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

Guide to conducting a duty of care review

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1 Introduction and purpose

1.1 Employers have a duty of care to those patients whose treatment or clinical management may need to be changed in the light of revised opinions arising from a review of a pathologist's or team's work. Ongoing review would normally take place through good clinical governance including regular audit, review of cases and internal quality processes, including appraisal. Where this has broken down, it may be necessary for a healthcare organisation to arrange a systematic review of cases to fulfil their duty of care.

1.2 This guide has been prepared to assist healthcare organisations to decide whether a duty of care review is indicated and to set out the process for commissioning such a review where necessary.

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.[1]

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 College's *Guide to conducting an investigative audit of cellular pathology practice*.[2]

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 healthcare organisation (see *Guide to invited reviews*).[3]

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

3.4 The Royal College of Pathologists does not itself provide a duty of care review service.

4 Principles of a duty of care review

4.1 Normally, a duty of care review should only be conducted when concerns or allegations about the performance of an individual or team have been substantiated.

4.2 If concerns are in the form of allegations, an investigative audit or referral to an alternative agency should be considered to substantiate the concern. It may be necessary to restrict practice whilst investigations are under way to prevent harm to patients.

4.3 The principle aim of a duty of care review is to detect and prevent possible harm to patients.

4.4 The healthcare organisation is responsible for organising, paying for and acting on the findings of the duty of care review.

5 Process for deciding if a duty of care review is indicated

5.1 Duty of care reviews are expensive and time consuming, so it is important to ensure they are entered into at the appropriate time and are properly conducted.

5.2 A duty of care review should be considered by the board of a healthcare organisation when a concern about performance is proven. Concerns may be established through a variety of investigative processes, including:

- investigative audit
- invited review
- performance assessment
- behavioural assessment
- occupational health assessment
- fitness-to-practise processes.

5.3 If a concern has been proven and it has the potential to impact on the care provided to a group of patients, a duty of care review will be required.

5.4 The outcome of the processes listed in 5.2 will inform the scope of the duty of care review required, by identifying the nature and extent of the concern(s) about practice. This may enable any necessary duty of care review to focus on, for example, specific areas of practice or specific periods of employment.

5.5 If the concern has not been proven, the healthcare organisation should consider immediate referral to another agency, further internal investigation or commissioning an investigative audit. Healthcare organisations are encouraged to seek advice from the Professional Standards Department of The Royal College of Pathologists at this stage.

6 Process for commissioning a duty of care review

6.1 The healthcare organisation should prepare a scope to inform the commissioning of the duty of care review. This should be based on the proven concern(s) and must outline what is to be reviewed, the order of the review to maximise patient benefit and reporting required including its timeframe.

6.2 The prioritisation of a review should normally take account of the seriousness of any potential outcome (e.g. cancer cases with significant risk of major morbidity or mortality). However, each situation may have unique characteristics which might influence prioritisation. Normally, it would be advisable to concentrate resources on reviewing more recent cases (e.g. within the past five years), where patient benefit is more likely to be maximised. Again, each situation may have unique characteristics which might influence prioritisation. Specialist advice from the Professional Standards Department of The Royal College of Pathologists should be sought.

6.3 The healthcare organisation is encouraged to seek advice from The Royal College of Pathologists on the scope before commissioning the review.

6.4 In order to deliver the duty of care review, the healthcare organisation may wish to undertake the review themselves, commission other pathologists or involve a pathology outsourcing company.

6.5 A formal contract should be agreed to establish the scope, payment schedule and the format and timing for reporting the findings.

6.6 Regardless of how the review is to be delivered, The Royal College of Pathologists recommends that the pathologists undertaking the duty of care review should be:

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

6.7 The healthcare organisation and the reviewers should ensure that the review is carried out in accordance with the GMC's guidelines on confidentiality.[4]

7 Overview of the principles for delivering a duty of care review

(details to be organised by the commissioning party)

7.1 The healthcare organisation must prepare the list of cases for review and provide associated documentation to the reviewers.

7.2 The reviewer should provide a new written report on each case. Each report should detail any changes from original report and should provide a discrepancy classification according to The Royal College of Pathologists' system of categorisation (please see Appendix 1).

7.3 All discrepancies identified by this process should be reported by two reviewers, initially blinded to the views of each other in order to confirm the error.

8 Contacts

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References

1. General Medical Council. *Good Medical Practice*, 2013. www.gmc-uk.org/guidance/good_medical_practice.asp

2. The Royal College of Pathologists. *Guide to conducting an investigative audit of cellular pathology practice*, 2014. www.rcpath.org/professional-standards/performance

3. The Royal College of Pathologists. *Guide to invited reviews,* 2014. www.rcpath.org/professional-standards/performance

4. General Medical Council. *Confidentiality*, 2009. www.gmc-uk.org/guidance/ethical_guidance/confidentiality.asp

Appendix 1

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).