

Agenda item:	5
Report title:	Outcome of the single clinical incident provisional enquiry pilot
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Action:	To consider

Executive summary

A report on the outcome of the single clinical incident (SCI) pilot. The paper includes an analysis of the outcome of provisional enquiries relating to the first 86 doctors whose complaints were included in the SCI pilot and have been completed. The paper also sets out our proposals to begin an extension to the project which will focus on expanding the pilot to include single clinical concerns.

Recommendations

The Executive Board is asked to:

- a** Note the outcome of the SCI provisional enquiries pilot.
- b** Agree the proposal to do further work on enquiries where the events are very recent (generally primary care) and extend the pilot for this purpose.
- c** Approve the draft decision making guidance attached at Annexes B1 and B2.

Outcome of the SCI provisional enquiry pilot

Issue

- 1** In 2015, following a pilot, we rolled out provisional enquiries (PEs) to better filter information prior to deciding whether to open a full investigation (Stream 1). The pilot targeted cases where it was clear that 1 or 2 pieces of information could determine whether there was an allegation of impaired fitness to practise.
- 2** In July 2016, we commenced a pilot to use PEs in cases involving a single clinical incident, ie an allegation of poor clinical care involving a single consultation or procedure.
- 3** The aims of the pilot were to determine if PEs are an effective mechanism for addressing single clinical incident cases and to assess the effectiveness and efficiency of the pilot model.
- 4** We have now completed SCI provisional enquiries relating to 86 doctors and present the findings from the pilot for consideration by the Board. The Evaluation Report is at Annex A. Guidance for triage staff and PE decision makers based on the pilot learning is at Annexes B1 and B2.

Pilot volumes and outcomes

- 5** Of the provisional enquiries completed, relating to 86 doctors, 69% were closed. When four cases that closed due to lack of consent to proceed are removed, the overall closure rate is 67% (58% primary care and 72% secondary care. The most common reason for promotion for full investigation was that we identified serious concerns in the information that we collected and remediation information to provide assurance that the concerns would not be repeated was not available.
- 6** As part of a lessons learned exercise we carried out further analysis of the PEs that were subsequently promoted for full investigation and where the investigation has concluded. Of 11 concluded investigations, all but 1 closed with no further action (3 of those were closed with advice). In all, the information necessary to close the case was not available at triage. 6 of those closed cases received a critical expert report in Stream 1 (S1) and were primary care cases where the incident was not known locally at the PE stage and remediation information was not therefore available at that stage. As the numbers of cases that have concluded in S1 following the pilot are low we propose to continue to monitor these to identify any future learning.
- 7** While a 67% closure rate is adequate, since the evaluation was conducted performance has reduced, with the current closure rate running at 61%. Given that cases referred to S1 following a PE have experienced a two month delay, a closure rate of 61% is not ideal.

- 8** Part of the pilot has involved developing our thinking about the threshold for referral of an SCI direct to S1 on the grounds that, even if a one-off, we should consider action on public confidence grounds. While that learning was underway, staff took a more cautious approach to referral to S1 and this may be a key factor in the reduced closure rate. We have now completed our threshold review and more detailed guidance to staff is contained in the attached guidance. This guidance is likely to increase the closure rate to a similar level to the pilot evaluation cases but we will keep this under review.
- 9** It is worth noting that PE in SCIs in primary care performs far less well than secondary care (58% compared with 72% closure rate). This is due to how recent most of the complaints we receive about primary care are and the lack of close engagement that ROs have with the doctors for whom they are responsible. This affects getting meaningful feedback from Responsible Officers (ROs) at the PE stage about the seriousness of the incident and the doctor's response to the matter and this has a significant impact on the overall performance of the pilot.
- 10** We propose to extend the pilot to do some further work to consider if there are ways to further filter SCI cases based on how recent the events complained about are to see if we can improve the closure rate of PE in cases relating to primary care.

Quality of decision making

- 11** To ensure the quality of outcomes, a QA audit was conducted. The QA team commented:

'In every case, we found that the correct decision had been made (in line with the guidance). Moreover, we found that the decision rationale in every instance was excellent and, in many cases, exemplary.'

- 12** One case that was closed in the SCI PE pilot was referred to Rule 12 and reviewed. The review upheld the SCI PE decision to close the case.

Process duration and effectiveness

- 13** The median duration of the completed SCI PEs was 66.5 days, which compares to 245 days for formal investigations. Cases completed on the basis of feedback from ROs are faster and the median duration for those cases is 64 days. The need to seek medical case examiner or expert advice adds to case length.
- 14** Feedback from ROs obtained via the Employer Liaison Service was very positive about the new process. We have also received positive feedback from medical defence organisations. Feedback from the staff who conduct patient meetings is that complainants appear in general to be satisfied with the approach but that meetings are much shorter because they have lower expectations at this stage. One

of our concerns about promoting these cases to S1 was raising expectation which, as our data shows they have very high closure rates, were generally not met. It would appear that the process helps to avoid that.

Assessing the costs and benefits of the provisional enquiry process

- 15** The key benefits of the provisional enquiry process are resolving complaints quicker which reduces the impact on complainants and doctors and targets our resources on the complaints that require full investigation.
- 16** However, we are also responsible for ensuring that we use our resources efficiently and effectively and in view of this we assessed the cost/benefit of the new process. The cost benefits of SCI PEs are similar to traditional PEs. Based on the pilot evaluation, SCI PEs should deliver a cashable cost saving in saved expert fees of £32,712 p.a.
- 17** In addition, given closure rates, 118 full investigations per annum should be avoided, saving staff resource. We propose to do more work to establish the staffing requirement for a business as usual SCI PE model and will be able to specify such staff time savings in the future. Should we increase closure rates as a result of our work on better filters for recent complaints then the cost benefit will improve.

Scenarios and approaches tested

- 18** During the pilot we have tested different approaches. Where a doctor had an RO and there was also an RO at the incident location we tested whether communicating directly with the incident location RO as well as the doctor's RO was beneficial. Although there was not significant measureable benefit, direct communication with incident location ROs was significantly preferred by ROs and GMC staff. We also tested whether employer liaison advisers (ELAs) approaching ROs to raise queries about SCIs improved response quality and times and it was found that there was no benefit from that approach. While we propose to extend the pilot to further test filtering of complaints, we propose that as we now have clear evidence about the performance of the scenarios tested, that going forward from this point we seek direct communication with incident location ROs and discontinue using ELAs to approach ROs to raise queries about SCIs.

Longer term aims - single clinical concerns

- 19** Once we have completed work to improve the filters for primary care cases and once SCI PEs are fully implemented (assuming the Board approves roll out in due course), we propose to develop and launch a pilot of using provisional enquiries to consider single clinical concerns (more than one procedure or consultation but confined to a single course of treatment by a single doctor).

- 20** Our data does not allow us to report reliably on the number of single clinical concerns we investigate but from previous sampling undertaken we believe, together with single clinical incidents, it is between 15-20% of S1. Like single clinical incidents these cases can typically take around 183 to 234 days to complete with over 90% of these concluding with no further action being taken against the doctor. As such they can cause stress and inconvenience for both doctor and complainant alike and do not represent the best use of our investigation resources.
- 21** This work is part of a wider programme of reform to ensure that we focus our activity on those cases that require action in the public interest.

Supporting information

How this issue relates to the corporate strategy and business plan

- 22** Strategic Aim 3: to improve the level of engagement and efficiency in the handling of complaints and concerns about patient safety.

How the issues support the principles of better regulation

- 23** Provisional enquiries have been shown to deliver a more proportionate, targeted response to complaints received and better allocation of our resources ensuring that we continue to investigate thoroughly complaints that raise serious concerns about a doctor's fitness to practise.

How the action will be evaluated

- 24** Within this paper we have presented our findings from an analysis of the first 86 completed provisional enquiries. We have considered the process duration, the effectiveness of the process, the quality of the outcomes.

What engagement approach has been used to inform the work (and what further communication and engagement is needed)

- 25** Prior to the launch of the pilot we discussed our approach with a number of external stakeholder groups including medical defence organisations, the BMA and, through our employer liaison advisers, Responsible Officers. We will update our key groups on the outcome of the pilot.

What equality and diversity considerations relate to this issue

- 26** As 67% of SCI PEs closed at triage, this approach benefits doctors over-represented in our procedures by reducing the need for S1 investigations.

Annex A

General
Medical
Council

Piloting Provisional Enquiries for Single Clinical Incidents

Executive Report – September 2017

Working with doctors Working for patients

Contents

- Success of pilot
- Effectiveness of PE SCI enhancements
- Success of options tested
- Cost/benefit
- Learning to be incorporated into roll out
- Recommendations

General Medical Council

Glossary

AoI – Allegation of Impairment

AR – Assistant Registrar

BAU – Business As Usual

DD – Documented Discussion

DB – Designated Body

ELS - Employment Liaison Service

ELA - Employment Liaison Advisor

F2F – Face to Face meetings

FtP – Fitness to Practise

GMC – General Medical Council

IL-RO – Incident Location Responsible Officer

MCE – Medical Case Examiner

PDL – Patient and Doctor Liaison

PE – Provisional Enquiries

PLOs – Patient Liaison Officers

PID – Project Initiation Document

RIT – Regional investigation Team

SCI – Single Clinical Incident

SCC – Single Clinical Concern

SLA – Service Level Agreement

RO – Responsible Officer

SCI enquiry – an enquiry forwarded from Triage potentially concerning multiple doctors.

SCI case – a single case about a single doctor when a decision has been taken to process via SCI.

Executive Summary

- The SCI process has been successful in delivering the stated aims of the pilot (SPB July 2015).
- The process provides an effective mechanism to address a cohort of concerns that previously would have been promoted to Stream 1 investigation, although effectiveness affected by how recent events were that led to complaint.
- Overall, the pilots cases were completed in similar timescales to existing PE process; but slightly longer.
- Audit of decisions found the outcomes and recorded decisions to be of a high quality.
- Enquiries involved:
 - ROs providing details of local investigations and details of remediation;
 - Medical records and documented discussion with experts;
 - Discretion in the pilot to consider remediation in deciding whether the GMC threshold is met.
- Using the ELS to facilitate communication with ROs in SCI process does not improve timeliness or quality of RO response when compared with requests sent directly by Triage team.
- Those SCIs where we do not need to obtain expert clinical opinion, conclude significantly quicker than those where expert input needs to be obtained.
- For rollout more formal guidance based on learning from the pilot is needed to support consistency before senior management oversight is removed (pilot was designed to inform such guidance).

¹ The scenarios reflect the differing circumstances of doctors in the pilot. Where doctors have an RO and there is also an incident location RO we piloted two options to test which was the most effective (scenarios 3 and 4).

Success of Pilot

Closures

- 67% of cases included in the pilot were closed with no further action (72% secondary care and 58% primary care). 48 had documented discussion with external expert. 28 of those closed as beneath investigatory threshold.

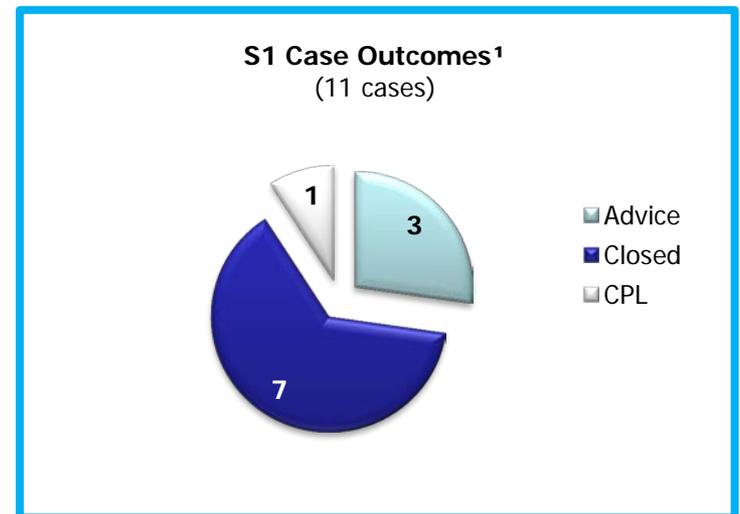
Timeliness

- Median time to complete SCI PE is **66.5 days**¹ (245 days for formal investigations).
- DD/MCE advice adds to case length. Median time for cases closed due to feedback from ROs was 64 days.

Quality

- QA team (SCI decisions audit April 2017) commented: *'In every case, we found that the correct decision had been made (in line with the guidance). Moreover, we found that the decision rationale in every instance was excellent and, in many cases, exemplary.'*

- 1 SCI had Rule 12 review - SCI decision upheld.
- Analysis of 10 cases closed with/without advice in S1 - 6 received critical S1 expert report³ were **primary care, hadn't been through local processes** and evidence of **remediation** not available at PE stage. Further analysis required for when greater numbers of referred SCIs have resolved at Stream1.

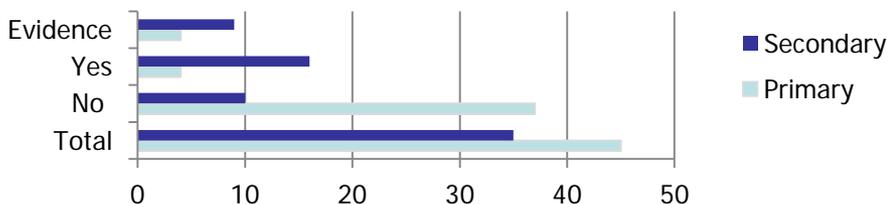


¹ - This reduced after late October 2016 when the pilot team started requesting medical records earlier in the process.

The SCI model enhancements

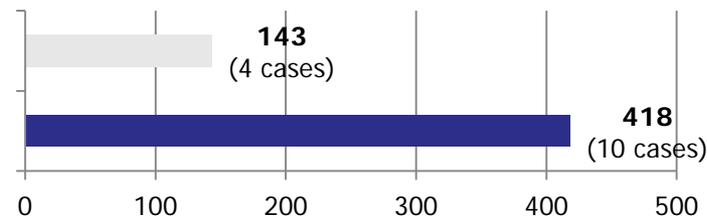
- 11 SCIs closed without approaching independent clinical expert based on information about doctor remediation provided by RO and ability to consider this in decision making at PE (13 of the pilot’s SCIs).
- ROs unaware of incidents disclosed to them 57% of time; low feedback rate expected to improve as local procedures adapt to SCI PE approach.
- Average time to receive RO response to our prescribed questions across all scenarios 14.1 days (80 doctors) – on average 19 days when holding information about incident; vs. 10 days when unaware.
- ROs in secondary care cases more likely to have prior knowledge of SCI than primary care (71% v 18%); and more likely to provide evidence of remediation in response (26% v 9%).

Awareness of RO of incident per SCI case



- In those SCIs where RO not aware of incident closure rate is 65%; when the RO is aware increases to 74%.

Mean days incident > complaint when RO is aware of incident and provides remedial info

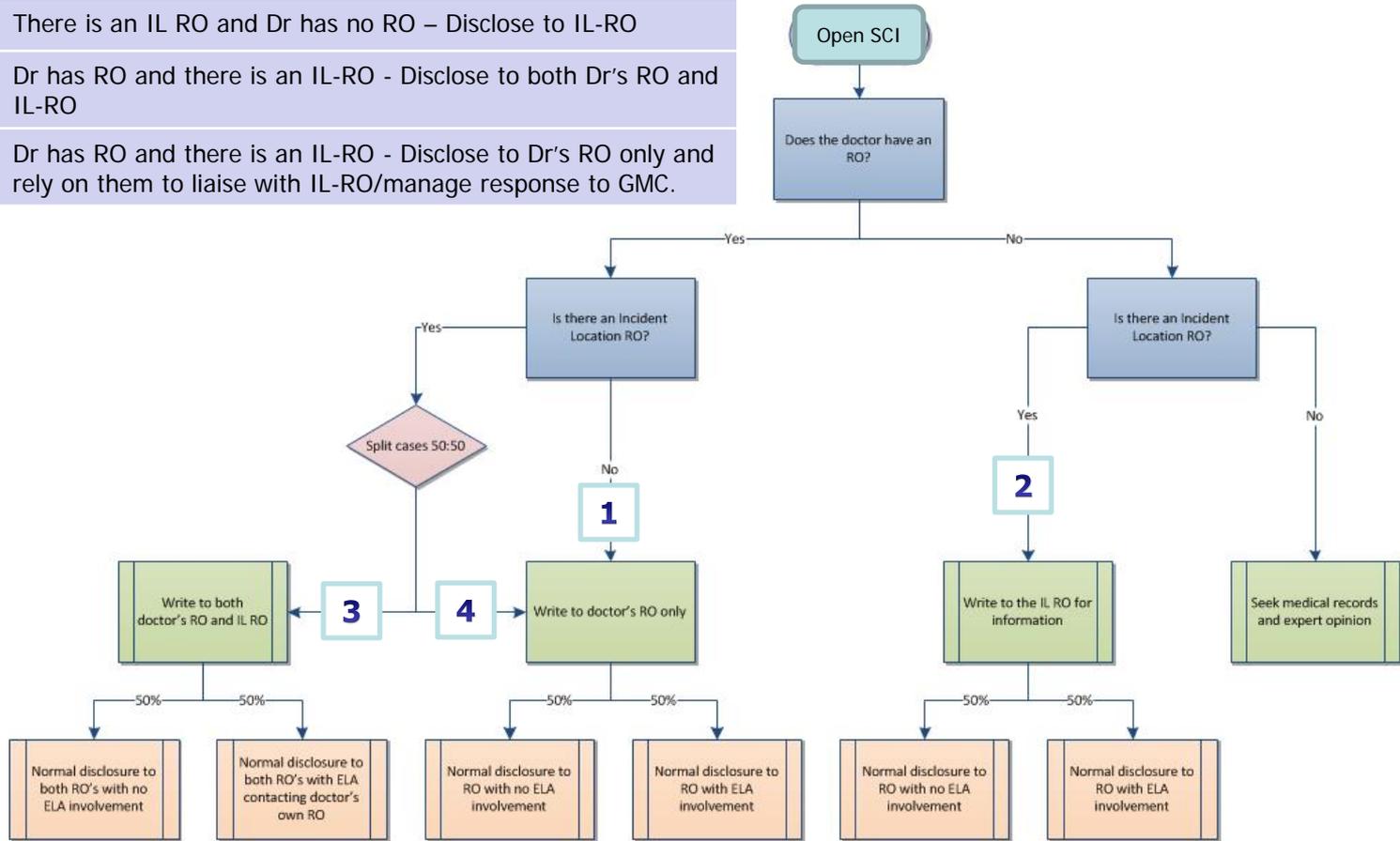


- Primary-care SCIs reach GMC far quicker than secondary-care SCIs, which decreases likelihood of availability of local investigations and any subsequent remediation undertaken by doctor.
- An additional AR review of all SCIs found in **around 25%**, traditional PE process would not have provided tools to address concerns at the triage stage¹. This is result of access to information about remediation from doctors’ ROs and our discretion to assess that information at triage.

¹ - Some, but not many, of these cases could have been included in traditional PE. A small number of closed cases were referred to the Notify RO Process to ensure minor concerns were considered in future appraisals.

Background – pilot process

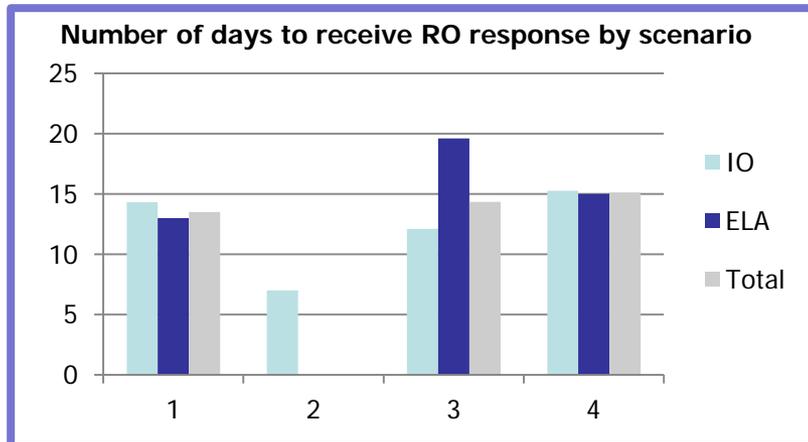
Scenario 1	Dr has RO and there is no IL-RO - Disclose only to Dr's RO
Scenario 2	There is an IL RO and Dr has no RO – Disclose to IL-RO
Scenario 3	Dr has RO and there is an IL-RO - Disclose to both Dr's RO and IL-RO
Scenario 4	Dr has RO and there is an IL-RO - Disclose to Dr's RO only and rely on them to liaise with IL-RO/manage response to GMC.



Success of Scenarios Tested

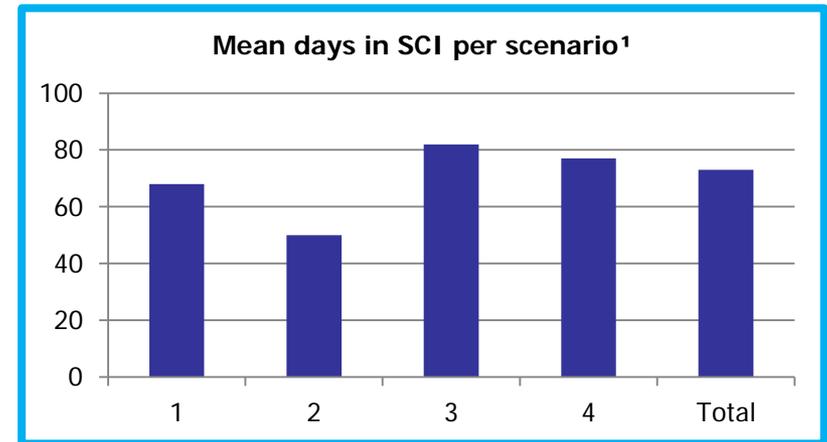
Testing ELA involvement

- No significant difference in timeliness of RO response or duration of SCI between those facilitated by ELA and those following standard process via investigations staff.



- Of total SCI cases, ELAs had prior knowledge in only 3 incidents; prior knowledge of those 3 did not speed up outcome.
- Closure rate for ELA facilitated SCIs was lower than for those that were investigation facilitated.

Testing communication solely with Dr's RO (scenario 4) vs. also with incident location RO (scenario 3)



- Anecdotal feedback from ROs via ELAs on scenario 4 considered it burdensome and confusing:

'adherence to only contacting the doctor's RO as a first line approach does not work in those complaints that relate to doctors with different employment / workplace and RO connections (e.g. trainees, locums etc.)'

Similar concern from investigative staff.

¹ - Data on scenario 2 relates to only 1 SCI case.

Cost / Benefit

- Fiscal benefits from adopting SCI will broadly correlate with savings offered by standard PE³ in comparison with Stream 1.
- Pilot cases reviewed cover a 6 month period so assumption of 172 SCI PEs p.a involving 92 documented discussions.
- Given closure rate of SCI PES, 118 S1 investigations avoided p.a. saving significant staff time.
- In relation to cashable savings on expert costs; cost of documented discussions in SCI £27,600² compared to cost of £60,312 formal expert reports for those cases where S1 referral avoided; net saving of £32,712.

¹ - as of 18/05/2017

² - DD cost is usually £300

³ - *Outcome of the first phase of the provisional enquiry pilot*, GMC Strategy and Policy Board, July 2015

Learning to be incorporated into roll out

- Our experience in SCI has highlighted several lessons and areas where guidance can be expanded:
 - Information on remediation required to mitigate FtP concerns and relationship with severity of the clinical issue and extent of doctor's culpability.
 - Consideration of doctor's previous FtP history, current open cases, conflicting witness evidence and thresholds relating to seriousness.
- Policy guidance is being developed to clarify these issues and support consistency of our approach.
- Along with policy guidance, enhanced decision making tools have been developed based on the pilot's learning, to replace the daily review meetings - it is likely further time savings will be achieved by this.
- The opportunity for increasing cohort of closed SCIs lies in communication to ROs, MDOs and doctors of value of remedial information and evidence in early stages of SCI complaint/referral.
- Further exploration of the poor performance of the pilot model in primary care is needed.
- A review of use of patient meetings in PE cases to be carried out to consider best model. Analysis and feedback have raised questions about effectiveness of traditional approach.
- ELS feedback proposes changes to storage of notes of RO meetings to enable investigation staff to access.
- Positive feedback from investigations staff of value of increased access to senior and clinical GMC staff in pilot. Review of how to provide that post-pilot.

Recommendations

1. Introduce SCI pilot process with decision making tools, detailed guidance and senior input via weekly meeting.
2. Re test of scenarios 3 and 4, **opt for scenario 3**. Monitor post-pilot.
3. Discontinue using ELAs to approach ROs, but as per interim evaluation, review use of ELA notes at triage.
4. Value of early remediation information to be raised with ROs, MDOs and doctor representative groups.
5. Continue to seek medical records at outset of every SCI unless specific information to suggest of minimal value.
6. Further develop and refine the SCI proforma including considering tailored primary and secondary care forms.
7. Review model for patient meetings at PE.
8. Review feedback from staff for detailed improvements.
9. Review challenges experienced in cases involving primary care and consider any improvements.
10. When more cases referred to S1 have been concluded, review any learning for the SCI PE model.

Annex B (1): Guidance for decision makers at Triage on assessing the suitability of allegations for a single clinical incident provisional enquiry

Introduction

- 1 The purpose of this guidance is to help decision-makers at Triage identify single clinical incident (SCI) allegations that are suitable for a single clinical incident provisional enquiry (SCI-PE).
- 2 The guidance will set out the factors to consider when making the decision to define an allegation as an SCI at Triage and provide information on the circumstances in which an SCI allegation is suitable for an SCI-PE, or whether disposal by other means should be considered.
- 3 Decision-makers at Triage may find it useful to review the SCI/PE tool and to consult supplementary guidance, including:
 - a *Provisional enquiries guidance (Rule 4(4))*
 - b *Guidance on categorising Stream 1*
 - c *Allocating cases to the National Investigation Team*

Definition

- 4 An SCI will usually:
 - a relate to the care of a single patient, and;
 - b comprise of a concern involving (only) a single consultation or clinical procedure.
- 5 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 procedure or doctor's shift) can't be considered an SCI.

Factors to consider in determining when an allegation is suitable for an SCI PE

- 6** 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 (Cohen v GMC [2008] EWCH 581 (Admin)).
- 7** 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 principles of Cohen) allow us to take into account evidence of remediation during our Single Clinical Incident (SCI) Pilot.
- 8** An SCI on its own (unless it is very serious) is unlikely to lead to a finding of impairment, providing the doctor has taken appropriate follow-up action and therefore most SCIs are suitable for a PE. There are however some factors that would render an SCI unsuitable for a PE.
- 9** In deciding whether an SCI is suitable for an SCI PE, decision-makers should take the following factors into account:
 - a** Whether the allegations are linked to clinical practice.
 - b** Whether the concern, including any current open cases and/or previous history, meets the S1 threshold.
 - c** Whether the inquiry is a single clinical incident, involving only one patient and a single consultation or doctor's shift.
 - 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 are any health concerns that meet the S35A threshold.
 - f** Whether there are any probity/misconduct issues that meet the S35A threshold.
 - g** Whether there is a significant dispute of witness evidence that is relevant to the allegation (such disputes cannot be resolved at the PE stage).

10 A PE is unlikely to be appropriate where:

- a** The allegation is so serious that it will be clear that a full investigation will be required.
- b** 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).
- c** An enquiry is linked to an existing investigation, where it may be more suitable to link the allegation to the existing case.
- d** The incident giving rise to the allegation predates another concluded case about the same doctor and the concerns have been dealt with.
- e** There is a significant dispute about the facts or an allegation of dishonesty that can only be resolved by establishing credibility through witness testimony or otherwise cannot be resolved by obtaining a discrete piece of information.
- f** The concerns relate to systemic rather than fitness to practise issues.

Determining whether the allegation meets the threshold for Stream 1 investigation

- 11** For a case to be suitable for an SCI PE, it must meet the threshold for investigation into a doctor's fitness to practise, as set out in section 35C(2) of the Medical Act 1983. In making this assessment, it may also be useful to consult further guidance (see the introduction of this document for further details). If there is sufficient information to close a matter at Triage because it does not meet the investigation threshold, the PE process should not be used to obtain more information. The PE process is only suitable for those cases that meet the investigation threshold and/or where there is insufficient information about a serious matter to be able to close the complaint.
- 12** If it is unclear whether the allegation should be closed, promoted to Stream 1, or referred as a PE/SCI PE, the AR may seek further information to assist in making a decision. For example, the AR may approach the complainant to:
 - a** identify relevant doctors
 - b** obtain any missing documents
 - c** seek clarification of places and dates.
- 13** Further information can be sought in the Triage operational manual.

Ambiguity over the nature of clinical concerns

- 14** Where there is ambiguity over the nature/seriousness of clinical concerns, the AR may also seek the view of a medical case examiner (MCE).
- 15** MCE advice may be of particular use in the following situations:
 - a** To provide information on the frequency of a particular complication (resulting from a procedure/drug).
 - b** To assess the significance of drug-reported side effects.
 - c** To help clarify the responsibility of each doctor in multi-doctor enquiries.

Ambiguity over the nature of non-clinical concerns

- 16** The view of a lay case examiner may also be sought where there is a lack of clarity relating to non-clinical aspects of an allegation.

Previous history

- 17** A doctor's previous history should be taken into account when determining:
 - a** whether a current allegation meets the threshold for Stream 1 investigation, and;
 - b** whether the current allegation can be considered an SCI.
- 18** When considering a doctor's fitness practise history, decision makers may find it useful to consult GMC *Guidance for decision maker on when to take a doctor's fitness to practise history into account*.
- 19** Where a doctor has a history of FTP allegations, it is unlikely that the allegation will be suitable for consideration under the SCI PE stream. For example, if a doctor has received previous FTP action as the result of allegations which are similar in nature to those which are currently under assessment, then it is unlikely that the case can be viewed as an SCI. This is because multiple similar concerns may indicate a repetition of clinical failings.
- 20** A previous similar allegation, resulting in FTP action, may also mean that the current allegation is viewed in a more serious light as the repetition of an incident may indicate a lack of insight/remediation, and/or a pattern of concerns.
- 21** For example, where a doctor has a number of previous complaints of clinical under-performance that have been closed as insufficient to amount to misconduct or deficient professional performance or isolated clinical incidents/concerns which were insufficient to amount to impairment. These previous incidents, in light of the current

allegation, could be sufficient to give rise to an allegation of deficient professional performance where:

- a** The previous allegation is similar to the current allegation and/or paints a pattern of concern that, in totality, could give rise to an allegation of deficient professional performance. Low levels of poor performance, which of themselves might not reach our threshold, can accumulate, and together meet the threshold.
- b** The reason that the previous case was closed relates to seriousness rather than the credibility of the allegation. Where the previous matter was closed because there was insufficient evidence to support it, it would not be appropriate to take it into account, without new evidence to reopen it under Rule 12. If however there was sufficient evidence to support it and it was closed on the grounds that it was insufficiently serious in itself to meet the threshold, then, as evidence of a pattern, it may be relevant to the current allegation.
- c** An apparently single clinical incident or concern and a previous a clinical incident has been closed on the grounds it was an isolated incident (i.e. unlikely to recur). If a doctor has a previous history that relates to clinical practice it will not be appropriate to consider a new matter as a single clinical incident unless the previous matter was found not proved or was a significant time ago or where the nature of the incidents are very specialised and completely unrelated.

22 Where a doctor has received previous allegations or regulatory action that is not connected to the current allegation, the allegation may be suitable for an SCI PE.

23 For further information, please see the *Guidance for decision makers on when to take a doctor's fitness to practise history into account*.

Links to open cases

24 In determining whether an allegation can be treated as an SCI, the Triage AR will also need to consider whether there are any links to open cases.

25 Where there is an existing open case, the current allegation should be joined to it, meaning that it would not be suitable for an SCI PE. This is particularly important where the current allegations are similar to those in the open case. However, this principle may be applied to all cases because it is important to consider a doctor's fitness to practise as a whole.

26 Where a case is at a critical point, e.g. it is about to go to Tribunal, or a Tribunal has already commenced, it may not be possible to join the cases.

27 Where an allegation cannot be joined to an existing case, the Triage AR must still consider the impact that the open case has on the current allegation. For example, it

would not be appropriate to consider an allegation within the SCI PE process if we have a current ongoing case that relates to clinical practice.

Health concerns

- 28** Where an allegation includes both clinical practice and health concerns, the enquiry will not be suitable for a PE SCI where the health allegations meet the threshold for Stream 1 investigation.
- 29** If the health concerns do not, at the outset, meet the threshold for Stream 1 investigation, and there are no other concerns in relation to the SCI, then the enquiry may be suitable for the PE SCI stream.

Misconduct/probity

- 30** Where an allegation includes both clinical practice and conduct concerns, the case would not be suitable for an SCI PE. Examples of this include:
- a** Removal of life supporting treatment despite knowledge of a family seeking a court order.
 - b** Refusal to provide treatment due to a disagreement about lifestyle choices.
 - c** Subsequently amending a consent form after a procedure has taken place.

Seriousness

- 31** There will be some allegations where the concerns about clinical care are so serious that it will be clear that, even though they relate to a single incident, a full investigation is required. These cases may also need immediate IOT referral.
- 32** 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 reckless disregard for patient safety, must appear to be 'gross', in the sense of outrageously or shockingly bad.
- 33** 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 is 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 reckless 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 is such that action is required.

- 34** In practical terms at SCI, there are likely to be two situations where we conclude that, despite the evidence of remediation that could be obtained, 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 SCI, if the seriousness of the error, or reckless 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 expresses very serious concerns about the seriousness of the error, or reckless disregard for patient safety such that they could be considered to be particularly gross (outrageously or shockingly bad) then the case should be transferred to Stream 1.

Disputed witness evidence

- 35** If there is disputed witness evidence that is material to the allegations that meet the threshold for investigation, then the case cannot be considered under SCI PE because such disputes cannot be resolved at Triage. Decision makers should consult the guidance on *Handling disputed witness evidence at Triage* for further information.

Multiple doctor cases

- 36** In assessing whether multiple doctor cases can be treated as an SCI, where there are no other factors about the incident that would exclude it from the SCI PE process, the Triage AR will need to consider the matter on a case by case basis and should consider the following factors:
- a** Whether there is clarity about the role that each of the doctors has played in the incident.
 - b** The likely complexity of the enquiries/investigation required to understand what has happened and the involvement that each doctor has played.

Voluntary erasure cases

- 37** As we only carry out a PE in cases which suggest the information raises a question about the doctor's fitness to practise. VE should not generally be granted until the outcome of the PE has been concluded.

Public interest concerns

- 38** Where a case involves a public interest concern (PIC), it should be considered for the PIC process and not for the SCI process. However, in cases where there a history of raising a PIC, and the case does not meet the criteria for the PIC process, if it relates to an SCI and otherwise meets the criteria for the SCI process, it may be progressed as an SCI.

Doctors without a connection

- 39** Allegations about an SCI relating to a doctor who has no connection (either RO or SP), will still be suitable for SCI PE consideration.

Annex B (2): Guidance on assessing 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 An SCI will usually:
 - a relate to the care of a single patient, and;
 - b comprise of a concern involving (only) a single consultation or clinical procedure.
- 4 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 (ie

about more than one consultation or doctor's shift) can't be considered an SCI. Aim of carrying out a PE in SCI cases

- 5 The objective of an SCI PE is to determine whether the incident and/or a doctor's actions following the incident raise questions about a doctor's fitness to practise or are capable of supporting a finding of impairment.
- 6 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 (Cohen v GMC [2008] EWCH 581 (Admin)). 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 principles of Cohen) allow us to take into account evidence of remediation during our Single Clinical Incident (SCI) pilot.

Opening an enquiry: review of the Triage decision

- 7 When the PE SCI 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 investigation manager should consider the following questions:
 - a Whether the allegations are linked to clinical practice.
 - b Whether the concern, including any current open cases and/or previous history meets the S1 threshold.
 - c Whether the inquiry is a single clinical incident, involving only one patient and a single consultation or doctor's shift.
 - 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 are any health concerns that meet the S35A threshold.
 - f Whether there are any probity/misconduct issues that meet the S35A threshold.
 - g Whether there is a dispute of witness evidence that is relevant to the allegation (such disputes cannot be resolved at the PE stage).
- 9 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

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

Medical records

- 14 Medical records should be sought in the majority of SCI PE cases.
- 15 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.
- 16 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.
- 17 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.
- 18 Medical records are also likely to be of use where the complaint or alleged chronology of events appears unclear or confused in places.

Exceptions

- 19 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.

- 20** 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

- 21** After obtaining medical records, given the clinical nature of these cases, it is likely the IO will need to seek either the view of a medical case examiner (MCE) or an independent expert.
- 22** Medical CE or independent expert advice will provide information on the seriousness of the incident in question, which will help the AR to assess whether the incident meets the threshold for investigation.

Medical CE advice

- 23** To help determine whether an SCI warrants investigation, a medical CE can be asked to advise 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).
- 24** 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

- 25** 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)
- 26** 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. At this stage, the independent expert is not being asked to assess the standard of care but rather whether, on the face of it, the complaint raises significant issues about the standard of care.

Lay case examiner/in-house legal team advice

- 27** 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 an allegation. 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

- 28** Enquiries made to the RO or ELA may provide further information on an incident.
- 29** ROs may also be able to provide an indication of expected timescales relating to any current local investigations.
- 30** 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.
- 31** 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 to RO directly.

Where a doctor has no responsible officer/designated body

- 32** 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.
- 33** 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

- 34** 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.
- 35** 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)

- 36** 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.
- 37** 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

- 38** 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.
- 39** 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

- 40** Where an SCI PE relates to an alleged error committed by a doctor in training, the AR should take the following information into account.
- 41** 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.
- 42** 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.
- 43** 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.
- 44** 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

- 45** Decision-makers should consider the following factors when making a decision about an SCI PE.

- 46** 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 the inquiry 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 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

- 47** The SCI PE decision maker should determine whether, given the evidence received, the incident meets the threshold for investigation.

Single clinical incident

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

Seriousness

- 49** 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.
- 50** 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, a full investigation is required. These cases may also need immediate IOT referral.
- 51** 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 reckless disregard for patient safety, must appear to be 'gross', in the sense of outrageously or shockingly bad.

- 52** 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 is 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 reckless 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 is such that action is required.
- 53** In practical terms at SCI, there are likely to be two situations where we conclude that, despite the evidence of remediation that could be obtained, 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 SCI, if the seriousness of the error, or reckless 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 expresses very serious concerns about the seriousness of the error, or reckless disregard for patient safety such that they could be considered to be particularly gross (outrageously or shockingly bad) then the case should be transferred to Stream 1.

Remediation

- 54** 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.
- 55** 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.
- 56** 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 serious concerns about a doctor's actions, more cogent evidence of remediation would be required than in less serious cases.

- 57** If the remediation evidence clearly shows that a concern has now been resolved and that the allegation is not capable of supporting a finding of impairment, then an SCI PE enquiry may be suitable for closure.
- 58** However, evidence of remediation will be devalued in the following circumstances:
- a** Where information is received to suggest that similar new clinical concerns have emerged.
 - b** 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).
 - c** 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).
 - d** Where the doctor's fitness to practise history may raise concerns about the effectiveness of any remediation.
- 59** 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*. Although this guidance is aimed at case examiners, the principles around the mitigating impact of remediation will remain the same.

Insight and apology

- 60** Evidence of insight and apology into an error that has occurred should be viewed as the starting point for any consideration of remediation.
- 61** 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.
- 62** The AR may find it useful to consult CE *Guidance on assessing insight when considering whether undertakings are appropriate*.

Health or misconduct/probity concerns

- 63** The decision maker should examine whether any evidence of health or misconduct/probity concerns has arisen through the course of the enquiry which meet the threshold for Stream 1.

Links to open cases

- 64** 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.
- 65** Where a new case has been opened, the existing enquiry should generally be joined to the existing case.

Receipt of new allegations

- 66** 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 similar, it is unlikely that an existing matter can be treated as an SCI.

Information provided by an RO

- 67** 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.