

Review of Histopathology Services provided by North East Wales NHS Trust

Healthcare Inspectorate Wales

Bevan House
Caerphilly Business Park
Van Road
CAERPHILLY
CF83 3ED
Tel: 029 2092 8850
Fax: 029 2092 8877

www.hiw.org.uk

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Chapter 1: Introduction and Background to the Review

1.1 In autumn 2007 North East Wales NHS Trust (the Trust) became aware that a small number of histopathology results had been incorrectly reported upon as being negative. These had been reported by one Consultant Histopathologist. Having satisfied itself that errors had indeed occurred, the subsequent management of the issue by the Trust was open and transparent, including contacting the patients concerned, retesting samples reported by the relevant Consultant Histopathologist between October 2004 and September 2007, reporting up to the Welsh Assembly Government and conducting briefings for the media. The Trust also had discussions with Healthcare Inspectorate Wales about its wish for an independent review, the terms of reference for which were agreed as:

1. To conduct an independent external review of histopathology services provided by the Trust which would include:
 - Investigation of the circumstances in which erroneous reporting of results from tissue samples occurred between October 2004 and September 2007.
 - Examination of current policy, procedures, systems and practice in place in the Trust to deliver histopathology services.
 - Consideration of any other matters relevant to the purposes of the Review.
2. To report upon the findings and make recommendations to ensure any necessary improvement in services or encourage development of best practice.

1.2 A Review Team was established. It considered documents obtained from the Trust. The major part of the fieldwork for the Review was conducted between 2 and 5 June 2008, although some interviews were conducted later in the year. The detailed arrangements for the review are set out in Annex B.

1.3 This report sets out the findings of the Review and the recommendations made.

1.4 The particular Consultant Histopathologist concerned in the misreporting of histopathology results had retired prior to our review. Although we invited him to contribute to the Review he declined to do so. As a result we have been unable to consider any direct evidence from that consultant in respect of factors relating to his working environment or practice which might have had a bearing upon our findings.

1.5 However, through discussions with other staff, observations and examination of documents, policies and procedures, we have been able to form a picture of the broader circumstances within the Histopathology Department at the time of the investigation. This enabled us to reach conclusions about the Trust's arrangements with the aim of ensuring that errors arising from an individual's work are minimised in the future.

1.6 In Chapter 2 of this Report we describe the Trust. In Chapter 3 we firstly give a broad description of histopathology and the general arrangements we would expect to find in relation to practitioners' competence, organisational performance and quality assurance. Secondly we address the particular circumstances relating to the reporting errors the Trust has identified. In the course of doing so, we set out our findings in relation to the general arrangements for the delivery of histopathology services at the Trust as we found them in June 2008. Given the extent of our terms of reference, it should be noted that some of our findings relate to current arrangements for histopathology where we believe improvements could be made, even though we do not believe these have any bearing upon the errors in reporting which prompted this review. Chapter 4 sets out the recommendations we have made to the Trust.

Chapter 2: The Trust

North East Wales NHS Trust: 1999 - July 2008

2.1 The former North East Wales NHS Trust was established in 1999 as part of a reconfiguration of NHS Trusts in Wales. The Trust provided a comprehensive range of acute, community, and mental health services to a population of approximately 300,000 people. Its catchment area extended beyond Wrexham and Flintshire to include South Denbighshire, North Powys, the Mawddach Valley (South Gwynedd) and South Cheshire. Patients were also drawn from neighbouring areas in North West England, the English Midlands and West and Central Wales.

2.2 The Trust's Headquarters were at Wrexham Maelor Hospital, which continues to provide a comprehensive range of medical and surgical specialities, as well as paediatric, maternity, critical care and rehabilitation services. The Trust ran community hospitals in Chirk, Deeside, Flint, Holywell and Mold. These all provided inpatient care, outpatient clinics and therapy services and there were minor injuries units at all hospitals apart from Deeside. The Trust Board, led by a Chairperson, comprised Executive and Non Executive Directors. The Executive Directors were responsible for the operational management and development of the Trust. The Non Executive Directors were members of the general public who were appointed to the Board because they brought specific qualities and experience relevant to the NHS. The Trust's clinical services were managed through a structure of five Clinical Directorates, each led by senior members of clinical staff and a Directorate General Manager.

2.3 The Histopathology Department was part of the Pathology Division of the Diagnostics and Clinical Support Directorate of the Trust. It was located at Maelor Hospital. At the time of the Review the department consisted of three Consultant Histopathologists (soon to become four), a laboratory manager (Head Bio-Medical Scientist (BMS) Histopathology) and seven BMSs. There

were three laboratory assistants. Administrative staff supporting this team consisted of two fulltime clerical staff and one working 20 hours a week. In addition three technical staff were employed within the mortuary.

2.4 Consultant Histopathologists are medically trained staff, registered with the General Medical Council, who have undertaken specialist training. BMSs are registered within the Health Professions Council and have undertaken specialist training, or are currently undertaking academic study and training to obtain the necessary qualification. BMS staff are responsible for the preparation of the samples which the consultant histopathologists interpret and report upon. These staff are supported by Medical Laboratory Assistants and administrative staff.

The Delivery of Trust Services in North Wales since July 2008

2.5 On 1 July 2008 the North East Wales Trust merged with the Conwy and Denbighshire NHS Trust to form the North Wales NHS Trust.

2.6 The Minister for Health and Social Services has recently announced further changes to the organisation of health services in Wales. As a result the present North Wales NHS Trust will merge with North West Wales NHS Trust and the 6 Local Health Boards (LHBs) covering the same geographical area as the Trusts to become Betsi Cadwalader University Health Board.

2.7 This report addresses matters as they existed in the then North East Wales NHS Trust in the summer 2008. The recommendations are made to the North Wales NHS Trust and, in as much as a number of those recommendations will require work through 2009/10, to the proposed Betsi Cadwalader University Health Board.

Chapter 3: Evidence and Findings of the Review

Histopathology Services and Performance and Quality Assurance Arrangements

3.1 Histopathology is the branch of pathology concerned with the examination and understanding of tissues. Typically histopathologists conduct microscopic examination of tissue samples taken from patients to determine whether tissue cells show any signs of abnormality associated with illness, for example the presence of cancerous cells in biopsy of skin tissue. Histopathologists also investigate causes of death by conducting post mortem examinations.

3.2 This work requires high levels of training and skill. Unlike some other areas of pathology, where for example a test might produce a clear result with a numerical value, histopathological conclusions depend to a greater degree upon the judgement of the practitioner interpreting what is seen in the light of his or her experience.

3.3 In any area where professional judgement and skill are necessary, there is always a risk of error. Organisations delivering services in such environments need to develop structures, systems and procedures to minimise the likelihood of errors occurring, in addition to ensuring that they have a group of well trained and highly skilled staff.

3.4 In Histopathology the risk of errors occurring is normally managed through the regulation of individual competence to practice and quality assurance of services delivered. Those are addressed in a number of ways.

3.5 In relation to an individual's competence to practice:

- Consultant Histopathologists, in addition to their general medical training, will have received specialist training. They will be registered with the General Medical Council. Typically they will have developed their experience over a number of years working in less senior roles and will be members of the Royal College of Pathologists (RCPATH). In addition, Trusts would generally assure themselves of Consultants' individual performance by requiring that they participate in the RCPATH's Continuing Professional Development Scheme, as well as engaging in the Trust's own job planning and appraisal processes.
- Staff working as BMS will have received the appropriate academic qualification and received specialist training relevant to their grade. They will be registered with the Health Professions Council and will be required to comply with the Trust's appraisal process.

3.6 As far as the quality assurance of services delivered:

- The Welsh Assembly Government requires diagnostic services to enrol in accreditation schemes¹. The relevant accreditation scheme for pathology laboratories (including histopathology laboratories) is Clinical Pathology Accreditation (CPA). Details of CPA are set out in Annex C.
- Laboratories participate in External Quality Assurance schemes (EQA)²; through which they exchange tissue samples with other laboratories in order to assure the quality of each others' results.

¹ The Welsh Assembly Government's expectations are set out in 'Welsh Health Circular (2004) 061', The Circular was informed by 'Getting results: a diagnostic strategy for Wales' 2004, and has subsequently been reiterated in "The Future Delivery of Pathology Services in Wales" 2008 and the 'National Pathology Framework' 2008.

² EQA schemes are accredited by CPA (EQA). The EQA scheme in which the Trust participates is operated by the National External Quality Assurance Scheme (NEQAS).

- Laboratories may also have their own internal arrangements for 'double reporting', or 'referral for a second opinion' through which a local consultant will provide a second report upon a tissue sample. Such arrangements for histopathology are local and there is variation between laboratories and clinical conditions. For example, in some cases all 'positive' results (those in which disease or malignancy is identified) are subject to double reporting, whilst other guidance advises that all 'negative' biopsies should be double reported'.
- Histopathology Departments should normally have an annual programme of clinical audits or participate in a wider programme of Pathology clinical audit.
- Trusts should have in place arrangements to detect, review and learn from untoward incidents occurring in clinical practice across all disciplines.
- Analysis of job plans and appraisals should provide information about areas where additional training, mentoring etc might be necessary.
- Multi-Disciplinary Team (MDT)³ meetings should bring together clinicians who jointly provide care and treatment for individual patients to ensure that information is shared and appropriate medical or surgical interventions are planned. These MDT meetings enable histopathology results to be considered alongside the results of other tests and examinations to draw a fuller picture of the patient's condition and, to that extent, provide a system of 'checks and balances' to challenge histopathology or other results. The meetings should provide a forum in which reporting errors might be identified.

³ In this report we use the term multi-disciplinary team in two ways. Here and whenever the abbreviation MDT is used in the report we are referring specifically to a meeting of clinicians from across disciplines to plan the care and treatment of individual patients. Where in the report we write in full, in lower case, multidisciplinary team we are referring to the team of staff in the Histopathology Department which consists of Consultant Histopathologists, junior doctors, BMS, MLA and secretarial staff.

Histopathology Services at North Wales NHS Trust

Errors in Reporting of Testing of Tissue Samples

3.7 As stated earlier the reporting errors identified by the Trust had been made by one Consultant Histopathologist.

3.8 The initial discovery of three errors in reporting was made when a consultant other than the Histopathologist who had originally reported the cases reviewed slides in preparation for MDT meetings. The Trust instigated an investigation. Advice was sought from the RCPATH about the extent of the investigation and the level of further checking that should be undertaken. The Trust notified the public through the media which gave extensive coverage to the concerns which had arisen within the Trust. A helpline was established to respond to patients who wished to contact the Trust about their own histopathology results. As individual errors were identified, patients were informed and appropriate support and re-examination or medical/surgical interventions provided. Throughout the process of investigation the Trust maintained contact with the Welsh Assembly Government to provide information and seek advice.

3.9 The details available from the Trust show identified reporting errors of varying degrees of seriousness in relation to 21% of the benign reports produced by the Consultant concerned. RCPATH sets out three categories of errors which might occur:

Category 1: A diagnostic error, which is likely to have a definite influence on clinical management and possible outcome.

Category 2: A misinterpretation or oversight, which has the potential to affect clinical management or outcome.

Category 3: A minor discrepancy of disease categorisation, which is likely to be of little clinical significance.

3.10 In all, the Trust arranged for the re-examination of 11,671 tissue samples upon which the particular Consultant Histopathologist had reported between October 2004 and September 2007 (All reported negative - that is benign - cases between April 2004 and September 2007). The re-examination of those cases reported as negative suggested that in 181 (1.6%) cases there had been a category 1 error, in 479 (4.1%) cases a category 2 error had occurred and in 1799 (15.4%) there had been a category 3 error. Thus the number of cases in which an error which may have had an effect upon clinical management or outcome was 660 (5.7%).

3.11 We could identify no available guidance from the RCPATH or any other source about what error rate might be expected in general histopathology in respect of the type of reporting for which the consultant was responsible. There have been academic papers published in British and American Journals examining definitions, levels of error occurring and causes of errors in pathology, but we could not find a common view or professional guidance concerning the extent to which reporting errors might be expected.

Workload and Staffing Arrangements at the Trust

3.12 We understand from medical and scientific staff who were working in the Histopathology Department at the time that the errors occurred that the size of the workload could produce difficulties. The consultant responsible for the erroneous reporting had been the Trust's Medical Director from April 1999 until April 2003, while continuing to undertake work within the Histopathology Department. During that period we were told his workload had been high. As one of only two Consultant Histopathologists in the Department he took responsibility for 50% of the consultant workload. He was the person to whom most people in the Department would turn to help address problems, both professionally and personally. Clinicians seeking an urgent report would generally request his help because he was known for his willingness to assist and for achieving quick turn around times for results.

3.13 The Trust, having had difficulties in recruiting to Consultant Histopathologist posts, was content to see the Consultant return to work on a locum basis in the Histopathology Department following his retirement from the Trust in 2004 on completion of his time as Medical Director. He remained one of two Consultant Histopathologists working in the department until in November 2006 a third Consultant took up post. A fourth post was filled in 2007.

3.14 It is clear from the documents we reviewed that the matter of workload pressure was the subject of considerable discussion within the Trust during 2005 in particular. It had been agreed that additional Consultant Histopathologist time was necessary to manage the workload the Department was experiencing and an additional two posts were agreed by the Trust. Difficulties in recruiting to the new posts, despite the Trust offering what it believed to be generous terms of employment, reflected the general shortage of suitable applicants for Consultant Histopathology posts across the United Kingdom at that time.

3.15 Pending successful recruitment to the new Consultant posts, the Trust put in place arrangements to manage the increasing histopathology workload by offering additional sessions to its own staff and out-sourcing work to a nearby Trust and to private laboratories.

3.16 In addition to the workload pressures that the Histopathology Department was confronting, we consider the following circumstances to be relevant:

- The Trust had not taken steps to assure itself that histopathology examinations and reporting were conducted by Consultants with appropriate registration and competence.
- 'Double reporting' extended only to initially identified malignancies and, prior to appointment of a new Consultant Histopathologist in 2007, formal arrangements for double reporting do not appear to have been robust.

- There was a lack of clinical audit.
- Team working among Consultants was not strong.
- While Consultant Histopathologists were committed to MDTs and attendance was good, the practice of reviewing slides for MDT meetings had ceased to be standard practice.
- Different report formats were used by the Consultants in the Department.
- Leadership within the Department was weak and management processes poorly implemented.

3.17 We comment further upon a number of these factors below to the extent that they continue to be features of the Histopathology Department.

3.18 In the absence of evidence from the particular Consultant concerned in the erroneous reporting of results, we can draw no definitive conclusions as to the reasons for the errors occurring. However we have identified above some of the circumstances which may have contributed to the errors being made and we draw attention to the organisational weaknesses which contributed to the errors not being picked up and reviewed at the time they were made.

3.19 At the time of our Review all medical and BMS staff working within the Histopathology Department at the Trust were properly qualified to undertake their work. That had also been so in relation to the particular Consultant involved in the erroneous reporting. Many staff had considerable experience established through many years working within the Department. They were registered with the appropriate regulating bodies. However, in the light of experience the Trust should assure itself that it has sufficiently robust systems for checking that medical staff are both registered for, and are maintaining their competence in undertaking the specific tasks they perform.

3.20 One of the Consultant Histopathologists undertook the role of Head of Department and in that respect was responsible to the Clinical Director for Pathology. The laboratory manager was responsible for the day to day

management of the laboratory and the supervision of the BMS and Medical Laboratory Assistant (MLA) staff. He reported to the General Manager of the Pathology Division and, in respect of clinical matters, was responsible to each of the Consultant Histopathologists for the work which they reported upon and more broadly to the Head of Department.

3.21 All the clerical staff working within the Department were of equal status. They reported to the Consultant Histopathologists for some dedicated work, but also for work which was 'pooled'. However, in respect of line management and human resource matters, they were responsible to the personal assistant to the General Manager for pathology.

3.22 It is clear to us that since 2004 there have been concerns about staffing levels in the Histopathology Department. For much of that time the issues have related to the provision of Consultant time. Having had an establishment of three Consultant Histopathologists in 2003 (albeit one of them was also carrying out the role of Medical Director for the Trust) the resignation of one consultant resulted in a period of three years during which there were only two Consultant Histopathologists carrying an increasing workload.

3.23 By mid-2008 workloads had been resolved by the appointment to two additional posts, bringing the number of consultants up to four.

3.24 Concerns among staff during the course of our Review focused upon BMS and Secretarial roles. A human resource audit might usefully be undertaken by the Trust and set alongside workload data to determine whether it would be appropriate to set new levels of staffing in BMS roles. However, we found some scope for re-organisation of current resources and a reassessment of the value of continuing with some processes to which the laboratory is committed at present. We noted that, in comparison with some other hospitals, the current workload in relation to BMS staff in the Histopathology Department would appear lower, while taking longer to complete. Any re-examination of human resources which may be undertaken should include the work of MLAs and secretarial staff.

3.25 BMS, MLA and secretarial staff reported that relationships within the Department were good. More junior staff felt well supported and commented positively upon the quality of supervision and support received to obtain qualifications.

3.26 Overall we found that:

- During the period in which the errors had been reported there had been a long standing shortage of Consultant Histopathologist Resources, but this has now largely been resolved by appointments in 2007/08.
- There has been an increase in workload since 2004 and given the perceptions of staff a review of the current BMS/MLA/Secretarial resources might be helpful, but that should not overlook the potential, within existing resources, for more efficient structures, systems and procedures.
- The Trust needs to assure itself that it has robust systems in place for checking that medical, and other professional staff, are registered for specific tasks they perform and regularly update their knowledge and skills to maintain their competence.

Accreditation of the Histopathology Department

3.27 The Department was enrolled with Clinical Pathology Accreditation (CPA): see Annex C. It had been conditionally approved by CPA until the CPA standards were changed in 2001/02. At the time of our visit to the Trust in June 2008, the Department had been reviewed by CPA in the previous week and was awaiting the results of that visit. Subsequently the Department was conditionally approved in July 2008.

Leadership and Management Arrangements

3.28 It is clear to us that, for a long time, there had been little collegiate working among the Consultant Histopathologists in the Trust. While, colleagues might from time to time have sought a second opinion from each other, there was no systematic formality to the process and relationships between the Consultants did not provide a strong, informal network within which they could share, consult and challenge each other.

3.29 We found little evidence of management processes being in place. Job plans, appraisal and agreed collaborative working arrangements were scant or absent throughout the management line. From our discussions with senior staff it is clear that issues arising within the consultant grades were most likely to be addressed informally in the 'Consultants dining room' rather than through formal management processes. While individual Consultant Histopathologists took responsibility for their own work and respected each other's expertise, evidence of their taking corporate responsibility for improving practice or the development of the department was limited. This is not to suggest that individual Consultants had not attempted to introduce changes and improvements to the management arrangements. However, where changes had happened, they had generally been short lived or proved a frustrating experience.

3.30 The formal structures which were in place within the Histopathology Department were weak. For example the role of Head of Department had tended to exist in name only, rather than providing an effective and supportive focus for medical leadership, good management and professional development. Management reporting lacked the rigour normally expected. The Trust did have systems in place to support good management. For example there were arrangements for job planning and for appraisal in the medical line. However, with regard to the Histopathology Department, there was a gap between the policies which were in place and their implementation.

3.31 While the laboratory manager was more clearly taking a management role in respect of the BMS grades, we consider that that role was not fully developed. It had grown from the senior practitioner role within the BMS team but, with competing demands upon it and the individual focus of the Consultant roles, it had not become a leadership or transformational role within the department. Budgetary responsibilities lay elsewhere. The laboratory manager in post at the time of our review had been supported to obtain Advanced Practitioner status but that qualification was not being fully exploited.

3.32 This report comments above on the lack of team work among the Consultant Histopathologists. It is unsurprising, therefore, that we found little evidence of genuine multidisciplinary team working in the Department. In the main it seemed to operate on the basis of practices long established, the individual relationships between Consultants and BMS grades and an acceptance that the difficulties the Department encountered would be dealt with as they arose rather than through leadership, staff engagement and forward planning.

Organisation and Systems

3.33 The organisation of the laboratories had developed organically rather than as a result of detailed consideration and design, which was one reason for the less than optimal environmental conditions. There was little evidence of the ability of managers to draw the whole team together to plan service delivery. There was no structure of meetings to ensure effective communication, to offer a forum to discuss developments or to provide opportunities for effective management of the department.

3.34 Arrangements for audit and other clinical governance activity were weak. Some staff told us that audits were undertaken but we were not provided with clear evidence of a systematic programme of audit which provided a basis for improved practice.

3.35 The Department took part in EQA systems to provide assurance of the accuracy of its reporting. Whilst the evidence we heard in interviews was not clear the Trust has assured us that double reporting of positive samples was in place and auditable on the basis of double signatures on reports. The extent to which internal random or targeted 'double reading' of negative (benign) samples should be undertaken is a matter the Trust should determine drawing upon the advice of the RCPATH.

3.36 Historically, each Consultant Histopathologist has provided reports in his or her own format, although in a fashion consistent with the RCPATH guidelines. There are likely to be benefits in terms of quality and consistency if there were an agreed format for reports. That is a matter for Consultants within the Department to consider, taking into account the views of their clinical colleagues.

3.37 There were good levels of commitment to attendance at MDTs and we were told that the contributions of the Consultant Histopathologists to those meetings were valued. However, the practice of reviewing slides at these meetings had changed over the years. Irrespective of whether slides would be reviewed at MDT meetings, the good practice of some Consultant Histopathologists reviewing slides prior to discussion at MDT was one way in which any errors in initial reporting might be identified.

3.38 Staff we met at all levels were committed to their work. Most had been employed at the Trust for a major part of their working life and were keen to provide good services for patients. However the organisation and systems established by the Trust in relation to the Histopathology Department, together with the inadequacy of the management arrangements, provided only limited support to staff to deliver the good services to which they aspired.

3.39 Some staff had considerable experience established through many years working within the Department. While senior staff were providing good support to more junior staff in obtaining qualifications and the Trust had provided resources to enable the laboratory manager to study for the advance

practitioner qualification development, opportunities for staff appeared to be constrained. We heard that Continuous Professional Development (CPD) records were being maintained but also that there was no work time available for keeping up with reading professional journals or for attending conferences. Staff felt it was impossible to take time away from the bench because of the additional pressure that would place upon colleagues. The Trust should be finding ways to extend the opportunities for staff to share and extend their experience and encourage professional development.

3.40 Overall we formed the view that:

- Leadership and management within the Histopathology Department requires further development.
- Formal processes to support good management arrangements introduced by the Trust, need to be implemented in the Department including appraisal and audit.
- Multidisciplinary Team working requires strengthening.
- Consultants within the Department should, taking into account the views of their medical colleagues, develop, agree and implement a common reporting format.
- Consultant Histopathologists, taking into account guidance from the RCPATH, should agree the extent to which MDT meetings should review slides. They should also agree their approach to their reviewing of slides prior to MDT meetings.
- The matter of the appropriate extent of 'double reading' in relation negative results should be examined with the assistance of RCPATH.

Reporting and Management of Untoward Incidents

3.41 The Trust had developed policies and procedures for the reporting and management of untoward incidents. Discussions with staff of the Histopathology Department demonstrated that they were aware of the procedures to be followed and believed that these were followed when incidents arose within the Histopathology Department.

3.42 The Trust's arrangements for reporting incidents are clear and a standard form is used for that purpose. Incident reporting has improved within the Trust and encourages managers to believe that any shortfalls there may be in reporting of incidents are declining. However medical staff tend to be less diligent about reporting incidents relying, perhaps, upon nurses and others to ensure that processes for reporting are complied with. The Trust was hoping to introduce an electronic system for reporting to replace the current paper based system.

3.43 Untoward incidents are managed at two levels. Having identified such an incident, local managers and staff should take any immediate steps necessary to neutralise a problem or deal with any immediate consequences, putting in place any immediate action necessary to ensure there is no repetition of the incident. When the Untoward Incident Report Form is received by the Risk Management Department, it is reviewed and 'scored' and a decision taken whether or not a further investigation is necessary. The recently revised Incident Reporting Policy had provided clear guidelines for investigating incidents and a number of Trust staff had been trained in the use of Root Cause Analysis to investigate complaints.

3.44 Each Directorate within the Trust receives a monthly report from the Risk Management Department which is discussed at monthly Directorate meetings. The Risk Management Department tries to produce basic trend analysis of untoward incidents, but that has not always happened because of a backlog of incident report forms in relation to which it has been decided no further investigation is necessary.

3.45 We reviewed a list of untoward incidents which occurred in the Histopathology Department in 2006 and 2007. In total 15 incidents had been reported. Four of those dating from August 2007 were among the initial reporting errors which gave rise to the fuller investigation by the Trust of a particular Consultant Histopathologist's cases discussed above. Other incidents related to mislabelling, misfiling or exposure to spillages. Immediate corrective or consequential actions are recorded for all reported incidents bar one. The exception was in relation to an audit which had shown a large number of mislabelled samples being received by the Department.

3.46 There had been two Trust investigations into recorded incidents, one relating to escape of fumes from a fume cabinet and the other concerning the failure to report an alarm sounding out of hours which indicated an equipment malfunction. In addition the errors in reporting were investigated by the Trust (see paragraph 3.8).

3.47 Overall we concluded that:

- The Trust has in place the necessary policies to support the reporting and management of untoward incidents.
- Staff in the Histopathology Department were aware of their responsibilities regarding the notification of untoward incidents.
- Levels of reporting of untoward incident were rising across the Trust, although medical staff should improve their attention to the matter of reporting incidents.
- Guidance has been provided on investigation of untoward incidents and a number of staff have received appropriate training to conduct investigations.
- The Trust has responded appropriately to the discovery of the errors in reporting of histopathology results.

Location and Premises of the Histopathology Department

3.48 The Histopathology Department is located on the site of Maelor Hospital in Wrexham. The Department is housed together with some other pathology departments in a building which, although originally purpose built, had long since passed its optimal usefulness. As a result, histopathology staff in the department find themselves working in accommodation increasingly less conducive to the delivery of the quantity and quality of work required by a modern service. The Trust has had plans to re-house pathology services for some time but had not yet been able to realise them.

3.49 At the time of the Review the clinical areas of the Department were cluttered and untidy. Within the main laboratory a significant part of the bench area was used for storage. Space under benches was similarly cluttered and gave an impression that little 'housekeeping' was undertaken in order to maintain a clear and clean working environment. The corridor on the first floor of the building was used for storage and 'office' spaces contained clinical equipment (for example a centrifuge) which was in regular use. While the inadequacies of the laboratory space may present challenges, the clutter and untidiness could be significantly reduced, if not eliminated.

3.50 Overall:

- The premises provided for histopathology services do not provide an optimal environment for service delivery.
- Absence of basic 'housekeeping' has led to a cluttered and untidy laboratory environment.

Equipment and Materials

3.51 The laboratories had reasonable levels of equipment which was sufficiently up to date to meet the needs of the workload. However, positioning of equipment was not, in all cases, optimal. Within the laboratory area equipment which had been replaced, but which was not entirely redundant, had been retained for possible future use.

3.52 Reagents and other materials were stored appropriately, but at the time of the review, we found that, in some cases, labelling was not as detailed as we would have expected.

3.53 Tracking of samples delivered to the department for testing was undertaken through a system of forms from which labelling of samples was undertaken. The laboratory manager believed that the system could be improved through an electronic sample identification system in which he hoped to convince the Trust to invest.

3.54 Overall we concluded that:

- Equipment and materials were adequate for staff to perform the required tasks.
- Labelling of reagents and other materials could benefit from further attention.

Chapter 4: Recommendations

4.1 The Trust should assure itself that it has robust systems in place for checking that medical, and other professional staff, are registered and competent to perform the specific tasks they undertake, and that they regularly update their knowledge and skills to maintain their competence.

4.2 Led by the Consultant Histopathologists, the Histopathology Department should review and formalise arrangements for:

- clinical audit,
- 'double reporting' of histopathology results,
- reviewing slides preparatory to MDTs,
- the format of reports.

4.3 Under the leadership of the laboratory manager the department should take steps to:

- remove clutter from the laboratory and tidy work areas, thereafter establishing a housekeeping regime to ensure the laboratory does not again become cluttered or untidy. The Trust should support that activity by identifying suitable storage areas for displaced equipment or records,
- ensure that reagents and other materials are labelled appropriately.

4.4 In the medium term, the Trust should identify and implement a plan to provide improved accommodation for the Histopathology Department.

4.5 The Trust should take steps to identify the extent to which either improved use of staff resources or increases in establishment might enable the workload of the Department to be managed with greater efficiency and effectiveness.

4.6 The Trust should ensure that the formal arrangements it has made to support good leadership and management are fully implemented within the Histopathology Department.

4.7 The Trust should take steps to:

- support the Consultant Histopathologists in developing a more collegiate approach to their work,
- encourage multidisciplinary team working in the Department,
- develop the leadership skills of those in senior roles in the Department.

Healthcare Inspectorate Wales

Healthcare Inspectorate Wales is the independent inspectorate and regulator of all healthcare in Wales. HIW's primary focus is on:

- Making a significant contribution to improving the safety and quality of healthcare services in Wales
- Improving citizens' experience of healthcare in Wales whether as a patient, service user, carer, relative or employee
- Strengthening the voice of patients and the public in the way health services are reviewed
- Ensuring that timely, useful, accessible and relevant information about the safety and quality of healthcare in Wales is made available to all

HIW's core role is to review and inspect NHS and independent healthcare organisations in Wales to provide independent assurance for patients, the public, the Welsh Assembly Government and healthcare providers that services are safe and of good quality. Services are reviewed against a range of published standards, policies, guidance and regulations. As part of this work HIW will seek to identify and support improvements in services and the actions required to achieve this. If necessary, HIW will undertake special reviews and investigations where there appears to be systemic failures in delivering healthcare services to ensure that rapid improvement and learning takes place. In addition, HIW is the regulator of independent healthcare providers in Wales, the Local Supervising Authority for the Statutory Supervision of Midwives and is responsible for monitoring approved nurse education programmes provided by higher education institutions in Wales.

HIW carries out its functions on behalf of Welsh Ministers and, although part of the Welsh Assembly Government, protocols have been established to safeguard its operational autonomy. HIW's main functions and responsibilities are drawn from the following legislation:

- Health and Social Care (Community Health and Standards) Act 2003
- Care Standards Act 2000 and associated regulations
- Mental Health Act 1983 and the Mental Health Act 2007
- Statutory Supervision of Midwives as set out in Articles 42 and 43 of the Nursing and Midwifery Order 2001
- Ionising Radiation (Medical Exposure) Regulations 2000 and Amendment Regulations 2006

HIW works closely with other inspectorates and regulators in carrying out cross sector reviews in social care, education and criminal justice and in developing more proportionate and co-ordinated approaches to the review and regulation of healthcare in Wales.

Arrangements for the Review

The Review Team

The Review was announced on 23 January 2008. A Review Team was constructed to include relevant expertise. The members of the Team were:

| | |
|------------------------|-----------------------------|
| Dr Richard Fitzmaurice | Consultant Histopathologist |
| Dr Maria Nayagam | Consultant Histopathologist |
| Andrew Usher | Histology Services Manager |
| Jenny Hepworth | Lay Reviewer |
| Michael Frost | Investigations Manager |
| Rhys Jones | Investigations Officer |
| Jonathan Matthews | Inspections Coordinator |

The Review consisted of three stages:

- (a) collection and analysis of documents,
- (b) fieldwork during which the Trust was visited and staff interviewed,
- (c) identification of findings, formulation of recommendations and completion of this Report.

Document Collection and Analysis

The Review Team considered documents obtained from North Wales NHS Trust. These included policy and procedures set down by the Trust for the provision of histopathology services, details of the reporting of untoward incidents, staff lists etc.

In addition, the Review Team took into account relevant policy and guidance issued by the UK Department of Health, the Welsh Assembly Government and the relevant Royal Colleges.

Documents were analysed by HIW staff and considered by the whole Review Team.

Fieldwork

The fieldwork for the Review consisted of interviews and observations conducted at Wrexham Maelor Hospital, specifically within the Pathology Department from which the then North East Wales NHS Trust provided histopathology services. In addition a small number of consultants who had once been employed by the Trust but who at the time of the Review were working elsewhere were interviewed.

The major part of the fieldwork took place between 2 June and 5 June 2008. However some interviewees were not available at that time and the period of interviewing extended to ensure that all those identified for interview were seen.

Clinical Pathology Accreditation

The Clinical Pathology Accreditation (UK) Ltd provides a means to accredit Clinical Pathology Services and External Quality Assessment Schemes (EQA) through a system of specialist advisory committees. By declaring a defined standard of practice and having this independently confirmed, by onsite visits and documentation, accredited organisations are able to attain a hallmark of performance and offer reassurance to users of their service. CPA is co-owned by the Royal College of Pathologists (RCPATH), the Institute of Healthcare Management (IHM), the Institute of Biomedical Science (IBMS), the Association of Clinical Pathologists (ACP), the Association of Clinical Biochemists (ACB) and a representative organisation for the Independent Sector.

CPA involves an external audit of the ability to provide a service of high quality by declaring a defined standard of practice, which is confirmed by peer review. The standards are presented in eight sections:

- Organisation and quality management system
- Personnel
- Premises and environment
- Equipment, information systems and materials
- Pre examination process
- Examination process
- The post examination phase
- Evaluation and quality assurance

CPA Inspectors can recommend full or Conditional Approval. Those laboratories given Conditional Approval are given a schedule of items which have to be corrected in a given time span. The emphasis of the inspection is not only on the technical aspects of the laboratory function but also on qualification of the staff, pre and post-analytical functions such as interpretation of results and performance in external quality assessment schemes.

Glossary

Advanced Practitioner - An advanced practitioner is an experienced registered healthcare professional who has developed their theoretical knowledge and clinical skills to a high standard in a specific and often specialised area of practice.

Audit - Originally applied to assessment of the accuracy and probity of financial accounting; now extended to cover any assessment activity which sets out to assess the extent to which a product/outcome matches the criteria set.

Biomedical Scientist (BMS) - A biomedical scientist carries out laboratory tests on human samples to help clinicians diagnose illness and evaluate the effectiveness of treatment.

Clinical Governance - a “framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish” (Welsh Office: ‘Quality Care and Clinical Excellence’).

Clinical Pathology Accreditation (CPA) - The Clinical Pathology Accreditation (UK) Ltd provides a means to accredit Clinical Pathology Services and External Quality Assessment Schemes (EQA) through a system of specialist advisory committees. See Annex C for full definition.

Consultant Histopathologist - is the title of a senior doctor who has completed all of his or her specialist training and been placed on the specialist register in their chosen specialty, for example, Histopathology.

Continuous Professional Development (CPD) - Continuous Professional Development (CPD) is the process whereby any individual can maintain current standards of best practice within their profession.

External Quality Assurance (EQA) - Arrangements through which laboratories exchange tissue samples with other laboratories in order to quality assure each others’ results.

Fume Cabinet - Also called ‘Fume Cupboard’ or ‘Fume Hood’. A fume cabinet is a large piece of scientific equipment common to chemistry laboratories designed to limit a person's exposure to hazardous and/or unpleasant fumes.

General Medical Council (GMC) - The General Medical Council registers doctors to practise medicine in the UK. Its purpose is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine.

Histopathology - Histopathology is the branch of pathology concerned with the examination and understanding of tissues. See page 7 for full explanation.

Local Health Boards (LHB) - statutory bodies responsible for implementing strategies to improve the health of the local population, securing and providing primary & community health care services and securing secondary care services.

Multi-Disciplinary Team meetings (MDT) - Meetings bringing together clinicians who jointly provide care and treatment for individual patients should be in place to ensure information is shared and appropriate medical or surgical interventions are planned. See page 10, footnote 3.

Medical Director - A physician who has responsibility for the medical control and direction of hospital departments. The medical director is also responsible for doctors working for the Trust: for their work contracts, for supporting them in training to be specialists and if they get into difficulties.

Medical Laboratory Assistant (MLA) - MLA's work throughout the NHS on wards, or in clinics and laboratories, providing support to biomedical scientists, pathologists, clinical scientists, and medical staff.

National Health Service (NHS) Trust - A self-governing body within the NHS, which provides health care services. Trusts employ a full range of health care professionals including doctors, nurses, dieticians, physiotherapists etc. Acute trusts provide medical and surgical services usually in hospital(s). Community trusts provide local health services, usually in the community, e.g. district nurses, chiropodists etc. Combined trusts provide both community and acute trust services under one management.

Pathology - is the study and diagnosis of disease through examination of organs, tissues, bodily fluids, and whole bodies (autopsies).

Post Mortem Examination - is a medical procedure that consists of a thorough examination of a corpse to determine the cause and manner of death and to evaluate any disease or injury that may be present.

Royal College of Pathologists (RCPATH) - The Royal College of Pathologists was established in 1962 to co-ordinate this development and maintain the internationally renowned standards and reputation of British pathology. Today the College advises on a vast range of issues relating to pathology.

Reagent - A usually available or readily made compound or known mixture of compounds used to treat materials, samples, other compounds or reactants in a laboratory.

Serious Untoward Incident - A 'serious untoward incident' (SUI) is something out of the ordinary or unexpected. It is an incident – or a series of incidents – that, if left unattended, may pose a risk to service users or the health and safety of staff, visitors and others.

Trust Board - a group of people who are by statute responsible for major strategy and policy decisions in each NHS Trust. Typically comprises a lay chairman, five lay members, the Trust Chief Executive and Executive Directors.