A closer look - carrying out the investigation

This is draft material and is not live guidance. It is shared for information and will be tested with organisations who have agreed to pilot the new Complaint Standards.

1. Introduction

1.1 This guidance is part of a range of guidance modules produced to help you implement and deliver the expectations set out in the Complaint Standards. Insert link

1.2 This module explains what you need to do when carrying out an investigation. It covers:

- how to deal with complaints which overlap with other investigations or reviews
- clarifying the complaint
- planning your investigation
- calculating timescales for responding to complaints
- identifying and gathering evidence,
- acting fairly during the investigation
- reaching a conclusion
- considering financial or other redress and potential legal claim
- sharing initial views
- issuing a final response letter
- how to deal with complaints concerning issues that may give rise to disciplinary or health professional fitness to practise procedures
- good investigation record keeping
- dealing with unreasonable or disproportionate behaviour

1.3 This guidance should be read in conjunction with the following modules:

- Identifying a complaint Insert link
- Who can make a complaint, consent and confidentiality Insert link
- Early Resolution Insert link
1.4 This is good practice guidance and should not predetermine the outcome of individual complaints.

2. Standards and relevant legislation

2.1 The relevant Complaint Standards expectations are:

**Being thorough and fair**

- Organisations make sure staff are properly trained and have the appropriate level of experience and authority to look into complaints thoroughly.

- Organisations make sure all staff who look at complaints have the appropriate resources, support and protected time to do so in order to meet these expectations consistently.

- All staff who handle complaints do so fairly. Where possible, organisations make sure they assign complaints to staff who have had no prior involvement or who have no actual or perceived conflict of interest. Where this is not possible, staff take clear steps to demonstrate how they have looked at the issues fairly.

- Staff make sure everyone involved in a complaint (including staff) know how they will look into the issues. This includes what information complaints staff will need, who they will speak to, who will be responsible for providing the final response and how they will communicate their findings.

- Staff will agree timescales with everyone involved and will agree how people will be kept informed and involved. Staff provide regular updates throughout.

- At all times, staff have the freedom to look for ways they can resolve complaints at the earliest opportunity.

- Staff make sure everyone involved in a complaint has the opportunity to give their views and respond to emerging information. Staff act openly
and transparently and with empathy when discussing this information, making sure they take everyone’s comments into account.

**Giving fair and accountable responses**

- Staff give a clear, balanced account of what happened based on established facts. Each account compares what happened with what should have happened. It gives clear references to any relevant standards, policies or guidance, based on objective criteria.

- In more complex cases, staff make sure they share their initial views on a complaint with everybody involved and give people the opportunity to respond. Staff make sure they take these comments into account in their final response to the complaint.

- Organisations make sure staff are supported and encouraged to be open and honest when things have gone wrong or where improvements can be made. Staff balance the need to be accountable for their actions, to identify what learning can be taken from a complaint, and how the learning will be acted on to improve services and support staff.

- Wherever possible, staff explain why things went wrong and identify suitable ways to put things right for people. Staff make sure the apologies and explanations they give are meaningful, sincere, and openly reflect the impact on the individual or individuals concerned.

2.2 The relevant Regulations that apply are:

The Local Authority Social Services and National Health Service Complaints (England) Regulations 2009. Section 13 paragraph (7) says ‘At the time it acknowledges the complaint, the responsible body must offer to discuss with the complainant, at a time to be agreed with the complainant—

(a) the manner in which the complaint is to be handled; and

(b) the period (‘the response period’) within which —

(i) the investigation of the complaint is likely to be completed; and

(ii) the response required by regulation 14(2) is likely to be sent to the complainant.

(8) If the complainant does not accept the offer of a discussion under paragraph (7), the responsible body must —

(a) determine the response period specified in paragraph (7)(b) and

(b) notify the complainant in writing of that period.
Regulation 14(1) states that a responsible body to which a complaint is made must—

(a) investigate the complaint in a manner appropriate to resolve it speedily and efficiently; and

(b) during the investigation, keep the complainant informed, as far as reasonably practicable, as to the progress of the investigation.

With reference to the time period for investigation the 2009 Regulations go on to say at section 14 paragraph (3) that there is a ‘relevant period’ for handling a complaint. This means the period of 6 months commencing on the day on which the complaint was received, or such longer period as may be agreed before the expiry of that period by the complainant and the responsible body.

(4) If the responsible body does not send the complainant a response in accordance with paragraph (2) with the relevant period, the responsible body must -

(a) notify the complainant in writing accordingly and explain the reason why; and

(b) send the complainant in writing a response in accordance with paragraph (2) as soon as reasonably practicable after the relevant period.

3. What you should do

3.1 The key principle is ‘investigate once, investigate well’. Your aim is to carry out one investigation to deal thoroughly with the concerns raised, rather than multiple, sequential investigations. These can result in protracted and sometimes open-ended investigations and correspondence, which absorb disproportionate time and resources.

Complaints which overlap with other investigations or reviews, such as patient safety investigations

3.2 Everyone has a right to make a complaint and have it investigated and responded to in a full and timely manner. This is true regardless of what other reviews or investigations are taking place into an incident or death. During your consideration of a complaint you may identify that another process should take place, such as a patient safety investigation. In these cases it is good practice to discuss the matter with relevant colleagues and agree how best to work together. Likewise, if the issues you are considering overlap with issues already being investigated or reviewed elsewhere. You should also discuss with the person making the complaint what concerns and questions they want answered. If possible, you should work with colleagues
to incorporate these into their investigation/review to provide a comprehensive response which meets the needs of both processes.

3.3 The person making the complaint should have a single point of contact who can keep them updated and informed about both processes. They should always be advised of the availability of independent advocacy and advice to support them through the process. Insert link to advocacy guide

**Clarifying the complaint**

3.4 Problems can start right at the beginning if you do not take the time to fully understand the complaint, what you are investigating and the outcome being sought. There is a separate guidance module on this very important step Insert Link.

**Planning your investigation**

3.5 It is important to plan your investigation carefully. Good planning will help you calculate a realistic estimate of the timescale for completion, which you must share at the start with the person raising the complaint and the other parties involved. Having an investigation plan helps you stay focused and will help make sure you do not miss anything crucial. It will also help you keep track of progress of the investigation and quickly alert you to any changes that are needed to the timescales so you can update the parties.

3.6 The scale and scope of your investigation should be focused on the matters you are investigating and should use resources effectively and proportionately. The investigation should be cost effective, while taking full account of customer service and legal requirements. Discussing your plan and seeking the views of a colleague or others who may be involved in investigating the complaint may also help ensure your plan is robust.

3.7 For straightforward, single issue investigations your plan can be drawn up quickly. Incidents which may involve serious failings or numerous issues will require much more detailed planning, often in discussion with colleagues who will be involved in helping you with your investigation.

3.8 You must share the outline of your investigation plan with the person making the complaint, their advocate (if they have one) and any member(s) of staff complained about. It is always worthwhile asking if they think you have missed anything that might be helpful and consider any comments and suggestions before finalising your plan.

3.9 A good investigation plan:

- Includes your agreed communication plan, setting out how and when you will update the parties involved and any reasonable adjustments that are needed.
- Sets out the issues to be investigated, which you have agreed with the person making the complaint.

- Sets out the requested outcomes requested by the person making the complaint.

- Includes an assessment of risk and consideration of any broader patient safety or public interest concerns (taking account of other individuals who may be affected by the same issues and any systemic concerns).

- Sets out the evidence you will need to obtain and consider to address each issue. This will always include:
  
  o evidence to establish what happened
  
  o evidence to establish what should have happened

- If you are delegating the investigation or any part of it to somebody else:
  
  o details of who that is, what exactly you are asking them to investigate (and how), and the agreed timescale for completion and submission of their response/report.

- If the complaint involves clinical matters, details of who will provide you with a view, on behalf of your organisation, on whether the care or service provided was appropriate. This should be someone who is suitably qualified but who has not been directly involved in the care of the person affected.

- Includes estimated timescales for:
  
  o sharing what you have found with the parties involved and to seek their comments
  
  o completing your investigation and drafting your final response to the complaint
  
  o securing any quality assurance and sign off by the Responsible Person or their delegate.

**Calculating timescales for responding to complaints**

3.10 Having set out the work involved in investigating the complaint and the likely time needed for each part, you should be able to identify a realistic timeframe for completion that you can share with the parties. Each complaint will have its own timescale depending on the requirements and complexity of the case. Complaints with numerous heads of complaint, involving different departments or multiple organisations are likely to take
much longer than a complaint about a single issue. This should be explained at the outset.

3.11 Although each complaint will have its own timescale, you should measure your overall timescales for completing your consideration of all complaints against the following targets:

<table>
<thead>
<tr>
<th>Complexity rating</th>
<th>Timescale for completion (from date of receipt to issue of our final response)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Straightforward/single issue</td>
<td>95% within 3 months</td>
</tr>
<tr>
<td>Complex/multiple issue or multiple organisations</td>
<td>50% within 3 months</td>
</tr>
</tbody>
</table>

3.12 The 2009 Regulations say that if the investigation cannot be concluded (and a final response issued) within 6 months (or longer if that has been agreed with the person making the complaint at the outset), you must write to the person to explain reasons for the delay and give the likely timescale for completion. This letter should be sent by the Responsible Person or a senior manager who should also then maintain oversight of the case until it is completed and a final written response issued.

3.13 Having recorded the complaint on your complaints handling system when you receive it, the Complaint Handler for the case should keep track of (and record) progress against the plan and take responsibility for monitoring the smooth running of the investigation, making sure that regular updates are provided as agreed and timescales are met. Occasionally, issues may be uncovered or events occur that mean that you will need to revise your target date for completion. If this happens, the person making the complaint, their representative and any staff complained about must be informed immediately of the reasons for any delay. That said, you should always focus on providing a response as quickly as possible because the longer it takes to deal with a complaint, the more stressful it can be for everyone involved.

3.14 For reporting purposes, you should maintain a record of each complaint received, the subject of the complaint, the outcome, and whether your final written response was sent to the person who made the complaint within the timescale agreed at the beginning of the investigation.

**Identifying and gathering evidence**

3.15 Once the specific points of complaint and the desired outcomes are established, you can use these to focus the scope of your investigation. You can delegate the investigation or any part of it to a Complaints Lead(s) within your organisation who has specific knowledge of the service area being looked into. As the Complaint Handler for the complaint, you should maintain oversight of the overall investigation.
3.16 A good investigation starts with a thorough review of the circumstances being complained about. The Complaint Handler and/or Complaint Lead should seek to establish:

- what happened
- what should have happened
- the cause of any identified failings
- what can be done to rectify any failings
- the impact the failings had on the patient/person making the complaint
- how that impact be put right for the person and others who may be similarly affected.

Your conclusion must be based on an objective analysis of the evidence and should explain this analysis clearly.

3.17 The evidence you will need to gather to find out what happened could include:

- evidence from the person making the complaint to support what they say
- evidence from family, friends and carers
- staff interviews or statements and evidence to support what they say
- evidence from any witnesses
- information from relevant clinical records
- information from other sources if necessary (for example CCTV, phone records).

3.18 This is not an exhaustive list and you need to consider what evidence will or may be available to help you in your investigation. As part of sharing your investigation plan (and during any updates) you should talk to the people involved about the evidence you will be/are looking at and ask if they think anything is missing.

3.19 The evidence you will need to gather to find out what should have happened could include:

- relevant national policies, standards, procedures and guidance
- local policies, standards, procedures and guidance
- if the complaint involves clinical matters, a view, on behalf of your organisation, on whether the care or service provided was appropriate and in keeping with the relevant standards, procedures, policies and guidance. This should be provided by someone who is suitably qualified but who has not been directly involved in the care of the person affected.
Acting fairly during the investigation

3.20 The person who made the complaint and anyone complained about should have the opportunity to say what happened in relation to a complaint, to provide evidence to support what they say, and to say whether they agree with any conclusions. The person investigating and responding to the complaint should not prejudge the outcome, or favour either the complainant or the person complained about.

3.21 Where possible, the person investigating the complaint should have had no previous involvement in the events complained about. If this is not possible, you should be open at the start. Explain to the person making the complaint how you will investigate, and how you will make sure you provide a balanced account of what happened and reach conclusions based only on the evidence.

3.22 The Francis Report recommended that hospitals (and ideally other organisations) should always use an independent investigator (someone from outside their organisation) in circumstances where:

- a complaint amounts to an allegation of a serious untoward incident
- subject matter involving clinically related issues is not capable of resolution without an expert clinical opinion
- a complaint raises substantive issues of professional misconduct or the performance of senior managers
- a complaint involves issues about the nature and extent of the services commissioned.

3.23 This can take time to arrange, so you may wish to enter into agreements with other organisations, confirming that you will provide support and independent investigations for each other should the need arise.

3.24 You should provide people who have made a complaint, and those who have been complained about, with an opportunity to submit relevant information and evidence, and keep them fully informed and updated throughout the process. Before you issue a final response, it is good practice to give them the opportunity to comment on any initial findings and conclusions and have their comments considered.

3.25 The person making the complaint, and anyone complained about, should know they have a right to help and support during the process if they want it. You should make sure the person complained about is aware of your local NHS advocacy provider (or any relevant national support organisations). You should also make sure that anyone complained about is supported through the process and has access to a named contact who can help them (if needed) with support relating to the complaints process. This may be their line manager, but should not be the person who is responsible for investigating or making decisions about the complaint outcome. It is not the role of this person to form a view about the merits of the complaint.
Reaching a conclusion

What happened (did something go wrong?)

3.26 Determining what happened can usually be established by using the evidence gathered during your investigation. Where there is conflicting evidence or uncertainty about what did happen, you should consider whether something is more likely than not to have happened, based on the balance of probability.

3.27 In some cases, there may not be enough evidence, or the evidence is so equally balanced that even on the balance of probability a view cannot be reached. In such cases, you should clearly explain why this is the case, setting out and explaining all of the evidence you have considered.

What should have happened

3.28 It is not enough just to explain what happened. You should also determine what should have happened in the particular situation so that you can compare the two to see if anything has gone wrong. What should have happened must be based on evidence and not opinion. To determine what should have happened, you will usually look at things like:

- legislation, statutory powers and duties
- nationally recognised policy, guidance or standards.
- local policies and procedures
- relevant professional standards
- any other recognised standards in place at the time of the events complained about.

3.29 You must identify whether there was a gap between what happened and what should have happened. This should be done by comparing what happened against the standards relevant to the case.

3.30 In cases involving clinical care, you will probably need to seek a view on the matter from a suitably qualified clinician who has not been directly involved in the care provided. Again, any advice must be based on relevant standards, policies and procedures. The Ombudsman’s clinical standard provides more information on this. Insert Link

Considering the impact

3.31 Where your investigation has found that something has gone wrong, the next step is to consider what impact this had on the patient, service user and/or the person making the complaint. This will make sure you are clear on what you are putting right with your remedy. This should also include thinking about whether the failings(s) you have found could affect other service users, or on services your organisation provides in the future.

3.32 At the beginning of your investigation, you will have discussed the impact with the person making the complaint and they will have told you how they
feel they have been affected. You should now consider if that is the case or if there are wider issues that they are not aware of.

3.33 The impact of something going wrong could include:

- **Inconvenience and distress.** This could have been caused by cancellations, failures, or delays in service provision, by failures in communication, or where the handling of the complaint has been unreasonably prolonged.

- **Being denied an opportunity.** For example, the person was denied the opportunity to make an informed choice because they were not given the full facts or an explanation of the risks (such as when obtaining consent for surgery or when making decisions about care). This may have led to a lost opportunity for a better outcome, recovery or prognosis, or to unnecessary or additional surgery or treatment.

- **Physiological injustice.** For example, minor pain, permanent or serious injury or harm.

- **Bereavement.** Such as avoidable death, or a bereavement exacerbated by a poor standard of care or poor communication with family.

- **Loss through actual costs incurred.** For example, care fees, private healthcare, and loss of benefits.

- **Other financial loss.** For example, loss of a financial or physical asset (such as loss or damage to possessions), reduction in an asset’s value, and loss of financial opportunity.

3.34 Again, this list is not exhaustive and if you think it is necessary, you should have a further discussion with the person making the complaint or the person they are representing to make sure you have understood the impact fully.

**Considering financial or other redress and potential legal claims**

3.35 If you identify what may be a serious failing or impact, you will need to consider whether the person may have a potential legal claim. The complaints process is not designed to determine legal liability or to provide compensation which might be awarded by a court. As part of the complaints procedure, your organisation can make a payment that acknowledges pain, distress and inconvenience. Even if you identify a potential legal claim during the course of your investigation, you should still be able to offer a financial remedy as part of your response to the complaint without the need for legal action. In these cases, you should discuss the matter with your legal team or defence organisation and NHS Resolution. You should also refer to the joint NHS Resolution/PHSO guidance on resolving NHS complaints and claims.

3.36 Where you have identified that someone may have a potential legal claim, the person making the complaint should be informed and told about the availability of independent advice from organisations such as the charity
Action against Medical Accidents (AvMA) [Insert Link] or from solicitors specialising in the relevant field.

**Sharing initial views**

3.37 By this point you should have identified whether something has gone wrong and, if it has, have a good idea of the impact it has had. You will also be thinking about what you need to do to put that right. (See providing a remedy for more information [Insert Link]).

3.38 Before you come to a final conclusion, and to make sure you have acted fairly, you should always consider giving the person making the complaint, and any person complained about, the opportunity to comment on what you have found so far.

3.39 When deciding whether to share your initial findings, proportionality will be an important factor. You should always do this in more complex cases (for example, cases with multiple issues or covering complex clinical matters) or where the claimed (or identified) impact is significant. For more straightforward cases (for example, complaints covering single issues, and/or where the claimed (or identified) impact is minor) it may not be necessary to share your emerging views. You must always consider what is the best approach for each case in the interests of fairness and transparency. Bear in mind that the purpose of this communication is to make sure that nothing has been missed and that any final thoughts and comments are considered before a final response is issued. You can take a proportionate approach and do this by phone, email or local meeting, in line with the person’s communication preferences.

3.40 When sharing your initial views, in some instances, you may want to share a draft of your final response letter. The best way to do this may be to tell the person making the complaint that you are nearing the end of your investigation, but before making a final decision, you would like to share what you have found in case you have misunderstood anything or have missed something. You can tell them that you will be sending them a draft letter and would like to receive any final comments. If they ask what you have found, depending on your findings, you could either say that following your investigation you have not found that anything was done wrongly and that hopefully your letter will clearly explain what happened. Or that you have found that something did go wrong, what that is, and apologise.

3.41 When you are deciding how to share your initial views and before you have the discussion, you should always consider the sensitivity of the information to be shared and the likely impact on the person making the complaint. You should show empathy and offer apologies for any failings. In the most serious cases, you may want to meet face to face with the person making the complaint, their family and representative and relevant members of staff to explain what you have found so far. This is a good opportunity to
discuss the issues and identify any unanswered questions before providing your final written response.

**Issuing the final response letter**

3.42 Once you have shared your initial views, completed your consideration of any comments and carried out any further investigation that is needed, you are in a position to conclude your investigation and issue a final response. This should be signed and issued by your Responsible Person or their delegate. See writing the final written response for more information [link].

**Complaints involving issues that may give rise to disciplinary or health professional fitness to practise procedures**

3.43 The complaints procedure itself is not a disciplinary procedure. However, while considering or investigating the complaint you may identify issues that require a member of staff to be subject to remedial or disciplinary procedures. If that happens, you will need to discuss this with relevant colleagues. If the complaint includes those issues, you should advise the person making the complaint in broad terms that such action is being taken. You should take legal advice about how much information you are allowed to disclose. Where the person making the complaint has already referred the matter to a health professional regulator, or where they subsequently choose to, it should not affect the way their complaint is investigated and responded to. They should be signposted to sources of independent advice. See guidance on complaints and other processes.[link]

**Good investigation record keeping**

3.44 It is important to keep a central record of the complaint and all relevant evidence. This will make sure you have a full audit trail of what you have done and how you have reached a conclusion, which you will need if the complaint is referred to the Ombudsman, the Regulator or pursued via a legal claim. This record should be stored centrally in a complaint/investigation file (either electronic or hard copy).

3.45 Key documents you will need to include are:

- a copy of the original complaint or complaint statement
- the investigation plan
- all telephone, meeting and interviews notes or recordings with the date, time and names of those present
- any statements from staff
- any statements from witnesses
- copies of any relevant extracts from clinical records
- notes of any updates provided or discussions about the case
- copies of all evidence reviewed in the course of the investigation
• a copy of any advice received, including reference to any relevant standards, policy and guidance
• a statement about any action taken/to be taken in response to the complaint, or specific resolution reached on the matter, including clear reasons for decisions made
• details of any comments received from the parties on initial findings and how they have been addressed
• the final written response
• if relevant, any action plans for delivering agreed actions
• if relevant, details of how the person making the complaint will be involved and updated until any necessary actions are completed.

Dealing with unreasonable or disproportionate behaviour

3.46 You should respond fairly to complaints and treat people with dignity and respect throughout the complaint resolution process. Equally, someone who makes a complaint is expected to treat staff reasonably.

3.47 If someone behaves unreasonably in their interactions with staff, and this creates health, safety, resource or equity issues for the organisation, steps to address the behaviour and limit access to services (or contact with the organisation) can be taken.

3.48 Access restrictions must be considered as a last resort. Before issuing an access restriction, the person must be told:

• the reason for the restriction, including a description of their concerning behaviour
• that they have received warnings before about their conduct
• how they can contact the organisation, including the name of and contact information for the person they are permitted to contact, and any limits on the frequency of contact
• how long the restriction is in place for
• how they can request a review of the restriction
• what is required for the restriction to be lifted.

3.49 Where you are responding to someone who has complained many times before, you must take special care to make sure that a new complaint is not dismissed outright as lacking credibility. A person’s history of raising unsubstantiated complaints does not preclude there being a valid issue when they raise a new complaint. It is important that you approach each complaint with an open mind and a commitment to fully considering the fresh evidence a person provides in support of their complaint.

4. Examples and case studies

4.1 Good practice examples:
• Good staff statements - To follow
• Good clinical advice examples - To follow
• Examples of good conversations - sharing initial views - To follow

5. Practical Tools

5.1 Practical tools:
• Investigation flow chart - To follow
• Investigation plan template - To follow
• Good conversation check list - To follow
• Good meeting check list - To follow
• Ombudsman’s clinical standard - Insert Link

6. Version control

6.1 Pilot Draft - March 2021