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.