The Royal College of Pathologists
Pathology: the science behind the cure

Review of the categorisation of discrepancies in histopathology

November 2008

Unique document number	G080
Document name	Review of the categorisation of discrepancies in histopathology
Version number	1
Produced by	The College's Professional Standards Unit and the Specialty Advisory Committee on Histopathology
Date active	July 2008
Date for review	~~July 2010~~ Archived July 2016 - This document is **withdrawn**. All content has been incorporated into College documents on performance: https://www.rcpath.org/profession/professional-standards/performance.html
Comments	In accordance with the College's pre-publications policy, this document was put on The Royal College of Pathologists' website for consultation from 14 July to 12 September 2008. 60 items of feedback were received. The authors considered them and amended the document accordingly. Please email publications@rcpath.org if you wish to see the responses and comments. **Professor Carrock Sewell** **Director of Publications**

The Royal College of Pathologists
2 Carlton House Terrace
London, SW1Y 5AF
Tel: 020 7451 6700
Fax: 020 7451 6701
Web: www.rcpath.org

Introduction

The classification of discrepancies/errors provided in the Royal College of Pathologists publication entitled 'Concerns about performance in pathology: guidance for healthcare organisations and pathologists' (2006) is:

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.

Recent cases of both alleged and proven poor performance have raised doubts about the appropriateness of this classification system. The Professional Performance Panel at its meeting on 10 May 2007 acknowledged the problem and requested that the SAC on Histopathology discuss this further and make recommendations. Recommendations were submitted to the Professional Standards Unit in November 2007. This paper summarises the proposals arising as a result of this work.

Definitions:

- A **discrepancy** can be defined as a difference of opinion between the original interpretation and the interpretation at review
- A discrepancy can only be considered an **error** when the discrepancy is confirmed by two independent reviewers.

Discrepancies are evaluated for two distinct purposes.

1. **Response to an expression of concern about a doctor's performance:** to ascertain if there is substance to concerns about a doctors performance, to identify where these concerns lie and what could be done about these concerns.
2. **Duty of care review:** to identify patients whose care may have been sub-optimal with a view to rectifying any deficiencies in care. This is usually undertaken when concerns about performance have been established.

A single classification system cannot adequately fulfil the differing needs of these two purposes.

In the context of a duty of care review the evaluation of the potential impact on clinical care of any discrepancy is an obvious and vital component. However, for performance assessment purposes the impact on clinical care is not a consistent or reliable measure of performance.

For example a diagnostic error might be so absurd that it would raise concerns about a pathologist's competence, but it might nevertheless have no possible impact on patient care. However, a very difficult diagnosis, where even experts disagree, might generate a completely understandable error from a competent pathologist that has a profound adverse impact on the patient.

The classification system has therefore been revised as follows in order to meet the needs of the two purposes defined above.

The remit of this document is limited to the classification of discrepancies/errors. It does not attempt to address how reviews should be set up or managed. That is the function of the College document 'Concerns about performance in pathology: guidance for healthcare organisations and pathologists' (2006)

The calculation of discrepancy/error rates by any classification system has severe limitations in measuring individual performance. Performance is a multi-faceted construct influenced by numerous factors. Error rates can be heavily influenced not only by the classification system but also by the characteristics of an individual's routine workload.

Consequently it is not possible in guidance such as this to define an 'acceptable error rate'. Judgement based on the circumstances of each individual case will inevitably be needed.

The classification of discrepancies as suggested below may help to identify underlying problems, but the pseudo-mathematical addition of numbers in different categories is strongly discouraged. Letters, rather than numbers, have been used to identify the categories with the specific intent of discouraging such manipulation.

In practice, it is likely that when cases are being reviewed it will be necessary to use both these systems, so that information will be generated that is relevant to an assessment of pathologist performance and also to patient management.

1. The categorisation of discrepancies identified through expressions of concern about a doctor's performance

The evaluation should be based on information and material available at the time that the report was issued. In the context of the evaluation of a doctor's performance, information which became available later is irrelevant, unless this information should have been actively sought before a report was issued.

Category (Expression of concern)	**Description**
A	**Inadequate dissection, sampling or macroscopic description** Where relevant, this should be assessed against guidance such as the College datasets and tissue pathways. It should be remembered that the pathologist issuing the final report may not have dissected, described and sampled the specimen.
B	**Discrepancy in microscopy** 1. A diagnosis which one is surprised to see from any pathologist (e.g. an *obvious* cancer reported as benign) 2. A diagnosis which is fairly clearly incorrect, but which one is not surprised to see a small percentage of pathologists suggesting (e.g. a moderately difficult diagnosis, or missing a small clump of malignant cells in an otherwise benign biopsy) 3. A diagnosis where inter-observer variation is known to be large (e.g. disagreements between two adjacent tumour grades, or any very difficult diagnosis) (Note: In deciding where a specific discrepancy lies in this classification, consideration should be given to the range of responses that might be expected if the case was used in a relevant interpretive external quality assessment scheme. (1) would be a surprising diagnosis even from one participant; (2) would be unsurprising from a small minority of participants; (3) would generate diagnoses so varied that the case could not be used for scoring purposes.)
C	**Discrepancy in clinical correlation** This would represent a failure to answer the clinical question (if clearly expressed on the request form), despite that answer being evident from the material available; or a failure to indicate that a specimen is clearly inadequate to answer the clinical question.
D	**Failure to seek a second opinion in an obviously difficult case** This could imply over-confidence
E	**Discrepancy in report** This would include typographical errors and internal inconsistencies or ambiguities in the report which should have been corrected before authorisation

2. The categorisation of discrepancies identified during duty of care review

When identifying discrepancies during a duty of care review all discrepancies should be categorised into one of the above 5 classes (A-E). However, each discrepancy should also be categorised as to the severity of the outcome on clinical care, as below.

The assessment of the severity of outcome on clinical care will require careful definition. It is based on professional judgement in the form of peer review. The reproducibility of this will need to be evaluated. Pathologists should recognise that they may be unable to provide a reliable evaluation of patient impact if working in isolation from the clinical context; collaboration with or review by relevant clinicians will be needed before plans for remedial action are initiated.

In this setting it is important to consider all available information, including information that becomes available after the original report was produced.

Category (Duty of care)	**Description** (with examples)
1	**No impact on care** • No harm: erroneous report not transmitted or received • Near miss: erroneous report received but ignored or disregarded
2	**Minimal harm (no morbidity)** • Delay in diagnosis only, <3 months • Unnecessary non-invasive further diagnostic efforts (e.g. blood sampling, radiograph, computed tomography) • Delay in therapy only, <3 months • Unnecessary therapy based on diagnostic error without morbidity
3	**Minor harm (minor morbidity)** • Delay in diagnosis only, >3 months • Unnecessary invasive further diagnostic efforts (e.g. biopsy, angiogram) • Delay in therapy only, > 3 months • Delay in therapy with minor morbidity e.g. unnecessary therapy
4	**Moderate harm (moderate morbidity)** • Moderate morbidity due to delay in diagnosis or therapy • Moderate morbidity due to otherwise unnecessary diagnostic efforts • Moderate morbidity due to otherwise unnecessary therapeutic efforts
5	**Major harm (major morbidity**) • Loss of limb or an organ or function of an organ system due to unnecessary diagnostic efforts • Severe morbidity due to delayed or unnecessary therapeutic efforts • Death

Definitions:
Minor morbidity indicates effects and events that can be demonstrated objectively and that do not require admission to hospital or surgical intervention for example, fever, thrombocytopenia, wound erythema, swelling.
Moderate morbidity indicates effects and events that require admission to hospital or surgical intervention, but do not result in dismemberment or loss of life.
Major morbidity indicates dismemberment, loss of an organ or the function of an organ system - an arm/limb, eye/sight, ear/hearing, speech, or the uterus of a woman of reproductive age).