# A Report of a review of the work of a Consultant Histopathologist (Dr. E.) at University Hospital Galway in 2004 and of issues arising from a related help-line

**April 2009**

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## 1. Executive Summary

This report describes the review conducted at Galway University Hospital (GUH) into the work of a pathologist referred to in the report as Dr. E. was employed as a locum consultant at GUH for a six week period in 2004. In December 2007 Management at GUH were alerted to concerns about Dr. E's work in the UK subsequent to his employment in GUH. On foot of these concerns GUH acted immediately to institute a review of Dr. E's work at GUH in 2004. The report includes details related to the management of calls to a help-line which was established by GUH related to the Dr. E. review and also the help-line that related to the Health Information and Quality Authority investigation of symptomatic breast services, commenced in July 2007 and published in July 2008.

The practice of histopathology and cytopathology is concerned with the diagnosis of disease based on the examination of tissues and cells taken from a site or sites in the body. The material taken form the body is prepared and then examined under a microscope. The examiner forms an opinion as to whether the tissue or cells are normal or abnormal and the nature of any abnormality present. Extensive training is required in the interpretation of the patterns seen under the microscope however the process remains one of judgement and even in the best of circumstances differences of opinion arise and areas of abnormality can be missed.

### 1.1 The review of the work of pathologist Dr. E.

Dr. E. was recruited in 2004 in accordance with a detailed process that included obtaining references. There was no basis for concern regarding the competence of Dr. E. at the time of his appointment.

Of the 448 histopathology cases reviewed there were 37 cases (8.3%) in which the report was amended. In 23 cases (5.1%) the change was a matter of detail and in 14 cases (3.1%) the amendment was to the substance of the report. The 14 cases that were changed in substance comprised of 7 prostatic biopsies and the remaining tissues were from colon (3), skin (2), uterine cervix (1), and breast and chest wall (1). The errors had an impact on care of 3 patients. In the case of two patients the diagnosis of

prostate cancer was delayed however this appears not to have resulted in long term clinical impact. Cancer of the prostate often progresses very slowly. In the third patient a second procedure to remove a wider area of skin was performed on the basis of the first report. The amended report indicated that the second procedure was not necessary.

Of 121 diagnostic cytology cases reviewed there were 19 cases (15.7%) in which the report was amended. The 19 cases comprised of 7 breast, 4 thyroid, 4 urine and 4 other specimens. The errors had no impact on care of patients.

Of 413 cervical smear tests (Pap smears) examined by Dr. E. there were 2 discrepancies identified on review (0.5%). The discrepancies had no impact on patient care.

### 1.2 Work Reviewed Arising From the Helplines

In total 268 histopathology specimens from 130 patients were reviewed arising from the helplines. The review included the work of 19 consultants (including permanent consultants and short and long term locum consultants) with 1 to 47 specimens reviewed for each consultant. One patient was identified where prostate cancer went undetected in 2 separate sets of biopsies. Although the error resulted in a 5-year delay in diagnosis there appears to have been little impact on the patients' health.

As outlined in this report, patients and their doctors have already been informed of the issues that related to their individual care. The purpose of this report is to make a record of the incident and the management of the incident by Galway University Hospitals available to patients and the wider public. Galway University Hospitals is very conscious of the hurt and distress caused to patients by the problems outlined in this report and would like to again apologise to those patients and their families. The Hospital acknowledges that this report cannot adequately reflect the impact of the failings of the service on the individual patients and would like to thank patients, their families and their doctors for their patience, support and understanding.

## 2. Report of Review of the Work of Dr. E. at Galway University Hospital in 2004

On December 3rd 2007 a manager in the UK National Health Service left a telephone message for the Medical Manpower Manager at Galway University Hospital, regarding the work of a Consultant Histopathologist referred to in this report as Dr. E. Dr. E. had worked at GUH from 16th February to 28th of March 2004 (a six week period).

The Medical Manpower Manager initially brought this matter to the attention of the General Manager at GUH on 6th December 2007. The General Manager and Clinical Director of Laboratory Medicine discussed the issue with the Medical Manpower Manager on the evening of December 6th. On the morning of December 7th there was a further meeting of the above individuals, together with the Consultant with Administrative Responsibility for Histopathology. Initial data gathering on the work performed by Dr. E. while at GUH commenced pending confirmation of the information from the UK.

The Medical Manpower Manager at GUH made a number of efforts to contact the caller from the NHS by telephone over subsequent days but was unable to make contact again until December 12th. On December 12th the Medical Manpower Manager at GUH was informed of the following by this colleague in the UK.

- Dr. E. worked as a Consultant Histopathologist for a Health Authority in the UK from March 2006 to March 2007. He worked as one of three Histopathologists in a hospital. The Health Authority was informed that arising from differences of opinion that emerged at Multi Disciplinary Meetings in relation to diagnosis and findings reported by Dr. E. that concerns had emerged regarding the work of Dr. E.
- The Health Authority undertook a review of his work and found there was an 18% error rate in his reporting (normal variance 2.5%). A total of 1800 pathology specimens /reports were reviewed and 279 reported variances.

The NHS Manager informed the Medical Manpower Manager at GUH that the registration of Dr. E. had been suspended by the General Medical Council (GMC) in the UK. The Medical Manpower Manager at GUH subsequently confirmed with the GMC that the registration of Dr. E. had been suspended since September 2007 for 18 months for "professional related issues."

Between December 12th and 19th this issue was discussed among Hospital Management at GUH, the Clinical Director of Laboratory Medicine at GUH, the Consultants with administrative responsibility in Histopathology and Cytopathology at GUH, the Network Manager and the National Hospitals Office (HSE) and the Health Information and Quality Authority (HIQA). It was agreed that GUH would conduct an internal review of the work of Dr. E. and would request external advice on the way in which the review was conducted.

On December 19th 2007 the Clinical Director of Laboratory Medicine GUH telephoned the Dean of the Faculty of Pathology of the Royal College of Physicians of Ireland to inform him of the incident and to request that the Faculty of Pathology provide external advice as to the methodology of the review. On January 8th the Clinical Director formally wrote to the Dean of the Faculty outlining the issue and requesting advice. The Dean of the Faculty agreed to convene a group to advise GUH on terms of reference and the process for conduct of the review.

The Medical Council were informed of this incident by the GUH Medical Manpower Manager on January 2nd 2008.

**The work performed by Dr. E. at GUH comprised of**

| | |
|---|---|
| Histopathology cases | 448 |
| General Diagnostic Cytology cases | 121 |
| *Gynaecological Cytology (Pap smears) | 413 |

* *Note* Gynaecological screening cytology slides are usually examined by two medical scientists. The scientists refer all Pap smears with a potential abnormality for further review by the Consultant Cytopatholgist/Histopathologist. Although the Consultant has overall clinical responsibility for the operation of the service he/she

does not examine all of the slides. There were 413 slides that were examined by Dr. E. although 3498 slides in total were examined during the period when he had overall responsibility for the service.

**3. The Review Process**

The Terms of Reference for the review were agreed with the Faculty of Pathology (Appendix 1). The process of the review was agreed as follows.

Two GUH Consultant Histopathologists would independently review all histopathology cases originally reported by Dr. E. If the opinions of the two GUH Consultants concurred no external opinion would be required. In the event that there was a difference of opinion or uncertainty of diagnosis following duplicate internal review the case would be referred to an external Histopathologist with the assistance of the Faculty of Pathology.

Two GUH Consultant Histopathologists with an interest in Cytopathology would review all diagnostic cytology cases. If the opinions of the two GUH Consultants concurred no external opinion would be required. In the event that there was a difference of opinion or uncertainty of diagnosis following duplicate internal review the case would be referred to an external Histopathologist with the assistance of the Faculty of Pathology.

The Gynaecological Cytology work was reviewed using the same methodology employed in the HIQA investigation into the provision of services to Ms. A published in July of 2008. This process involved reviewing the 3498 slides signed out by Dr. E. and identifying those (413) actually viewed by Dr. E. as a result of the initial screening by the Medical Scientists. The data on the slides viewed by Dr. E. were examined to identify those in which there were significant differences of opinion recorded between the three people (2 medical scientists and Dr. E.) that had examined the slide. Where differences of opinion were noted between the 3 people who originally examined the slides (24 cases) two Consultant Cytopatholoigts/ Histopathologists reviewed those slides.

The performance of the review posed significant challenges. The Consultant Staff in the Department of Histopathology and Cytopathology were at that time still engaged in work related to finalising the "Report of the investigation into the provision of services to Ms A" conducted by the Health Information and Quality Authority in addition to maintaining a busy routine diagnostic service. The Consultant staff who agreed to take on the additional work for the review had already been working extended days and through weekends for some months. A number of colleagues in other hospitals in Ireland had also been engaged in additional work related to the HIQA investigation. Sending the work outside of Ireland was considered but this also posed logistical challenges and it was not clear that this would lead to a more rapid review.

The review of histopathology material commenced in March 2008 and was completed in May 2008. The review of the cytology material commenced in March and was completed in April 2008.

### 3.1 Findings and Output of the Review

#### 3.1.1 Histopathology

Of the 448-histopathology cases the original report was confirmed in 411 specimens from 404 patients. There were 37 cases (8.3%) from 37 patients in which the report was amended. In 23 cases (5.1%) the change was a matter of detail and in 14 cases (3.1%) the amendment was to the substance of the report. An error rate of 3.1% is outside the accepted recognized error rate of 1 – 2 %. The 14 cases comprised of 7 prostatic biopsies and the remaining tissues were from colon (3), skin (2), uterine cervix (1), and breast and chest wall (1).

#### 3.1.2 Cytology (Diagnostic and Gynaecological)

Of the 121 diagnostic cytology cases reviewed there were 19 cases (15.7%) in which there was an amendment to the original substance of the report. The amended reports related to 4 thyroid specimens, 7 breast specimens, 4 urine specimens, 2 specimens of pleural fluid, and 1 each of peritoneal fluid and lymph node.

Of the 413 gynaecological cytology cases viewed by Dr. E. 2 patients (0.5%) were identified for whom an amendment of the report was required.

## 4. Communication and Follow Up of Cases

Following the completion of the initial review there was a period of cross checking and collation of information on patients and their doctors contact details and consideration as to the most appropriate process for informing patients of the results.

### 4.1 Histopathology

With respect to 23 histopathology cases and 1 diagnostic cytology case in which the amendment to the report represent a matter of detail the amended report was sent to the clinician concerned with a covering letter explaining the basis for the amended report and inviting the clinician to contact the Clinical Director of Laboratory Medicine at GUH if any further discussion was required (Appendix 2). There was one telephone call from a General Practitioner arising from this correspondence and seeking clarification which was provided.

In the 14 cases where there was a change in the substance of the histopathology report the Clinical Director of Laboratory Medicine or the Consultant with Administrative Responsibility in Histopathology telephoned the clinician concerned in the first instance to brief them on the issue. This process commenced in June. The amended report was then mailed to the clinician together with a covering letter requesting that he/she review the clinical notes and complete a report for GUH indicating if the error in the original report had any impact on the care of the patient and asking if the doctor could assist in contacting the patient to inform the patient of the issue. These letters were dispatched on July 2nd 2008. (Appendices 3 and 4) Appendix 3 = sample letter with doctor and patient identifiers removed. Appendix 4 = the blank form for completion

### 4.2 Cytology (Diagnostic and Gynaecological)

In respect of the 19 diagnostic cytology cases and 2 screening gynaecological cytology cases (Pap smears) the Clinical Director of Laboratory Medicine made an initial telephone call to the clinician. This was followed by mailing to the clinician the amended report, covering letter and template for reporting on the clinical evaluation.

The intended process was to arrange for contact with the patient when GUH had received information from the clinician who cared for the patient in 2004 to indicate what, if any impact the error had on the patient's health. This was consistent with the approach taken in relation to the HIQA investigation into the provision of services to Ms. A. The intention was to have complete information for the patient at the time of initial contact so as to minimise distress related to waiting to hear if the error had impacted on the patient's health. When complete information was collated the intention was to make contact with the patient wherever possible through a doctor (Consultant or General Practitioner) with whom they had an established relationship.

**5. The Release of the HIQA Report "Report of the investigation into the provision of services to Ms A".**

On July 10th 2008 HIQA informed GUH of its decision to launch the "Report of the investigation into the provision of services to Ms. A" on July 15th. The group dealing with these issues at GUH took the view that it was essential to inform the public of the review of the work of Dr. E. at the time of release of the HIQA report. The group considered that this was essential because it was possible that some patients and members of the wider public could perceive failure to disclose the Dr. E. review at that time as an attempt to conceal the issue and that this could undermine public confidence in the hospital's commitment to full disclosure related to errors.

GUH considered therefore that it was essential to make immediate contact with all patients concerned prior to the date of the release of HIQA report (July 15th) although evaluations had not been returned from all clinicians at that time. Within this time frame it was not possible in all cases to make contact as originally planned through the relevant Consultant or General Practitioner. Therefore a decision was taken by the General Manager GUH, the Clinical Director of Laboratory Medicine and others to make direct contact with the patients or families concerned. The process commenced on the evening of Monday July 14th and was largely completed by Tuesday July 15th. One family was not contacted until early August because the GUH group was aware of a recent bereavement. It was considered appropriate to defer the contact until a month after the bereavement.

A team of senior GUH staff including the Clinical Director of Laboratory Medicine and the Director of Nursing made initial contact. Patients were offered an immediate opportunity to discuss the issue with the Clinical Director where necessary and were provided with a call back contact number for subsequent questions or concerns. An individual letter to each patient was issued as follow up to the telephone call. (Appendix 5).

## 6. The Impact of the Errors on Patient Care

The following summarises the patient impact of the amended histopathology reports.

### 6.1 Histopathology

The histopathology errors were assessed as having no impact on patient care by the clinician in 11 of the 14 patients. In 2 patients the diagnosis of prostate cancer was delayed by 2 years because a focus of carcinoma was not reported in the 2004 biopsies. In both men the diagnosis was subsequently made in 2006 and both had received treatment in 2006. The response to treatment in 2006 was considered satisfactory and both patients were well at the time of follow up.

In addition one patient had undergone a second surgical procedure in 2004 to remove an additional area of skin because the original 2004 report indicated that wider excision would be prudent. The skin lesion as described in the amended report following review would not have required the additional surgery.

### 6.2 Cytology

The diagnostic cytology errors were assessed as having no impact on patient care in any of the 19 cases. The 2 errors in relation to gynaecological cytology were assessed as having no impact on the care of the patient.

7. **Summary Tables for Amended Reports Related to Review of Work of Dr. E.**

| **Histopathology Cases** | | |
|---|---|---|
| **Type** | **Number** | **Clinical Impact** |
| Prostate Biopsies | 7 | 2[a] |
| Colon | 3 | 0 |
| Skin | 2 | 1[b] |
| Uterine Cervix | 1 | 0 |
| Breast & Chest wall | 1 | **0** |
| **TOTAL** | **14** | **3** |

a. Delay in diagnosis of prostate cancer.

b. More extensive skin excision than was necessary.

| **Diagnostic Cytology Cases** | | |
|---|---|---|
| **Type** | **Number** | **Clinical Impact** |
| Thyroid Specimens | 4 | 0 |
| Breast Specimens | 7 | 0 |
| Urine Specimens | 4 | 0 |
| Pleural Fluid | 2 | 0 |
| Peritoneal Fluid | 1 | 0 |
| Lymph Node | 1 | 0 |
| **TOTAL** | **19** | **0** |

| **Gynaecological Cytology Cases** | | |
|---|---|---|
| **Type** | **Number** | **Clinical Impact** |
| Cervical smear Specimen | 2 | **0** |

| **Source of Specimens for which Substantive Amendments to Reports were issued** | |
|---|---|
| **Name of Hospital** | Number of Specimens |
| GUH | 25 |
| Outside referrals | 10 |
| **Total** | **35** |

| **Summary Table of Clinical Impact of Substantive Errors on Patient Care** | | | |
|---|---|---|---|
| **Total Number of cases** | **Delayed Diagnosis** | **Unnecessary Procedure** | **No Change to Management** [1] |
| 35 | 2 (2 yr delay in Prostate Ca diagnosis) | 1 (More extensive skin excision than necessary) | 32 |

1. Some of these 32 patients indicated that they suffered significant anxiety and distress when they were informed of the diagnostic errors although the error did not impact on their clinical management.

## 8. Review of Reports at Patients Request through the Help-Line

In response to publicity relating to the HIQA investigation into the provision of services to Ms. A and the review of the work of Dr. E. three separate help lines were established at different time periods as shown in the table below. A total of 198 calls were received.

**Process**

- The General Manager (GM) in collaboration with the Quality and Risk Management department agreed the help-line protocol and the process was initiated by announcing the help-line numbers in the media.
- The General Manager requested that a series of multidisciplinary meetings (surgery, radiology and histopathology) be convened to review cases arising from the help-lines.
- The Quality & Risk Manager managed the help-line call system.
- Calls were logged on an excel spread sheet and included all relevant detail relating to the callers request. This data sheet was made available to specific members of staff involved in the review on a live basis.
- Callers were given a guarantee that an appropriate professional would respond by telephone within 24 hours in all cases.
- Daily briefing on the calls and the status of follow up of calls was conducted by the Quality & Risk Manager with the lead Consultant and General Manager. Any day-to-day issues arising regarding the management of the calls were discussed and actions initiated.
- Each week a summary of all calls received and actions taken were reviewed by the lead Consultant in the relevant Directorates.

**Outcomes**

A total of 198 patients contacted the help-line as outlined in the table.

| **Helpline** | **Total** | **GUH Patients** | **Other Hospitals** |
|---|---|---|---|
| 7th Aug 07-10th Sept 07 | 103 | 86 | 17 |
| 29th Nov 07 – 19th Dec 07 | 49 | 48 | 1 |
| 15th July 08 – 28th July 08 | 46 | 40 | 6 |
| **Total** | **198** | **174** | **24** |

The first helpline (August 2007) was set up at the time that the establishment of the initial HIQA investigation into the provision of services to Ms. A was publicly announced. The second helpline (November 2007) was established following the announcement of a review of radiological tests at another hospital. The third helpline (July 2008) was established at the time that the HIQA investigation was published.

**Disposition of Calls**

All callers were contacted and followed up as appropriate.

| | |
|---|---|
| Caller ended the call and did not leave contact details | 4 |
| General queries / requests for information dealt with on call | 10 |
| General complaints passed to the complaints office | 4 |
| Callers cases notes referred to special multidisciplinary meeting (MDM) | 180 |
| **TOTAL** | **198** |

**Follow up on Calls**

The records at GUH were checked for each individual caller. In some cases there was no record that the patient had any radiological or histopathological examination performed at GUH. For most callers either a radiology record, or histopathology

record or both were identified. A letter was issued to the patient in relation to each patient reviewed at the MDM.

In total 268 histopathology specimens from 130 patients were reviewed arising from the helpline. The review included the work of 19 consultant histopathologists (permanent consultants and short term and long term locum consultants) ranging from 1 to 47 specimens reviewed for each consultant. The number of specimens reviewed related to the length of time the consultant had worked in the Department.

A single patient in whose case errors had been made was identified. The patient was a male who had six needle biopsies of the prostate gland in 2003 and 2005. In 2003 all six biopsies were reported as showing no cancer. However on review a small focus of carcinoma was observed on one of the six biopsies. The original 2003 report was not made by Dr. E. or by either of the doctors (referred to as Dr B. and Dr. C. in the earlier HIQA report). This doctor is referred to here as Dr. Z. The 2005 report on six further needle biopsies from this same patient described an area of "atypia" in one of six biopsies. On review however carcinoma was observed in this biopsy and in 1 of the other 5 biopsies. The original 2005 report was made by a different Doctor (Dr. Y). In summary this patient was diagnosed in 2008 as a result of the review of these biopsies from 2003 and 2005.

As a result of the helpline and a review relating to work performed for a private hospital (previously published in 2008) other material examined by Dr. Z. and Dr. Y. was reviewed. No other errors in their work were detected.

The patient was informed of this error through his Consultant and has been clinically evaluated by his Consultant. The General Manager and the Clinical Director of Laboratory Medicine have apologised to the patient and discussed the issue in detail and corresponded with a family member nominated by the patient to represent him. The patient has been provided with appropriate care for his condition and is receiving follow up. Although the error resulted in a 5-year delay in diagnosis on the basis of the information available at present there appears to have been little or no impact on the patient's health. Cancer of the prostate can be a very slowly progressive disease.

## 9. Commentary and Learning Points.

### 9.1 Reducing the Risk of Future Episodes

Many of the issues raised by this review have previously been identified in the HIQA "Report of the investigation into the provision of services to Ms A". The learning points in most cases are not specific to Galway University Hospitals but represent general issues that apply to the delivery of similar services in other hospitals. They are also relevant in dealing with similar incidents in the future should they arise in any setting within the health service.

The process of appointing the locum Consultant Histopathologist, including obtaining of references, was consistent with procedures in general use at the time. Subsequently recommendations for a more robust recruitment procedure have been made and are now applied (Appendix 6).

In 2004 the number of permanent Consultant Pathologists at GUH was 5 which created a significant dependence on short-term locum Consultants to sustain the service. The number of consultant pathologists has now increased to 8.5 Whole Time Equivalents (WTE). The number of consultant posts should be maintained at a level that provides capacity to deal with a surge in workload or short term absence due to leave (including annual, maternity, parental and sick leave).

Consideration should be given to a review of a representative sample of Locum Consultants work during the initial period after their appointment. The specific areas of competence of all new Locum Consultants should be identified and a written agreement defining the scope of the work they may undertake in the Department agreed.

The system of multidisciplinary team meetings now in operation in the hospital was developed to minimize the risk of errors and to increase the likelihood that a Histopathologist with a pattern of error is likely to be detected. In addition the process of internal consultation between histopathologists regarding individual cases

has been made more formal and is documented using a system of colour coded cards to record the opinions (Green Card System).

The Departments of Histopathology and Cytopathology already participate in External Quality Assessment Schemes and staff participate in appropriate continuing professional education. Progress with implementation of an externally accredited quality management system is underway to strengthen systems and reduce risk of error. At present a random sample of 5% of prostate biopsy cases that are reported as benign are reviewed by a second consultant. The Faculty of Pathology of the Royal College of Physicians of Ireland issued a document Histopathology QA (Quality Assurance) Programme in April 2008 which is being implemented in the Department of Histopathology in association with the process of implementing a total quality management system and application for accreditation.

http://www.rcpi.ie/Faculties/Documents/Histopathology%20QA%20QI%20Scheme%20Version%201%20-%20April%202008.pdf

A laboratory information system should ensure that current histopathology specimens are linked with previous cytology or histopathology specimens and diagnostic codes on the same patient. The new laboratory information system implemented in the Department of Histopathology in late 2008 will facilitate linking current with previous biopsies in a way that was not possible with the previous system. Where appropriate, review of previous histopathology, diagnostic cytology or screening cytology reports in the context of a current diagnosis of malignancy could provide an important quality assurance check. This may have significant resource implications.

Implementation of such a system of routine cross-checking may be more challenging where services are provided from multiple laboratories. Representatives of one patient expressed surprise that such a system of cross checking is not a matter of routine indicating that there is a difference between patient expectations and current practice. The use of a unique national patient identifier and greater information sharing within the health service would facilitate linking patient care episodes however there may be technical challenges with respect to information systems as

well as significant public policy issues relating to privacy and data protection that need to be considered.

**9.2 Views of Patients on the Process of the review**

Some patients stated that they were angry that the issue was identified to the hospital in December 2007 but that they did not receive communication until more than 6 months later. GUH acknowledges that there was an interval of some months before the review commenced in early March 2008. This was related to time taken to agree the process and terms of reference of the review and time to prepare for the review and develop the response in the context of another ongoing enquiry (the HIQA investigation into the provision of services to Ms. A ) and the volume of routine work which must be sustained. However GUH accepts that from the patient's perspective these constraints are not a sufficient justification for the delay and acknowledges the view expressed by some patients that it was a reasonable expectation that the process could have been dealt with more quickly.

The sequence followed in this review, and to our knowledge most similar reviews has been to examine all, or a substantial group of, the cases in the first instance and then proceed to the clinical management. One patient indicated to the Clinical Director very clearly that it was not acceptable that a significant time may have elapsed between the detection of the error and the contact with the patient. GUH accepts that this is entirely reasonable and a learning point from this process is that seen from a patient's perspective this additional delay in informing them after the error has been detected is not acceptable and may add to their sense of hurt and disappointment. In the event of future reviews patients should be contacted promptly on an on going process as errors are detected.

This issue of contacting patients as the review is ongoing raises issues in relation to how to manage information. If a patient chooses to make public the fact of the error the performance of the review may become public before the review is completed and before other patients have been informed. It appeared therefore to those managing the review that there were legitimate reasons to manage the flow of information as patients involved are entitled to expect that they do not learn about an incident

involving themselves from media reports. Furthermore premature media reports based on incomplete information may generate alarm among patients that are not affected. The public response to such reports can overwhelm the capacity of the service to deal with the issue and make it difficult to remain focused on those patients most directly involved. Nevertheless the patient's right to be informed should take precedence over concerns regarding management of the public release of information. The role of independent advocacy services should be developed in all hospitals. In any case our experience would suggest that most if not all patients are very sensitive to the needs of other patients and will not wish to make a public statement while the review is ongoing if they are satisfied that the review is being performed in a timely and transparent manner, they are satisfied that they have received appropriate apology, consideration and care from the time of detection of the error and that the institution is committed to publication of the review on completion.

**9.3 Communication with Patients**

The decision made in early July 2008 to make direct contact with patients before their doctor had made contact with them and in some cases before the clinical significance of the impact of the error was determined was a difficult one. Subsequent to this, one doctor expressed serious concern to the Clinical Director that this decision was entirely inappropriate. The basis for the decision was outlined in subsequent correspondence to all clinicians involved (Appendix 7). One doctor wrote to indicate his support for the decision under the circumstances.

Most patients and families, including those who were initially upset, expressed their appreciation that they had been informed. One patient and her family had a number of follow on discussions and a face to face meeting with the Clinical Director. She and her husband expressed the view that while they did need to be informed the process of contacting her was not well timed, lacked sensitivity and caused great upset. It is clear therefore that the communication process did not work well for all patients. Most patients, including those on whom the error had no impact indicated that they considered it important that they were given the information.

Direct communication with patients from GUH, although it caused significant upset to one patient had the advantages that GUH could take full responsibility for managing the communication and that the patient had immediate contact with GUH for further questions and concerns. Communication with patients through an intermediary (Consultant or General Practitioner) as used for most patients in relation to the HIQA investigation worked very well for most patients. However some doctors declined to contact the patient regarding the issue and there was also one very significant instance of communication failure that came to attention using that process.

The use of intermediaries made it much more difficult for the hospital to ensure the nature of the information communicated the process of communication and to confirm that the patient had received full information. It is difficult to define which process is most appropriate. On balance direct communication between the hospital and the patient appears to be the best way to ensure that the hospital is seen to accept its responsibility and to ensure effective communication. Initial contact through a doctor known to the patient may help to minimize distress and may be appropriate but should then be followed up by direct communication.

Given that a small number of doctors expressed the view that direct communication with patients is never appropriate hospitals should bring to the attention of all medical practitioners and health care workers that responsibility for patient care is a shared responsibility. While the relationship of the patient with their chosen doctor is and should generally be respected the institution must reserve the right to make direct contact with the patient if this is warranted in specific circumstances.

Greater care is needed around communication of negative results of investigation to patients. Even in the best of circumstances diagnostic testing processes are far from perfect. The quality of the result depends on the quality of the specimen received in the laboratory (was the correct specimen taken at the right time and stored and transported properly) and the quality of the clinical information provided. The process depends on the training and expertise of the laboratory staff and on the quality assurance systems in place. Even when all of these elements are state of the art false positive results and false negative results will occur. Under-graduate and post-graduate education of health care workers must continue to emphasize the need for

caution regarding the interpretation of laboratory results and the need for clinical correlation in all cases.

Communication related to the limitations of diagnostic testing to health care workers and the public is most important in relation to screening tests intended for the early detection of disease. By definition screening tests are performed in patients who have no clinical features and so there is little chance that clinical clues will point out a false negative result. It is clear from discussions with patients related to the errors identified in this review process that this is not generally understood. Many patients appear to understand a negative screening test or diagnostic test result as an "all-clear". While patients may be assured that an undetected cancer or other disease is much less likely if they have had a negative screening test it is essential to find a way of communicating clearly to patients that it is never possible to guarantee a patient that all will remain well for any period of time. Screening tests may reduce the uncertainty in our lives but do not remove it.

There was considerable debate amongst those involved in this process regarding the appropriateness of contacting families of deceased patients in circumstances in which the erroneous report had clearly made no impact on the patient's management. Although some families were initially upset by the telephone call, in all cases the families ultimately expressed the view that they appreciated that they had been informed and supported the hospitals decision to contact them.

**9.4 Follow Up of Patients**

On the whole the process of follow up of patients who were identified as needing follow up worked well. Most medical practitioners in GUH and elsewhere recognised that the review of the patients' records and, where appropriate, review of the patient was deserving of high priority and dealt with the matter very promptly. Most delays were related to absence on leave of a specific doctor. The system of Clinical Directorate structures within GUH was very valuable in supporting clinical review and follow up.

Follow up of patients from outside of GUH (General Practitioners and other hospitals) was more challenging but again in almost all cases doctors dealt with the issues very promptly.

### 9.5 Communication with the Public and Media

The process of ensuring that the findings of a review remains private until it is complete and all of the patients have been informed has been justified on the basis of (1) ensuring the right of the individual patient to know before the general public knows (2) on the basis of minimising stress for patients who may be included in the review but for whom the original report is confirmed (3) minimising stress for patients who are not involved in the review but who may fear that they are involved. These considerations are significant but should be subordinate to ensuring that individual patients are contacted promptly when an abnormality is detected.

At a more general level there is a need to assure the public that all errors will be dealt with promptly and thoroughly and that there is full disclosure on completion of all reviews or investigations.

# Glossary of Terms and Abbreviations

| | |
|---|---|
| **Benign** | Non cancerous |
| **Biopsy** | The removal and examination of a sample of tissue from a living body for diagnostic purposes. |
| **Carcinoma** | Cancer of epithelial cells |
| **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 |
| **Cytology** | The study of cells |
| **Cytopathology** | The study of cells in diagnosis of disease |
| **Galway University Hospitals** | University Hospital Galway & Merlin Park University Hospital. |
| **General Medical Council U.K.** | The Council responsible for regulation of the Medical Profession in United Kingdom. |
| **GUH** | Galway University Hospital |
| **HIQA** | Health Information & Quality Authority |
| **Histology** | The study of tissue |
| **Histopathology** | The study of tissue in diagnosis of disease |
| **HSE** | Health Service Executive |
| **Medical Council** | The Council responsible for regulation of the Medical Profession in Ireland. |
| **Multidisciplinary Meeting (MDM)** | The review of test results by a team of Specialists. |
| **NHS** | National Health Service |
| **The Faculty** | The Faculty of Pathology of the Royal College of Physicians of Ireland |
| **WTE** | Whole Time Equivalent |

**Appendix 1.**

## TERMS OF REFERENCE FOR REVIEW

**(01-02-2008)**

Purpose

- To conduct a review of diagnostic work carried out by

Dr. E during the period 16/02/04 – 28/03/04 while employed as Consultant Histopathologist at University Hospital Galway in order to identify and prioritise which, if any, of these patients may need further diagnostic or therapeutic interventions.

Management of the Review

A GUH Steering Group to manage the review will be convened as follows

- Professor M. Cormican, Clinical Director, Laboratory Medicine Chair GUH
- Ms. B. Howley, General Manager GUH
- Mr. P. Commins, A/Deputy General Manager GUH
- Fiona McHugh, SEO, GUH
- Dr. John Callaghan, Consultant with Administrative Responsibility in Histopathology, GUH
- Dr. Mary Casey , Consultant with Administrative Responsibility in Cytopathology, GUH

The Faculty of Pathology will establish a Panel which will be available to the GUH Steering Group. The panel will consist of:

- The Dean, Dr Gerard Boran
- The Honorary Secretary, Dr Tom Crotty

- The Vice Dean, Dr Conor O'Keane (effective Feb 8 2008)
- Dr Mairead Griffin (advisor on gynaecological cytology)

The Faculty Panel will:

- Provide advice on the methodologies used in the review
- Provide feedback to the Steering Group on the report at the drafting stage
- Identify or recommend additional reviewing pathologists as required
- Review cases where there is a difference of opinion between the reviewing pathologists at GUH to assist in reaching a conclusion.

Other pathologists may be co-opted to the Faculty Panel.

Conduct of review

The review will be conducted according to the agreed documented methodologies. Any changes to these methodologies must be reviewed by the Faculty panel before proceeding.

Output and Actions arising from the review

- To arrange prompt clinical assessment and/or diagnostic investigations for any patient identified during the review as possibly requiring further diagnostic or therapeutic intervention.

- In the case of any patient identified as needing further diagnostic or therapeutic intervention, the hospital is to make this information available to the patients concerned and/or their G. P. or their Consultant

- To arrange rapid access to diagnostics and treatments where required.

Report

- The Steering group will submit draft report to faculty panel. On completion of the review by the faculty the report will be made available to the National Hospitals Office, the Department of Health and Children and the Health Information and Quality Authority.

- Every effort will be made to complete the report by: 1 June 2008.

Changes to Terms of Reference

- Where circumstances arise during the course of the review such that it becomes necessary to change the Terms of Reference, such changes must be discussed and agreed by the Steering Group and the Faculty. It may also be decided that a separate review is more appropriate under such circumstances than changing the Terms of reference of this review.

**Appendix 2.**

**Sample of Covering Letter accompanying 23 histopathology and 1 diagnostic cytology reports with amendments of detail.**

Date

Doctor Name

Re: Patient Name, DOB, Hospital Number; Laboratory Report number

Dear Mr / Dr.

A review of this patient's biopsy material was carried out by Dr. ---------- and Prof ---------- as part of a review of the work of a locum consultant Histopathologist, Dr. [redacted] who worked at GUH for a short period in 2004. I enclose a copy of the original report from Dr. [redacted] and an amended report from Dr. ---------- and Prof. ----------. The amendment represents a modification of the original report, which appears to me to be minor, but nevertheless my colleagues and I considered it appropriate to bring it to your attention. I apologise for the need to amend the report. If you wish to discuss the matter further please feel free to contact Dr. ---------- Consultant Histopathologist (extension ------ ) or myself (---------).

Yours sincerely

---

Clinical Director of Laboratory Medicine

**Appendix 3.**

**Template of Letter Accompanying Reports with substantive change.**

Date

**PRIVATE & CONFIDENTIAL**

**Mr _____.**
Consultant _____
Galway University Hospitals

Re: Review of Pathology reports of Locum Consultant Histopathologist during the period of his employment of 16/02/04 – 28/03/04 at University Hospital Galway _____

Reference No: [redacted] ____ (GUH)

| Patient Name | RH Number | Specimen Type |
|---|---|---|
| _____ | _____ | _____ |

Dear Mr. _____,

Galway University Hospitals recently received information that a pathologist who was employed in GUH for the period of 16/02/04 – 28/03/04 was the subject of a subsequent investigation in the UK. The investigation indicated a higher than expected rate of errors in reports. As a result of this information this Hospital informed HIQA and with the support of the Faculty of Pathology of the Royal College of Physicians of Ireland has undertaken a review of all the work of the doctor concerned during the period of his employment here. Our information is that he left

Ireland at the end of his period of employment here and did not work at any other hospital.

A patient who was under your care is among those for whom a slide review has indicated a change from the original report.

The original report was as follows

_____

Following independent internal review by two histopathologists the amended report is as follows

_____

_____

Copies of the original and amended reports are attached. Dr. ---------- has attempted to identify any other reports, related to this patient from around the time when the specimen in question was submitted. I enclose copy of all relevant reports.

It is now necessary to determine if the error in the laboratory report had any impact on the care of the patient and I would be very grateful if you can assist with this process. If you are able to assist I would be grateful if you could complete the attached form (Patient Case Management) and return to Dr. ----------, Department of Histopathology as soon as possible. If you would like to discuss the matter further please telephone Dr. ---------- or Prof. ---------- at 091 ------- and 091 ------ respectively.

I appreciate that the completion of the review and form is a significant undertaking but would be grateful if you can give this a high priority. To assist you in reviewing the patient records they have been retrieved and are available for immediate access by contacting ----- -------, Deputy General Manager's Office at ext [redacted].

**If you do not feel that you are able to assist in dealing with this matter please let me know so that alternative arrangements can be made.**

I apologise to you for this error. I would like to say how sorry I am that this error was made with the patients sample and I very much regret if this had any impact on the care of the patient.

Yours sincerely,

_____

Ms. ----------

General Manager,

Galway University Hospitals.

Enc.

**Appendix 4.** Reporting template for completion by clinician reviewing patient.

Galway University Hospitals
Ospidéil na h-Ollscoile Gaillimh
UNIVERSITY HOSPITAL GALWAY
MERLIN PARK UNIVERSITY HOSPITAL

**Highly Confidential Patient Case Management**

Please complete and return to [redacted], Clinical Director, Department of Pathology Medicine.

| | | | |
|---|---|---|---|
| **GP Name/ Consultant:** | | **Phone No:** | |
| **Address:** | | | |
| [redacted] **Reference** | | **Histology / Cytology Number:** | **DOB:** |
| **Patient Name and Address** | | | |
| **Contact Tel Number** | **(Home)** | **(Mob)** | |

| | |
|---|---|
| **Management** | |

| | |
|---|---|
| | |
| **Action taken and Outcome** | |
| **Patient Response** | |

Please note any other comments you wish to make in relation to this case

| Date / Time | Follow up Details | Signature |
|---|---|---|
| | | |

**Appendix 5:**

**Sample letter to patients**

**GENERAL MANAGER'S OFFICE**

University Hospital Galway

Newcastle, Galway Ireland

Tel:

Fax:

Date _____

Name _____

Address _____

Dear Ms. _____,

I am following up on a telephone call that you received some days ago from one of the staff at Galway University hospital.

In December of 2007 the hospital received information from the UK about concerns regarding the work of a doctor who had worked in Galway for a brief period in February and March of 2004. When the doctor finished working in Galway he went to the UK. After he had been working in the UK for some time the hospital he worked at became aware of concerns regarding his practice. They carried out a review of his work and found that he had made a number of mistakes. When Galway University Hospitals learned about this we contacted the National Hospitals Office, within the HSE and the Health Information and Quality Authority (HIQA) to discuss it. With advice from the Faculty of Pathology we started to review all of the work that doctor did while he was in Galway.

Among the specimens that the doctor looked at while he was working in the lab in Galway was a ---------- taken from you by Dr. _____ in March 2004. The doctor that looked at the specimen in 2004 reported _*patient specific text*[a]_. The two doctors who looked again at the specimen from 2004 report that *patient specific text*[a] . Dr. _____ has reviewed the clinical notes and I understand that the change in the laboratory report makes *no difference/ patient specific text*[a] to the treatment you required.

I apologise to you for the mistake made on your test in 2004. If you have any concerns about this and would like to discuss it further please telephone my office at 091---------- and we can arrange for a meeting to discuss it. I plan to send you a copy of a report on the review of the work of this pathologist in due course when it is complete. If you do not wish to receive a copy of the final report please let me know.

Yours sincerely

_____

General Manager

a. A non-technical explanation specific to each patient was inserted at this point.

**Appendix 6**

**Process for Recruitment of Locum Consultants**

**Galway University Hospitals – Process for Appointment of Temporary and Locum Consultants**

This process has been drawn up and will be implemented, in accordance with the Commission for Public Service Appointments Codes of Practice for Recruitment and all relevant HSE Circulars.

**Temporary Consultants**

In accordance with *HSE HR Circular 012/2007* dated 26/06/07 (see attached), Temporary Consultants are employed on a limited fixed term or specified purpose basis to cover a vacancy (approved and funded post). The vacancy may have arisen for a number of reasons, e.g. retirement of the substantive post holder, the development of a new specific initiative, career break, etc. The Temporary Consultant is the only individual in receipt of pay in respect of the post.

**Locum Consultants**

As outlined in *HSE HR Circular 012/2007*, Consultants who are employed in a locum capacity are defined as those employed to provide cover for the substantive post holder who is on paid or statutory leave. This includes for example, sick leave, annual leave, statutory leave such as maternity leave, parental leave, etc. Locum status does **not** include situations where a locum Consultant is employed to provide cover for a career break or other unpaid leave, such as long term sick leave or to temporarily fill a vacant post.

***Appointment Process:***

1) Vacancy identified by the General Manager/ HR Manager/ Medical Manpower Manager and Clinical Director.

2) Approval to fill vacancy sought by HR Manager from General Manager/Hospitals Network Manager

3) Following receipt of approval, draft Job Specification sent by HR Department G.U.H. to Clinical Director for agreement.

4) Clinical Director submits the following completed documentation/information to HR Department G.U.H.:
    - Final Job Specification
    - Short-listing criteria based on job specification
    - Advertisement Template
    - Contact Name for informal enquiries
    - Interview board nominees (to be comprised of appropriate members, as set out in HSE HR Circular 011/2006 - see attached).

5) General Manager and Area Recruitment Manager to sign off on documentation outlined in 4) above

6) Vacancy advertised by Corporate HR Department.

7) Applications should be made by application form/C.V., which must include Photographic Identification.

8) Eligible/short-listed (if applicable) applicants notified and interview process conducted in accordance with Codes of Practice for Recruitment.

9) 'Offer' letter sent to successful candidate, who is requested to accept/decline the post. This offer is made subject to satisfactory receipt of all clearances/documentation, as listed below. Candidate is requested to provide (where applicable):

- Full names and contact details of Referees.

- Three references to be sought:
  - one from most recent employer (person must be a lead consultant or have supervised the applicant)
  - two other employers (see enclosed reference questionnaire)
- Garda/Police Clearance
- Occupational Health Clearance
- Evidence of Medical Council Registration
- Evidence of Work Visa/Work Permit

10) When documents referred to at 9) above have been verified and all clearances obtained, Start Date/ Practice Plan agreed by Medical Manpower Manager with Clinical Director/ Business Manager.

11) Medical Manpower Manager issues (a) Contract & Order of Appointment Letter to successful candidate and (b) copy of Contract and HR101 form to HR Department G.U.H.

12) HR Department G.U.H. carries out hire action on SAP HR system and scans relevant documentation to ADOS.

***Additional Notes:***

- Where consultants are recruited through a HSE-approved recruitment agency, all of the above steps are to be adhered to by the relevant agency, in conjunction with Medical Manpower Manager/HR Department G.U.H.

- Where consultants are recruited using video link or teleconferencing, an informal visit should be arranged to meet Consultant colleagues, Human Resources/Medical Manpower Manager and the Clinical Director. A formal offer should only be made following this visit and other mandatory documents/clearances having been received. Prior to holding a video-link interview, the candidate must submit clear Photographic Identification, which will be made available to the Interview Board.

- Short-term locums: There is often a shorter lead-in time, especially where the leave is of an unexpected or unplanned nature. In such circumstances, a Consultant may nominate a known person to cover the locum period. The Clinical Director or a Consultant nominated by the Clinical Director and Human Resources Department G.U.H. representative, must interview this person. Steps 8) to 10) inclusive above must be followed before any contract is issued.

**Appendix 7.**

**Sample of second letter to doctors.**

Histopathology Department
Galway University Hospitals
Ospidéal Na h-Ollscoile na Gaillimh

Correspondence Address
University Hospital Galway, Ireland

Tel

Date
**PRIVATE & CONFIDENTIAL**
**Dr. _____**
**Consultant _____**
**Galway University Hospitals**
**Galway**

Re:_____, DOB_____,_____

Dear _____,

This letter follows from a previous letter relating to errors made by a Pathologist who worked at Galway University Hospitals for in 2004. Thank you once again for you help in dealing with this matter.

In some cases possibly because people were on leave, had not received or noted the correspondence, or because of pressure of other commitments we did not receive a response from the relevant doctor. Because of the very tight time constraints the hospital was working to my colleagues and I considered it necessary in this case to make direct contact with patients before we had received a response from their doctor.

The time constraints arose because the Health Information and Quality Authority took a decision to issue their report on Tuesday July 15th. We believed that if we were to deal with the issues raised by the HIQA report without mentioning the second review under way that patients might consider that the hospital had been very disingenuous. Also it seemed very likely a question of other reviews was likely to be raised in which case it would have been impossible to delay speaking publicly of the second review.

Given these circumstances we considered that it was necessary in the interest of being open and honest with patients to include reference to the second review in the hospitals public statement. It followed from this that it was essential to make immediate contact with the patients concerned, in some instances before we had received a response to the letters sent to their doctor. We were committed to ensuring that patients would learn about this review from their doctor or the hospital rather than the media.

My colleagues and I understand that the decision to make direct contact with the patient before we had a response from all doctors concerned is not consistent with the normal etiquette of communication between the laboratory service and patients. I acknowledge that some doctors have expressed to me their dissatisfaction with this decision indicating that a belief that the circumstances in this case did not justify this departure from normal etiquette. While my colleagues and I agree that this process was not ideal I can assure that the decision to contact patients directly was made in good faith, and it was not made lightly. We made every attempt to ensure that the contact was made with the greatest possible sensitivity and in a way that minimised intrusion into the important doctor-patient relationship. We believe that it was a reasonable decision in difficult circumstances however we are sorry to have caused such annoyance to any patients or to colleagues because of the decision.

I enclose a letter to the patient relating to this incident. If you feel that you are in a position to make contact with the patient and discuss this letter with them I would be very grateful. Otherwise _____ intends to send the attached letter to the patient in the next couple of days. Please feel free to call me if you wish to discuss this further

Thank you once again for your support to the patient and to the hospital during this very difficult process.

Yours sincerely

_____

Clinical Director Laboratory Medicine
Galway University Hospitals