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

# Guide to conducting an investigative audit of cellular pathology practice

## August 2017

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## 1 Introduction and purpose

**1.1** From time to time, an incident or index case may arise that raises concerns about a pathologist's practice. To ensure a high standard of pathology practice and to safeguard patients, a further investigation may be deemed necessary.

**1.2** It is not possible to draw conclusions about an individual doctor's practice from a single incident or case. For this reason, it is sometimes necessary to conduct an audit of a wider sample of past practice to investigate whether concerns can be substantiated.

**1.3** This guide has been prepared to assist employing organisations decide whether to undertake an investigative audit and to outline the process to be followed when commissioning such an audit.

**1.4** This document relates to cellular pathology practice. The principles may be relevant to investigative audit in other specialties, but the guidelines cannot be applied directly.

## 2 Definitions

### 2.1 Duty of care review

This is the process of systematic review of individual patient cases to ensure the patient has received the correct or optimal care where there is evidence of a poor standard of practice.

### 2.2 Investigative audit

An investigative audit scrutinises a sample of cases to establish if there are valid concerns about the performance of an individual. In the specific instance of cellular pathology, discrepancies or errors identified through audit should be classified according to The Royal College of Pathologists' system of categorisation, as described in the College's *Guide to conducting an investigative audit of cellular pathology practice*.

**2.3** A duty of care review and an investigative audit are different processes with different outcomes and should not be confused.

## 3 Background

**3.1** The Royal College of Pathologists has a Professional Performance Panel (PPP) that oversees College involvement in reviews of individuals or pathology services. The PPP is chaired by the College President, and its members include elected College Officers, the Director of Professional Standards, a lay member and any co-options needed to provide a sufficient range of professional representation.

**3.2** The Royal College of Pathologists will organise and undertake invited reviews under terms of reference agreed with the employing organisation (see *Guide to invited reviews,* (https://www.rcpath.org/profession/professional-standards/performance.html).

**3.3** The Royal College of Pathologists provides advice and support to employing organisations dealing with concerns about performance and when commissioning investigative audits or duty of care reviews.

**3.4** The Royal College of Pathologists does not itself undertake audits of practice or commission them on behalf of employing organisations.

## 4 Deciding if an investigative audit of practice is required

**4.1** From time to time, untoward incidents, errors and discrepancies in diagnoses arise. These can be identified or reported in a number of ways.

Employing organisations will have various processes for ensuring the patient concerned receives the appropriate care and for minimising the risk of the incident reoccurring, such as serious untoward incident (SUI) investigations, root-cause analysis, independent case review and case-note review guidance.

Once these processes have been followed, the employing organisation may have remaining concerns about the performance of the doctor concerned. The findings of a single incident or case, or a small number of incidents over a period of more than one year, are not sufficient to draw an accurate conclusion about an individual doctor's performance.

Where concerns remain about the individual doctor, employing organisations are advised to conduct an investigative audit of a sample of past cases.

## 5 Process for conducting an investigative audit

**5.1** A sample of cases will be re-reported by another reviewing pathologist, blind to the original report at the time of reporting. This may be an internal exercise conducted by another pathologist in the same department or a review commissioned from an external provider. Where a discrepancy is identified, the cases must be reported by a further pathologist (or pathologists) blinded to the original report and that of the first reviewing pathologist.

**5.2** Each discrepancy should be categorised according to The Royal College of Pathologists' system of categorisation, as described in Appendix 1.

**5.3** The College recommends that the pathologists appointed to undertake the investigative audit should:

- be in active practice as consultants with a valid licence to practice
- have expertise in the area(s) under review
- be participating in appropriate external quality assessment (EQA)
- be satisfactorily participating in CPD
- work in a UKAS-accredited laboratory, or make a declaration of the reasons why the laboratory is not accredited, that can be assessed for relevance to the proposed investigation
- be prepared to make a declaration of any involvement in complaint or litigation proceedings against them
- not currently be under investigation for poor performance themselves.

### 5.4 Sample selection

A representative sample (type, time, size) of cases must be selected. The precise nature of the concern may influence the sample of cases to be subjected to audit. The sample selection should be determined on a case-by-case basis. The College is able to provide case-specific advice to employing organisations on request.

**Type**

For example:

- if the concern relates to one or more areas of subspecialty practice, the investigative audit should be confined to cases in the area of concern
- if the concern relates to the application of a classification system or grading of malignancy, the investigative audit should be confined to these specific cases
- if the concern is of a broader nature, it may be necessary to sample a cross section of work.

**Time**

The period of time from which the cases are selected will relate to the concern.

For example:

- if the concern relates to a period of time in the past, possibly involving an external factor, the cases should be selected from this time
- if the concern relates to an ongoing issue (e.g. ill health), the cases should be selected from the recent past and should not predate the episode of ill health
- if the concern is not time-related, the cases should be selected from throughout a one-year period.

**Size**

In order to withstand scrutiny and challenge, the size of sample selected for an investigative audit needs to be justifiable. The College can assist in identifying appropriate sample size.

## 6 Reporting on the investigative audit

The results of an investigative audit must be presented in a single report to the body commissioning the audit. The following information and documentation are required for an investigative report:

- details of when the investigative audit was conducted, by whom and for whom
- summary of the process used
- list of cases selected for audit
- anonymised copies of original reports
- anonymised copies of the re-reported cases
- anonymised copies of the re-reported cases where discrepancies exist
- list of cases where discrepancies were identified and the categorisation of the discrepancy according to College guidance
- summary of the investigative audit results, i.e. number of cases, number of discrepancies broken down by category
- findings and conclusions.

Anonymisation in this context refers to the removal of patient-identifiable information; the laboratory number should remain.

### 6.1 What do the results of an investigative audit mean?

The investigative audit results may indicate:

- no cause for concern about standard of practice
- minor concerns, which may indicate sub-optimal practice
- significant cause for concern, which may indicate seriously sub-standard practice.

"No cause for concern" generally means that the number and type of discrepancies or errors identified is within the range anticipated of a competent pathologist. This does not mean there will be a complete absence of errors. A specific acceptable percentage of errors cannot be given, as this will vary according to the balance of any individual's practice.

"Minor concerns" may reflect numbers of errors/discrepancies that appear to be above those generally expected of a fully competent pathologist but are not sufficient in number and/or seriousness to raise significant concerns. Caution should be exercised in comparing results with colleagues in the same department. Problems may relate to behavioural considerations rather than pure competency issues and also affect more than one pathologist in a department. If there is any suspicion of such a systemic failure, commissioning of an external review may be advisable.

"Significant concerns" arise from the observation of errors that would be unexpected in any pathologist's practice (e.g. an obvious cancer being called benign). This may occur very rarely in any competent pathologist's practice, but a pattern of such errors is not acceptable. It is important to distinguish between serious errors that have little or no impact on patient care and minor discrepancies involving fine or legitimately contentious distinctions in interpretation (e.g. tumour categorisation). The latter can have a devastating impact on patients but cannot necessarily be regarded as indicative of incompetence.

All such judgements are essentially subjective. If difficulty is encountered in making these judgements the College may be able to advise and/or provide a written report on the interpretation of the investigative audit results.

## 7 Contacts

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## Appendix 1 The Royal College of Pathologists' system of categorisation for discrepancies

| Category<br>(Expression of concern) | Description |
|---|---|
| **A** | **Inadequate dissection, sampling or macroscopic description**<br>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. This category also includes failure to request further work (e.g. histological levels, immunostains) where these are clearly required to make a diagnosis. |
| **B** | **Discrepancy in microscopy**<br>1. A diagnosis that one is surprised to see from any pathologist (e.g. an obvious cancer reported as benign).<br>2. A diagnosis that 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).<br>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).<br>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 were 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**<br>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**<br>This could imply over-confidence or may be indicative of dysfunctional relationships within a department. It is important that any second opinion is clearly evidenced within the report. |
| **E** | **Discrepancy in report**<br>This would include typographical errors and internal inconsistencies or ambiguities in the report that should have been corrected before authorisation. It would also include cases where there is a suspicion that reports may have been allocated to the wrong patient, case mix-ups etc. |