his base laboratory.
6. The findings will be documented in the Statement of Findings.

## Appendix 6: Protocol for Safe Transfer and Storage of Data Transfer

- *Important: transportation is not to commence until a specific instruction to do so is received.*
- *The HSE/CUH are responsible for the transportation of the materials until they are signed for at Tallaght Hospital.*
- *The estimated time of arrival must be notified to Tallaght Hospital.*
- *The package should be marked “URGENT HIQA REVIEW” and addressed to [name and address of Pathologist].*
- *Description and contents of package: The package should contain:*
  - *An inventory of contents (and any other accompanying documentation)*
  - *The requested slides*
  - *The appropriate request forms*
- *Receipt at Tallaght Hospital: The package will be checked against the inventory of contents upon arrival by the Laboratory Manager, Laboratory Medicine Department, Tallaght Hospital.*
- *Once the package’s contents have been verified, the package will be signed for by the Laboratory Manager, Laboratory Medicine Department, Tallaght Hospital to confirm delivery.*

### Storage

- *The time/date of receipt of the materials/records shall be recorded.*
- *The delivery must be signed for by [specified people] and opened in the presence of two people [specified].*
- *The contents of the package must be verified immediately upon receipt. Any discrepancies must be notified to the Dean immediately.*
- *The contents will then be brought to the reviewers according to the separate schedule. The time/date of passing the materials to/from the reviewers will be recorded.*
- *The slides together with copies of the clinical request forms (and any covering lists itemising the slides from the Rebecca O’Malley case and 24 further cases) from the Cork Laboratory are to be securely transported to the Histopathology Department, Tallaght Hospital, Dublin 24.*

- *In order to expedite the blind review without delay and avoid the need to separate out the original pathology reports from the slides, all other accompanying paperwork (including the copies of the original pathology reports) should be collated into a single separate sealed envelope and transported under separate cover. This package should be addressed to the Dean of the Faculty of Pathology.*
- *The time/date of passing on material between reviewers will be recorded.*
- *When not in use by the reviewers, the material will be locked in a secure location.*
- *The Access Policy to the Laboratory Medicine Department, Tallaght Hospital will be strictly enforced during the period of the review.*
- *The hospital's security department will be advised.*
- *Storage of records must be in compliance with provisions of the Data Protection Act.*

# Appendix 7: Classification of Pathology Specimens

[Extract from National Quality Assurance Standards for Symptomatic Breast Disease Services, Appendix 3: Minimum Dataset for Breast Cancer Histopathology Reports, pp.77-79]

## 1. Non-Operative Diagnosis

Triple assessment aims to achieve a diagnosis by combining the results of imaging with clinical examination and the use of fine-needle aspiration cytology (FNAC) or needle core biopsy (NCB). This approach to diagnosis minimises the need for open surgery in women with benign breast disease and permits definitive one-stage surgery in women with malignant disease. Non-operative diagnosis requires good communication between the clinician, radiologist and pathologist. In particular, the results of FNAC/NCB must be interpreted in conjunction with the radiological and clinical findings, and never in isolation.

### Fine-needle aspiration cytology

FNAC may be image-guided using ultrasound or stereotaxis, or freehand if the lesion is palpable. Samples are prepared using the direct smear, cytospin or thin-layer technique. Direct smears are air-dried for May Grunewald Giemsa (MGG) and alcohol-fixed for Papanicolaou (Pap) or haematoxylin and eosin (H&E) staining. Cytospin and thin-layer preparations are stained with Pap and/or H&E.

### Interpretation and Reporting

FNAC specimens are assigned to one of the following five categories as defined by the UK NHS (BSP) Guidelines.

#### *C1: Non diagnostic/Inadequate*

The specimen is poorly cellular (fewer than five groups of epithelial cells) or unsuitable for assessment due to drying, crush or spreading artefact, or to contamination by blood. A C1 diagnosis should not be taken as reassurance that a lesion is benign.

#### *C2: Benign*

The sample is adequate (at least five groups of epithelial cells) and displays the features of benign breast change. This usually takes the form of regular monolayers of benign ductal epithelial cells with a background population of individual and paired stromal nuclei. The exact composition of the aspirate depends on the nature of the lesion. Apocrine cells and foamy macrophages are frequent findings in aspirates from cystic change. Fibroadenomas produce cellular aspirates containing connective tissue

fragments and large numbers of stromal nuclei. In certain settings an aspirate which does not contain epithelial cells may be reported as C2, e.g. cyst fluid and aspirates from lesions suggestive of fat necrosis or abscess. Interpretation of benign cytological findings highlights the importance of triple assessment and multi-disciplinary review. A non-specific benign picture may be inappropriate for a discrete lesion, as the sample may have originated from benign breast tissue adjacent to rather than from within the lesion. A specific benign diagnosis (e.g. fibroadenoma, fat necrosis, intramammary lymph node) should be made only if the typical cytological features are present.

### *C3: Atypia, probably benign*

The cytological features suggest a benign process or lesion but some atypical features are present, e.g. increased cellularity, loss of cell cohesion, nuclear pleomorphism or nucleoli. The identification of papillary structures warrants a C3 diagnosis at least and, depending on the degree of nuclear atypia, may be reported as C4. C3 lesions require further investigation.

### *C4: Suspicious, probably malignant*

The appearances are suspicious of malignancy but there is insufficient evidence for a firm diagnosis. The specimen may be poorly cellular, with only a small number of malignant cells present, or may include large numbers of benign cells in addition to malignant cells. A single population of small cells with only mild nuclear atypia may be seen in lobular or tubular carcinoma. C4 lesions require further investigation.

### *C5: Malignant*

The specimen displays unequivocal cytological evidence of malignancy. Typically, the aspirate is cellular and is characterised by a single population of cells with nuclear pleomorphism, irregular chromatin and the presence of nucleoli. There is loss of cell cohesion and dispersal of malignant cells. Necrosis may be seen, more commonly in high-grade tumours. It is not possible to differentiate accurately between in situ and invasive carcinoma on FNAC alone. Certain conditions (e.g. fibroadenoma, silicone granuloma, apocrine change, radiotherapy change) may produce a cytological picture resembling C5, leading to a false positive diagnosis of malignancy. Therapeutic surgery must never be carried out on the basis of a C5 diagnosis in the absence of radiological and/or clinical evidence of malignancy.

## **Needle core biopsy**

NCB is image-guided by the use of ultrasound or stereotaxis. Sensitivity is related to needle size and to the number of samples taken. NCBs for evaluation of microcalcification are x-rayed to ensure that the sample is representative. Specimens are formalin-fixed, paraffin-embedded and sections are cut and stained with H&E. It is usual to examine three levels and to retain parallel spare sections for immunohistochemistry. Further levels may be necessary to detect microcalcification. Cam 5.2 is useful in the investigation of paucicellular lobular carcinoma. Smooth muscle actin stains assist the distinction of radial scar from tubular carcinoma and sclerosing adenosis from invasive carcinoma.

## Interpretation and reporting

NCB specimens are reported according to the UK NHS Breast Screening Programme (BSP) system that is similar but not identical to that used for FNAC.

### *B1: Normal tissue*

This indicates a core of normal tissue that may comprise glandular breast parenchyma, stroma, adipose or lymphoid tissue. Correlation with the radiological and clinical findings is necessary to determine whether the presence of normal tissue accounts for the screen-detected abnormality. A specimen of normal tissue from a patient who has a stellate lesion on mammogram would suggest that the lesion was not sampled. In contrast, normal-appearing tissue would be expected from lesions such as lipoma, involutinal change, hamartoma or intramammary lymph node. The B1 category is also used for specimens that are considered to be unsatisfactory for histological assessment.

### *B2: Benign*

There is evidence of a benign process or lesion, e.g. cystic change, duct ectasia, fat necrosis, sclerosing adenosis or fibroadenoma. NCBs performed for calcification are examined with polarised light for the detection of calcium oxalate crystals (Weddelite), which are not easily seen on H&E preparations. The pathological findings must account for the radiological abnormality and multi-disciplinary review is essential before the patient is reassured.

### *B3: Lesions of uncertain malignant potential*

This category is used for benign and atypical lesions that may be associated with the presence of breast cancer or the risk of developing it. Radial scar/complex sclerosing lesions are associated with co-existent malignancy in up to 25% of cases, and apparently benign papillary lesions on core biopsy may harbour foci of DCIS when the entire lesion is examined. Atypical lobular hyperplasia (ALH) is a risk factor for malignancy and does not in itself present a mammographic abnormality. The presence of ALH on NCB may signify a tumour in the vicinity.

An atypical intraductal epithelial proliferation on NCB may display some but not all of the features of DCIS. Taking account of the strict histological requirements for a diagnosis of DCIS, these proliferations are categorised as ADH. Up to 50% of lesions diagnosed as ADH on NCB prove to be malignant on subsequent excision. Depending on the degree of change, ADH may be assigned to either the B3 or B4 category.

Fibro-epithelial lesions with features suggestive of phyllodes tumour, e.g. increased stromal cellularity, stromal overgrowth, stromal mitotic activity, are also assigned to the B3 category.

B3 lesions require further evaluation, usually surgical excision for complete histological examination.

#### *B4: Suspicious of malignancy*

The appearances are strongly suspicious of malignancy but there is insufficient abnormality for a firm diagnosis, or interpretation is compromised by poor fixation or crush artefact. Small, detached fragments of invasive tumour in the presence of otherwise benign breast tissue are best assigned to this category. A diagnosis of DCIS is often suspected but cannot be confirmed due to the limited tissue available for study, leading to a B4 diagnosis. B4 lesions require further investigation, either repeat NCB or open surgical excision.

#### *B5: Malignant*

There is unequivocal evidence of malignancy, in situ or invasive. Due to sampling error, approximately 20% of lesions reported as in situ carcinoma on NCB will have accompanying invasion in the resected specimen. The B5 category is also appropriate for other malignant lesions, e.g. malignant phyllodes tumour, lymphoma, metastatic melanoma. It is important to specify the nature of these lesions for therapeutic reasons. If there is any doubt, further tissue should be requested for additional studies.







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