



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Report of the investigation into
the provision of services to Ms A
by the Health Service Executive
at University Hospital Galway
in relation to her symptomatic
breast disease, and the provision
of Pathology and Symptomatic
Breast Disease Services by the
Executive at the Hospital

9 July 2008

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 its 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.*

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1 Executive Summary

1.1 Background

This report outlines the findings of the investigation into the missed diagnosis of breast cancer on two separate occasions when a patient, referred to in this report as Ms A, presented with symptomatic breast disease in 2005 and again in 2007. It includes a review of clinical and pathology services for the care and treatment of patients with symptomatic breast disease provided by University Hospital Galway (UHG), a hospital managed by the Health Service Executive (HSE).

Ms A initially presented to her general practitioner in September 2005 with symptoms suggesting breast disease and was referred to Barrington's Hospital, Limerick, a private hospital. At this hospital she underwent a biopsy (tissue sampling) of breast tissue. It was the general practice at that time that pathology specimens from Barrington's Hospital were examined and reported on by staff at UHG. On a second occasion, Ms A was seen again at Barrington's Hospital in March 2007, when further breast tissue was taken by Fine Needle Aspiration (FNA) and sent for analysis at UHG. These two samples, separated by eighteen months, were reported on at UHG by different consultant pathologists (known in this report as Dr B and Dr C) as benign. Subsequent biopsy of breast tissue in March 2007, performed at Barrington's Hospital and reported on at the Bon Secours Hospital, Cork, confirmed that breast cancer was present. Later in March 2007, Ms A was treated surgically for this at Barrington's Hospital and was subsequently managed and treated for ongoing oncology and radiotherapy care at the Mid Western Regional Hospital in Limerick.

In July 2007, following the discovery of these errors, the Health Service Executive (HSE) and the Health Information and Quality Authority (the Authority) discussed the Authority undertaking an investigation. Also in July 2007, the Authority was sent information about concerns relating to the quality of care received by ten patients with symptomatic breast disease at Barrington's Hospital. Ms A was one of these patients. These patients, and others who were treated at Barrington's Hospital from September 2003 to August 2007, were subsequently involved in a review undertaken by the Department of Health and Children and Barrington's Hospital. The findings of this review are published in the 'Report on the Independent Review of Symptomatic Breast Care Services at Barrington's Hospital, Limerick.'¹

Subsequently, on 2 August 2007, the HSE formally requested that the Authority consider undertaking an investigation. On 9 August 2007, 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 the aspects of Ms A's care as they related to the pathology service at UHG. This was also to incorporate the Symptomatic Breast Disease Service at UHG. The Authority appointed Dr Michael Durkin, Medical Director, South West Strategic Health Authority, England to lead a team of experts from within the Irish healthcare

system to conduct the investigation (Appendix 1). Additional external expert advice was sought from the UK in relation to specific aspects of the pathology review.

Under the Health Act 2007, the investigation powers of the Authority relate to services provided or funded by the HSE only, and so the terms of reference of this investigation did not include any aspect of Ms A's care in Barrington's Hospital.

The Authority's investigation entailed a review of documentation including relevant strategic plans, policies and procedures and evaluations at UHG and correspondence relevant to Ms A's experience. It involved site visits and interviews with clinical and non-clinical staff, Ms A, and other patients. The Investigation Team carried out reviews of patient records, imaging material and pathological specimens.

During the course of this investigation, key themes emerged 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 may interpret the issues under investigation differently. However, it is satisfied that it has presented a fair, balanced, objective and accurate account of the findings of this investigation in line with the terms of reference.

It is relevant to note that the aforementioned 'Independent Review of Symptomatic Breast Care Services at Barrington's Hospital, Limerick' was conducted into the care of Ms A and other patients at Barrington's Hospital. The findings of this were reported on 1 April 2008. At the Authority's suggestion, the pathology aspects of the Barrington's review were conducted by the Faculty of Pathology, of the Royal College of Physicians of Ireland, which had also been engaged to undertake the pathology aspects of the Authority's investigation. This was to avoid unnecessary overlap between the two investigations and to allow the Authority to place reliance on any pathology review carried out as part of the Barrington's review.

1.2 Pathology Services

In the course of the investigation, a review was undertaken of a sample of the work of consultant histopathologist Dr B who had been employed at UHG at the time of the initial misdiagnosis in September 2005. Dr B had reported on Ms A's breast tissue specimen and made the initial interpretive error.

A similar review was undertaken of the work of Dr C who had been employed as a temporary consultant pathologist at UHG from September 2006 to March 2007. Dr C made the second interpretive error on Ms A's specimen in March 2007. Following this initial assessment, the review of Dr C's work was extended to include all breast cytology specimens that they reported on and all diagnostic cytology reported by them. In addition, a review of the gynaecological cytology reporting for which Dr C was responsible during their tenure at UHG was undertaken.

1.3 Findings

The main findings of the Investigation Team are outlined below.

1.3.1 Ms A's Diagnosis

Two significant errors were made in the examination and interpretation of Ms A's pathology specimens, one by Dr B and one by Dr C, both of whom were working within the Pathology Department of UHG. The first of these errors by Dr B in 2005, led to a diagnosis of a benign condition instead of breast cancer and contributed to a delay in commencing Ms A's treatment for breast cancer. The second error by Dr C occurred in March 2007. Ms A received a definitive diagnosis of malignancy shortly thereafter when a further biopsy of her breast tissue was reviewed and reported on at Bon Secours, Cork.

Ms A's clinical examinations, mammography tests and surgery were carried out at Barrington's Hospital. In addition, samples for pathology review were taken and the analysis of these was carried out at UHG, following which, the results were communicated back to Barrington's Hospital.

A small number of interpretive errors are a recognised feature of histopathology and cytopathology reporting. To mitigate the risk of such errors leading to a misdiagnosis there needs to be an effective system in place. This should allow for the diagnostic and clinical findings to be discussed by the relevant specialists (for example surgery, radiology, pathology) rather than individual results being relied upon in isolation. This is known as 'triple assessment' and is usually achieved through multidisciplinary team (MDT) meetings. MDTs provide a vital opportunity to identify discrepancies (known as 'discordant findings') so that further tests can be carried out if needed and the patient diagnosed and treated appropriately.

In Ms A's case there was no MDT meeting to discuss all of her triple assessment findings. The arrangement for reporting pathology specimens between Barrington's Hospital and UHG was informal in nature and was based on a long-standing private arrangement between individual clinicians.

The Investigation Team found that there had been no formal contract or agreement between UHG Pathology Department and Barrington's Hospital for reporting pathology specimens. There was no structured arrangement for consultant pathologists at UHG to participate in MDTs at Barrington's Hospital and as a result there was no opportunity to explore any discordant findings. This is not acceptable practice.

The Investigation Team believes that formal arrangements for referring surgeons, radiologists and reporting pathologists to discuss Ms A's diagnostic findings should have been in place. This is especially important in a situation where, as in Ms A's case, clinicians are based in different institutions. Putting in place this important safeguard for patients is a shared responsibility between individual clinicians and the institutions in which they work and the accountability for the oversight of the patient's care should be made explicit in such circumstances.

The Investigation Team concluded that, in Ms A's case, the absence of such arrangements was a significant contributory factor in her delayed diagnosis.

That Ms A experienced two interpretive errors, separated by 18 months, by different consultant pathologists serves to emphasise the importance of having fully functioning triple assessment and MDTs in place. Arrangements for MDTs should be in place, irrespective of whether patients are cared for in the public sector, private sector, or a combination of both.

1.3.2 The Response by UHG

In late June 2007, Ms A's oncology consultant (Dr D) asked UHG Pathology Department to review the original pathology samples of September 2005 and March 2007. This was completed in early July 2007. When the Pathology Department identified that errors had occurred (16 July 2007) they informed UHG senior managers. An adverse incident group was established by UHG (17 July 2007), which led to the request for an external independent review of symptomatic breast disease and related pathology services.

The UHG established a helpline for women who may have been concerned about their care as a result of Ms A's experience. In addition, they carried out their own internal review of a small sample of pathology reporting. This work was superseded subsequently by the Authority's investigation. The Hospital senior management, clinicians and administrative staff worked effectively together in setting up the helpline and managing the patients who came forward.

The Investigation Team is aware that the HSE is reviewing its procedures for responding to serious incidents and recommends that the approach adopted by UHG in setting up and managing a helpline are fed into this review. Hospital staff engaged in reviewing policies and procedures for services where adverse incidents or near misses have occurred, should be trained in carrying out root cause analysis and ways of achieving immediate changes in service re-design as a result of their analysis.

1.3.3 The Pathology Reviews

The Investigation Team reviewed a large number of pathology specimens reported on by Dr B and Dr C to identify whether there was a wider concern about their practice and to ensure, as far as possible, that other patients had not received incorrect or delayed diagnosis. Where this was the case, the Investigation Team sought to ensure that they were informed, given the offer of a follow up appointment, reviewed and where necessary treated promptly.

From the review of a representative sample of Dr B's breast histopathology reporting (200 patient cases), the Investigation Team concluded that Dr B made a significant error in the interpretation of the biopsy material of Ms A in September 2005. This had been reported as benign and should have been reported as malignant. Following the review of the representative sample, no further errors in diagnosis were identified.

The Investigation Team made an initial review of a representative sample of Dr C's cytology reporting which incorporated all their breast reporting and a random sample of other tissue types. From this review, the Investigation Team identified that Dr C made a significant error when reviewing material from a Fine Needle Aspiration (FNA) of breast tissue from Ms A. Dr C wrongly interpreted this specimen as benign. (FNA involves passing a thin needle through the skin to sample fluid or tissue from a cyst or mass.) As part of this initial review, other errors were identified. This led the Investigation Team to broaden the review of patient slides from Dr C's work to include all their diagnostic cytology work during their tenure at UHG. This review identified further errors.

Out of the total of 747 patient cases reviewed, 49 discrepancies were identified between the original report by Dr C and that of the Investigation Team. Where the discrepancies warranted patient follow-up, the Investigation Team liaised closely with UHG to ensure affected patients were reviewed and, where necessary, invited for follow up.

Of these 49 patients, the findings on follow-up were:

- *1 patient had a delayed diagnosis of thyroid cancer (9 month delay)*
- *1 patient had a delayed diagnosis of carcinoma in-situ of the bladder (16 month delay. Carcinoma in-situ means the cancer is non-invasive and has remained in the identified area)*
- *1 patient had a delayed diagnosis of carcinoma of the bladder (17 months)*
- *1 patient had a delayed diagnosis of a benign salivary gland tumour (1 month)*
- *1 patient experienced delayed management of their benign thyroid disease (8 month delay)*
- *7 patients experienced a delay in instigation of further urology investigations (ranging from 12–14 months)*
- *There was no change to the management of care or outcome in 37 other patients because they had received an accurate diagnosis through other tests or their condition was previously known*

These patients, and/or their relatives, have been contacted by the Investigation Team and UHG. UHG has informed the Investigation Team that all 49 patients, and/or their relatives, where appropriate, have subsequently had their findings explained to them either through correspondence or in one-to-one consultation.

Following the review of Dr C's cytology work, the error rate for Dr C's diagnostic cytology work was 6.5%, which is 5–6 times greater than the accepted range. The accepted error rate for diagnostic cytology work, according to international best practice, is 0.2–1.7%.²⁻¹³ Evaluation of breast cytology against accepted performance criteria for Dr C indicated false negative (failure to identify malignancy) reporting of 40% which is more than six times the accepted threshold of 6%.^{14(p50)}

The Investigation Team went on to review the gynaecological screening cytology workload for which Dr C was responsible. This included a selected slide review of cases reported on by Dr C. The arrangements for gynaecological screening cytology are different to diagnostic cytology. Gynaecology screening cytology cases are mainly reported by specially trained medical scientists under the supervision of a consultant pathologist. Slides that are negative or inadequate are screened and reported on by medical scientists. Slides that show any abnormality or uncertain findings on screening are referred to the consultant pathologist for review and reporting.

As the majority of cervical screening smears are negative, only a small proportion of slides are reviewed by the consultant. The slides that were reviewed by the Investigation Team were selected using a methodology designed by the Faculty of Pathology. To validate the methodology a review of quality assurance results and practices in gynaecological cytology was undertaken and this was found to be satisfactory.

During Dr C's tenure at UHG, 13,381 gynaecological cases were reported under their supervision. Of these, 9,877 cases were reported by the medical scientists as negative or inadequate and were therefore not reviewed by Dr C. Of the remaining 3,504 cases (which Dr C personally reviewed) there was agreement between their report and that of the medical scientists in 3,381 cases – that is 96.48% agreement. This left 123 cases where there was a difference between the medical scientists and Dr C's opinion. These were the cases selected for review by the Investigation Team.

A review of any cytopathologist's gynaecological screening caseload will identify some differences between the original opinion and the reviewer's opinion. In this review of 123 cases there was agreement with Dr C's opinion in 78 cases and a difference of opinion in 45 cases. In light of these findings, the Investigation Team advised precautionary follow-up of these 45 women. 10 women have already been seen by a gynaecologist and the remaining 35 women are being followed up by UHG.

The Investigation Team concluded that there was a high level of agreement between medical scientists and Dr C. The differences of opinion between the reviewers and Dr C in 45 cases were largely around grading the degree of abnormality present and these women have therefore been advised to have precautionary follow-up.

The Investigation Team considered whether to review the work of other consultant pathologists at UHG. It decided that this was not necessary having confirmed that the breast histopathology service in UHG was incorporated into a well established multidisciplinary system. This provides an internal mechanism for identifying errors or concerns about the standard of pathology reporting in relation to breast disease. This conclusion was supported by the outcome of slide reviews conducted by the Faculty of Pathology of the Royal College of Physicians of Ireland, as part of the Barrington's Hospital Investigation, which concluded there was no concern about the general interpretive accuracy of the department. This included the work of a range of consultant pathologists at UHG.

1.3.4 The Pathology Service

At the time of the investigation, the Pathology Department had a newly appointed Clinical Director who participated in the Hospital's Management Team. Consultant pathologists with specialist interests were identified and there was evidence of their participation in, and contribution to, MDTs for breast and other conditions. Quality managers have been appointed and the Pathology Service is pursuing external accreditation. A programme of visits has been arranged and, in preparation for this, policies and procedures are being developed. The Investigation Team observed the challenging environment in which pathology staff work, with cramped and outdated working conditions.

There were sufficient external checks and balances for breast diseases by the pathology team's involvement in MDT. This was supported by some examples of diagnostic breast audit being undertaken, although there was limited evidence of this being used as part of an integrated clinical audit programme. Clearer direction, with a more structured approach, is required for standards development and quality assurance in diagnostic cytology. Clinical audit for gynaecological cytology is carried out to a high standard. Notwithstanding this, it was noted that the Information Technology (IT) systems to underpin data collection in the Pathology Service to facilitate clinical audit are poor.

The Pathology Service receives specimens from within the Hospital and from other facilities. The technical quality of histology slide preparation is adequate; that of diagnostic cytology material is variable. The variability of diagnostic cytology is due to a combination of specimen collection techniques and also the processes for preparing the slides for review.

1.3.5 The Symptomatic Breast Disease Service at UHG

The Symptomatic Breast Disease Service at UHG was found to be a well functioning service with evidence of good interdisciplinary collaboration. The service has grown significantly in recent years and innovative approaches have been used to reduce waiting times for the first attendance of patients at out-patient clinics and their initial assessment.

Multidisciplinary team meetings at UHG are held twice a week and attended by the surgeons, pathologists, radiologists, nurses and, where appropriate, oncologists. The MDT meeting is a central pillar to the work of the team in relation to patients and their symptomatic breast disease and the Investigation Team observed strong commitment to this approach. Latterly the MDTs had been extended to include clinical staff at Letterkenny and there were plans to extend this further to Castlebar and Sligo clinics. However, no such arrangements were in place with Barrington's Hospital.

There was evidence that the growth of the Symptomatic Breast Disease Service had, to some extent, run ahead of available capacity in other areas such as radiology and nursing. Whilst there is capacity amongst the surgical team to see patients, there were indications that this increase in patient attendance leads, on occasion, to long waiting times for patients on the day of their clinic appointments.

For example, not all urgent diagnostic tests are carried out on the same day and on occasion, patients were asked to return for tests and/or the results of their diagnostic imaging rather than this being made possible at the same visit. In some instances this may be appropriate but some patients and staff, who were spoken with during the investigation, considered that with some re-organisation of clinics this could be avoided.

It was found that FNA was occasionally being used as a diagnostic technique at UHG in line with the internally agreed protocol. The use of FNA cytology should only be used in clearly prescribed circumstances and within a quality assured cytology service.

1.3.6 Service and Workforce Planning

The Investigation Team found no evidence that the pathology errors relating to Ms A were as a result of a shortage of resources, although some of those interviewed believe this could have been a contributory factor. In exploring staff resources, the Investigation Team found that historically there had been debate about the staffing levels necessary to meet growing demand for the pathology service. In the years preceding the period covered by the terms of reference of the investigation, there had been a trend of increasing workload. This workload was a combination of public and private activity. Although additional staffing appointments were made, the comments of staff interviewed, and other evidence received by the Investigation Team, suggested that there could be a protracted process between national approval, regional planning and local service provision in relation to consultant staff recruitment. This had led to a time lag between the needs of the service and the appointment of additional staff. These long lead-in times to recruit, after approval of additional posts, coupled with the difficulty of recruiting to pathology services, increased the use of temporary consultant staff in UHG.

In relation to the use of temporary and locum staff within the Pathology Department for the period of the terms of reference for the investigation, January 2005 to May 2007, the Investigation Team established the following.

A second post for a consultant pathologist with a special interest in cytopathology had been advertised nationally on a number of occasions. Despite applications, at the time of the investigation, UHG had not been able to recruit to this post and as a consequence had been relying on the use of temporary and locum consultant staff.

The UHG Human Resources (HR) Department has a procedure for the recruitment of permanent staff and this was also used for the recruitment of temporary and locum consultant staff. The Commission for Public Service Appointments had issued some guidance regarding this type of recruitment.¹⁵⁻¹⁶ The Investigation Team concluded that a specific procedure for the recruitment of temporary and locum consultant staff should be developed, particularly in relation to the take-up, validation and consideration of references, as well as the arrangements for working with specialist recruitment agencies. Since the investigation, the HSE has issued interim guidance on the recruitment of locum medical consultants.

Although not provided for by the consultant contract in place at the time covered by this investigation, the Investigation Team further concluded that arrangements for mitigating risk should also be strengthened in relation to temporary and locum consultant staff. This might include evidence of their existing technical competence being provided, as well as arrangements for their on-going development and support while in post. The new consultant contract should provide the basis for more explicit accountability of consultants through practice plans and a reporting relationship with clinical directors.

During the investigation, the team became aware that the HSE has established a Risk Sub-Committee which, among other things, is examining issues relating to recruitment, registration and competence assurance processes associated with the appointment of permanent, temporary and locum consultant staff. The Investigation Team suggests that the outcomes of this work should be made available as a priority as it believes that strategies, to mitigate risks associated with the appointment and on-going development of consultant staff, are required.

1.3.7 Leadership, Governance and Management

UHG has a clear framework for risk management with incident data beginning to be recorded and used for learning. UHG used the risk management framework appropriately when establishing the adverse incident group to investigate and respond to the pathology misdiagnosis of Ms A. However, the risk management arrangements in place had not identified the weaknesses in quality assurance systems highlighted by this investigation and therefore need to be strengthened.

There are clear plans for developing governance within UHG with the establishment of discrete units of clinical management known as Clinical Directorates; these are at an early stage in their development. There was a visible leadership style from the senior management team. This was valued by staff interviewed and was seen as particularly important when the initial review and helpline was found to be necessary. There was evidence of a culture of shared accountability in place between clinicians and managers.

1.3.8 Conclusion

In conclusion, two significant errors were made in the interpretation and review of Ms A's pathology specimens, one by Dr B and one by Dr C, both of whom were working within the Pathology Department of UHG. The first of these errors by Dr B in 2005, led to a diagnosis of a benign condition instead of breast cancer and contributed to a delay in commencing Ms A's treatment for breast cancer. The second error by Dr C occurred in March 2007 shortly before she received a definitive diagnosis from another hospital.

At the time, the clinical systems were not in place between UHG and Barrington's Hospital for multidisciplinary review of pathology findings. Neither were the explicit accountability and responsibility of individual clinicians evident in the pathway of care for Ms A. Consequently, in Ms A's case, the opportunity to identify and correct for these errors did not take place. The lack of MDT review meant that the interpretive errors in pathology were not identified. With the publication of the National Quality Assurance Standards for Symptomatic Breast Disease Services in May 2007, national mandated standards now stipulate that these diagnostic and treatment processes should not take place outside of an effective and well functioning multidisciplinary team environment, regardless of the care setting. The importance of clear multidisciplinary arrangements is even greater when more than one institution is involved in providing care and such arrangements should be governed by clear policies and service level agreements.

The Authority would regard adherence to these principles as an essential requirement of all centres and clinicians providing Symptomatic Breast Disease Services in Ireland whether in the public or private sectors.

The Investigation Team was appreciative of the full cooperation of UHG staff in relation to the provision of timely documentation and materials for all elements of the investigation. They responded promptly to all requests from the Investigation Team and provided additional information to assist with its enquiries. This was particularly evident in relation to the review of gynaecological cytology which entailed extensive sourcing of reports and materials. Their commitment to ensuring that patients affected by the ongoing outcomes of the investigation, particularly the pathology review, were informed and where appropriate treated, was evident throughout.

The Investigation Team would like to pay tribute to Ms A for allowing her story to provide a window into how services for others can be improved and for showing such courage in sharing her experiences with the Investigation Team for the future benefit of others. Her hope is that the findings and recommendations of this report are implemented by all those organisations who have a responsibility for symptomatic breast disease services.

A series of recommendations are made as a result of these findings. These are set out below.

2 Summary of Recommendations

Recommendation 1

The National Standards for Symptomatic Breast Disease Services (2007) should be applied to all centres providing Symptomatic Breast Disease Services irrespective of whether they are in the public, private or voluntary sectors.¹⁷

Where the care of patients is shared across more than one facility or institution, arrangements must be in place to ensure effective governance, management and review. Regular multidisciplinary team meetings must be held (at least weekly) and in particular, clear leadership of care planning must be maintained.

Implementation of these standards should be subject to a co-ordinated process of quality review.

Recommendation 2

Where diagnostic services are provided by a third party facility (for example a HSE laboratory providing services for a private hospital), such an arrangement should be subject to a formal Service Level Agreement, or contract, which is effectively managed and regularly monitored to ensure appropriate governance and quality assurance of the service.

The HSE and voluntary hospitals should undertake a review of all such arrangements to ensure appropriate service agreements and monitoring are in place. Equally, private sector providers are strongly encouraged to review all relevant arrangements where care of their patients is shared between organisations.

Recommendation 3

UHG's experience in responding to this incident, including the process adopted for patient management, should be captured and used to inform the development and implementation of national guidelines for handling adverse incidents.

Recommendation 4

Units using breast Fine Needle Aspiration (FNA) as a diagnostic modality should do so only in an appropriate triple assessment context and with robust quality-assurance. This should include:

- *Clarifying the role of FNA cytology in the investigation of breast disease and applying agreed patient selection criteria*
- *Auditing the service against 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*
- *Using the C1-C5 classification system to ensure reports are clear and unambiguous¹⁴*

Recommendation 5

A clearer direction is needed for the development and quality assurance of the diagnostic cytology service in UHG Pathology Department.

Recommendation 6

All pathology departments should implement the recommendations of the Faculty of Pathology's guidelines on histopathology quality assurance programmes in pathology laboratories.¹⁸ This incorporates, among other things:

- *Intra-departmental consultation/peer review*
- *Multidisciplinary case discussion*
- *Incident reporting*
- *Vertical case review/audit*
- *Cytology quality assurance*

Implementation of these recommendations must be supported by appropriate Information Technology systems.

Recommendation 7

The HSE should review workforce planning at national and local levels to ensure that recruitment of consultants is more responsive to changing service needs and reliance on temporary staff is minimised. This should include measures to reduce the time-lag between authorisation to appoint and staff taking up post.

Recommendation 8

It is recommended that the HSE Risk Sub-Committee progress and publish their work on mitigating risks associated with the employment of permanent and locum consultant staff. In the meantime, all local service providers should review recruitment policies and procedures to ensure robust verification and assessment processes are in place.

Recommendation 9

A formal policy for the recruitment of locum and temporary consultant staff should be established and implemented nationally to ensure more robust and effective arrangements and quality assurance mechanisms. This should include:

- *Formalised agreements with specialist recruitment agencies which will include; their role, responsibility and area of accountability in the recruitment process. These agreements should be regularly monitored*
- *The provision for appointment panels to view and discuss all written references as part of the assessment process and before recommendation for appointment*
- *Account to be taken of existing competency levels of applicants as well as arrangements for their on-going development and support as temporary employees*
- *An agreed programme of audit against compliance*

Recommendation 10

The recommendations of the Lynott Report (2002) should be implemented by the HSE and other service providers and compliance should be audited regularly.¹⁹

Recommendation 11

The role of independent advocacy services should be developed in all hospitals. These advocacy services should facilitate patients coming forward to raise concerns and have them addressed. Hospitals should encourage such services as part of a helpline and/or as part of patients' hospital attendance.

Recommendation 12

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 with milestones. Progress against the plan should be made public and reported to the Board of the HSE.

3 Introduction

In August 2007, the Health Information and Quality Authority (the Authority) became aware of a patient (known in this report as Ms A) who had been treated at Barrington's Hospital, Limerick, for her symptomatic breast disease and whose breast histology and cytology specimens had been reviewed by University Hospital Galway (UHG) Pathology Department. The central issue was that two separate interpretive errors, separated by 18 months, had been made in respect of Ms A's pathology specimens. On both occasions, the specimens had been reported as benign when they showed malignancy. This led to a considerable delay in Ms A's diagnosis and subsequent treatment for breast cancer.

The Authority was informed that an internal review at UHG had highlighted the two separate missed diagnoses of breast cancer from pathology specimens relating to Ms A. The first had been reported on in September 2005 by a permanently employed consultant pathologist (referred to in this report as Dr B); and the second was reported on in March 2007 by a temporary consultant pathologist (referred to in this report as Dr C).

At the end of July 2007, a hospital consultant, Dr D, sent information to the Authority regarding concerns relating to the quality of care received by ten patients with symptomatic breast disease at Barrington's Hospital. Ms A was one of these patients. These patients, and others who were treated at Barrington's Hospital from September 2003 to August 2007, were subsequently involved in a review that was undertaken by the Department of Health and Children and Barrington's Hospital. The findings of this review were published in April 2008 as the 'Report on the Independent Review of Symptomatic Breast Care Services at Barrington's Hospital, Limerick'.¹

On 2 August 2007, the Health Service Executive (HSE) formally requested in writing that the Authority consider undertaking an investigation. On 9 August 2007, having considered the information available, and believing on reasonable grounds that there was a serious risk to the health or welfare of a person or persons in receipt of certain services at UHG, the Board of the Authority took the decision to instigate an investigation under Section 9(1) of the Health Act 2007. Under the terms of reference (see below), the scope of the investigation was to consider all aspects of safety, quality and standards, including the governance arrangements, of the Pathology and Symptomatic Breast Disease Services provided to Ms A and other patients by the HSE at UHG.

University Hospital Galway, a HSE Hospital, was the focus of the investigation as it had undertaken the diagnostic pathology elements of Ms A's assessment of breast disease. However, the overall clinical management of Ms A's breast disease was, during the initial stages of treatment, at Barrington's Hospital which is a private hospital. The investigatory powers of the Authority relate only to those services provided by the HSE or providers on behalf of the HSE. Therefore, Ms A's treatment in Barrington's Hospital is not within the terms of reference of this investigation. These aspects of her care, and the care of other

patients who received Symptomatic Breast Disease Services at Barrington's Hospital from September 2003 to August 2007, were subject to a separate review undertaken by Barrington's Hospital and the Department of Health and Children.

Although Ms A's treatment for her symptomatic breast disease was not at UHG, it was decided by the Board of the Authority to include the Symptomatic Breast Disease Services at UHG in the terms of reference of the investigation. This was because Ms A's pathology specimens had been reported by the Pathology Department at UHG and this service is an intrinsic part of the Symptomatic Breast Disease Service at UHG and therefore it was necessary to assure patients and the public of the quality of the overall service.

This report sets out the approach taken to the investigation and its findings across a wide range of issues. It draws conclusions and makes 12 recommendations.

Many of these recommendations are linked to standards in the National Quality Assurance Standards for Symptomatic Breast Disease Services, 2007. The Investigation Team recognises these standards were not in place during the period covered by the investigation. However, the principles within them were well established and were identified in the "Development of Services for Symptomatic Breast Disease" report of 2000.²⁰

Terms of Reference

The investigation was conducted under the following 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 (the Investigation) into the provision of services to Ms A by the Health Service Executive (the Executive) at University Hospital Galway (the Hospital) in relation to her symptomatic breast disease, and the provision of pathology and Symptomatic Breast Disease Services by the Executive at the 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 the pathology and Symptomatic Breast Disease Services provided to Ms A and other patients by the Executive at the Hospital. The Investigation will seek to ensure that acceptable practice has been carried out and, if this is not the case, to ensure that where there may be serious risks to the health or welfare of a person receiving such services from the Executive, these shall be identified and recommendations can be made with a view to reducing 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 by the Executive at the Hospital, in respect of Ms A.
- 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 the 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. The means of Investigation may include (but not be limited to) inspection of medical records, imaging and slides.
- 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 the 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 sees 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 2.1.1, 2.1.2 and 2.1.3 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 sees 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.

4 Investigation Methodology

The investigation encompassed technical reviews of clinical practice and systems and processes within the services covered by the terms of reference. The methodology used incorporated:

- *review of documents*
- *site visits to UHG*
- *interviews with clinical and non-clinical health service staff, and patients including Ms A*
- *reviews of pathology reports, specimens and anonymous patient information from UHG*

This section now describes the approach in more detail.

4.1 The Investigation Team

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

Due to the subject matter of the investigation, a number of consultant pathologists (both cytopathologists and histopathologists) were included in the team. In total eight consultant pathologists contributed to the investigation.

4.2 Documentation Review

The Investigation Team obtained and reviewed documentation from the HSE, including UHG.

This documentation included:

- *hospital wide management arrangements and specific arrangements for symptomatic breast disease and pathology services*
- *policies and procedures in relation to safety, quality and governance arrangements*
- *clinical audit data*
- *workforce planning and staffing arrangements*
- *the results of the internal review by UHG of Ms A's cytology*

A list of documentation requested by the Investigation Team is detailed in Appendix 2.

4.3 Site Visits

Members of the Investigation Team visited UHG and took the opportunity to visit clinical and non-clinical areas. Informal conversations with staff were held as part of the visits in order for the Investigation Team to obtain background information and context for the investigation.

4.4 Interviews

A number of interviews were conducted with:

- *clinical and non-clinical staff at UHG, including permanent, temporary and locum staff*
- *additional HSE managerial staff*
- *Dr B, the consultant who reviewed Ms A's tissue from her first biopsy in September 2005*
- *Dr C, the temporary consultant who reviewed Ms A's cytology specimen in March 2007*
- *a previously employed temporary consultant pathologist*
- *Ms A*
- *Ms A's oncologist (referred to in this report as Dr D)*
- *eight patients who were attending the breast clinic in UHG – their consent to interview them was obtained by the Investigation Team (Appendix 3)*

In total 62 interviews took place. A total of 62 people were interviewed or contributed in some way to the investigation.

4.5 Pathology Review

The Investigation Team undertook reviews of cases reported on by the two consultant pathologists who reported on Ms A's specimens. Both of these consultants had made interpretive errors in relation to Ms A. This had been established previously by an internal review at UHG and was confirmed subsequently by the Investigation Team. The Investigation Team's reviews of these consultants' slides were carried out to establish whether the errors relating to Ms A were isolated or indicative of a wider problem in their clinical practice. Isolated errors are a recognised feature of histopathology and cytopathology interpretation which is one of the reasons why multidisciplinary review of diagnostic findings is so important.

The Authority engaged the Faculty of Pathology of the Royal College of Physicians of Ireland (“the Faculty”) to assist in this investigation. The Faculty identified consultant pathologists to conduct these reviews, who were appointed by the Authority as authorised persons. The Faculty developed the review methodologies and quality assured the review procedures. (See Appendix 4.)

Initially the Investigation Team focused on:

- *breast histology for Dr B (Group I)*
- *breast cytology and a randomly selected number of other diagnostic cytology reported on by Dr C (Group IIa)*

As a result of the findings of this initial review, the Investigation Team went on to look at:

- *all of the diagnostic cytology work carried out by Dr C during their tenure at UHG. This part of the review included diagnostic cytology such as thyroid and urology specimens from patients (Group IIb)*

As a result of the findings of the review of all diagnostic cytology, the Investigation Team went on to conclude the review by looking at:

- *all gynaecological cytology reporting under Dr C’s name (Group IIc)*

The case review followed an algorithm recommended by the Faculty. This used an escalating approach that started from a representative sample of 200 slides reported on by Dr B and 206 slides reported on by Dr C, through to the full review of Dr C’s diagnostic cytology work and finally their work in relation to the reporting of gynaecological cytology. The full review process is summarised in Figure 1 at the end of this section.

The Investigation Team considered whether further slide reviews of other consultants were necessary. It was decided by the Investigation Team that it was not necessary to extend the scope of the slide review for the following reasons:

- *the histopathology service at UHG was well integrated with the rest of the Symptomatic Breast Disease Service through the MDT meetings for all patients whose clinical care was at UHG. The Investigation Team was satisfied that this process provided adequate internal quality assurance which would have identified general concerns about possible errors in diagnostic work relating to individual patients with symptomatic breast disease.*

- *at the time this investigation was being initiated, a separate investigation into the care of patients at Barrington's Hospital was also launched. At the Authority's suggestion, the Faculty of Pathology was asked to provide the pathology case review aspects of that investigation. This was to ensure continuity of pathology methodology between the two investigations and to allow the Authority to place reliance on any case reviews carried out as part of the Barrington's investigation. The case reviews carried out by the Faculty included all patients whose samples were sent to UHG between 2003 and 2007 from Barrington's Hospital (total 406). This group included the work of ten different consultant pathologists working in UHG and identified no significant discrepancies between the initial diagnosis and that made by the review team.*

4.6 Review of Cases – Methodology of Associated Slide Review

The overall findings are set out in section 5 of this report. The following outlines the numbers of patients considered and the associated methodologies adopted by the Investigation Team.

Summary of Materials Reviewed

The following summarises the breadth of pathology cases considered by the Investigation Team:

Ms A: 1 set of histology slides and 1 set of cytology slides

Dr B: 200 breast histology patient cases (all associated patient slides were reviewed)

Dr C: 747 breast and non-breast cytology patient cases (all associated patient slides were reviewed. This figure includes Ms A's breast cytology)

123 gynaecological cytology cases (all associated patient slides were reviewed)

4.6.1 Ms A

The Investigation Team reviewed Ms A's:

- *histology report from her biopsy. Dr B had reported on this in September 2005*
- *cytology report from her fine needle aspirate. Dr C had reported on this in March 2007*

Ms A Methodology

The histopathology reported on by Dr B and the cytology material reported on by Dr C were both reviewed by two reviewers from the Faculty.

4.6.2 Breast Histology Reported on by Dr B

The Investigation Team reviewed a sample of 200 breast histology cases reported by Dr B (*Group I*).

4.6.3 Cytology Reported on by Dr C

The Investigation Team carried out an initial review of Dr C's work (*Group IIa*). As a result of the findings of this initial review, the Investigation Team proceeded to review two more groups of work (*Groups IIb and IIc*). Ultimately, the Investigation Team evaluated all Dr C's cytology work during their tenure at UHG as follows.

Group IIa:

All Breast Cytology and a Random Sample of Diagnostic Cytology

The Investigation Team reviewed:

- *all of the breast cytology specimens reported by Dr C – 119 patients*
- *a sample of other diagnostic cytology reported by Dr C – 92 patients*

Group IIb:

Further Review of All Diagnostic Cytology Reported by Dr C

The Investigation Team reviewed all 536 other diagnostic cytology patient cases reported by Dr C during their tenure at UHG.

Methodology - Groups I, IIa and IIb

The material was reviewed by consultant histopathologists (for Dr B's work) and consultant cytopathologists (for Dr C's work). As part of this methodology, the reviewers did not initially see the report of the original diagnosis when conducting their review.

Patient cases were reported according to the standard reporting system for breast histology and cytology¹⁴ and the appropriate reporting categories for non-breast cytology.

Where a discrepancy that would warrant patient follow-up was identified between the diagnosis of Dr B or Dr C and that of the reviewing pathologists, these were double checked by two reviewers. Where needed, a formal supplementary report was sent to the individual patient's managing clinician.

The Investigation Team liaised closely with UHG and a small number of other hospitals and general practitioners (GPs) to ensure patients were followed up as necessary.

Breast cytology performance criteria were evaluated for Dr C's reporting using the quality assurance standards matrix of the NHS Breast Screening Programme (NHSBSP).¹⁴

The error rate in non-breast cytology material was calculated using a definition of error as “a discrepancy in diagnosis which has the potential to adversely impact on patient management or outcome” (see Appendix 4).

Review of All Gynaecological Cytology Reported by Dr C

Group IIc

Due to the nature of the work being reviewed, a different methodology was employed for reviewing gynaecological cytology.

Gynaecological cytology is predominantly made up of the review of cervical smears of asymptomatic women, carried out as part of a preventative strategy in an organised or opportunistic screening programme or as a result of individual women coming forward for screening.

The standard practice is for cases to be double read by specially trained medical scientists. This is done under the supervision of a consultant pathologist. Under this system, only a minority of cases where there is an abnormality detected will be actually reviewed by a consultant pathologist. This was found to be the practice at UHG Pathology Department.

During their appointment, Dr C was responsible for the overall reporting of 13,381 cervical cytology smears. Of these, 3,504 cervical smears were actually reviewed and reported on by Dr C in accordance with standard practice. The remaining 9,877 were reported by medical scientists without any slide review by Dr C.

The initial review identified that out of the 3,504 cervical smears reported on by Dr C, in 3,381 cases there was agreement between the medical scientists’ opinion and Dr C’s final report.

For the remaining 123 cases there was a difference of opinion between the medical scientists’ opinion and that of Dr C’s final report. The Investigation Team decided to review these cases in more detail. This was done using a similar slide review methodology to groups IIa, and IIb with double reporting by reviewers who had not seen the original report.

In order to support this methodology for identifying cases to be reviewed, the Investigation Team also looked at the general accuracy and detection rate within the gynaecological cytology service at UHG. This included looking at the laboratory’s:

- *reporting profiles*
- *sensitivity of primary screening for the laboratory and individual screeners*
- *Positive Predictive Value (PPV) for CIN 2+ for the laboratory and for Dr C*

The review also looked at the quality assurance and operational procedures within the gynaecological cytology service including:

- *primary screening*
- *checking*
- *reporting by consultants*
- *management guidelines and authorisation of reports*
- *participation in external quality assurance*
- *multidisciplinary CIN meetings with colposcopy and histology*
- *in-house fortnightly review meetings*

4.7 Review of Pathology Services – Methodology

To augment the Investigation Team's technical review, documentary evidence was also examined and a number of interviews undertaken with senior management and clinical pathology staff.

The Pathology Department was visited and in addition to the formal interviews, the Investigation Team observed the working environment. The findings of the service review are outlined in section 5 of this report.

4.8 Transportation Arrangements

A protocol for the safe and confidential transfer of information and slides from UHG Pathology Department to the Authority's Investigation Team was drawn up and used.

5 Findings

5.1 Ms A

In mid-September 2005, Ms A attended her GP complaining of symptoms suggesting breast disease. Ms A was referred, at her request, to Barrington's Hospital and during the 15 and 16 September 2005 she underwent various tests and procedures at Barrington's Hospital. These included mammography conducted in 2005 (repeated in 2006) and a biopsy of her left breast. Ms A's biopsy specimen was received, logged and processed at UHG Pathology Department on 19 September 2005. This was reviewed and reported on by Dr B on 27 September 2005. The final pathology report was logged on UHG pathology computer system as benign.

In March 2007, Ms A re-presented with breast symptoms. She was seen at Barrington's Hospital where she had an FNA of tissue removed from her left breast. This was sent to the Pathology Department at UHG and reported by Dr C as benign.

Later in March 2007, Ms A underwent a further biopsy of breast tissue at Barrington's Hospital which was sent to the Bon Secours Hospital, Cork for analysis. This was reported as indicating malignancy. Ms A then underwent a mastectomy at Barrington's Hospital. She subsequently left their care and was referred to the Oncology Service at Mid Western Regional Hospital, Limerick for the ongoing clinical management of her breast cancer by Dr D.

In late June 2007, as part of Ms A's ongoing care, Dr D requested UHG Pathology Department to carry out a re-examination of Ms A's slides from September 2005. Re-examination of the slides by another consultant pathologist at UHG confirmed that cancer had been present. At the same time, UHG Pathology Department also reviewed Ms A's cytology report of early March 2007 and a revised diagnosis of malignancy was also made.

On 16 July 2007, senior managers and senior pathology staff at UHG were informed about the incidents of misdiagnosis. Immediate steps were taken to initiate UHG adverse incident procedure by establishing an incident steering group. Over the next week the incident was reported to senior managers within the corporate HSE and recorded on the STARSWeb national reporting system for adverse incidents. At the same time, the UHG incident group identified making contact with Ms A as a high priority.

On 27 July 2007, senior management at UHG wrote to Ms A following her discussion with Dr D about the diagnostic errors. The letter confirmed that an internal review of her pathology had been undertaken and that two errors had been made. Senior management at UHG apologised for the errors and stated that Hospital senior managers were available for discussion with her or her family. This letter also stated that an external independent investigation would be established.

The work of the Investigation Team confirmed that on two separate occasions Ms A's pathology specimens, sent from Barrington's Hospital to the pathology department at UHG, had been wrongly reported as benign, first by Dr B in September 2005 and then by Dr C in March 2007.

A small number of interpretive errors is a recognised feature of histopathology and cytopathology reporting. To mitigate the risk of such errors leading to a misdiagnosis there needs to be a system in place that allows for diagnostic and clinical findings to be discussed by the relevant specialists rather than individual results being relied upon in isolation. This is achieved through multidisciplinary team meetings.

In Ms A's case, no such forum existed and so the opportunity to identify and correct the errors did not arise.

The Investigation Team found that there had been no formal contract or agreement between UHG Pathology Department and Barrington's Hospital for reporting pathology specimens. This was based on a long-standing arrangement between individual clinicians. This arrangement did not include formal multidisciplinary review of diagnostic findings. Specifically, no 'triple assessment' of imaging, pathology and clinical findings for patients with symptomatic breast disease took place.

The Investigation Team believes there should have been a process in place whereby referring surgeons, radiologists and reporting pathologists discussed clinical and pathological findings. This is especially important in a situation where, as in Ms A's case, clinicians are based in different institutions. Establishing this important safeguard for patients is a shared responsibility between individual clinicians and the institutions in which they work. The accountability for the oversight of the patient's care should be made explicit in such circumstances.

That one patient should have experienced two separate diagnostic errors emphasises starkly the importance of multidisciplinary review for patients being investigated for symptomatic breast disease. This must be irrespective of where patients' care is being led from. The National Quality Assurance Standards for Symptomatic Breast Disease Services (2007) should be applied to all centres providing any aspect of diagnosis or initial treatment for breast disease.¹⁷

Where care is shared between organisations there must be explicit leadership, accountability and governance of the care pathway with a clearly identified consultant accountable for the overall provision and co-ordination of the patient's care.

Following Ms A's mastectomy and removal of axillary nodes, she underwent a planned programme of chemotherapy and has, at the time of publishing the Investigation Report, recently finished an extended course of radiotherapy. She is currently receiving a course of adjuvant therapy (Herceptin) and this is due to continue until December 2008. Her care is continuing to be managed at the Mid Western Regional Hospital, Limerick.

Recommendation 1

The National Standards for Symptomatic Breast Disease Services (2007) should be applied to all centres providing Symptomatic Breast Disease Services irrespective of whether they are in the public, private or voluntary sectors.¹⁷

Where the care of patients is shared across more than one facility or institution, arrangements must be in place to ensure effective governance, management and review. Regular multidisciplinary team meetings must be held (at least weekly) and in particular, clear leadership of care planning must be maintained.

Implementation of these standards should be subject to a co-ordinated process of quality review.

Recommendation 2

Where diagnostic services are provided by a third party facility (for example a HSE laboratory providing services for a private hospital), such an arrangement should be subject to a formal Service Level Agreement, or contract, which is effectively managed and regularly monitored to ensure appropriate governance and quality assurance of the service.

The HSE and voluntary hospitals should undertake a review of all such arrangements to ensure appropriate service agreements and monitoring are in place. Equally, private sector providers are strongly encouraged to review all relevant arrangements where care of their patients is shared between organisations.

5.2 The Hospital's Response in Relation to Ms A's Diagnostic Errors

As soon as the errors in Ms A's case came to light the senior management and senior consultant pathologists at UHG initiated the following actions:

- *instigated their internal adverse incident policy*
- *established an adverse incident group that agreed a number of actions*
- *made contact with Ms A apologising for the error, making themselves available for discussion and support*
- *contacted the senior managers in the corporate HSE with a view to seeking an independent review of pathology*
- *initiated an internal review into the errors. (However, this review was superseded by the Authority's investigation that commenced shortly thereafter)*

The managers and clinicians within UHG immediately put arrangements in place for a patient helpline. The Investigation Team reviewed the comprehensive clinical and administrative arrangements for the helpline and subsequent actions taken by the symptomatic breast disease team and consultant pathologists.

All of the 113 women who came forward to the helpline were promptly discussed in detail by a symptomatic breast disease multidisciplinary team within UHG where all the diagnostic results and case notes were reviewed. There was focused follow-up action in relation to each patient. Patients for whom there was any concern were telephoned directly and invited to attend special out-patient clinics that had been established for this purpose. Other patients, where no clinical concerns were identified, were either telephoned or written to, given assurances and extended the offer to talk to a member of the clinical team, either over the phone or by coming into a clinic if they preferred. The administrative arrangements ensured that each patient was 'tracked' from the point of coming forward to the helpline through to the point where an appropriate patient plan, or discharge from the process, was achieved. The symptomatic breast disease team and the adverse incident working group monitored the list of 113 patients.

In conclusion, once the two diagnostic errors had come to light, UHG's response in establishing an adverse incident review was appropriate. There was evidence of both managerial and clinical leadership in delivering both the helpline process and in participating in the subsequent local review and the Authority's investigation. The Investigation Team acknowledges that, for many women, the process of raising concerns and coming forward to challenge their diagnosis can be extremely daunting and it was clear to the Investigation Team that UHG staff wanted to ensure that patients had access to a timely and sensitive review.

It is the view of the Investigation Team that the processes adopted by the UHG leadership team and staff in establishing and running the helpline, and the subsequent individualised approach to patient management that was undertaken, should be shared across the Irish healthcare system. Similarly, the Investigation Team recommends that a review of current guidance, in relation to the management and set up of helplines for incidents of this nature, should be undertaken by the HSE and that UHG's experience could usefully be included to help shape future guidance. The role of independent advocacy to support patients coming forward should also be developed in the future.

Best practice guidelines in the process of local investigations should also be reviewed by the HSE to ensure the adequacy of root cause analysis and the rapid dissemination of lessons learned from such investigations.

Recommendation 3

UHG's experience in responding to this incident, including the process adopted for patient management, should be captured and used to inform the development and implementation of national guidelines for handling adverse incidents.

5.3 Pathology Review and Patient Management

The following section sets out the findings of the pathology review and patient management.

5.3.1 Ms A

The Investigation Team concluded that cancer was present in the biopsy sample of 2005 reported on by Dr B. Ms A went from September 2005 to March 2007 with this being undiagnosed. Similarly, cancer was present in the FNA sample reported on by Dr C in March 2007. (See Appendix 5.)

5.3.2 Group I: Breast Histopathology Reported by Dr B

The Investigation Team identified that Dr B made a significant error in the interpretation of Ms A's biopsy sample in 2005. Dr B reported the sample as benign and the review team found evidence of malignancy.

The Investigation Team went on to review 200 breast histology cases reported on by Dr B. This review showed the overall standard of reporting by Dr B to be within accepted ranges and no other significant errors were reported. The accepted range of significant error rates is 0.26% to 1.7%.²⁻¹³ (See Appendix 6.)

5.3.3 Dr C

Group IIa: All Breast and Random Sample of Diagnostic Cytology Reported by Dr C

The Investigation Team reviewed all the 119 breast cytology cases reported on by Dr C during their six month tenure at UHG. It also reviewed 92 diagnostic cytology cases reported by Dr C in order to look at the broader spectrum of their cytology work. Therefore, within this group, the total slides reviewed for Dr C related to 211 patient cases. (See Appendix 7.)

The review of these 211 cases showed that there were 17 discrepancies between what Dr C reported and what the Investigation Team reported which warranted case review and follow-up.

As a result of these findings, the Investigation Team extended the review to include all of Dr C's cytology work.

Group IIb:

Further Review of All Diagnostic Cytology Reported by Dr C

On the basis of the findings of the Investigation Team in relation to Group IIa, the Investigation Team went on to review the remainder of Dr C's diagnostic cytology cases, of which there were 536 cases. (See Appendix 7.)

The review of these 536 cases showed that there were 32 discrepancies between what Dr C reported and what the Investigation Team reported. Therefore, a total of 49 discrepancies were identified from Groups IIa and IIb. These were discrepancies that had the potential to affect the clinical management of patients.

The Investigation Team worked with UHG to determine how the patients from Groups IIa and IIb were being followed up.

Patient Management: Groups IIa and IIb

The Investigation Team contacted UHG, other hospitals and referring clinicians that had seen the 49 patients where a discrepancy between the Investigation Team's review and that of the original report by Dr C had been found. This was to ensure patients needing follow-up were identified, contacted and, where required, further treatment provided promptly. In doing so, the Investigation Team requested certain information including:

- *whether the patient had been definitively diagnosed and treated by UHG/other hospital in the meantime (patients may have been accurately diagnosed as a result of other investigations)*
- *if no to point above, had the patient subsequently been recalled as a result of the information provided by the Investigation Team*
- *whether there was any delay to treatment or any other adverse impact as a result of the original report*

UHG and the other hospitals responded promptly to this request for information. This contributed to the Investigation Team's overall findings in relation to Dr C's work and what this meant for the patients concerned. This is summarised together with the outcomes for patients in Group IIb, at the end of the following section.

Findings: Groups IIa and IIb

Taking the findings of Groups IIa and IIb together, in addition to Ms A (whose outcome was reported at the beginning of this section) a total of 49 patients required follow-up. The following summarises the consequences for these 49 patients.

- *1 patient had a delayed diagnosis of thyroid cancer (9 month delay)*
- *1 patient had a delayed diagnosis of carcinoma in-situ of bladder (16 month delay). Carcinoma in-situ means the cancer is non-invasive and has remained in the identified area*
- *1 patient had a delayed diagnosis of carcinoma of the bladder (17 months)*
- *1 patient had a delayed diagnosis of a benign salivary gland tumour (1 month)*
- *1 patient experienced delayed management of their benign thyroid disease (8 month delay)*
- *7 patients experienced a delay in instigation of further urology investigations (ranging from 12–14 months)*
- *There was no change to the management of care or outcome in 37 other patients because they had received an accurate diagnosis through other tests or their condition was previously known*

Information to Patients: Groups IIa and IIb

As a result of the Investigation Team's findings, where indicated, patients were recalled by UHG for further investigations, consultation, discussion and if necessary, further treatment.

UHG informed the Investigation Team that all 49 patients or, where appropriate their relatives, were formally informed by UHG of the discrepancies found by the Investigation Team. These included those patients for whom the revised diagnosis did not make a difference to their original diagnosis or their subsequent course of treatment.

Summary Outcome of Dr C's Cytopathology Work:

Groups IIa and IIb

In March 2007, Dr C made a significant error when reviewing biopsy material following an FNA of Ms A's breast tissue. At this presentation Dr C wrongly interpreted the specimen as benign and the review team found evidence of malignancy.

The error rate for Dr C's diagnostic cytology reporting was 6.5% which is 5-6 times the established acceptable error rate for such non-gynaecological cytology, i.e., 0.2-1.7%.²⁻¹³ Evaluation of breast cytology against accepted performance criteria for Dr C indicated false negative (failure to identify malignancy) reporting of 40% which is more than six times the accepted threshold of 6%.^{14(p50)}

Group IIc: Review and findings of Gynaecological Cytology reported by Dr C and the overall performance of the gynaecological cytology in the laboratory

The review of 123 cases where Dr C's opinion differed from that of the medical scientists (see Appendix 8) showed:

- *78 cases where the review agreed with the original report*
- *45 cases where there was a difference between the review and the original report*

Cervical screening cytology is based on interpretive opinion. It is therefore impossible to eliminate inter-observer variation and any review of gynaecological screening cytology will produce cases where there is a difference of opinion. As this is a screening test and not a diagnostic test, women should be managed according to the highest grade of abnormality reported. The professional opinion of the Investigation Team was that the performance of the laboratory as a whole was satisfactory. There was a high level of agreement between the medical scientists and Dr C. The differences of opinion between the reviewers and Dr C in 45 cases were largely around grading the degree of abnormality present and these women have therefore been advised to have precautionary follow-up.

The Investigation Team also reviewed the laboratory's overall performance which showed:

- *a high detection rate for high grade abnormality (2.75 -3.2%)*
- *PPV for CIN 2+ of 81%*
- *sensitivity of primary screening for high grade abnormality – 98%*
- *sensitivity of primary screening for all grades of abnormality – 96%*

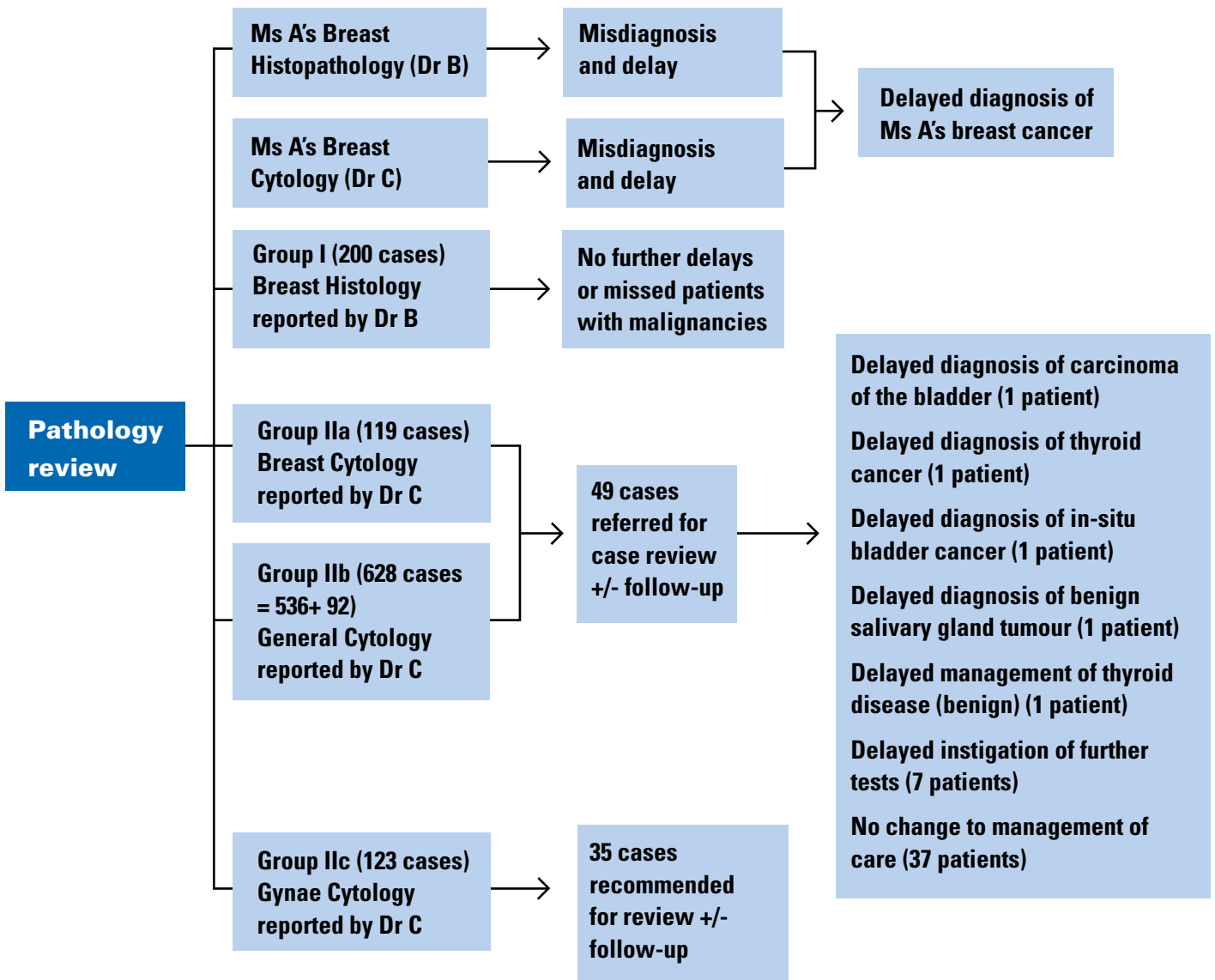
The Investigation Team's review of the quality assurance and operational procedures for gynaecological cytology concluded that these were satisfactory.

Patient Management: Group IIc

Of the 45 cases where there was a difference between the review and Dr C's original opinion, 10 women had subsequently had further tests and therefore needed no follow-up. The Investigation Team recommended to UHG precautionary follow-up for the remaining 35. This is normal practice in gynaecological cytology.

Information to Patients

UHG established a separate process to ensure timely and efficient follow-up of these patients. All patients were seen within two weeks of the Investigation Team’s review results having been made available. This process of patient case management was shared with the Investigation Team who concluded that the individualised patient letters and detailed communication with each of the patient’s referring clinician, general practitioner or senior manager at the facility where the gynaecological specimen had originally been taken, was of a high standard. All patients were offered the opportunity to discuss their case with the Hospital’s senior manager or a named senior pathologist at UHG. The approach adopted should be made available as part of any national review and guidance issued on dealing with such incidents.



5.3.4 Outcomes of Pathology Review in Relation to Pathology Services

As a result of the Investigation Team's extensive review of pathology slides, a number of observations about the type and quality of samples presented as well as the quality of the actual reviews, were made. These relate to breast and other conditions and the findings, together with the Investigation Team's recommendations, are as follows.

Core Biopsy

Core biopsy is the primary diagnostic method for breast cancer used by the symptomatic breast disease team and subsequently reported on by pathologists at UHG. This is standard practice. There are good arrangements in place to ensure that patients undergoing triple assessment at UHG are discussed at MDTs. Consultant pathologists with a special interest in breast disease and who routinely report on these biopsies participate in these MDTs.

Breast specimens, reviewed by the Investigation Team, were reported according to the standardised minimum datasets, as published by the NHS BSP 2005. However, a standard proforma for reporting breast specimens has not yet been implemented.¹⁴

The Role of Fine Needle Aspiration

Although there is a UHG protocol for the use of FNA, core biopsy is the preferred diagnostic technique used by the Symptomatic Breast Disease Service at UHG. Interviews with the pathology staff at UHG recorded some concerns about the unsatisfactory role of FNA due to the sporadic and limited use of the technique.

The role of FNA cytology in the investigation of breast disease in UHG should be clarified and breast FNA cytology should be subject to ongoing audit.

Recommendation 4

Units using breast Fine Needle Aspiration as a diagnostic modality should do so only in an appropriate triple assessment context and with robust quality assurance. This should include:

- *Clarifying the role of FNA cytology in the investigation of breast disease and applying agreed patient selection criteria*
- *Auditing the service against 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*
- *Using the C1-C5 classification system to ensure reports are clear and unambiguous¹⁴*

This recommendation should be read in conjunction with the recommendations of the Faculty of Pathology in Appendix 6.

5.3.5 Technical Considerations

The Investigation Team noted that some interviewees expressed concerns about the sub-optimal standard of some of the diagnostic cytology samples submitted to the Pathology Department by referring clinicians. This perception was supported by the work of the Investigation Team which found that the sample inadequacy rates in cases reported on by Dr C, reviewed by the Investigation Team, were at the upper end of the accepted range.¹⁴ It should be noted that the adequacy of the sample is predominantly the responsibility of the referring clinician. Overall, the Investigation Team noted variability in sample adequacy and technical preparation quality (including slide preparation, stain selection and use of ancillary techniques) in the diagnostic cytology material reviewed. This material had originated from a range of institutions sending samples to the UHG Pathology Department including UHG itself.

The Team believes that there is not a general concern about reporting accuracy within the department. This conclusion is supported by the outcome of slide reviews conducted by the Faculty of Pathology as part of the Barrington's Hospital review and which included the work of a range of consultant pathologists at UHG. However, there are a number of actions that can be taken to improve the overall technical standards and quality of specimen selection, review and reporting.

There was no formal audit programme being undertaken at UHG with regard to non-gynaecological cytopathology.

Recommendation 5

A clearer direction is needed for the development and quality assurance of the diagnostic cytology service in UHG Pathology Department.

5.4 Pathology Services

5.4.1 Staffing Arrangements

The Investigation Team found no evidence that the pathology errors relating to Ms A were as a result of a shortage of resources although some of those interviewed believe this could have been a contributory factor. In exploring staff resources the Investigation Team found that in the period prior to that covered by the investigation, staffing levels had been the subject of correspondence between senior management and clinical staff. This correspondence highlighted challenges in matching Pathology Department capacity to the incremental increase in workload. At the same time, a benchmarking exercise carried out by the Hospital suggested a high workload compared to similar institutions.

Prior to 2005, there were four consultant pathologists in post. Between 2004 and 2007 activity in the department increased significantly; for example surgical pathology cases rose from 17,619 to 25,256. During that period new consultant pathologists were gradually recruited to meet rapid clinical service developments including symptomatic breast disease. Where it was not possible to fill full-time consultant posts, locum and temporary staff were used; for example during 2005 there were three temporary consultant staff within a total of 8.5 posts.

At the time of the investigation, there were 8.5 pathologist posts available to provide services for all departments at UHG and some external hospitals and clinics. The Investigation Team noted that, as a result of the increase in new staff, the structures and workload patterns within the department have undergone significant changes. This has been achieved over a relatively short period of time.

In relation to the Symptomatic Breast Disease Service, three consultant pathologists have an interest in breast disease. These pathologists report on the majority of breast work and take a lead in providing the pathology expertise at the weekly symptomatic breast disease multidisciplinary meetings. One post remains unfilled and is currently filled by a temporary consultant histopathologist with a special interest in breast disease.

There is an allocation of 17.95 whole time equivalents for medical scientific staff within the department. However, the number of medical laboratory scientific staff in post, including laboratory aides, fell below this allocation. The Investigation Team notes the challenges faced by the Pathology Service in not being able to recruit to two posts. This has largely been due to a high turn-over of staff.

5.4.2 Working Arrangements between UHG and Other Facilities

In the course of the investigation, the Team found that UHG Pathology Department provided private diagnostic histopathology and cytology services to Barrington's Hospital from October 1992 to May 2007. There was no formal service level agreement for this arrangement, which was based on a long-standing private arrangement between individual clinicians, although financial agreements were in place between the two organisations. As a result, there were no formal governance arrangements or quality assurance procedures in place. Notably, there were no arrangements for MDT or the opportunity for consultant pathologists to participate in multidisciplinary discussion about the diagnosis and treatment plan for Ms A and/or other patients. The Investigation Team did find evidence of a standard procedure for packaging/boxing, transferring, receiving, recording and processing the materials.

There is a small but recognised potential for human error in diagnosis for breast disease. Therefore multidisciplinary review of pathology, imaging and clinical findings offers a vital opportunity for identifying discrepancies and initiating further tests if required. This 'triple assessment' is recognised best practice.^{17,20} The Investigation Team concluded that the absence of such arrangements in Ms A's case was most likely a contributory factor in her delayed diagnosis.

5.4.3 Clinical Practice

The Investigation Team found that consultant pathologists carry out diagnostic work across a range of pathology specialties as well as focusing on their particular area of interest. The consultants actively contribute to up to 13 multidisciplinary team meetings per week in UHG across a range of surgical specialties. There was evidence of clear leadership for gynaecological cytology. Significant attention has been given to this area due to the high volume of cases. There has been less focus on the development of diagnostic cytology and the Investigation Team is of the view that this service would benefit from clearer direction.

Sub-specialisation is not formalised in terms of workload planning or accountability arrangements. While this is not a requirement, the Investigation Team suggests it may be timely to consider moving to more structured arrangements given the increase in specialty throughput now being experienced in the Pathology Department.

As the Authority's investigative powers do not extend to private hospitals, the Investigation Team did not review the care pathway of, or quality of care received by, Ms A in relation to her care in Barrington's Hospital.

5.4.4 Quality Assurance and Audit

A robust, department-wide quality assurance programme is an essential component in assuring best pathology practice. Clinical audit is the principal method used to monitor clinical quality. It provides a powerful mechanism for ongoing quality improvement, highlighting incidents when standards are not met and identifying opportunities for improvement. Clinical audit should be considered within an integrated safety and quality governance framework.

Quality managers have been appointed and UHG Pathology Service is pursuing external accreditation. A programme of visits has been arranged. A number of protocols are in place and policies and procedures have been developed. This was particularly robust for the cervical screening service.

There was evidence of departmental meetings comprising of consultant pathologists, chief medical scientific officers and senior managers where some issues of service delivery and quality are discussed and evidence of some action being taken.

There is evidence of clinical audit being undertaken. As part of the Investigation Team's review of gynaecological cytology, they noted good examples of audit activity being used to assure the quality of service provision. There was evidence of audit of breast histopathology, for example the symptomatic core biopsy service was audited for the period January 2004 to December 2005. In addition, more recent examples of clinical audit activity being undertaken was evident. The Investigation Team believes that the individual strands of audit activity, and the clinical findings thereof, need to be drawn together to form a more integrated approach to quality assurance. An incomplete picture of clinical audit will result in a missed opportunity for service development. In an environment where there is no integrated quality assurance system, errors are less likely to be systematically identified.

Protocols for the processing and reporting of histopathology breast specimens are available within the pathology service. The Investigation Team were informed that these have been circulated within the Symptomatic Breast Disease Team. The Investigation Team believes that it would be beneficial to jointly review implementation of these protocols as part of the clinical audit programme.

It was noted that the Information Technology (IT) systems in the Pathology Service are poor. In the absence of effective IT systems, there is limited data collection to underpin audit activity. Given the increased volume and complexity of pathology activity in the department and the need for strengthened quality assurance programmes, the Investigation Team believes it is timely to review information management systems as part of the overall application of national standards, specifically the standards in relation to information technology.^{17 (7.17)}

Recommendation 6

All pathology departments should implement the recommendations of the Faculty of Pathology's guidelines on histopathology quality assurance programmes in pathology laboratories.¹⁸ This incorporates, among other things:

- *Intra-departmental consultation/peer review*
- *Multidisciplinary case discussion*
- *Incident reporting*
- *Vertical case review/audit*
- *Cytology quality assurance*

Implementation of these recommendations must be supported by appropriate Information Technology systems.

5.4.5 Pathology Department Facilities

The Investigation Team visited the Pathology Department and observed the working environment. The department is in an old building and was not designed for modern pathology practice.

In line with *Towards a Regional Pathology Service*,²¹ a costed option appraisal for the up-grade of laboratory facilities outlining deficiencies of the existing laboratory building was submitted from UHG to the HSE in September 2007. At the time of the investigation, the outcome of this submission was awaited.

Pathology has been discussed here and its place as part of the Symptomatic Breast Disease Service has been considered. The following findings relate to the Symptomatic Breast Disease Service as a whole, and cover other key clinical services.

5.5 Symptomatic Breast Disease Services

5.5.1 Staffing Arrangements

The Investigation Team found that the Symptomatic Breast Disease Service had grown significantly over the past four years. Historically, the department was seeing 40 new breast cancers per annum. This had risen to 130 patients in 2003. However, in 2004 and following implementation of the recommendations in the Development of Services for Symptomatic Breast Disease report (2000)²⁰ three new consultant surgeons were appointed and in 2005, 250 women newly diagnosed with breast cancer were treated. By 2007, this had risen to 263.

At the time of the investigation, consultant surgeon staffing is at the levels recommended by the 2000 report and the National Quality Assurance Guidelines for Symptomatic Breast Disease.^{20,17} This is also the case for consultant staffing in Pathology although there have been significant challenges in recruitment and

one post remains filled by a temporary consultant pathologist on a long-term basis. A fourth consultant surgeon has recently been appointed in preparation for the roll-out of BreastCheck. To meet the consequential effects of the roll-out of BreastCheck, that is a projected 450 patients per annum, the Investigation Team noted that a submission to the HSE for additional staffing had been made in August 2007. This covered consultant (surgery and pathology), nursing, allied health professionals and support services.

In relation to the Clinical Nurse Specialists for breast care, UHG has three posts available for providing this service. However, at the time of the investigation there were 2.5 clinical nurse specialists (CNS) in breast care in post and UHG was awaiting approval from HSE to recruit the remaining 0.5.

The Investigation Team noted that the rapid growth of the service, driven by the addition of surgical capacity within it, was placing pressure on other aspects of the service, especially radiology. Pathology, Radiology and Nursing staffing are covered in sections 5.4.1, 5.5.7 and 5.5.8 respectively.

The Team concluded that, if unaddressed, this could lead to sub-optimal patient experiences and hamper the future development of a high quality service. This issue is developed further later in this section.

5.5.2 Organisation and Planning

The Investigation Team noted a clear direction for the development of the Symptomatic Breast Disease Service at UHG as an integrated part of the Cancer Network Strategy for the Western Region. Strategic coherence in terms of planning and delivery of cancer services lies at regional level and the link to local service developments is discussed regularly through the Hospital's Cancer Steering Committee. The terms of reference for this group and minutes of meetings were reviewed by the Investigation Team. This Committee seemed to have a clear focus in its intention to achieve high quality standards for patients. At the time of the investigation, the Committee was working on the capital and resource planning required to deliver the cancer strategy and reconfiguration of services. There was evidence of good working relations between Hospital senior management and the regional network.

There was evidence that the surgical expansion was running ahead of capacity in other areas such as radiology and nursing. This led to long waiting times for some patients on the day of their clinic appointments and also patients being asked to return for the results of their diagnostic imaging rather than this being made possible at the same visit.

UHG's service plan for 2007 is clear in its intention to increase bed capacity for all cancer patients as a result of a 200% increase in the number of cancer patients treated surgically, and to improve the overall access to all aspects of cancer treatment. As a result, the bed capacity for oncology patients was increased in July 2006 from 26 to 57. The daily average for cancer patients is running at 74. There are 6 protected, 7 day beds for breast care with access to 5 day beds as well. There is also a 1 day ward session per week.

The relationship of the breast care team with the bed management service was reported to work well. In the main, admissions to dedicated wards were not compromised although staff reported that it is on occasions extremely tight because of the pressure from emergency admissions.

Staff within the Symptomatic Breast Disease Service are clear about their roles and responsibilities. All staff spoken to by the Investigation Team demonstrated their commitment to working as a team to provide a high quality service to patients. In support of their work, the Investigation Team noted a number of administrative policies, procedures and clinical protocols to guide all grades of staff. These are also used for training purposes.

UHG is in the process of embedding its Clinical Directorate structure. This is to be welcomed as a mechanism for enhanced accountability and more effective clinical engagement in the management and organisation of services. The Investigation Team noted, however, that the Symptomatic Breast Disease Service sits across a number of Clinical Directorates although it is predominantly represented through the surgical directorate. This may present challenges in ensuring cohesion and integration of the respective service elements and may hamper the effective devolution of budgets. This needs to be effectively managed, governed and led. It is suggested that the Directorate structure should be kept under review to ensure it is not inadvertently creating barriers to integration within the Symptomatic Breast Disease Services.

5.5.3 Patient Experience

Patients with a diagnosis of breast cancer are seen more than once by the consultant surgeons in out-patients prior to surgery and are also supported by the clinical nurse specialists, although the number of clinical nurse specialists was seen to be low compared to national recommendations.

Patient cases are discussed at the weekly multidisciplinary team meetings and breast surgeons and radiologists select cases for discussion. The meetings are attended by an appropriate mix of disciplines including consultant pathologist and clinical nurse specialists. Key indicators for breast cancers such as breast reconstruction rates are recorded routinely. These are verified at the MDT meeting.

The Symptomatic Breast Disease Service has made impressive progress in ensuring that patients are seen as quickly as possible for their first appointment. In April 2004, there was a waiting list of 1,700 patients with waiting times of up to three years. This waiting list for first attendance has now been cleared and all new patients are seen well within two weeks of their GP referral. To support clearing the 2004 waiting list a number of innovative, albeit time-limited measures were put in place, such as running out-of-hours clinics and Saturday radiology sessions.

In the course of the investigation, some patients reported to the Investigation Team that they had to wait a long time in out-patients before being seen. The clinics are 'block-booked' meaning a number of patients are booked into one appointment slot. This was confirmed by staff who reported that this can be distressing for patients returning to obtain results. Similarly, some patients reported to the Investigation Team having to wait a considerable length of time to have diagnostic imaging. At the time of the investigation, these patients were being encouraged to return on another day: this is not ideal and radiology should be available on the same day. The Departmental audit showed that approximately 80% of patients receive same day guided biopsy.

At the time of the investigation, the Symptomatic Breast Disease Services were considering implementing a second triple assessment clinic which would potentially eliminate these waiting times. In addition they were also considering having a dedicated out-patient clinic for the purpose of feedback to patients on their diagnostic results. The Investigation Team believes these developments would significantly enhance patient experience and they would encourage their implementation as soon as possible within available resources.

As a result of the service being built up over the past four years, a more comprehensive range of cancer services for breast disease is now available. For example, over the past two years there has been an improvement in the availability of patient chemotherapy and radiotherapy services. Prior to 2006, patients had to go outside of Galway for their out-patient chemotherapy but there is now a clear pathway from first appointment through to radiotherapy services. Some patients avail of the satellite day chemotherapy units in Portiuncula and Mayo General Hospital to facilitate easier access to treatment.

5.5.4 Multidisciplinary Team Meetings

All patients who have received triple assessment are included in discussion at the bi-weekly MDTs. The MDTs include surgical, pathology, radiology and nursing expertise. In addition, more recently a West of Ireland breast cancer network has been established by the HSE regional office which includes units in Castlebar, Sligo and Letterkenny. At the time of the investigation, a review was underway of how patients who are seen outside UHG are integrated into the MDT's and the Investigation Team supports this approach.

The Investigation Team found that the pathway of care for patients discussed at MDTs within UHG services is clear. This is less likely for patients seen by non-UHG consultants at private clinics who submit pathology specimens for reporting in UHG. This was the case in relation to Ms A. When more than one institution is involved in providing care, it is important that clear multidisciplinary arrangements should be in place. Such arrangements between institutions should be governed by clear policies and service agreements.

5.5.5 Clinical Practice and Outcomes

The Investigation Team had a range of clinical outcome data reported to it in the course of the investigation. Clinical audit data is collected through the University in Galway rather than as an integrated part of the Hospital's data management and clinical audit programme. According to audit reports, clinical outcomes compare favourably to the National Quality Assurance Standards for Symptomatic Breast Disease Services in the provision of quality care in breast cancer services. For example:

- *the breast conservation rate is around two-thirds with one third of women undergoing a mastectomy*
- *three quarters of women receive an immediate breast reconstruction which means that a quarter of women receive mastectomy alone*
- *sentinel node biopsy avoids the use of axillary clearance in over half of patients which means that only those patients with positive nodes undergo axillary clearance. This is in line with a general move towards providing more non-invasive procedures for patients and is in line with national standards¹⁸*

5.5.6 Clinical Disciplines

To ensure a full Symptomatic Breast Disease Service can be provided, clinical support departments such as pathology (consultant pathologists and medical scientists); radiology (consultant radiologists and radiographers); nursing and administrative support need to be fully integrated into the service. During the investigation, it was evident that these key disciplines, underpinning triple assessment, are well represented in all aspects of in-patient and out-patient nursing. However, room for improvement was noted by the Investigation Team, such as clarity regarding the role of pathology as a key diagnostic method and the timeliness of radiology services in relation to out-patients. In addition, staffing levels in key clinical departments need to be commensurate with the rapid increase seen in patient attendance. The Investigation Team considered these elements in some depth and the findings are covered in the service and workforce planning section of this report (Section 5.6).

5.5.7 Radiology

There are nine consultant radiology posts available providing a service to all specialities within the Hospital. This has increased from an establishment of six radiologists in 2001. There is one full-time locum in the department.

There are clear policies and procedures for the provision of radiology services to support Symptomatic Breast Disease Services. Radiology is an integrated part of Symptomatic Breast Disease Service MDTs. The Investigation Team noted that at the time of the investigation visit, there was one whole time equivalent consultant radiologist post dedicated to breast work although the post was divided between the provision of breast and general work. In addition there was one locum covering two sessions per week.

Two consultant radiologists are recommended for Symptomatic Breast Disease Service units.¹⁷ At the time of investigation there was little or no spare capacity to cover for annual or sick leave. Since the investigation, three sessions have been agreed from the Clinical Director of BreastCheck and a further consultant with a special interest in Symptomatic Breast Disease is being appointed.

The Investigation Team noted the significant commitment of the consultant radiologists and radiographers in breast care to offer extended services to four new breast clinics; they are planning for the imminent commencement of triple assessment out-patient clinics; and they contribute fully to MDTs. The Investigation Team's view was that this is unsustainable for the individuals concerned and the impact it may have in the longer-term on the service. There has, in the view of the Investigation Team, understandably been a slight impact on patient waiting times for same day urgent triple assessment.

The Investigation Team understands additional radiology resources will be coming to UHG as part of the BreastCheck development including two more consultant radiologists. Local discussions will be needed to explore how this resource can be used creatively to enhance the symptomatic service.

5.5.8 Nursing

There are currently three posts available for providing this service. However, at the time of the investigation there were 2.5 Clinical Nurse Specialists (CNS) in breast care in post and UHG was awaiting approval from HSE to recruit to the remaining 0.5.

The breast care nursing staff provide clinical, emotional, psychological and advocacy support to patients. There is a clear pathway for women being referred into the service and comprehensive policies and procedures to guide staff in the out-patient clinics and in-patient wards. The Investigation Team was impressed with the patient information leaflets that had been developed by the nursing team covering a range of breast care issues in an easy and accessible format.

The breast care nurses take a leading role in preparing and following through with appointment scheduling and follow-up calls to benign triple assessed patients after the multidisciplinary team meetings. The CNS is always present when women are given the outcomes of their investigations. Similarly, post-surgery when patients receive post-operative histology results, the CNS is present and will coordinate the patients' on-going adjuvant therapy. A nursing cardex on each patient is kept by the nursing team but they do not always have time to write up nursing care in patients' care pathway records.

Provision was made where possible for nursing staff to undertake further education. However some staff reported limited capacity to allow for study leave and having to ensure shifts are covered if they wish to take up further study.

5.6 Service and Workforce Planning

Historically, there had been correspondence within UHG and at regional and national levels about the number of staff required to handle the Pathology Department's workload both in terms of complexity and volume. According to some staff, at times there had been challenges in securing additional staff to keep pace with developments in other parts of the Hospital and in particular symptomatic breast disease. There had, at times, been a lag between planning and appointment of additional staff in pathology, radiology and breast care nursing.

This had not been helped by long approval pathways for new posts with delays of up to eighteen months. Post approval, the recruitment process also invariably took a considerable length of time. Planning for the numbers of pathologists needed had historically been based on the number of population served rather than planning being service led. This did not seem to the Investigation Team to be a sufficiently sensitive proxy for the volume and complexity of the service. Workforce planning should take account of the totality of the activity whether public or private.

The Investigation Team concluded that the long lead-in times and the difficulty in recruiting to pathology services, increased dependence on temporary consultant staff.

Since the period of the terms of reference, a number of additional appointments within pathology have been made, bringing the numbers to double what they had been in 2004. This in turn is reducing the historic dependence on a succession of temporary consultant appointments. Nevertheless the Investigation Team believes shorter elapsed times for the appointment of clinical staff should be possible and would help ensure service developments remain appropriate to demand.

Recommendation 7

The HSE should review workforce planning at national and local levels to ensure that recruitment of consultants is more responsive to changing service needs and reliance on temporary staff is minimised. This should include measures to reduce the time-lag between authorisation to appoint and staff taking up post.

5.6.1 Use and Appointment of Temporary or Locum Consultant Staff

The Investigation Team reviewed the recruitment process at UHG to confirm whether the process was in accordance with current guidance and to identify whether there were any lessons that could be learnt in relation to the recruitment of temporary or locum consultant staff. In addition, given UHG's on-going use of temporary consultant staff, the Investigation Team wanted to ensure that appropriate governance arrangements were in place for such staff.

At the time of the investigation, UHG's HR Department did not have a formalised procedure for the recruitment of temporary or locum staff but relied on the same principles and approaches as outlined in their internal policy used for the recruitment of permanent staff. The process consisted of a flow chart of the steps to be taken in the recruitment process and supporting documented policies and procedures. The process had received ISO 9001:2000 accreditation in November 2004 and has been reviewed and up-dated since. This had been developed using internal HR expertise and it draws on the Public Appointments Service Recruitment Code of Practice 2004.^{15,16}

UHG's HR Department routinely uses a range of specialist recruitment agencies to fill temporary and locum consultant posts. The Investigation Team were told that the recruitment agency assists the applicant in obtaining Medical Council Registration. This process includes obtaining relevant documentation and credentials. For applicants who come from outside of this jurisdiction, a letter of good standing from the applicant's current regulatory body and proof of registration is requested. In addition, Garda clearance is obtained by UHG's HR Department.

Within UHG procedure for the recruitment of permanent staff, the Investigation Team noted that the process of verification and assessment of references falls within the remit of UHG's HR Department. However, the Investigation Team was informed that custom and practice is to make references available to the interview panel. The Investigation Team is of the view that a formal opportunity should be provided to appointment panels to discuss all written references as part of the assessment of temporary or locum staff's suitability for employment before making a recommendation for appointment.

The following summarises the steps taken in the recruitment process for Dr C.

- *The agency submitted Dr C's curriculum vitae to UHG's HR Department as a suitable candidate for the post*
- *Dr C was interviewed by teleconference*
- *Two references were made available, via the recruitment specialist, to UHG's HR Department*
- *These references were available at the time of interview and seen by members of the interview panel*

- *A verbal recommendation had been received by the Pathology Department in respect of Dr C by another temporary consultant pathologist working at that time in UHG Pathology Department. These references were taken as satisfactory by the interview panel*
- *As a result of successful interview, Dr C was considered suitable for employment*
- *This suitability was confirmed to the recruitment agency that conveyed this information to Dr C*
- *The recruitment agency contacted Dr C to inform them of the offer*
- *This was subsequently confirmed to them in writing by UHG's HR Department*
- *A condition of this appointment was that Dr C gain accreditation in a particular gynaecology cytology method being introduced at UHG which was the liquid-based ThinPrep Morphology. Dr C agreed to this and obtained this accreditation shortly after appointment*
- *On arrival at UHG, Dr C signed a contract of employment and received orientation to the Hospital and the Pathology Department.*
- *They commenced their duties two days later after the Medical Council confirmed that they were eligible to practice. This was subsequently confirmed in writing a few days later in the form of the appropriate certification of proof of registration*
- *The recruitment agency took responsibility for supporting Dr C in obtaining Medical Council Registration*
- *The relevant Medical Council Registration was confirmed by phone for Dr C by UHG's HR Department before they commenced their duties*
- *Proof of registration was obtained after the appointment offer letter had been issued*
- *Garda clearance was obtained by UHG through the recruitment agency*
- *A further reference was received, via the recruitment agency, by the Hospital but given that the post had already been offered, this third reference, although reviewed by UHG's HR Department, was not shared with the Pathology Department. On reviewing this reference, and the two that had previously been submitted, in addition to the verbal reference obtained, the view of the HR Department was that Dr C was suitable for employment*

From its review of the process used by UHG's HR Department, the Investigation Team concluded that a formal policy for the recruitment of locum and temporary consultant staff should be established to ensure more robust arrangements and quality assurance mechanisms. This would, amongst other things include a requirement for:

- *Formalised agreements with specialist recruitment agencies; which will include their role, responsibility and area of accountability in the recruitment process*
- *Provision for appointment panels to discuss all written references as part of the assessment process*
- *Taking into account existing competency levels of applicants as well as arrangements for their on-going development and support as temporary employees*
- *That all job offers be made subject to satisfactory references*

The Investigation Team understands a process is underway to formalise nationally some aspects of the use of locum recruitment agencies.

The Commission for Public Service Appointments' principles are clear that appointments are made on merit, and "competence, abilities, experience and qualities" should be central to the selection process.^{15(p14),16(p12)} References form an integral part of the process of assessing candidates and the collection and use of references must also be made clear within locally developed procedures. Similarly, the Investigation Team is of the view that applicants should themselves be able to demonstrate their competence through, for example, presentation of evidence of continued professional development and outcomes of their work. Provision of such evidence will accord with the Medical Practitioners Act 2007 which provides for competence assurance to drive continuing medical education.²²

Proof of competence assurance will become an essential and accountable aspect of the work of HR departments for the recruitment of all healthcare professionals in Ireland as the movement of medical professionals within Europe continues to expand. The credentialing processes within each jurisdiction are different and it will be important to ensure that a uniform approach, at least within Ireland, is adopted.

The Investigation Team understands that a local procedure for the recruitment of locums and temporary staff was developed in January 2008 and ratified by UHG's Executive Management Team. The Investigation Team recommends that this is now activated, closely monitored and up-dated in the light of any new guidance that may be circulated from the HSE.

The Investigation Team understands from its interviews with the HSE that, following a review by the Commission for Public Service Appointments, it has commenced a process of introducing a uniform national HR policy for the recruitment of locum and temporary medical consultants across the public health system. The review is considering the need to put in place tender processes and recruitment and selection standards to be adopted by specialist recruitment agencies.

It is the HSE's intention to set up a Standardised National Qualification Databank. This will be a database of all employees and will specify qualifications for posts thereby articulating minimum mandatory requirements and experience levels. Their work will be in conjunction with external regulators including the Medical Council. The Investigation Team notes this work and expects to see the recommendations of the Lynott report,¹⁹ which relate to recruitment practices within Ireland and appointments of staff from outside the jurisdiction, to be reflected in this committee's work for the purpose of immediate implementation.

In addition, it is their view that creating a more structured supervisory environment could further mitigate risks associated with the appointment of temporary and locum staff. Such an environment should include a comprehensive induction programme and the provision of on-going supervisory support to enable locum and temporary staff to fulfil their duties to the desired standard. This would also be an assurance to employers of the locum's on-going competence. It is recognised that the previous consultant contract for all specialties (in place at the time covered by this investigation) did not provide for this type of arrangement as it considered consultants (including locum and temporary appointments) to be independent practitioners. The new consultant contract provides the basis for more explicit accountability of consultants through practice plans and a reporting relationship with clinical directors.

Recommendation 8

It is recommended that the HSE Risk Sub-Committee progress and publish their work on mitigating against risks associated with the employment of permanent and locum consultant staff. In the meantime, all local service providers should review recruitment policies and procedures to ensure robust verification and assessment processes are in place.

Recommendation 9

A formal policy for the recruitment of locum and temporary consultant staff should be established and implemented nationally to ensure more robust and effective arrangements and quality assurance mechanisms. This should include:

- *Formalised agreements with specialist recruitment agencies, which will include their role, responsibility and area of accountability in the recruitment process. These agreements should be regularly monitored*
- *The provision for appointment panels to view and discuss all written references as part of the assessment process and before recommendation for appointment*
- *Account to be taken of existing competence levels of applicants as well as arrangements for their on-going development and support as temporary employees*
- *An agreed programme of audit against compliance*

Recommendation 10

The recommendations of the Lynott Report (2002) should be implemented by the HSE and other service providers and compliance should be audited regularly.¹⁹

5.7 Management, Leadership and Governance Arrangements

5.7.1 Governance Arrangements

UHG is in the process of embedding Clinical Directorates. Clinical directorates are discrete service units where all the service, workforce planning, budgeting and overall management arrangements are held by the one team under the direction of a Clinical Director supported by Consultants with Administrative Responsibilities. The Clinical Directorate is supported by a business manager. The directorate is accountable for their services which includes meeting certain performance targets and quality standards and managing the overall resources approved by the executive management team.

The Executive Management Team was working to develop the Hospital infrastructure in terms of Clinical Directorates; coordinated strategic developments and clinical governance arrangements such as strengthened risk management and quality assurance processes. This was reflected in the

Terms of Reference of the Executive Team, the Management Team and the Clinical Quality Improvement and Risk Management Committees and through feedback from a considerable number of staff who expressed confidence in senior management and the way the Hospital is being developed. At the time of the investigation, Clinical Directors were not part of the Hospital Management Team although there were plans to resolve this and latterly the Surgical Directorate, which encompasses Symptomatic Breast Disease Services, was at the time of the Investigation represented. There was some frustration amongst clinical staff in relation to the limited devolved responsibilities for directorates for example budgeting. However, the Investigation Team note that the terms of reference for the Executive Management Team are clear in relation to this and 2007 was considered to be a shadow year once all directorates were in place.

Based on this investigation two key areas of governance were identified that need strengthening at UHG; both these have relevance for hospitals across the health service. The first arises from the arrangements for sourcing temporary and locum consultant staff via a third party agency and the need for clear procedures and governance of checking and reviewing references and other pre-employment sources of assurance. The Investigation Team understands a national policy in this area is being developed, however in the interim, all hospitals should review their arrangements to ensure they are robust.

The second area relates to the need for clear governance of services provided for or on behalf of a separate organisation such as in the example of the pathology service being provided by UHG to Barrington's Hospital (now discontinued). It is not appropriate for such arrangements to be on the basis of individual arrangements. They should be covered by written agreements specifying issues such as service volumes, quality assurance and financial recompense. They should also be subject to regular, formal review.

5.7.2 Leadership

Symptomatic Breast Disease Services at UHG have gained in profile over the past four years as higher volumes of patients are now being referred to the service. The Investigation Team found evidence of clear clinical and managerial leadership and evidence that this translates into motivated operational and administrative staff. This was further evidenced by such initiatives as the waiting list reduction referred to earlier and successful clinical outcomes.

In July 2007, Pathology was the last directorate to be established. The difficulty in recruiting to posts; the dated working environment of the laboratories; and the ever increasing demands placed on the service, have been particularly challenging in terms of service development and the implementation of quality assurance initiatives. The Investigation Team was encouraged by the new management arrangements since the establishment of the Directorate. The relatively new consultant pathology appointments, together with existing staff, demonstrate vision and commitment to developing and raising the profile of the service within the Hospital and region.

In line with the early development of directorates, medical scientists report to the laboratory manager who reports to the clinical director. However nursing lines of accountability have remained directly with professional heads although efforts have been made to clarify reporting arrangements for administrative duties that fall within the scope of the directorate leads.

5.7.3 Risk Management

UHG was found to have a clear corporate framework for risk management. Incident reporting was taking place and there was evidence of near misses beginning to be reported particularly in relation to pharmacy. For example, a full review of the administration of cytotoxic drugs was undertaken as a result of a near miss. Staff should feel confident in routinely reporting concerns, near misses and incidents, as an integrated part of their daily work.

While the Investigation Team found no evidence of staff reluctance to participate in this level of risk management, UHG should continue its efforts to ensure that proactive management of risk is encouraged. Changing practice as a result of learning from mistakes should be encouraged as part of the organisation's culture.

UHG used the risk management framework appropriately when establishing the adverse incident group to investigate and respond to the pathology misdiagnosis of Ms A but only once the error had been identified.

The risk management arrangements in place did not proactively identify the weaknesses in quality assurance systems since highlighted by this investigation and therefore need to be strengthened. It is expected that this would be addressed through the emerging directorate system.

5.7.4 Patient involvement

In relation to responding to patient feedback, there is a documented patient complaints procedure and evidence of training initiatives coming from analysis of data. However, some staff and the patients who took time to speak to the Investigation Team, thought that there was an over reliance on the complaints procedure and expressed the view that a patient advocacy approach would in some instances be more preferable. This view is supported by the Investigation Team.

Patients are not routinely involved in service developments and some of the patients who came forward for interview expressed their willingness to be involved in this regard.

In summary, there is a sense of clear direction in the establishment of a Clinical Directorate system of management for UHG and the culture of this partnership approach from senior management and clinical leaders was seen to be in place. At the time of the investigation these were in 'shadow' form and budgeting had yet to be devolved although this was planned.

The Investigation Team found there to be a visible leadership style emanating from the senior management team. This visibility was held in high regard by staff and was seen to prove valuable when the initial review and helpline was found to be necessary. There is in place a culture of putting the patient experience at the heart of the Hospital's work and this should be recognised. There is however, opportunity to strengthen this by further developing the accountability arrangements in the areas of clinical and non-clinical governance as referred to within the body of this report.

Recommendation 11

The role of independent advocacy services should be developed in all hospitals. These advocacy services should facilitate patients coming forward to raise concerns and have them addressed. Hospitals should encourage such services as part of a helpline and/or as part of patients' hospital attendance.

6. Conclusions

This investigation arose from the distressing experience of Ms A. Her diagnosis and treatment for breast cancer was delayed significantly as a result of diagnostic errors within the Pathology Department at UHG and the absence of a multidisciplinary team to effectively assess her triple assessment findings. Triple assessment did not take place because Ms A's care was split across two different hospitals and no arrangements had been put in place for this by the clinicians or institutions concerned.

Investigating the causes and issues surrounding these errors has led the Investigation Team to conduct a substantial technical review of pathology slides incorporating both breast tissue and a wider range of tissue types. It has examined the management and organisation of the pathology service and the broader Symptomatic Breast Disease Service. In doing this, the investigation has explored other issues such as service and workforce planning and consultant recruitment. This section sets out the conclusions drawn by the Investigation Team.

Ms A's Misdiagnosis

In September 2005, Ms A was being investigated for her symptomatic breast disease in Barrington's Hospital, a private hospital in Limerick. As part of her diagnostic pathway, a tissue biopsy specimen was sent to the Pathology Department at UHG and was reported by consultant histopathologist Dr B as benign. In March 2007, having re-presented to the same private facility with breast symptoms, Ms A had an FNA cytology sample sent from Barrington's Hospital to the Pathology Department at UHG. This sample was reported by consultant pathologist Dr C as benign. A further biopsy later in March 2007 was taken at Barrington's Hospital. This was reviewed and reported on at Bon Secours, Cork and showed malignancy. This was subsequently confirmed and Ms A underwent a mastectomy, including removal of some auxiliary nodes at Barrington's Hospital and was referred for treatment to a consultant oncologist at the Mid Western Regional Hospital Limerick.

Subsequently, Ms A's histology slides from 2005 and her cytology slides from 2007 were reviewed internally at UHG and both reported as showing malignancy. These slides have since been reviewed independently by the Investigation Team. They have confirmed that both showed clear signs of malignancy.

The service provided by UHG Pathology Department to Barrington's Hospital was based on a private arrangement between individuals. Financial arrangements were in place between the two organisations, however, there were no formal governance arrangements and no provision for structured multidisciplinary review of diagnostic findings. Neither did clinical staff ensure that such discussions took place. Specifically, there were no arrangements for 'triple assessment' of imaging, pathology and clinical findings.

A small number of interpretive errors is a recognised feature of histopathology and cytopathology. This is why multidisciplinary review and triple assessment are so important. They provide an opportunity to compare findings from different diagnostic and clinical processes and therefore the potential to identify 'discordant' findings. They allow interpretive errors such as those described here potentially to be highlighted. This offers a 'safety net' for patients to protect them from the adverse consequences such errors can create.

In Ms A's case, this did not happen and so the opportunity to identify and correct for the errors did not arise.

That one patient should have experienced two separate diagnostic errors emphasises starkly the importance of clear arrangements for multidisciplinary review of patients being investigated for symptomatic breast disease. This should be irrespective of where patients' care is being led from. The National Quality Assurance Standards for Symptomatic Breast Disease Services (2007) should be applied to all centres providing any aspect of diagnosis or initial treatment for breast disease. Where care is shared between organisations there should still be clear leadership of the care pathway.

University Hospital Galway's Response to the Errors

On discovering the errors that had affected Ms A, staff at UHG instigated a patient centred response that included senior management acknowledging the errors, apologising to Ms A and offering to meet with her. In addition, UHG promptly established a helpline for patients who might be concerned about their care at the Hospital. This included individual multidisciplinary review within special clinics set up for the purpose.

UHG's response included an adverse incident process that led to the issue being raised within the National Hospitals Office of the HSE. This led ultimately to the request for an independent investigation.

In the course of the investigation, as the case reviews have progressed, UHG managed the process of tracking patients and where necessary recalling them for review. They have also coordinated a communication process with patients implicated in any diagnostic errors identified by the Investigation Team.

The Investigation Team believes that wider lessons could be learned from the experiences of UHG in responding to the incident and that the HSE and the Authority should liaise to develop best practice guidelines for responding to adverse incidents in the future.

Case Reviews

The review of 200 histopathology cases reported on by Dr B revealed one significant interpretive error – that of Ms A. No other significant errors were identified.

The review of cytopathology cases reported on by Dr C incorporated two areas: diagnostic cytology (including breast cytology) and gynaecological cytology.

For diagnostic cytology, the review of cases reported on by Dr C identified that 49 errors, in addition to Ms A's FNA sample, had been made. This represents an error rate of 6.5%. This is 5-6 times greater than the accepted error rate internationally, which is 0.2–1.7%.²⁻¹³

Evaluation of breast cytology against accepted performance criteria for Dr C indicated false negative (failure to identify malignancy) reporting of 40% which is more than six times the accepted threshold of 6%.^{14(p50)}

In relation to gynaecological screening cytology, the performance of the laboratory as a whole was satisfactory with a high level of agreement between the medical scientists and Dr C. Gynaecological screening cytology interpretation is subject to inter-observer variation and therefore, a review of any cytopathologist's caseload will identify some differences between the original opinion and the reviewer's opinion. In this review of 123 cases there was agreement with Dr C's opinion in 78 cases and a difference of opinion in 45 cases. In light of this review, the Investigation Team advised precautionary follow-up of these 45 women. 10 women have already been seen by a gynaecologist and the remaining 35 women are being followed up by UHG.

The Authority will submit these findings to the Medical Council for its consideration.

Pathology Department

Regarding the wider pathology service as it relates to symptomatic breast disease; the team concluded that the wider participation of histopathologists at UHG in the multidisciplinary review process provides sufficient assurance that there is not a general concern about reporting accuracy within the department. This conclusion is supported by the outcome of slide reviews conducted by the Faculty as part of the Barrington's Hospital investigation and which included the work of a range of consultant pathologists at UHG.

There is a move towards sub-specialisation within the Pathology Service at UHG. The Investigation Team believes that consideration should be given to a more structured approach to this area, although this is not national requirement.

The technical quality of cytology slide materials submitted to the pathology service from a number of facilities and reviewed by the Investigation Team was found to be sub-optimal in some instances. This was due to a combination of the quality of samples presented for interpretation and slide preparation techniques.

In the Pathology Service there is evidence of audit being undertaken but it is less clear how this is linked into a quality assurance programme that leads to continuous services improvements, including technical slide preparation quality issues. An ongoing clinical audit programme which could identify errors was not in place. At the time of the investigation it was noted that the department was preparing to apply for laboratory accreditation and this will require the establishment of an integrated clinical audit programme. The Pathology Service should implement the quality assurance guidelines recently published by the Faculty of Pathology.¹⁸ This will support implementation of a quality audit programme.

Symptomatic Breast Disease Service

The overall conclusion of the Investigation Team regarding the Symptomatic Breast Disease Service at UHG is that it is a well functioning service with effective multidisciplinary collaboration. The service had grown significantly over a number of years and innovative approaches had been employed by the service to reduce waiting times for initial assessment.

The Investigation Team noted however, that the rapid growth in some aspects of the service was out-stripping capacity in other clinical areas, for example pathology, radiology and nursing. The Investigation Team saw examples of this leading to long waiting times for some patients on the day of their clinic appointments and also patients being asked to return for diagnostic imaging which, ideally, should be carried out at one visit.

The use of FNA as a diagnostic technique at UHG was occasionally taking place. FNA cytology should only be used in clearly prescribed circumstances and within a quality assured cytology service.

Management, Governance and Leadership

UHG has been implementing a system of Clinical Directorates. At the time of the investigation these were in 'shadow' form and budgeting had yet to be devolved although this was planned. Pathology had been the most recently established Clinical Directorate and this model will be helpful in developing the service further. This programme of reform of governance structures appeared to be based on productive relationships between senior management and clinicians.

UHG was found to have a clear corporate framework for risk management with incident data beginning to be recorded and used for learning. In relation to Ms A, the existing adverse incident procedure was implemented effectively. However, governance arrangements were lacking for work with third parties, for example, other facilities providing 'joint' healthcare or organisations providing a specific service (such as recruitment agencies). This should be addressed as a matter of importance by the Hospital.

Workforce Planning

The Investigation Team found that service planning has at times been out of step with service demands. This has had the effect of creating pressure on certain services and driving reliance on temporary or locum consultant staff. Workforce planning needs to be grounded in detailed understanding of the total workload, including public and private activity. In addition, long approval pathways for recruiting consultants have been a further factor leading to the use of temporary or locum staff. A national effort will be needed to reduce the time it takes to appoint a consultant once approval to recruit has been given.

Use and Appointment of Temporary or Locum Consultant Staff

The Investigation Team explored the process used to recruit Dr C. While UHG followed its process for the appointment of permanent staff, there was no specific procedure for the appointment of temporary or locum staff. Such a procedure should be aligned to the procedure for the recruitment of permanent consultant staff and should provide clear guidance on the use of recruitment agencies as well as guidance on receipt, review and assessment of references.

Currently, when locum, temporary or permanent consultant staff are appointed, they are presumed to be capable of operating as a consultant and therefore not in need of any special induction or ongoing support. However, a new consultant coming into a technical discipline would appear to raise risk factors that would be mitigated by a more structured working environment.

The current recruitment process for permanent, temporary or locum consultants does not include objective assessment of technical ability; but relies on the subjective opinion of referees. The Investigation Team expects that planned developments in competence assurance of healthcare professionals, enhanced quality assurance programmes, and specific corporate HSE guidance on the recruitment of all consultants will help to address this issue in the future.

Concluding Remarks

This investigation has highlighted again the crucial importance of clearly defined patient pathways for symptomatic breast disease and especially the multidisciplinary review of diagnostic findings. It has also highlighted the value of having robust quality assurance processes, including coordinated programmes of clinical audit. This report contains a great deal of detailed technical information that underpinned the Investigation Team's work to ensure as far as possible no patient was at risk of remaining undiagnosed. However, the key message that should be taken from the experience of Ms A is that all patients deserve the same standard of care regardless of where they are treated.

Clinicians and managers in all facilities, providing some or part of the diagnostic pathway for breast disease, should take note of the recommendations in this report and ensure they are implemented. The Investigation Team hopes that the findings and recommendations from this report will provide a watershed in Irish healthcare so that experiences like those of Ms A become increasingly rare.

The Authority expects the HSE to performance manage UHG in relation to the findings of this report and its recommendations. They should also consider at a corporate level where the recommendations should be applied nationally. The Authority will agree a time frame with the HSE for the Authority to monitor periodically the implementation of these recommendations.

Recommendation 12

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.

The Investigation Team would like to pay tribute to Ms A for allowing her story to provide a window onto how services for others can be improved and for showing such courage in sharing her experiences with the Investigation Team for the future benefit of others.

Finally, the Investigation Team would like to thank all those staff and patients who participated so openly and positively in this investigation.

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8 Glossary of Terms and Abbreviations

Adjuvant therapy: *treatment given in addition to the main treatment, for instance, radiotherapy after surgery.*

Aspirate: *sample of cells taken from a body organ or tissue for analysis*

Atypical: *abnormal, requiring further evaluation*

The Authority: *The Health Information and Quality Authority*

Benign: *non-cancerous*

Carcinoma: *cancer of epithelial cells*

Carcinoma in-situ: *a cancer that is non-invasive and has remained in the identified area*

Clinical Directorates: *Discrete service units in which all the service, workforce planning, budgeting and overall management arrangements are held by one team under the direction of a Clinical Director*

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*

CNS: *clinical nurse specialist*

Cytology: *the study of cells.*

Cytopathology: *the study of cells in diagnosis of disease*

Epithelial cells: *cells covering the internal and external surfaces of the body*

The Faculty: *The Faculty of Pathology of the Royal College of Physicians of Ireland*

Fibroadenoma: *a benign lump in the breast*

Fine Needle Aspiration (FNA): *use of a thin needle to take cells from a body organ or tissue for diagnosis*

HIQA: Health Information and Quality Authority

Histology: the study of tissue

Histopathology: the study of tissues in diagnosis of disease

HSE: Health Service Executive

Malignant: cancerous

MDT: multidisciplinary team

Multidisciplinary team review: the review of tests results by a team of specialists

Neoplasm: tumour

NHSBSP: National Health Service Breast Screening Programme (UK)

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

Suspicious: probably cancerous but without sufficient evidence to give a definite diagnosis

Triple assessment: assessment of three methods of investigation of breast disease: clinical examination, imaging and pathology tests

Urology: The study of the urinary tract

9 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 Regulation 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 Tom Crotty is a Consultant Histopathologist at St. Vincent's University Hospital since 1997. His sub-specialty interests include breast pathology. He is currently the Honorary Secretary of the Faculty of Pathology.

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. She was previously Quality Assurance Pathologist for the Irish Cervical Screening Programme. She is a member of the 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.

Dr Michael Jeffers is a graduate of Trinity College Dublin and is Consultant Histopathologist at The Adelaide and Meath Hospital, incorporating the National Children's Hospital, Dublin (AMNCH) and at Naas General Hospital. Dr Jeffers has over 10 years experience as a consultant in Ireland, and 2 years as a consultant at Aberdeen Royal Hospitals, UK (1996-1997). He is lead pathologist for breast pathology and non-gynaecological cytology. He was instrumental in establishing the rapid assessment breast clinic at the Hospital and chairs the Tallaght Breast Unit audit committee. He was Clinical Director of Laboratory Medicine at AMNCH from 2004 to 2007 and oversaw the successful application for Laboratory Accreditation awarded in October 2007. He is a founder member of the steering group for the Irish National External Quality Assurance scheme in diagnostic Histopathology.

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 and she 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, and Quality Assurance Radiologist, Northern Ireland Breast Screening Programme.

Dr Conor O’Keane is Consultant Histopathologist, Mater Misericordiae University Hospital and Associate Clinical Professor of Pathology, UCD School of Medicine and Medical Sciences. He has held a number of administrative posts at the Mater Hospital and is currently Deputy Chairman of the Medical Board and a member of its Executive Management Committee. On a national level he is currently Vice-Dean of the Faculty of Pathology. Among his interests are quality and accreditation in the laboratory and hospital and he has been involved in these processes on a national and international basis.

Health Information & Quality Authority

Jon Billings, Director of Healthcare Quality

Hilary Coates, Head of Safety and Learning

Andrea Groom, Project Manager

Appendix 1b

Faculty of Pathology, RCPI Review Team

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External Expert Advisor

Dr Karin Denton
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NHS South West England

Appendix 2

Documents Requested

The following documents were requested and used to inform this investigation into the circumstances surrounding the provision of services to Ms A by the Health Service Executive (the Executive) at University Hospital Galway (the Hospital) in relation to her symptomatic breast disease, and the provision of pathology and Symptomatic Breast Disease Services by the Executive at the Hospital.

Corporate Arrangements

- *Organisational structure*
- *Clinical governance, accountability and line management structure within UHG*
- *Board minutes in relation to the Ms A case and the pathology services*
- *Minutes of clinical governance and/or risk management committee for the last 1 year*
- *Copies of correspondence relating to the Symptomatic Breast Disease Service and Pathology Service as it relates to Ms A's case*

Symptomatic Breast Disease Services

- *Contract between UHG and any other partner services involved in triple assessment or provision of Symptomatic Breast Disease Services in relation to the case of Ms A*
- *Operational or Service plan and any relevant patient information for Symptomatic Breast Disease Services*
- *Quality assurance arrangements over the last 3 years for Symptomatic Breast Disease Services; either individual services or across services*

Pathology Service — Structures and Minutes

- *Organisational and clinical governance structure within the Pathology Department*
- *Regional / national networked pathology meetings participation over the last 3 years*
- *Number of staff working, and respective roles within pathology services, since the time of the case*
- *Quality assurance arrangements over the last 3 years for the pathology service*

- *Adverse incident and near miss reporting procedure (draft submitted: further information required)*
- *Minutes of multidisciplinary 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 multidisciplinary meetings with other disciplines and hospitals relating to the pathology service*
- *Previous serious adverse events in relation to the Pathology Department for the last 3 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*
- *The results of the internal review by UHG of Ms A's cytology*

Pathology Service — 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*
- *Copies of any relevant service level agreements or contracts with third parties*

Appendix 3

Invitation to Interview

PATIENT FEEDBACK

Symptomatic Breast Disease Services

University Hospital Galway

Why are we asking you for feedback

The Hospital has asked the Health Information and Quality Authority to undertake an assessment of the symptomatic breast services at the Hospital. The Hospital want to ensure they are providing safe, high quality standards of care for their patients

How you can help

As part of this process, it seems right that you, the patients 'have your say' about the services. We would like to take 20 minutes of your time to ask you a few questions about your experience at the Hospital. We won't ask you to talk about individual members of staff or your clinical condition. We are interested in knowing about what has worked well for you and what, if anything, could have been done differently to improve your experience.

Confidentiality

All interviews are confidential and carried out by a member of HIQA staff. You don't need to give us your name and you will not be identified in any way. We want to gather up as many views as possible, identify the key recurring themes and, as part of the overall assessment report, feed these back to the Hospital.

If you are happy to participate, please speak to The Receptionist or a member of nursing staff who will point you in the right direction.

Thank you.

Health Information Quality Authority

Appendix 4

Summary of Methodology and Terms of Reference for the Pathology Review



The Faculty of Pathology of the Royal College of Physicians of Ireland in association with the Health Information and Quality Authority

General principles

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

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

Materials Requested

1 Audit of pathology reports (computer reprints) by Dr C and other items UHG was requested to provide:

1. *A summary description of the circumstances of the index case including the initial lumpectomy and the FNA in 2007. This was to include the details of the reporting pathologist, whether locum/permanent and dates of appointment*
2. *All of the pathology (histology and cytology) slides for the index case. This was to include copies of all reports issued and the request forms if available*
3. *Computer printouts of all pathology reports by Dr C for the entire period of appointment at Galway*
4. *Copies of reports of any follow-up/corroborating histology received*
5. *Notes on the progress/findings of the 10 before/10 after internal audit conducted on the work of Dr C*

6. *Notes on progress or findings of any internal audit conducted around the initial lumpectomy*
7. *Notes on the progress or findings of the internal audit being conducted for screening (cervical) cytology where Dr C was involved*

2 Audit (workload profile) of Dr B

UHG was requested to provide:

1. *A profile (in the form of a table) of Dr B's workload for 2005, itemised into the number of specimens reported in the major common categories (i.e. breast histology, gastrointestinal, etc). Also a summary of the workload in each category for each month in 2005 including the months of November and December in 2004 in order to give an annualised view*
2. *(If any cytology was reported by Dr B) the workload and whether there was any audit/corroboration of these (e.g. for screening gynaecological cytology)*

3 Request for slides made to UHG following interviews in connection with Dr C

211 cases were reviewed. These consisted of 119 breast cytology cases (i.e. all of the breast cytology cases reported by Dr C) together with 92 non-breast cytology cases (the most recent consecutive cases). Dr Michael Jeffers and Dr Mairead Griffin shared the review of these cases.

Following the review of the initial 211 cases which, as discussed at a team meeting, it was decided to proceed to review all of the diagnostic cytology work reported by Dr C at Galway. The total number of cases was approximately 747, of which 211 had been reviewed, leaving a balance of approximately 536 to do.

Four histo/cytopathologists (Drs Jeffers, Loftus, Griffin, Nicholson) divided the remaining cases among them (approximately 134 each).

4 Request for slides made to UHG following interviews in connection with Dr B.

200 cases were reviewed. These consisted of the 200 most recent consecutive breast histology cases. Dr Conor O’Keane and Dr Tom Crotty reviewed 100 cases each.

Procedure – general terms

1. *The Dean (or another Officer) of the Faculty of Pathology facilitated the review panel*
2. *The objective of this review was to determine whether errors have occurred, to provide a commentary on their nature and extent, and to produce a Statement of Findings which was then deliverable and formed an input into the Authority’s overall investigation*
3. *The Faculty recommended seven reviewers, including one reviewer from another jurisdiction. The criteria for selection of reviewers was as follows:*
 - a. *Reviewers were consultant histopathologists, including at least two with a special interest and actively reporting breast cytology*
 - b. *Reviewers were not connected with any of the hospitals or laboratories in Ireland or the UK that have been identified in the cases*
 - c. *Reviewers were on the Histopathology division of the appropriate register of medical specialists and had good communication skills*
4. *The materials required for the review were made available to the Faculty as stated above*

Procedure – specific terms

1. *For cytology, an audit of computer printouts was arranged for the work of Dr C in order to determine the need for further actions including slide review*
2. *For histology, a workload profile for Dr B was obtained in the first instance in order to decide on further actions*

Detailed instructions for safe transport of material to the pathologists were issued to UHG. A protocol for safe storage of material was established.

Dean, Faculty of Pathology

December 6th, 2007

Appendix 5

Summary of Review of Histology and Cytology for Ms A Reported by Dr B and Dr C



The Faculty of Pathology of the Royal College of Physicians of Ireland in association with the Health Information and Quality Authority

Histology slides from Ms A's original breast biopsy, University College Hospital, Galway, were reviewed by two pathologists (Dr O'Keane and Dr Crotty).

Subsequent FNA cytology specimen was reviewed by two pathologists (Dr Griffin and Dr Jeffers).

Histology Review: 2005 biopsy (Reported on by Dr B)

Histology Report University College Galway S111111

Macroscopy:

Received 5H&E slides (4 blocks A,B,C 2H&E) and D labelled S111111 University Hospital Galway (UHG). In addition 7 immuno stained slides and 3 negative control slides for block B and 3 immuno stained slides and 1 negative control slide for block C, (total 19 slides). Also received corresponding pathology reports (original and revised).

Microscopy:

Slide A: Fibrocystic disease with sclerosing adenosis and mucinous change around ducts and benign microcalcifications.

Slide B: Microscopic foci of invasive lobular carcinoma, 3mm in aggregate adjacent to each other at one edge of the section. (This is at an edge of pathologist sampling of the specimen and not a surgical margin).

Carcinoma cells infiltrate around benign acini in two lobules and also infiltrate the intervening stroma but do not form a discrete mass. Although the infiltrating cells are intermediate to high grade (grade 2-3)

they are obscured by mucinous changes described in the previous benign sections and are further obscured by a lymphocytic and plasma cell infiltrate in the lobules.

Slide C: Ductal carcinoma in situ predominately intermediate, focally high grade 10mm max. at one edge of the section (this is a Pathologist sampling edge and not a surgical margin).

No invasive carcinoma present.

Calcifications are present in DCIS. No adjacent benign tissue. (2 slides see reviewed).

Slide D: Sclerosing adenosis with calcifications. No tumour present.

Subsequent immunohistochemistry ER stain: No tumour remaining cut section (tumour cut out of block).

PR stain: Insufficient tissue on sectioning for evaluation.

HER 2: No tumour present on section to evaluate status.

P63 stains (3 separate slides). Interpretation not possible due to loss of tissue as part of the immunohistochemistry process (tissue lifted off and missing).

In addition tissue is folded over.

An actin stained 2mm focus of tumour, negative for actin confirming invasive carcinoma.

Immunohistochemistry section C:

ER 50% of DCIS nuclei are moderately ER positive.

PR <10% of DCIS nuclei are PR positive.

Hercept test: Weak incomplete membrane staining of <10% of DCIS cells for HER 2 protein.

Interpretation:

DCIS moderately ER positive, PR negative, HER 2 negative.

Summary

The original report by Dr B on this tissue in 2005 was benign breast disease (fibrocystic change). When subsequently revised in University Hospital Galway, the appropriate revised diagnosis of ductal carcinoma in situ with a focus of invasive carcinoma was made. Review by Faculty of Pathology confirmed the revised diagnosis in University Hospital Galway, of ductal carcinoma in situ (DCIS with a small focus of invasive carcinoma). The original error in diagnosis identified on review in UHG is confirmed.

Comment

1. DCIS

DCIS is a 10mm focus and is not difficult to observe and diagnose. Some difficulty might arise in the grading of DCIS between intermediate and high grade. Failure to identify a 10mm focus of DCIS would represent a serious error on the part of an individual pathologist.

2. Invasive carcinoma focus.

This is a much more difficult lesion to diagnose. Reasons for the difficulty have been reported in the description above and include:

- (a) *The focus is small and at an edge of the tissue sample*
- (b) *Lobular carcinoma is notorious as a subtle diagnosis in that it infiltrates around and between normal structures and often does not produce a discrete mass particularly when present as a small focus as in this case. The infiltrating carcinoma cells and the two lobules affected are obscured by an accumulation of mucin in the periglandular stroma and a moderate lymphoplasmacytic inflammatory infiltrate which obscured the tumour cells*
- (c) *Nevertheless the tumour cells are grade 2-3 and can be diagnosed as unequivocally invasive*

Final Comment: We believe the error in missing this focus of invasive carcinoma is understandable given the context in which it is present.

Cytology Review: 2007 FNA (Reported on by Dr C)

Cytology report University College Hospital Galway N1111111

FNA cytology specimen was reviewed by two pathologists. (Dr M. Griffin and Dr M. Jeffers)

Gross Description:

Received 2 direct smears, stained PAP and H+E labelled N1111111. UHG together with corresponding cytology report.

Diagnosis:

FNA Breast: Malignant Cytology (C5)

- *Abundantly cellular breast aspirate containing cohesive groups and many single large pleomorphic malignant epithelial cells.*
- *Fragments of fibroadipose stroma are also present.*

- *Slides show airdrying and spreading artifact.*
- *Appearances are those of a poorly differentiated ductal carcinoma.*

Comment

The FNA specimen shows sufficient malignant criteria i.e. abundant cellularity, dyshesion, nuclear pleomorphism for a confident diagnosis of malignancy. Failure to identify these criteria represents a serious error on the part of the pathologist.

While the presence of airdrying and crush artifact may compromise accuracy of diagnosis, in this instance the marked nuclear pleomorphism and cellularity override any diagnostic reservations in air dried specimens.

Original report on Ms A's cytology (by Dr C)

Two smears showing adipose tissue with crush artefact and inflammatory cells. No malignancy seen. C2.

Supplementary Report on Ms A's cytology (review at UHG):

Review of two slides labelled N111 and corresponding to the original request form N1111111, shows severely atypical cells in an eosinophilic background. Artefact is present, but even allowing for this, these cells are at the least C4 and probably C5. Either way a confirmatory biopsy would have been indicated prior to definitive surgery.

Appendix 6

Summary of Review of Breast Histology: Dr B



The Faculty of Pathology of the Royal College of Physicians of Ireland in association with the Health Information and Quality Authority

Audit (Workload Profile) of Dr B

200 most recent consecutive breast histology cases, according to protocol (see Appendix 4, above)

Methodology

100 cases each were reviewed by Dr Crotty and Dr O'Keane following nomination by the Faculty. In a small number of cases (6) where the question of a discrepant diagnosis arose, cases were reviewed jointly by Dr Crotty and Dr O'Keane and a consensus diagnosis reached in all cases.

Results of the review have been tabulated and are on file in the Faculty.

Summary of results

Major discrepant diagnosis – None.

Minor discrepant diagnosis – One (UHG Lab No. 1111111): see detailed discussion below.

Overall comments

The standard of macroscopic descriptions was high. Sampling of sections for microscopy was appropriate. The standard of histology slide preparation was good to excellent.

A number of breast cases in fact include skin specimens from skin of breast. These were appropriately and well reported including diagnosis of benign neurofibroma and appropriate diagnosis of mast cell disease.

The standards of the histopathology reports were high, Cancer reports were appropriately complete for purposes of staging. In particular, several examples of appropriate pathology practice were noted including appropriate reference to previous cytology and histopathology reports. There was appropriate use of second opinion in the context of an unusual diagnosis.

Minor discrepant diagnosis

UHG Lab No. 1111111

Original diagnosis: Intraductal papilloma.

Review diagnosis: Atypical ductal hyperplasia with numerous microcalcifications.

Comment

Both the original and review diagnoses are variants of proliferative breast disease. The risk of subsequent carcinoma is slightly higher with atypical ductal hyperplasia. Interobserver variation among pathologists in the interpretation of proliferative lesions of the breast is well recognised (see for example Rosai J 1991) (abstract attached).

Recommendation

Patient should be recalled for clinical and mammographic review.

Following further discussion and review at UHG, it became clear that this case had already been reviewed at UHG and sent, with the previous core biopsy, for second opinion to a UK expert who concurred with the 'atypical' difficult proliferative breast disease diagnosis and further concurred this fell short of DCIS.

Summary and conclusions

The overall standard of reporting was very high. No major and one minor discrepant diagnosis was identified. The minor discrepant diagnosis had already been identified by intradepartmental review and external consultation.

Several examples of pathology best practice were identified.

Dr. T. Crotty & Dr. C. O'Keane

on behalf of the Faculty of Pathology.

Borderline epithelial lesions of the Breast

The concept of borderline epithelial lesions of the breast remains a controversial one, both at the conceptual and practical levels. The work of Page and collaborators (17-20) has suggested the existence of a continuum between hyperplasia and carcinoma in situ, and that the risk for the development of invasive carcinoma correlates with the degree of proliferation and atypia. A small survey made among a group of five experienced surgical pathologists to test the degree of interobserver variability in this field indicates that this variability remains unacceptably high. Unfortunately, none of the special techniques that have been employed to date in an attempt to achieve a sharper and more reproducible separation between the various groups has yet fulfilled this goal. Since an element of subjectivity in the microscopic interpretation persists and is unlikely to be completely eliminated, and in view of the fact that the current terminology suggests a sharper division than what the evidence seems to indicate, consideration could be given to adopt a terminology such as mammary intraepithelial neoplasia (MIN) of either ductal or lobular types, followed by a grading system.

An abstract of Rosai J. Borderline epithelial lesions of the breast. *Am J Surg Pathol.* 1991 15(3):209-21. Available (26/06/08): www.pubmed.gov

Appendix 7

Summary of Review of Non-Gynaecological Cytology: Dr C



The Faculty of Pathology of the Royal College of Physicians of Ireland in association with the Health Information and Quality Authority

The index case cytology material was reviewed by two reviewers (Dr Michael Jeffers and Dr Mairead Griffin) as described in Appendix 5 above.

Cases of diagnostic non-gynaecological cytology material were reviewed by four reviewers.

An initial review of 211 cases (119 breast, 92 non-breast) was carried out by two reviewers (Dr Jeffers and Dr Griffin). A subsequent review of an additional 536 cases was carried out by the original two reviewers and an additional two reviewers (Dr Loftus and Dr Nicholson).

On review of the non-gynaecological cytology material, discrepancies exist between the original diagnosis and review diagnosis. These discrepancies are important in two contexts: (1) diagnostic performance and (2) patient management. Issues relating to diagnostic performance are reflected in the type and number of discrepancies and an overview of the entire cohort is useful in terms of comment on performance. Issues relating to patient management are case specific and are dependent on whether or not additional diagnostics were performed at the time of the index cytology sample. This requires correlation with other histopathology and/or cytology specimens and additional information from the treating clinician.

Results

1a. Diagnostic Breast Cytopathology Review

Total number of breast cytopathology specimens reviewed: 118 (excluding the index case)

Figure A7.1: Results of review

Category	Dr C	Review
C1 non-diagnostic	29 (24%)	41 (35%)
C2 benign	84 (71%)	67 (57%)
C3 atypical	2 (2%)	6 (5%)
C4 suspicious	3 (3%)	0
C5 malignant	0	4 (3%)

Notes on Figure A7.1

- *benign C2 includes cysts*
- *one case reported initially as “inflammatory cells”, contains lymphoid material, reported on review as C3. Follow-up not required*
- *two cases reported as atypical on initial report, C3 on review, follow up not required*

Number of significant discrepancies between original and review reports: 6 (*significant discrepancy = C1-2 versus C3-5*).

Figure A7.2: Details of discrepant cases

Case number	Review Diagnosis	Primary Diagnosis	Final Diagnosis
HIQA 1	C5	Benign	Ductal carcinoma
HIQA 2	C3	Epithelial cells	Benign
HIQA 6	C3	non-diagnostic	Benign
HIQA 7	C3	cyst	Benign
HIQA 1	C3	Benign C2	Benign (triple assessment)
Index case	C5	Benign	Ductal carcinoma

Diagnostic performance criteria were calculated for Dr C using the statistical matrix recommended by the NHSBSP. These are presented here, together with the recommended minimum values in parentheses:

Absolute sensitivity	0%	(60%)
Complete sensitivity	60%	(80%)
PPV (C4)	100%	(>98%)
False negative rate	40%	(<6%)
False positive rate	0%	(<1%)
Inadequate rate	24%	(<25%)

1b Diagnostic Non-Breast Cytopathology Review

There were 628 cases for review. The table below breaks down specimen types.

**Figure A7.3: Non-Breast Cytopathology Review:
Breakdown of specimen types**

	n=	Review diagnosis	Original Diagnosis	Original Diagnosis	Discordant
		Malignant/ Suspicious/ Atypia	Concurrent	Negative	Rate
Respiratory	87	2	2	0	
Serous Fluid	116	15	9	6	5% (40%)
Thyroid	33	2	0	2	6% (100%)
Urine	215	22	9	13	6% (59%)
CSF	58	0	0	0	
Ovary	39	0	0	0	
Lymph node FNA	22	9	4	5	22%** (33%)
Salivary FNA	9	0	0	0	
FNA other	9	3	1	2	22% (66%)
Miscellaneous	40	1	1	0	

Overall Diagnostic Cytopathology Review

Figure A7.4: Summary of Breast and Non-Breast Cytopathology Review

	n=	Review diagnosis Malignant/Suspicious/Atypia	Original Diagnosis Concurrent	Original Diagnosis Negative	Discordant Rate
Total Non-Breast	628				
Breast FNA	118	10	5	5	4% (50%)
Breast FNA Including Index case	119	11	5	6	5% (55%)
Total	747	65	31	34	4.5% (52%)

Cytology Findings: Neoplasm or Suspicious of Neoplasm (C4/C5)

65 cases were identified on review as atypical /suspicious for malignancy/ malignant or positive for benign neoplasm. Primary diagnosis by Dr C in these 65 cases was: malignant (18), suspicious (14), negative (28) and non-diagnostic (5). The false negative rate of primary diagnosis in these 65 cases is 43%.

In addition, 5 cases of false positive reporting (primary diagnosis suspicious for malignancy, review diagnosis negative) were identified and 2 additional cases were identified as false negative reporting of significant inflammatory lesions.

The overall error rate, expressed in terms of the whole cohort of diagnostic cytology is 6.5%. (This assumes that an "error" is a discrepancy in diagnosis which has the potential to adversely impact on patient management or outcome. There is significant variation in the published error rate in diagnostic pathology. Significant error rate has been reported as in the region of 0.2-1.7%⁸⁾

Clinical Impact/Individual Patient Follow-up

49 cases were identified in which follow-up was considered warranted on the basis of the discrepancy between the primary diagnosis and review diagnosis. Each case was subject to clinical review and further investigations if appropriate. Clinical reviewers were also asked to assess the potential impact on case management arising from the original report.

The outcome of this review exercise in terms of clinicopathological correlation with the review diagnosis and the potential impact on case management is outlined below:

- *In 20 cases there was an established diagnosis of malignancy, no further investigations were required, and there was no adverse impact*
- *In 12 cases, there was no evidence of malignancy on case review, no further investigations were required, and there was no adverse impact*
- *In 11 cases, patient follow-up was advised, the outcome was negative, no further action was required, and there was no adverse impact*
- *In 4 cases, further intervention was required, and malignancy was confirmed. In these cases there was delayed diagnosis with potential adverse impact*
- *In 1 case surgical intervention for thyroid disease was warranted. Final histology on thyroidectomy was benign*
- *In 1 case further intervention is required on the basis of review diagnosis (awaiting review and further tests)*
- *Index case: 1 case*

In summary, the clinical impact of the diagnostic variance is:

- *Index case: delayed diagnosis of breast cancer*
- *1 case: delayed diagnosis of thyroid cancer(*)*
- *1 case: delayed diagnosis of carcinoma in-situ of bladder*
- *1 case: delayed diagnosis of carcinoma of bladder(*)*
- *1 case: delayed diagnosis of salivary tumour (benign)*
- *1 case: delayed management of thyroid disease (benign)*
- *7 cases: delayed instigation of further urology investigations (*)*
- *37 cases: no impact on patient management / outcome (despite diagnostic variance)*

** Notes: thyroid cancer case was a papillary carcinoma, stage pT1, unlikely to be prognostically significant; urology investigations in cases of atypical urine cytology are often negative reflecting inherent low sensitivity and specificity of this test. Bladder cancer cases: one case atypical/suspicious cytology on repeat sample, one case low grade urothelial carcinoma stage pTa in a patient with previous diagnosis of grade 3 TCC bladder.*

Comments on Cytopathology Diagnoses:

- *All discrepant cases have been reviewed by two consultant cytopathologists and the final diagnosis is a consensus diagnosis*
- *Discrepant cases include false negative diagnosis (failure to identify malignancy) and false positive diagnosis (interpretation of benign changes as malignant or suspicious for malignancy)*
- *Many urine cytology samples are categorised as atypical: this reflects the inherent limitations of cytology in differentiation between the effects of instrumentation, lithiasis and low grade urothelial neoplasia. The lack of clinical information regarding specimen type (i.e. instrumentation specimen or voided urine) is a limiting factor in diagnosis in this context*
- *Breast FNA category designation differs significantly between review and primary diagnosis across the "C" category spectrum*
- *Some cases reported as acellular contain diagnostic material*
- *Some cases are reported as "acellular, not representative" in circumstances where an acellular specimen is acceptable as negative (eg cerebrospinal fluid samples)*
- *Occasional reports specify a specific low number of representative cells (eg "one cell cluster") when the slides contain significantly more material*
- *Use of terminology is inconsistent: the "C" diagnostic category for breast cytology is applied to non-breast samples. The "C" categories are also used in an incorrect way (eg "negative C1"; "atypical C2 mesothelial cells")*
- *Inappropriate cell types are referred to in reports (eg "mesothelial cells" in bronchial samples; "epithelial atrophy" in serous fluids)*
- *Stain selection is based on historical practice, but would not be ideal in certain circumstances (eg thyroid FNA, lymph node FNA, serous fluids) where the use of Giemsa would be considered appropriate¹*

Comments of Cytopathology issues in clinical context

- *Sample quality is suboptimal in many cases, particularly FNA material: slides are thick, stain penetration is variable and interpretation is compromised. The preparation of material from FNA is operator dependent and is beyond the control of the laboratory in situations where FNA is performed by clinical staff. Appropriate guidance notes may be of assistance to improve the quality of FNA material. The NCCLS guidelines may be useful in this regard⁴*

- *Use of ancillary studies is limited. This is largely beyond the control of the laboratory where limited material is supplied by clinical staff submitting samples (guidance notes and training may be useful in this context (see above)). Where material is available for further study (e.g. serous fluids) the use of ancillary techniques is recommended to facilitate diagnosis^{2,3}*
- *The role of cytology and its weighting in the patient investigation process is not clear, particularly in the context of breast disease*
- *Low incidence of malignancy in respiratory exfoliative cytology material (2.3%). This raises the question of what role cytology plays in the diagnostic pathway for suspected lung malignancy and what selection criteria are in place for cytology at bronchoscopy*
- *Clinical information is suboptimal, criteria for microscopic examination of cyst fluid are unclear and criteria for patient selection for FNA are not apparent: appropriate algorithms for the use of FNA are advisable. Appropriate diagnostic categories should be used where systems exist for disease classification to assist patient management⁷*
- *The adequacy rate of breast FNA is suboptimal (35% C1 rate based on review diagnosis, 25% on original diagnosis). This is operator dependent and may be due to sampling technique, specimen preparation or to patient selection*

Diagnostic breast FNA service should be subject to audit^{5,6} of both sampling and diagnosis and appropriate practice developments introduced on the basis of audit data.

Final Faculty comment re Dr C's performance

The error rate in diagnostic cytology was 6.5% which is 5 – 6 times greater than the accepted range (Arch Path Lab Med May 2006, 602-649). In non-gynaecologic cytopathology, diagnostic performance criteria demonstrated significant false negative reporting in both breast cytology (false negative rate 40%) and diagnostic cytology (false negative rate 43%). This is more than six times the acceptable error rate of 6%.⁵

Recommendations:

1. *The role of FNA cytology in the investigation of breast disease should be clarified.*
 - a. *Patient selection criteria for breast FNA should be clearly defined*
 - b. *Action protocols for abnormal breast FNA results should be defined within the triple assessment system*
 - c. *Breast FNA cytology should be reported using the "C" classification system.*

2. *Breast FNA cytology should be subject to audit and should achieve satisfactory performance as described in the NHSBSP guidelines.*
 - a. *Sample adequacy is dependent on patient selection and on operator skills and experience. Guidance notes on specimen acquisition and preparation should be considered if samples are to be taken by clinical staff.*
 - b. *Source-specific adequacy rates should be available if FNA samples are submitted from multiple off-site locations.*
 - c. *If audit demonstrates that minimum standards are not achieved, appropriate actions should be taken to improve service quality. These actions should be agreed by the relevant specialists in the multidisciplinary team.*
3. *Targeted review of cytology sample preparation protocols should be undertaken including the selection of stains used according to specimen type. Internal quality assurance protocols should be in place to ensure acceptable sample quality.*
4. *The use of, and availability of, ancillary techniques in diagnostic non-gynaecological cytology should be reviewed and the use of ancillary techniques expanded as appropriate.*
 - a. *Ancillary techniques, particularly immunohistochemistry, are invaluable in the diagnosis of malignancy in certain cytology specimen types (eg serous fluids) and the regular use of these techniques should be encouraged. The use of cell blocks allows technical protocols in place for histopathology specimens to be applied to cytology material.*
 - b. *Use of ancillary techniques requires access to adequate amounts of material of adequate quality. This is particularly important in material obtained by Fine Needle Aspiration and appropriate protocols for specimen acquisition and preparation may be required to ensure specimen adequacy and quality.*
5. *Sufficient throughput of FNA cytology should be achieved in order to maintain diagnostic competence.*
6. *Development and maintenance of protocols and quality assurance mechanisms is facilitated by clear governance. Consideration should be given to nomination of a lead consultant pathologist with responsibility for diagnostic non-gynaecological cytology*
7. *The role of non-consultant hospital doctors / doctors in training in the non-gynaecological cytology service should be clarified, particularly in relation to generation of reports.*

Dr Michael Jeffers and Dr Mairead Griffin

on behalf of the Faculty of Pathology

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Appendix 8: Summary of Review of Gynaecological Cytology: Dr C



The Faculty of Pathology of the Royal College of Physicians of Ireland in association with the Health Information and Quality Authority

A review was conducted of the gynaecological cytology for which Dr C was responsible during the entire period of employment in University Hospital Galway.

The review included:

- A) review of laboratory documentation and standard operating procedures
- B) review of laboratory quality assurance data
- C) selected slide review
- D) external validation of the review process

Methodology

A Standard operating procedures operative in the cytology laboratory at UHG were reviewed for:

- i) primary screening cervical smears*
- ii) checking by senior medical scientific staff*
- iii) reporting by consultant pathologist*
- iv) management guidelines*
- v) authorisation of reports by consultant pathologists.*

B Quality Assurance data for gynaecologic cytology were reviewed and these included:

- i) laboratory reporting profiles*

ii) sensitivity of primary screening for the laboratory and for individual screeners

iii) positive predictive value for CIN 2+ for the laboratory and for Dr C

iv) participation in External Quality Assurance

v) multidisciplinary CIN meetings with colposcopy

vi) in-house fortnightly review meetings

C Selected slide review of 123 cases reported by Dr C.

D External validation of the audit methodology and comment on findings.

Findings

A Standard operating procedures in place in the laboratory at UHG for cervical screening are satisfactory. The management protocol takes account of past history from the Irish Cervical Screening Programme database as well as cytology and histology history held in the laboratory. For some cases there is a rule base for automated generation of management guidelines. This can be overruled if necessary i.e. additional history and manual management recommendation generated as appropriate. All reports with management advice are finally checked and authorised by the consultant pathologist.

B Quality Assurance data indicate that overall laboratory performance is satisfactory. Reporting profiles for 2006 and 2007 are similar with the exception of unsatisfactory rates. The laboratory converted to liquid based cytology in this time period and this explains the 4% drop in unsatisfactory rates. The laboratory has a high detection rate of high grade abnormalities; 3.2 % in 2006 and 2.75% in 2007.

Laboratory sensitivity of primary screening for detection of all abnormalities is 96% and for detection of high grade lesions is 98% for the investigation period September 2006 to March 2007.

Individual screener sensitivities for 2007 are within the ABC guidelines of 95% for high grade lesions ¹.

Individual screener sensitivities for 2006 showed 3 screeners with sensitivities of 92.94%, 94.7% and 94.54% for high grade abnormalities. However, this was during the conversion phase to liquid based cytology. One of these screeners had a high grade sensitivity of 94.7% and acted as a checker. The 2 high grade cases for this checker, picked up on rapid review were difficult and open to interpretation.

- *Positive predictive value for CIN 2+ for the laboratory was 81.6%*
- *Positive predictive value for CIN 2+ for Dr C was 83.3%*
- *The laboratory holds a record of participation in External Quality Assurance*

C The algorithm for slide review of Dr C work is as follows:

- *Dr C was responsible for the reports issued on 13,381 cervical smears*
- *9,877 cervical smears were either negative or unsatisfactory, and were therefore not reviewed by Dr C*
- *3,504 cervical smears were reviewed by Dr C and in 3,381 cases there was agreement between the opinion of the senior medical scientist who checked the case and Dr C. This represents 96.4% agreement*
- *This left 123 cases where there was a difference of opinion between the senior medical scientist who checked the case and Dr C*

As the quality assurance data for laboratory performance were satisfactory and the senior medical scientists who act as “checkers” have satisfactory primary screening sensitivity, it was decided that expert review was required only in the cases where there was a significant difference of opinion between the “checkers” and Dr C.

A significant difference of opinion was defined as:

- *Negative versus abnormal*
- *Low grade versus high grade*
- *High grade versus low grade*

123 cases were reviewed by consultant histopathologists with expertise in gynaecologic cytology. The review showed agreement with Dr C in 78 cases and a difference in opinion in 45 cases. Of these 45 cases:

- *20 were reported as low grade by Dr C but were high grade on review. It is also worth noting that 18 of these 20 were also called high grade by the “checkers” indicating good performance by the ‘checkers’. All these women require colposcopy, and at the time of the investigation 7 have already been seen at colposcopy*
- *13 were reported as low grade by Dr C but were negative on review. These women have been advised to have annual cytology until they have 3 consecutive negative smears*
- *8 were reported as high grade by Dr C but were low grade on review. These women have been advised to attend colposcopy*
- *1 was reported as negative by Dr C but was low grade on review. This woman has also been invited to attend colposcopy*
- *3 were reported as low grade by Dr C but were inadequate on review. 2 of the 3 have had follow up negative smears. The remaining woman is advised to have a repeat smear*

- D** External validation of the review process was carried out by Dr Karin Denton, Director of Cervical Screening Quality Assurance, South West England Region.

Conclusions

- (1) *The basic assumption that expert review was only required in cases where Dr C disagreed with checkers is sound, provided that the checkers do not have any evidence of poor performance in primary screening.*
- (2) *Cervical cytology is not an exact science - it is impossible to eliminate inter-observer variation. The performance of the laboratory as a whole falls within acceptable limits. The proportion of cases in which Dr C disagreed with the checkers is not excessive.*
- (3) *Any review of cytology will produce cases where the diagnosis changes. Women should then be managed according to the worst possible outcome.*

Additional Comments

Clarification was sought around operating procedures in the laboratory as raised by the external reviewer and the Investigation Team are satisfied that there is no concern around these.

In particular the consultant pathologist reviews the report including management recommendations and authorises the report. There are 4 senior medical scientists involved in checking and the chief medical scientist also participates in this activity.

A quality manager has been recently appointed and quality data is generated and reviewed quarterly.

There is open access for the medical scientists to the consultant pathologist rostered on cytology to discuss cases.

Summary

Laboratory procedures, quality assurance data and ongoing monitoring of quality parameters in the laboratory ensured that the standards for the gynaecologic cytology were high.

Overall there was good agreement between the senior medical scientists and Dr C. A small number of women have been advised to attend colposcopy, or to have follow up cytology.

Dr Mairead Griffin

on behalf of the Faculty of Pathology.

Reference

1. *Achievable standards, Benchmarks for reporting and Criteria for evaluating cervical Cytopathology – Second edition NHSCSP Publication No.1 May 2000).*

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