

# Guidance on conducting and deciding the outcome of single clinical incident provisional enquiries

## Introduction

- 1 The purpose of this guidance is to support the single clinical incident provisional enquiries team to:
  - a Assess whether an allegation can be treated as a single clinical incident provisional enquiry (SCI PE).
  - b To outline the information that can be sought as part of an SCI PE.
  - c To make a decision on action to be taken at the closure of an enquiry.
- 2 Decision makers may find it useful to consult the SCI PE tool and to consult supplementary guidance, including:
  - a *Provisional enquiries guidance (Rule (4)4)*
  - b *Guidance on categorising Stream 1 and Notify Employer/Notify RO*
  - c *Allocating cases to the National Investigation Team*
  - d *Guidance for decision makers at triage on assessing the suitability of allegations for a single clinical incident provisional enquiry*

## Definition

- 3 A provisional enquiry involves obtaining limited and targeted information at triage to help inform a triage decision about whether the information amounts to an allegation that a doctor's fitness to practise is impaired and therefore requires a full investigation.

- 4 The decision does not involve making findings of fact as a Medical Practitioners Tribunal (MPT) would, but is about assessing information to determine whether a concern amounts to an allegation of impairment.
- 5 A SCI will:
  - a Usually relate to the care of a single patient, and;
  - b comprise of a concern involving (only) a single consultation or clinical procedure.
- 6 An SCI may encompass a doctor's whole shift, where the SCI relates to the same clinical issue, e.g. where an obstetrician is alleged to have failed to monitor a CTG trace over several hours. However, allegations about two separate single incidents (i.e. about more than one consultation or doctor's shift) can't be considered an SCI.

## **Review of the triage decision: factors to consider in reviewing whether an SCI PE is suitable**

- 7 When the PE team receive an allegation from triage, the triage decision must be reviewed by an investigation manager (IM) to determine whether the allegation is suitable for an SCI PE.
- 8 The GMC's approach to fitness to practise investigations is influenced by case law. There are some cases in which we can properly conclude that an act of misconduct was an isolated error on the part of the medical practitioner and that the chance of it being repeated in the future is so remote that his or her fitness is not currently impaired. This was established in the case of *Cohen v GMC* [2008] EWCH 581 (Admin).
- 9 This takes into account firstly that the conduct which led to the charge is easily remediable, second that it has been remedied and third that it is highly unlikely to be repeated. This approach (generally referred to as the Cohen principles) allows us to take into account evidence of remediation during a SCI enquiry.
- 10 In order to assess whether an allegation is suitable for the SCI PE process, the assistant registrar should confirm the following:
  - a That the allegations are linked to clinical practice.
  - b That the concern, including any current open cases and/or previous history meets the S1 threshold.
  - c That based on the currently available information, including any current cases and/or previous history, the enquiry is a single clinical incident that, on the face of it, involves only one patient and a single consultation or doctor's shift.

- 11** If a concern is clearly an SCI suitable for a PE, it should be dealt with in the SCI PE process and not in the traditional PE process, as remediation cannot be assessed in the traditional PE process.
- 12** A case is unlikely to be suitable for the SCI PE process if:
  - a** From the currently available information the incident, while a one-off, is so serious such that regulatory action is likely to be required even if the risk of repetition is low. This is because failure to take action may impact on public confidence in the medical profession. This was established in the case of CHRE v NMC and Grant [2011] EWHC 927 (Admin). See paragraphs 56, 57, 58 and 59 for more information on these cases.
  - b** The case is not an SCI because there is a current open case and/or previous history that relates to a doctor's fitness to practise.
  - c** The case is not a single clinical incident because there are health/language concerns that meet the S35A threshold.
  - d** The case is not a single clinical incident because there are probity/misconduct/criminal issues that meet the S35A threshold.
  - e** There is a significant dispute of witness evidence that is relevant to the allegation (such disputes cannot be resolved at the PE stage).
- 13** The concerns are such that we would ordinarily close the case (i.e. rule 4(4) should not be used to validate a decision to close the case where the criteria for closure are met).
- 14** There is an existing investigation about the same doctor. If so, the allegation should be added to the existing case regardless of the nature of the concerns.
- 15** The incident giving rise to the allegation predates another concluded case about the same doctor and the concerns have been dealt with.
- 16** The concerns relate to systemic rather than fitness to practise issues.
- 17** For more detailed information on making a decision about whether an allegation meets the criteria for the PE SCI stream, please consult the following document:  
*Guidance for decision-makers at triage on assessing the suitability of allegations for a single clinical incident provisional enquiry.*

## Seeking information as part of an SCI PE

- 18** The following information may be requested as part of an SCI PE. Based on the nature of the allegations, the assistant registrar (AR) should determine what information should be sought during the course of a PE.
- 19** The type of information needed will depend on the nature and complexity of the SCI allegation(s), and the specialist input required.
- 20** The doctor must be notified before any external enquiries are carried out. Investigation managers can provide further advice on the type of information that can be sought during an SCI PE.

### Medical records

- 21** Medical records should be sought in the majority of SCI PE cases.
- 22** ARs should only request the specific information from the medical records that will help them to resolve the current concerns and close the enquiry, e.g. records relating to a particular time period. The AR should be able to justify why obtaining these records would be of use to an enquiry.
- 23** In SCI cases, specific types of information may need to be sought, e.g. information from a specific period of a CTG trace, or alternative types of medical records, including those from a care home etc.
- 24** It is particularly important to seek medical records in primary care cases as the responsible officer (RO) is less likely to be familiar with a particular incident, due to their distance from the location of care provision.
- 25** Medical records are also likely to be of use where the complaint or alleged chronology of events appears unclear or confused in places.

### *Exceptions*

- 26** Medical records may not need to be sought where a healthcare provider, regulator, or coroner has conducted a thorough review of the incident, and has shared a copy of a report relating to this review with the GMC.
- 27** In addition, it may not be necessary to seek medical records where a doctor has admitted their error, has not challenged the alleged chronology of events, and this has been documented.

## Medical case examiner advice and expert opinion

- 28** After obtaining medical records, given the clinical nature of these cases, it is likely the investigation officer (IO) will need to seek either the view of a medical case examiner (MCE) or an independent expert.
- 29** Medical CE or independent expert advisers are able to provide information on the seriousness of the incident in question, which will help the AR to assess whether the matter is egregious and is therefore unsuitable for a PE and needs to be referred for a full investigation.

### *Medical CE advice*

- 30** To help determine whether an SCI warrants investigation, a MCE can be asked to advise on whether the doctor's actions raise a question about their fitness to practise. Medical CE advice can be given in relation to general or specialist issues (where the CE has the appropriate specialism).
- 31** At this stage, the medical CE is not being asked to advise whether the RPT is met. Instead, the Medical CE should be asked to advise on whether the SCI appears to raise a significant issue.

### *Independent medical expert opinion*

- 32** An independent expert opinion should be considered in the following circumstances:
- a** Where we don't have specialist knowledge within the GMC.
  - b** Where a local investigation is inconclusive.
  - c** To clarify the seriousness of a particular error/complication (e.g. to determine whether the incident was within a normal error range or not).
- 33** The independent expert will provide a view on whether the complaint contains any information that suggests the doctor's actions meet the threshold for further investigation or whether they appear to be just below this standard.

### *Lay case examiner/in-house legal team advice*

- 34** The view of a lay case examiner or in-house legal team may also be sought where there is a lack of clarity relating to non-clinical aspects of the enquiry. At this stage, the CE or legal adviser is not being asked to advise whether the RPT is met but whether the complaint raises significant issues about the doctor's fitness to practise that should be investigated.

## **Responsible officers and designated bodies**

- 35** Enquiries made to the RO or employer liaison adviser (ELA) may provide further information on an incident.
- 36** ROs may also be able to provide an indication of expected timescales relating to any current local investigations.
- 37** If a doctor's deviation from local guidelines/protocols (where these are in place) forms part of the concerns raised about a doctor, copies of these guidelines should be requested from the RO. In general, unless it is clear they are likely to be provided imminently, an SCI PE should proceed without awaiting the outcome of a local investigation.
- 38** If an RO has alluded to remediation information but has not provided information of this in their response, the IO should contact the ELA for advice in the first instance. If the ELA is not aware of the specific details of the incident, it may then be appropriate to approach the RO directly.

### *Where a doctor has no responsible officer/designated body*

- 39** Where the doctor has no RO or designated body, or the incident occurred at a previous workplace, the IO may approach the organisation in question for further details.
- 40** Where an institution is not a designated body, the IO should first approach the relevant ELA for advice on employer disclosure. It may then be appropriate to write to the Chief Executive or Medical Director for further information.

## **Third-party enquiries**

- 41** ARs can seek information from third parties, e.g. HM Coroner. However, more than two third-party disclosures may mean that the matter would be more appropriately treated as a formal investigation.
- 42** If as a result of making third-party enquiries it is clear that an organisation with which a doctor does not have a prescribed connection holds relevant information (e.g. information relating to their own internal investigation), the AR should make an effort to seek this information.

## **Formal investigations by public bodies (e.g. other regulators, coroners, National Fraud Office)**

- 43** We may receive a complaint that concerns the outcome of a formal process. We should obtain a copy of the report if the complaint gives us reason to believe that the report will resolve the issue and the report has been produced by a credible body.

- 44** Given the timeframe of the provisional enquiry process, consideration should be given to whether or not the investigation is complete and, therefore, whether the report is likely to be available within the timescales for a PE.

### **Doctor comments**

- 45** Doctors don't have to comment on allegations during a provisional enquiry. However, there may be circumstances where the allegation can only be resolved by an explanation from a doctor.
- 46** Where doctor comments are sought, ARs should check that a doctor's explanation is consistent with the medical records relating to the incident.

### **Doctors in training**

- 47** Where an SCI PE relates to an alleged error committed by a doctor in training, the AR should take the following information into account.
- 48** As an RO is unlikely to be aware of the specific details relating to an alleged incident committed by a doctor in training, the AR should consider obtaining information directly from the organisation in which the incident took place.
- 49** When assessing remediation evidence relating to doctors in training, the AR should take into account any evidence of remediation provided by the doctor's educational and clinical supervisors.
- 50** If a trainee doctor has passed their Annual Review of Competence Progression (ARCP) in the time since an incident took place, an AR may also take this into account when weighing up evidence on remediation, but they should seek particular details relating to the incident in question.
- 51** Trainee doctors that are in permanent employment and a structured training environment are more likely to have effective structures in place to aid remediation.

## **Factors to consider when making a decision about an SCI PE**

- 52** Decision makers should consider the following factors when making a decision about an SCI PE.
- 53** Following an assessment of the evidence, decision makers should consider:
- a** Whether the incident, including any previous fitness to practise history and/or any current open cases meets the S1 threshold.

- b** Whether, taking into account any previous history and/or any current open cases, the enquiry can still be viewed as a single clinical incident, involving only one patient and a single consultation or doctor's shift.
- c** Whether any further allegations have been received.
- d** Whether the incident, while a one-off, is so serious such that regulatory action might be required even if the risk of repetition is low.
- e** Whether there is sufficient evidence of remediation.
- f** Whether there are any health concerns that meet the S35A threshold.
- g** Whether there are any probity/misconduct/criminal/language issues that meet the S35A threshold.
- h** Whether there is a dispute of witness evidence that is relevant to the allegation (such disputes cannot be resolved at the PE stage).

### **Threshold for investigation**

- 54** The SCI PE decision maker should determine whether, given the evidence received, the incident meets the threshold for investigation. If enquiries have clarified that the investigatory threshold is not met, the matter should be closed.

### **Single clinical incident**

- 55** Following a review of the evidence, a decision should be taken about whether the allegation should still be considered a single clinical incident.

### **Seriousness**

#### *Cases that raise public confidence issues*

- 56** The AR should consider the seriousness of the concerns. In SCI cases, the view of the Medical CE or independent medical expert will be particularly important in determining the level of seriousness of an incident.
- 57** There will be some allegations where the concerns are so serious that it will be clear that even though they relate to a single incident, action is required. This is because failure to take action in these cases would undermine confidence in the medical profession. Such cases would normally be referred directly to Stream 1. However, if information obtained in an SCI PE clarified that this issue falls into this category, referral to Stream 1 should be made following an SCI PE. These cases may also need immediate IOT referral.

- 58** In determining whether the concerns are so serious as to require a full investigation, we must ask, despite the evidence of remediation presented by the medical practitioner, whether a finding of impairment may still be required in order to uphold proper professional standards and public confidence in the individual and in the profession (CHRE v NMC and Grant [2011] EWHC 927 (Admin)). This principle should be considered in all SCI cases but is likely to be engaged in only a small number of cases where the seriousness of the error, or disregard for patient safety, appears to be 'gross', in the sense of outrageously or shockingly bad.
- 59** Those working at the GMC will, in the course of their work, see a volume of serious matters. The judgment as to whether the error in question is in this sense "gross" should be judged by whether a matter would be likely to be viewed as outrageously or shockingly bad by a reasonable, fair-minded and informed member of the public. In considering this at triage, if there is a likelihood that an error or disregard for patient safety could be considered gross, the matter should be referred to Stream 1 so that a case examiner can make a decision about whether the error or disregard for patient safety is such that action is required.
- 60** In practical terms at SCI, there are likely to be two situations where we conclude that, despite evidence of remediation, a Stream 1 investigation must be opened as there is a possibility that a finding of impairment may still be required in order to uphold proper professional standards and public confidence:
- a** When the suitability of a referral or complaint is being considered for the SCI PE process, if the information available at that point indicates that the seriousness of the error, or disregard for patient safety could be considered particularly gross (outrageously or shockingly bad) then a Stream 1 case should be opened.
  - b** When an SCI has been opened and a documented discussion or other independent evidence from the SCI PE process clarifies the seriousness of the error or disregard for patient safety are such that they could be considered to be particularly gross (outrageously or shockingly bad) then the case should be transferred to Stream 1.

*Cases that do not raise public confidence issues - remediation*

- 61** Most SCIs will not raise public confidence issues and therefore the principles outlined in paragraph 8 in relation to Cohen will apply.
- 62** When making a decision about whether an SCI allegation meets the investigatory threshold, the AR should consider whether a concern is remediable, evidence that remediation has been carried out and the likelihood of recurrence.
- 63** Remediation is where a doctor addresses concerns about their knowledge, skills, conduct or behaviour. It can take a number of forms, including coaching, mentoring,

training and rehabilitation (this list is not exhaustive), and where fully successful, will make impairment unlikely.

- 64** The AR should weigh the extent of the clinical concerns against the weight of the remediation evidence that is provided. For example, where an independent expert raises very serious concerns about a doctor's actions, more cogent evidence of remediation would be required than in less serious cases.
- 65** If the remediation evidence clearly shows that a concern has now been resolved and that therefore the allegation is not capable of supporting a finding of impairment, then an SCI PE enquiry may be suitable for closure.
- 66** However, evidence of remediation will be devalued in the following circumstances:
  - a** Where there is doubt about whether the alleged conduct is likely to be repeated (if repetition is likely, a Stream 1 investigation will be required).
  - b** Where the remediation evidence appears superficial (e.g. where evidence of remediation, such as an apology, only arrives a long time after the event took place, or re-training is not targeted or is superficial, such as an online CPD course).
  - c** Where the doctor's fitness to practise history may raise concerns about the effectiveness of any remediation.
- 67** In addition, if similar clinical concerns have emerged, this may indicate that the current matter is part of a pattern of poor practice rather than an SCI, and therefore remediation of the current matter may not be sufficient to address the issue. In this instance, the current matter may need to be reviewed as part of wider investigation into the doctor's fitness to practise.
- 68** Further information on remediation can be found in the following document: *Making decisions on cases at the end of the investigation stage: Guidance for case examiners and the investigation committee*.
- 69** Although this guidance is aimed at case examiners, the principles around the mitigating impact of remediation will remain the same.

### *Insight and apology*

- 70** Evidence of insight and apology into an error that has occurred should be viewed as the starting point for any consideration of remediation.
- 71** Expressions of apology can be considered as evidence of a doctor's insight into their error and can be used as part of any assessment of a doctor's remediation.

- 72** The AR may find it useful to consult the paragraphs on assessing insight in the *Guidance for decision makers on agreeing, varying and revoking undertakings*.

### **Health/English language/misconduct/probity/criminality concerns**

- 73** The decision maker should examine whether any evidence of health/English language/misconduct/probity/criminality concerns has arisen through the course of the enquiry which meet the investigatory threshold. If so, the matter cannot be considered to be an SCI (e.g. about a single clinical incident).

### **Links to open cases**

- 74** Although links to open cases are checked at the beginning of the SCI PE process, decision makers should check again at the end of the enquiry that no new cases have been opened. New cases are likely to indicate a wider pattern that suggests the current concerns about a doctor do not relate to an SCI, e.g. are not purely related to a single clinical incident, including where further concerns are not similar to the clinical incident.
- 75** Where a new case has been opened, the new enquiry should generally be joined to the existing case.

### **Receipt of new allegations**

- 76** Where new allegations have been made since the SCI PE was opened, decision makers should consider the impact of these on the SCI. Where the allegations are likely to meet the GMC threshold, it is unlikely that the fitness to practise concerns about the doctor can be treated as an SCI.

### **Information provided by an RO**

- 77** The AR should take into account any information provided by an RO, including information related to remediation and mitigation. This information should be considered alongside any other information that has been collected as part of the SCI PE process.
- 78** Where the RO is of the same speciality as the doctor under investigation, the decision maker may place greater weight on the RO's opinions about the clinical incident and the doctor's response.