

Guidance on the identification and management of significant concerns

The work of the Significant Concerns Group and its supporting guidance represents an important initiative to support NHS Resolution's key initiative to 'Further develop a cross organisation managing concerns group, linked to a system wide escalation process, taking urgent action where indicated in relation to safety concerns' (Business Plan 2019/20).

The delivery of this initiative will continue to evolve and the terms of reference for the Group will be kept under review and may be amended at any time subject to SMT approval.

Contents

Use of this guidance – what does it cover and who does it apply to?	3
What is a significant concern?.....	3
Principles.....	4
Process	4
Local responsibility for the identification of significant concerns.....	4
Significant Concerns Group	5
Information governance.....	7
Governance and reporting.....	7
Annex A: NHS Resolution function indicators to support the identification of a significant concern.....	10
Annex B: Process overview.....	13
Annex C: Function leads	14
Annex D: Notification to Significant Concerns Group	15

Use of this guidance – what does it cover and who does it apply to?

1. All of those engaged in NHS Resolution work have a duty, if they identify a significant concern, to act upon it. This guidance provides a framework to support the identification and management of significant concerns where these give rise to the need for a coordinated organisational response by NHS Resolution. It provides an overarching framework for the consideration of significant concerns that have been identified and acted on locally by an individual NHS Resolution service function ('function') and then notified by the relevant function lead to the Significant Concerns Group.¹
2. The framework is intended to be implemented in conjunction with, and not to replace, local protocols within individual functions. However, local arrangements must be compatible with and support the escalation of significant concerns in line with this framework. Explicit provision should be made for how each function will respond to circumstances which indicate that there is an **immediate need to act** in order to support the reduction of risk of harm or further harm.
3. This guidance applies to all NHS Resolution staff and contractors.

What is a significant concern?

4. A significant concern is where we identify that there is the potential for significant harm to be caused, or where significant harm has actually been caused, in relation to:
 - a patient or
 - a healthcare practitioner or other employee or
 - a service or
 - an organisation
 And
 - We hold information which we consider, if shared with an appropriate individual(s) within the organisation using our services and/or third parties, would support the prevention of harm or further harm.
5. This guidance contains indicators of significant concerns which have been developed by a number of individual functions (see Annex A) and may be helpful in determining if a significant concern has arisen in respect of their areas of work. These are not rigid criteria, and it is important to note that the question of whether a significant concern has arisen is ultimately a matter of considered judgement.
6. Our consideration of significant concerns is not limited to our work with NHS bodies, patients and services. We provide services to, and receive information about, healthcare organisations that are not part of the NHS. By including these

¹ This guidance does not apply to circumstances where staff and relevant others may wish to raise concerns about NHS Resolution. Separate arrangements for such circumstances are in place under the *Freedom to Speak Up: Raising Concerns Policy*.

in any consideration we increase the likelihood of being able to identify and act on concerns, with the aim of supporting reduction in the risk of harm.

Principles

7. The following principles underpin our approach to identifying and responding to significant concerns:
 - As an NHS body, our paramount concerns are patient and staff safety, and public protection.
 - We are committed to using what we know to improve safety, and identifying opportunities for wider improvement and learning from the information we gather as part of our work.
 - We operate within the law and within the parameters of our role, including being cognisant of requirements in relation to information governance.

Process

8. A high-level flowchart of the process for escalation and management of significant concerns is at Annex B. The process is explained in detail below.

Local responsibility for the identification of significant concerns

9. Individual functions must ensure that they have robust and documented arrangements in place for identifying and managing significant concerns and, in all cases, promptly notifying the Significant Concerns Group ('the Group') of those concerns.
10. Where there is a potential risk of harm to patients or doctors the relevant function should seek advice from the NHS Resolution Responsible Officer (RO) to determine whether an exchange of information using the 'RO to RO' information sharing framework is appropriate.
11. NHS Resolution can sometimes receive expressions of significant concern from external sources during the course of our work. Where the individual raising concerns is regarded as a 'whistleblower', any steps we take should include directing their concerns to the relevant prescribed body and in a manner that is consistent with our overriding duty towards patient and staff safety, and public protection.
12. Prior to notification of the significant concern to the Group, a check should be made for any other relevant information held (or activity undertaken) by other NHS Resolution functions and the outcomes summarised on the notification form. To safeguard the sharing of confidential information between functions, these checks should be carried out between the relevant function leads (see Annex C for a list of post holders), who should give appropriate consideration to what information should be shared, and seek advice from Information Governance as appropriate.

13. The point at which notification to the Group takes place is a matter of judgment for the function lead. Appropriate local management of the concern should start before any notification to the Group, but the notification should be made sufficiently promptly to enable the Group to consider whether further steps may be necessary beyond the immediate functional response. If there is an urgent need for the Group to consider the matter, this should be highlighted clearly in the notification.

Significant Concerns Group

14. The overarching purpose of the Group is to support prompt and effective management of significant concerns identified by individual functions where these give rise to the need for a coordinated organisational response, in order to support the reduction of risk of harm or further harm. The terms of reference set out further detail on the membership and operation of the Group.
15. All notifications to the Group should be made using a pro-forma (Annex D) and approved by a function lead responsible for the functional area in which the concern has been identified.
16. Notifications should contain the minimum amount of personal data necessary to enable the Group to consider it. For example, if the concern identified relates to a team or organisation then it is unlikely to be necessary to identify named individuals. However, if the concern relates to a specific individual (or individuals), then it may be necessary to do so.
17. The Group should consider each notification on a case-by-case basis. The consideration should include, but not necessarily be limited to, the following factors:
 - What is the nature of the significant concern and is it ongoing?
 - What is the extent of NHS Resolution's involvement (that is, across all of our functions)?
 - Does NHS Resolution hold unique information and/or have a unique perspective that is not available to any other part of the healthcare system?
 - What action has NHS Resolution already taken across all functions?
 - What remedial action has already been taken?
 - What is our view on the organisation's capability to address the concern?
 - Are any other organisations involved? (For example, regulators, professional bodies etc.)
 - Have any of the concerns already been made public (for example, through media coverage)?
 - Should NHS Resolution's RO be notified if this has not already happened?
 - Should the Chief Executive of NHS Resolution and/or SMT be notified?

- 18.** The key decision, for each notification, will be whether NHS Resolution should take any further action at an organisational level in order to support the reduction of the risk of harm or of further harm. This is not simply a question of whether there has been harm or there is a risk of harm.
- 19.** The Group should reach decisions on a consensus basis whenever possible. However, the Group Chair will make the final decision where there is not a consensus, seeking advice from Senior Management Team members as appropriate. The Group will take collective responsibility for making organisation-wide decisions on significant concerns that are referred to it.
- 20.** Where the Group decides that action should be taken, it must also decide what specific action to take. This will normally focus on:
 - Any individuals or organisations that we should share the information with
 - What assurance we require from those we share information with about action to be taken to reduce the risk and the routes for further escalation (both internal and external) if assurances are not received
 - How and when the information will be shared
 - Any further advice, support or intervention we can offer to support the resolution of the significant concerns that have been identified.
- 21.** Where a decision is made to share information, the recipient(s) are likely to be drawn from the following (this list is not exhaustive):
 - The relevant healthcare organisation (for example, the Trust directly involved in the case). Information will be shared with a senior member of staff, usually the Medical Director or other executive or senior manager.
 - NHS England and/or NHS Improvement.
 - Regulators of healthcare professionals (for example, the General Medical Council).
 - Regulators of healthcare services (for example, the Care Quality Commission).
 - Healthcare Safety Investigation Branch.
- 22.** The rationale for all decisions and any agreed actions will be fully documented, including assigned responsibilities for any actions and their review. The Group may seek further advice from Information Governance, the RO, Caldicott Guardian or legal advisers as required.
- 23.** Unless agreed otherwise, responsibility for any agreed actions will rest with a function lead in the functional area in which the concern was raised, who should report back to the Group on progress against agreed actions and their completion.
- 24.** The Group should also consider whether, in order to raise awareness of and share learning from the consideration of significant concerns, fully anonymised case summaries should be documented and shared with the NHS Resolution

functions. In all such cases, advice from Information Governance should be sought before the sharing of information. The Group may present proposals for consideration by the Senior Management Team to share learning more widely with users of our services and other external stakeholders.

Information governance

- 25.** Group members must treat any personal or sensitive information referred to the Group as confidential, unless there is a justified need, aligned to the Group's purpose, to share it further.
- 26.** Any sharing of confidential information with and between members of the Group (and outside the Group, to both internal and external parties) must be on the basis that it is necessary to do so in the public interest. The justification for the sharing of information should always be considered on a case-by-case basis and must always be aligned to the purpose of supporting the reduction of the risk of harm or further harm. The justification for sharing of personal or sensitive information should be clearly documented by the Group.

Governance and reporting

- 27.** The chair of the Group will submit a summary report to the NHS Resolution Senior Management Team on the Group's activity on a 6-monthly basis.
- 28.** The Chair's key responsibilities and tasks are to:
 - Ensure the decisions and actions of the Group are procedurally robust (by ensuring this guidance and the Group's terms of reference are adhered to)
 - Ensure that the Group has considered fully the information provided
 - Ensure the expertise and informed opinions of individual Group members are brought into the decision making process
 - Facilitate discussion to ensure the Group reaches an agreed decision supported by clear rationale
 - Ensure the Group's discussions are outcome-focused in line with NHS Resolution's aims and within the parameters of our role
 - Recognise where discussions on the case need further information or clarification
 - Summarise and reflect back rationale for decision making to ensure agreement.
- 29.** The Group Chair will, supported by the Group's Secretariat, also ensure that:
 - All notifications to the Group are documented
 - Group decisions are documented (including rationale)
 - Agreed actions are allocated, recorded and monitored
 - All information about the Group's activities is stored and managed appropriately.

Date approved/reviewed (plus implementation date if different)	Version number	Main changes	Next review date
01/03/2019	1.0	New guidance	01/09/2019
26/03/2019	2.0	Addition of new para 21 (likely recipients of disclosure). Lead Assessment and Intervention Adviser added to Annex C	26/09/2019
10/04/2019	3.0	Addition of Caldicott Guardian to para 22	10/10/2019
19/06/2019	4.0	Amendment to notification form (Annex D) – new page for 'follow up actions'	19/06/2019
11/12/19 (19/12/19)	5.0	Updated following SMT. Updated introduction text; information gathering with other parts of NHS Resolution to be summarised in notifications (para 12); added 'Does NHS Resolution hold unique information...' (para 17); previous NHS Resolution action should be clarified 'across all functions' (para 17); added 'scale of the concern and the urgency of need to act' to the Advice indicators (Annex A); flowchart updated (Annex B); change to job title (Deputy Director) and Group membership (new Primary Care Appeals rep and addition of RO) (Annex C); 'Claims position' section added to notification form (Annex D).	30/04/2020

Date approved/reviewed (plus implementation date if different)	Version number	Main changes	Next review date
16/6/20 (22/06/20)	6.0	Addition of updated notification form to Annex D	16/12/20
21/10/20	7.0	Addition of Primary Care Appeals indicators to Annex A	30/4/21
1/02/21	8.0	Addition of updated notification form to Annex D	01/02/22
26/05/2021	9.0	No substantive changes but reviewed as part of regular reporting to SMT	26/11/21

NHS Resolution function indicators to support the identification of a significant concern

This annex sets out the indicators developed by a number of individual NHS Resolution functions to support the identification of significant concerns in respect of their areas of work. These are not exhaustive and do not represent rigid criteria. It is important to note that the question of whether a significant concern has arisen is ultimately a matter of considered judgement, based on the specific circumstances of each case.

Claims Management

The concern identified requires urgent action to:

- safeguard a patient, patients and/or the public (including staff) and/or
- help to ensure the safety of the practitioner and/or
- help to ensure the provision of a safe service

And

- if not addressed urgently, the concern poses an immediate or potential risk of significant harm to the individual(s) or service affected or
- there is evidence that significant harm has already been caused.

Further possible indicators of a significant concern:

- multiple claims in respect of the same clinician / team / department / organisation / service
- concerns about conduct that indicate gross negligence
- prior complaint about the same events was rejected where breach of duty is admitted later
- absence of duty of candour discussion where there should have been one
- where the Trust's initial comments say that a claim is unmerited but expert evidence confirms a breach
- a 'never event' has occurred
- when an expert asks if staff have been referred to regulator and they have not done so
- Identifying significant lack of knowledge or training
- Trust has made regulatory referral
- Serious deficiencies in care
- Serious concerns as to how an organisation is working.

It is also important to note that a significant concern:

- can arise at any stage of the claims process
- may or may not relate but is likely to relate to the clinician against whom negligence is alleged or likely to be alleged
- may relate to wider service provision, organisational systems or equipment

- may or may not relate but is likely to relate to the care provided to an individual patient or patients
- may or may not relate to the overall care provided to a range of patients which, only when considered together, raise a significant concern about practice
- is likely to mean that the practitioner's overall performance falls below the standard reasonably expected and
- may prompt the need for urgent advice, follow up and/or patient recall to help safeguard those who are or may be affected by the concern.

Practitioner Performance Advice

A significant concern can arise in the context of either advising on a case or assessing a practitioner.

Case advice

Indicators for a significant concern can include one or more of the following characteristics as a feature of the organisational response to managing individual performance concerns:

- a failure to take basic steps to understand/diagnose the nature of the performance concerns
- a persistent failure to follow overarching HR processes/local procedures or other external frameworks, for example Maintaining High Professional Standards
- the absence of a management plan or oversight leading to an uncoordinated approach, potentially exacerbated by the involvement of multiple staff/agencies
- the behaviours of the practitioner/team in which the practitioner works have escalated beyond the employer's management capability
- poor behaviours displayed by the employer/practitioner in response to the performance concerns
- resistance to following the advice provided, with no clear rationale for alternative action and/or insufficient safeguards
- information provided by a practitioner in the context of whistleblowing
- failure to involve appropriate authorities such as the police when there appears to be evidence of criminal action.

In addition to the specific indicators listed above, the scale of the concern and the urgency of need to act should be considered as additional factors when assessing a potential concern.

Assessments and other interventions

The concern identified requires urgent action to:

- safeguard a patient, patients and/or the public (including staff) and/or
- help to ensure the safety of the practitioner and/or
- help to ensure the provision of a safe service

And

- if not addressed urgently, the concern poses an immediate or potential risk of significant harm to the individual(s) or service affected or
- there is evidence that significant harm has already been caused.

It is also important to note that a significant concern:

- can arise at any stage of the process
- may be indicated by any single assessment component or a combination
- may or may not relate to the practitioner under assessment
- may be in relation to a practitioner's performance, health or conduct, or in relation to wider service provision, organisational systems or equipment
- may or may not relate to the care provided to an individual patient
- may or may not relate to the overall care provided to a range of patients which, only when considered together, raise a significant concern about practice
- may or may not necessarily mean that the practitioner's overall performance falls below the standard reasonably expected
- may prompt the need for urgent advice, follow up and/or patient recall to help safeguard those who are or may be affected by the concern.

Primary Care Appeals

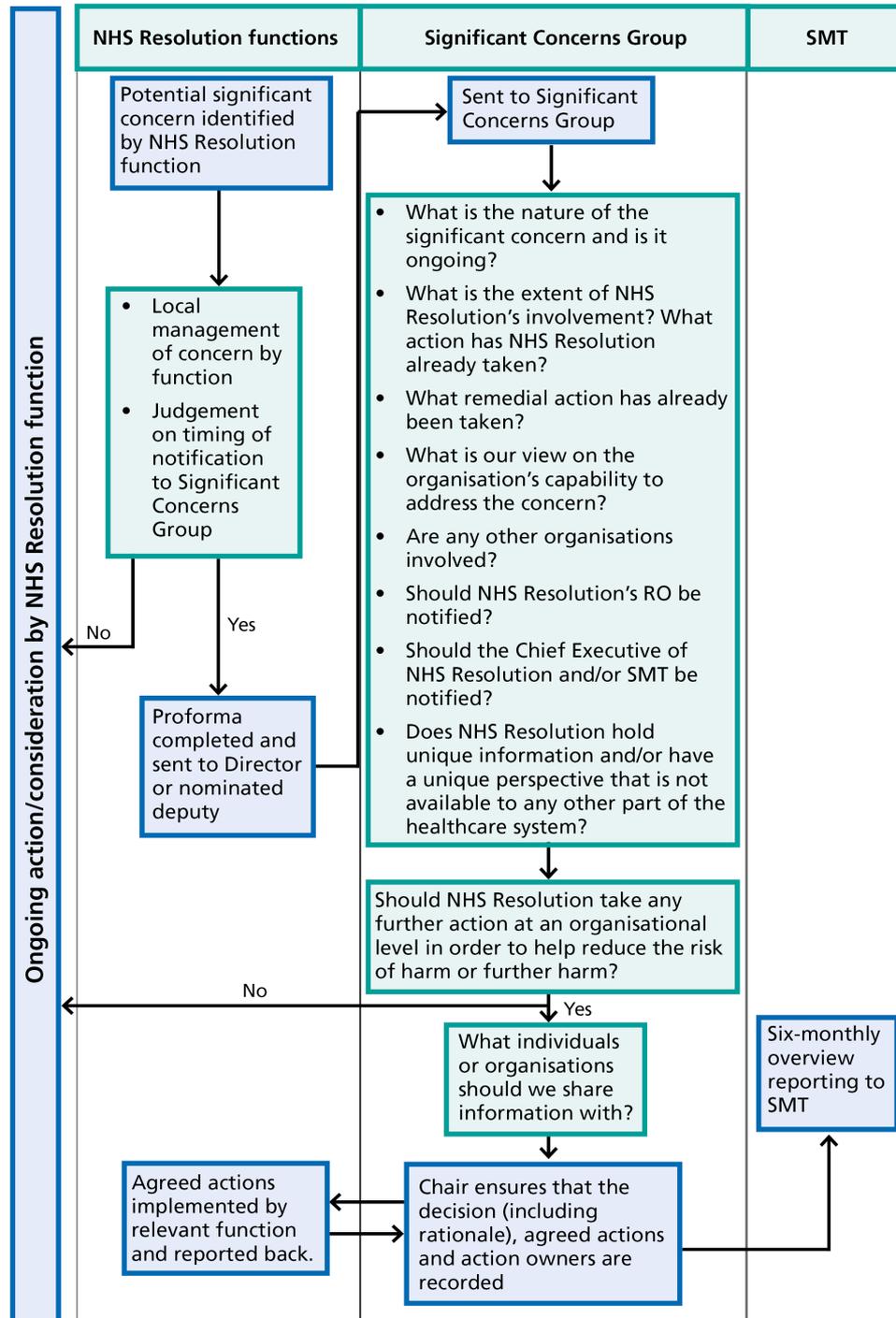
A significant concern can arise in the context of either processing or determining an appeal or dispute or the discharging of any of its other functions.

Indicators for a significant concern can include:

- procedural issues within and across organisations leading to systemic failures that have the potential to compromise patient safety
- indications that a person is or has been subject to harm
- indications of potential fraudulent activity
- indications of activity that has the potential to harm a patient or patients
- poor behaviours displayed by a party to an appeal or dispute

In addition to the specific indicators listed above, the scale of the concern and the urgency of need to act should be considered as additional factors when assessing a potential concern

Process overview



Function leads

The post holders identified below are the significant concerns leads for their respective functions and, together with their function representative on the Significant Concerns Group, are responsible for:

- ensuring effective arrangements are embedded within their local functions for the identification and management of significant concerns
- acting as a specialist resource for identifying and handling significant concerns at a local level, as well as signposting notifications to the Significant Concerns Group
- acting as champions for this framework within their respective functions, including capturing and disseminating learning to staff and contractors who rest within their local functions as appropriate.

The function leads are:

- Director of Claims Management²
- Deputy Director of Claims
- Technical Claims Director
- Assistant Technical Claims Director
- Head of Early Notification
- Senior Clinical Representative, Early Notification
- Director of Practitioner Performance Advice
- Deputy Director, Practitioner Performance Advice
- Lead Adviser, Practitioner Performance Advice
- Lead Assessment and Remediation Adviser, Practitioner Performance Advice
- Responsible Officer and HPAN Lead
- Director of Safety & Learning
- Deputy Director of Safety & Learning
- Head of Operations, Primary Care Appeals
- Director of Finance and Corporate Planning
- Director of Membership and Stakeholder Engagement

² Note: Concerns identified by Panel firms should be escalated to the Group through Claims Management

Please submit the fully completed form at least 5 working days before the meeting

Notification to Significant Concerns Group

1 General information	
a) Name:	
b) Director responsible:	
c) Organisation(s) involved:	
d) Specific individual(s) involved at external organisations (if relevant):	
e) Indicators of potential for harm/harm caused:	
f) Summary of issue leading to significant concern:	
<p>i.e. the circumstances in which it has arisen, including specific dates</p> 	
2. Questions	
a) Claims Management information	
<p>This should be brief, anonymous (where possible) and a purely factual account of the case position. Please do not append or quote directly from any documents or case-related material protected by privilege.</p> 	

b) What information sharing has already taken place within NHS Resolution?
c) What action has been taken so far?
e.g. by organisation and/or NHS Resolution
d) What has been done to date in response to the action taken?
e) Other organisations involved
e.g. regulators, professional bodies

f) Are there any other relevant issues that the Group should be aware of?

For example, particular sensitivities, media coverage etc.

g) Advice from the NHS Resolution Responsible Officer (RO)

The form must be forwarded to the RO for comment and completed prior to submission to the Significant Concerns Group

3. Options and recommendations

a) Please set out the options for further action – this section must be completed

Summarise the different options, including any advantages and disadvantages

b) Recommended action – this section must be completed

From the options set out above, please give your recommendation and explain the reasons behind it (with particular reference to: any further specific steps we need to take to support the reduction in the risk of harm or further harm, including timescales for completion.)

Outcome of Significant Concerns Group discussion

4. Outcome of Significant Concerns Group discussion			
a) Group decision and rationale:			
Including agreed actions and timescale			
b) Member of staff responsible for action:			
c) Date of Group meeting:			
d) Chair and Group members present:	•		
e) Secretariat and other attendees:	•		
f) Outcome confirmed by:		Date:	

Follow up actions³

5. Follow up actions following Group discussion			
a) Required action and timescale:			
b) Member of staff responsible for action:			
c) Action update			
d) Outcome confirmed by:		Date:	

³ Delete page if not applicable

Case resubmission⁴

6. Information to support resubmission of a case			
a) Reason for resubmission			
Explain briefly why the case is being resubmitted			
b) New or updated information			
Summarise the key developments and changes since the previous consideration of the case			
c) Recommended action			
d) Outcome			
Include decision and rationale			
e) Date of Group meeting			
f) Outcome confirmed by:		Date:	

⁴ Delete page if not applicable