1. Introduction and purpose

Everything that we do at the Royal College of Physicians (RCP) aims to improve patient care and reduce illness.

The Invited Service Reviews (ISR) was formed in 1998, and offers consultancy services to healthcare organisations on which they may require independent and external advice. One of the types of reviews the ISR offers are clinical record reviews (CRR), which offers independent expert opinion on the management of a specific case or series of cases. Generally speaking, the main reasons why CRRs are requested are due to the following:

- Concern that the practice of clinical medicine may not be in line with national good practice and guidelines
- Complaints made by the patient and/or their relatives
- Specific serious untoward incident(s) and/or aspects organisational care
- Concerns raised by colleagues and or members of the wider medical team.

By dealing with problems at an early stage, healthcare organisations may avoid the need to approach the General Medical Council, Care Quality Commission, Healthcare Inspectorate Wales or the National Clinical Assessment Service.

The purpose of a CRR is to analyse the clinical management of care and whether this meets the expected RCP or specialty association standards. The RCP works closely with the relevant specialty associations to deliver this work.

By the nature of the issues involved, each CRR is unique. We wish to ensure that the reviews are open and fair to all. This guide is designed to inform and assist all those involved in the review process.

2. Governance

The Invited Service Reviews is overseen by the ISR Oversight Group, and is made up of the medical director for ISRs and senior college representatives of the RCP. The group meets twice a year to discuss learning and experience from invited reviews, and any feedback which supports the improvement and development of the service. The college representatives also provide advice on the handling of reviews, support to the medical director and lead review visits.

Members of the Oversight Group and relevant specialty association representatives’ will quality assure all ISR reports.

3. When is a clinical record review inappropriate?

It is the role of the medical director to assess whether a clinical record review is likely to be beneficial to the healthcare organisation. The preliminary telephone discussion will indicate on the outset whether
the RCP will be able to offer assistance. However, there are some circumstances when a clinical record review would not be appropriate.

- When the General Medical Council, Care Quality Commission or National Clinical Assessment Service are in the process of an active investigation.
- When the Parliamentary Ombudsman Service has undertaken a review.
- Where it is judged that an individual physician’s competence or behaviour is so serious that the matter should be taken directly to the General Medical Council.
- When significant litigation is already in progress.

4. **Indemnity**

The healthcare organisation commissioning the review is required to indemnify the RCP, the specialist society/association and members of the review team by signing a Deed of Indemnity. A review cannot take place until a signed copy of the Deed of Indemnity has been received by the RCP.

5. **Review conditions**

In addition to the requirements and completion of the Deed of Indemnity, there are terms and conditions that are required for the review to proceed. By completing a request proforma and commissioning a review, it is understood that:

1. The Trust management of the healthcare organisation agree to the clinical record review taking place.

2. All those directly involved in the clinical management of the patient(s) is to be informed in advance of the purpose of, and arrangements for, the review.

3. Any action taken following a clinical record review is the responsibility of the healthcare organisation. The RCP, the specialty society/association and/or the reviewers reserve to themselves the right to disclose in the public interest but still in confidence to a regulatory body such as the General Medical Council, or the Care Quality Commission or any other appropriate recipient, the results of any investigation and/or of any advice or recommendation made by the RCP, the Associations and/or the Reviewers to the healthcare organisation.

4. The primary responsibility for sharing information about an ISR resides with the healthcare organisation. However, if the RCP is asked to confirm (by regulators) if a review has taken place it will do so. In such circumstances the RCP will also make contact with the organisation concerned and support them to be open about the circumstances of the review that has taken place.
5. The RCP expects the Trust management to share the final report with those who are directly involved in the clinical management of the patient(s).

6. Throughout the review process, all information that is created, stored and received in exchange between the RCP and the healthcare organisation must comply with obligations and confidence under the Data Protection Act 1998 and NHS Code of Confidentiality.

7. Upon completion of the review meeting the RCP will send an invoice to the healthcare organisation for the clinical record review fee and this will be paid in full prior to the delivery of the final report. In addition to the clinical record review fee the healthcare organisation is required to pay the meeting room, accommodation (if required), subsistence and travel expenses of the review team.

8. When the RCP makes a request for feedback on recommendations, the commissioning organisation will provide the RCP with an updated action plan or complete the progress form.

**Process – clinical record review**

**Initial contact – requesting a clinical record review**

Formal requests should be made by completing the RCP clinical record review proforma form by the medical director or chief executive and should be sent directly to the ISR coordinator at invitedreviews@rcp.ac.uk. The proforma form should include an accompanying letter formally requesting a review. Once a request has been received the ISR coordinator will arrange for a preliminary telephone call between the requestee and the medical director of ISRs.

The initial telephone discussion will enable the medical director to understand the background of the request and to give a decision as to whether the RCP is able to provide assistance.

The ISR team will liaise with the relevant specialty association to nominate suitable reviewers to undertake the review.

**Terms of reference**

When a CRR is considered appropriate and the RCP is able to offer assistance, terms of reference setting out the scope of the review are jointly agreed between the RCP and the medical director or chief executive of the healthcare organisation.

The aim of an RCP clinical record review is to provide an independent and expert view on the care provided based primarily on a review of the patient medical records. The RCP advises it is good practice that the commissioning organisation shares the terms of reference with the consultant physician(s) and the patient and/or their relative(s).
Remit of the review

Where clinical record reviews are requested as a result of a patient or patient family complaint, it is the RCP standard policy to not provide details of the clinicians asked to review the case. This is primarily to protect the reviewers from potentially being contacted directly and to ensure that all correspondence relating to the review is sent via the RCP. The same policy also applies to the names of our quality assurers.

In providing an independent and expert opinion on the clinical care provided to the patient(s), the review team focus primarily on the clinical notes available and to assess the standard of care against good practice and national guidelines. It is not our normal practice in such reviews, for members of hospital staff or relatives to be interviewed as part of this process. The RCP is not a body that arbitrates on individual complaints. As the commissioners of this review we would ask the healthcare organisation to liaise directly with patient(s) and their relatives on all matters relating to the review.

Composition of the review team

The composition of the review team will be dependent upon the terms of reference and the nature of the issues to be reviewed, but will normally comprise of a clinician/member of the ISR Oversight Group (lead and chair of the review) and two relevant specialists. The RCP works closely with specialty society/association in appointing the appropriate clinicians with the relevant medical expertise and knowledge.

Data collection and structured judgement tool

The review team undertakes the review of patient medical records using two structured judgement tools. The first tool is adopted from the RCP’s National Mortality Case Note Review (NMCRR) Programme\(^1\), where each phase of care is analysed and rated based on the information in the records. The reviewers will then make a judgement on the overall quality of care using the judgement tool adopted from the National Confidential Enquiry into Patient Outcome and Death (NCEPOD)\(^2\).

Patient medical records and background documentation

When agreeing the terms of reference the RCP may request additional background documentation if relevant to addressing the terms of reference of the review.

The medical director or chief executive of the healthcare organisation should make available the patient medical records and documentation required. These should be collated as soon as possible and sent to the review team members no later than 4 weeks prior to the review meeting taking place. All documentation should be sent by secure methods and this should be agreed with the ISR coordinator.

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\(^1\) [https://www.rcplondon.ac.uk/projects/outputs/national-mortality-case-record-review-nmcrn-programme-resources](https://www.rcplondon.ac.uk/projects/outputs/national-mortality-case-record-review-nmcrn-programme-resources)

\(^2\) [http://www.ncepod.org.uk/grading.html](http://www.ncepod.org.uk/grading.html)
All background information relating to the review that is created, received, stored or exchanged must comply and adhere at all times with the Data Protection Act 2008, information governance principles and NHS Code of Confidentiality including dealing with any confidential and personal information.

Any information identifying patients provided should, so far as possible, be anonymised.

The ISR coordinator will provide the healthcare organisation with specific guidance on how to collate and send the patient medical record(s).

**The review meeting**

The clinicians involved will first be asked to undertake an independent review of the patient medical record(s), before attending a review meeting with the chair. The purpose of the review meeting is for the chair and the reviewers to meet to discuss their findings and conclusions based on their analysis of the patient medical records. The meeting is usually held in our RCP, London offices.

**Written report**

Following the completion of the review meeting, the RCP aims to issue the final report as soon as possible and this is normally within 8-10 weeks. However, on occasion there may be a slight delay where this is the case the RCP will inform the healthcare organisation when they are likely to receive the report.

The patient medical records and any other background documentation will be relied upon in the writing of the report and addresses the terms of reference. Where the review team are making judgements about standards of clinical care or aspects of organisational care these will be where possible referenced to published standards documents within the specialty concerned. Where these do not exist, or the issues are more general, documents such as the GMC’s *Good Medical Practice* will be referenced.

The findings and conclusions of the report will be the independent, external opinion of the RCP.

Draft reports are quality assured internally by the ISR Oversight Group and representatives of the relevant specialty association. The RCP will then send the draft report to the medical director or chief executive of the healthcare organisation for correction of matters of fact. Draft reports are to be considered as confidential between RCP and the healthcare organisation and so are not for publication or disclosure.

Following any corrections of fact, the final report is issued and it is for the healthcare organisation to decide how the report should be used and who should see. However, the RCP expects that the report be shared with the consultant physician(s) and the patient(s) and their family.
**Recommendations**

Clinical record reviews are not regarded as a replacement, or negation for the healthcare organisation’s disciplinary procedures and own decision making. The review team analyses and makes judgements based on the information in the patient medical records, and to provide an overall perspective of overall the quality of care provided to the patient(s). The RCP has no statutory authority to implement actions following a clinical record review, and can only give advice and recommendations for consideration - it is for the healthcare organisation to decide on the most appropriate action. It must be emphasised that any action taken following a clinical record review is the responsibility of the healthcare organisation.

However, if a serious concern has been highlighted and no action is taken by the healthcare organisation it is open to the RCP review team to inform the General Medical Council or Care Quality Commission in accordance with their own responsibilities as registered medical practitioners.

The following advice or recommendations may be given, for example.

- Recommendation for the report to be discussed at a clinical governance meeting and consideration for a review of the relevant systems and processes.
- Recommendation for the report to be used as part of a clinician’s reflective practice.
- The healthcare organisation to reflect on organisational factors to mitigate current and potential future problems.
- Recommendation to review and/or update protocols and pathways to ensure these are in line with national good practice and guidelines.
- Sufficient concerns were highlighted from the review of the patient medical record(s) and the healthcare organisation should seek advice from the General Medical Council or National Clinical Assessment Service.

**Service evaluation and follow up**

**Service evaluation**

Following the issue of the clinical record review report, an online evaluation form is sent to the healthcare organisation for completion and return. A similar online evaluation form is also sent to the review team.

All feedback received is collated and reviewed by the ISR Oversight Group, and where necessary actions are made to improve the service.

**Follow up**

The follow up process indicates the final stage of the review.
Around six months after the final report has been issued the RCP will send a progress form to the healthcare organisation for an update to measure the outcome of the review, and whether recommendations made in the report have been implemented.

This provides an opportunity for the healthcare organisation to review progress following a clinical record review, and whether further assistance may be required.

**Sharing information with regulators**

The primary responsibility for sharing information about a clinical record review resides with the commissioning organisation. However, if a regulator has contacted the RCP to ask if a review has taken place we will confirm the name of the healthcare organisation and the medical specialty that was reviewed. In such circumstances the RCP will also contact the organisation concerned and support them to be open about the circumstances of the review that has taken place.
Clinical record reviews

Fee structure

Clinical record review fees cover administrative costs, reviewer fees, quality assurance and production of the report.

The fee for each clinical record review is calculated on a case-by-case basis. The total fee will take into account the quantum of medical records to be reviewed, complexity of each case, and if the review relates to any serious incident(s) or outcome of a serious incident investigation.

The reviewer fee is calculated at £450 per day.

In addition to the review fee, postage and packaging; travel expenses; meeting room hire costs and any other subsistence required for the review to take place must be met by the healthcare organisation.

Cancellation charges

In the event of cancellation the following charges will apply:

<table>
<thead>
<tr>
<th>Stage of invited review process</th>
<th>Cancellation charges</th>
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<tbody>
<tr>
<td>Once request approved</td>
<td>10% of fee charge + VAT</td>
</tr>
<tr>
<td>From when the review documentation (formal letter including deed of indemnity etc) sent to</td>
<td>25% of fee charge + VAT</td>
</tr>
<tr>
<td>healthcare organisation</td>
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<tr>
<td>30 days prior to the review meeting</td>
<td>25% + VAT</td>
</tr>
<tr>
<td>Postponement of review meeting date by the healthcare organisation</td>
<td>Any meeting room hire costs, and travel expenses incurred by the review team</td>
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<td></td>
<td>Plus reviewers fees for work already undertaken, travel expenses incurred, and room hire costs</td>
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