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[1] 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.

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.*

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%.[2] 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.

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.*

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[3]. 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.[1]

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.*