Policy No. 011
Template Ver: April 2023

Patient and Family Services Complaints and Concerns Policy and Procedure	
Originated by: Date Ratified: Ratified by:	Quality Lead 07/2017 Director of Patient and Family Services
Revised by: David Traynier, Head of Quality and Compliance Revision No. 003 Date: 22/03/2023 Ratified by: Clinical Policies and Procedures Review Group Date ratified: 06/04/2023	
Date of next review: 01/04/2026	
Document Owner:	Risk and Incident Group
Document Classification:	Internal

Revision Summary

- 03/2023 Deadline for sending investigation reports changed to 28, following SLT decision of 25th January 2023. 'Senior Management Team' updated to 'Senior Leadership Team'.

Revision History

- 07/2022 Minor revisions to Items 14 and 15 of the complaints procedure (pp. 12-13) to remove reference to the CQC and add reference to NHS Suffolk and North East Essex Integrated Care Board (ICB). Clarification added to Item 14 that St Helena cannot guarantee that the PHSO will accept a referral. All references to North East Essex Clinical Commissioning Group updated to the ICB.
- 06/2020 Revised in response to a complaint regarding our complaints management process (see Complaint 061). The information on timescales has been revised and there are new appendices detailing proper investigation procedure, an example agenda for investigation meetings, root cause analysis methodology, and a template response letter.
- *02/2017* Substantial update with new reference to the Sentinel incidents, complaints, and risk management system.

Policy Statement

What is this policy intended to achieve?

To ensure that St Helena has 'an effective and accessible system for identifying, receiving, handling and responding to complaints'[1] affecting Patient and Family Services (PFS) from service users or their families/carers/relevant persons.'[2] To further ensure that all complaints and concerns are investigated thoroughly, Root Cause Analysis will be used (See Appendix 2 on page 29). This will ensure that any necessary actions are taken to respond to failings and that this is done in a way that is open, transparent, fair and satisfactory to all parties involved. This will enable St Helena to learn and improve the quality of care for patients and carers.

This policy and procedure also describe a Complainant's options should they remain unsatisfied at the conclusion of their complaint.

To whom does this policy apply?

All St Helena staff and anyone raising a concern or complaint about PFS.

Who should read this policy?

All St Helena staff working in PFS. Managers in other directorates should be familiar with this policy to the extent that they can enable their staff to convey a complaint (or Complainant) about PFS to a manager within the directorate.

This document will be made freely available to the public via the Policies section of St Helena's public website and will be updated as required. It will not be withdrawn without the formal approval of the Clinical Governance and Compliance Group (CGCG) or its successor body.

Definitions and Terminology

[1] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 16.

[2] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20.

Apology means, with respect to the Duty of Candour, "an expression of sorrow or regret" that does not necessarily entail "an admission of guilt."[3]

Candour is the forthcoming and open communication to patients and carers of any harm caused to them in the process of the care we provide to them and the offer of an appropriate remedy. For the avoidance of doubt, 'carer' may indicate any family member or any other person, paid or otherwise, authorised to act on behalf of a patient. For more detail, see the Duty of Candour Policy [012].

Complaint means an expression of dissatisfaction from a patient or carer about the care or service they (or the person for whom they care) have received. It will require investigation and usually a written response.

Complainant For the sake of clarity, in this policy and procedure, a Complainant is anyone making a complaint or registering a concern. If the complaint made by a person is on behalf of somebody else, that latter person is the Person Affected.

Concern is a notification that an aspect of our service is, or might be, unsatisfactory; but not so much that the Complainant feels they, or a person they care for, has personally suffered as a result. A concern generally will not be serious or complex and can be addressed promptly with minimal intervention. It is unlikely to require a written response.

Openness is enabling complaints and concerns to be raised freely, without fear of recriminations or punitive consequences, and with a commitment to answer questions.

Transparency means providing accurate, clear, and complete information about performance to staff, patients and carers, the public, partner organisations, and regulators.

[3] Section 2 of the Compensation Act (2006) states that 'An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty'.

General Principles

For clarity, the general principles of this document are grouped under the (PHSO) Principles of Good Complaint Handling. This document should also be read alongside the Duty of Candour Policy [012], which also outlines the Being Open principles.

Note. Complaints that identify or allege a Serious Incident (SI) must also be logged as such on the Sentinel Incident Module, in accordance with the Serious Incident Management Policy and Procedure [014].

Getting it Right

- Initial responsibility for handling complaints and concerns resides with the individual staff members receiving them, until such time as they are reported via Sentinel.
- Staff should use common sense to respond to urgent concerns promptly and report them to their line manager. Urgent concerns must still be logged on Sentinel with a full recording of any immediate actions taken.
- Once they have been reported, the Risk and Incident Group (RIG) has operational responsibility for managing concerns and complaints concerning PFS. This includes ensuring staff are sufficiently trained to receive, report, and investigate concerns and complaints.
- The RIG will ensure that an adequate record is made of all concerns and complaints, including all correspondence, investigation findings, outcomes and actions. Without exception, where no action is taken, the reasons for this should be recorded.
- The RIG will ensure compliance with all actions mandated in response to concerns and complaints, referring to the Clinical Governance and Compliance Group (CGCG) as required.
- At its discretion, the RIG may raise the status of any concern to a complaint, regardless of whether the person reporting the concern has requested this. In this event, the investigation process should place no additional undue burden on the Complainant.

- **All activity** relating to a complaint or concern – communications, meetings, investigations, learning, changes to policies, and actions – must be documented on the appropriate record of the Sentinel Complaints Module. Complaints should not be logged on the Incident Module. All staff are expected to maintain the Sentinel record as they would a patient's clinical record. All material and information relating to a complaint should be attached to the record and staff should use their good judgement to anticipate what information will likely be needed to either investigate the complaint internally or refer it to an external agency.

  At the absolute minimum, the reporter must record the identity and contact details of the Complainant and the full particulars of the complaint.

Being customer focused

- Anyone should be able to make a complaint or raise a concern with any member of staff, either verbally or in writing. This includes 'worried bystanders' –third parties with no other involvement with St Helena.[4]
- In the spirit of Healthwatch England's position that there should be 'no wrong door' when making complaints, managers in other St Helena directorates should ensure that their staff are equipped to record and communicate a complaint or concern to an appropriate manager within PFS or to put the Complainant directly in touch with that manager. Complainants **should never** be directed to seek out a member of PFS staff for themselves. This requirement should be incorporated into other St Helena complaints policies where required.[5]
- St Helena should ensure that guidance on how to raise a concern is made readily available to the public, patients, and carers. This should be done using the public website and in printed material displayed in St Helena facilities and supplied to patients on referral or admission. Complainants should be fully supported to raise

[4] Healthwatch England (2014), "Suffering in Silence," p. 6.

[5] Op. cit.

concerns or make complaints and this support may entail, for instance, advocates or interpreter services.

- Concerns or complaints received anonymously should be dealt with as fully as practicable. When anonymity means the complaints or concern process cannot be applied fully, any exceptions or limitations should be documented and explained. Anonymity should never prejudice the credibility of a complaint or concern.

Being open and accountable

- Consent and confidentiality, including such wishes as expressed by the Complainant, must not be compromised during the complaints process unless there are professional or statutory obligations that make this necessary, such as safeguarding. Complainants' consent should be sought before sharing their information with other organisations and this documented. Complainants should be directed to the online St Helena Privacy Notice or offered a hardcopy.
- Confidential information about a patient may only be shared with their duly authorised representative. This authorisation must be properly recorded. In cases where the patient has died, staff should establish whether a potential representative is suitable.
- Complainants, and those about whom complaints are made, must be kept informed of the status of the complaint and its investigation, and be advised of any changes made as a result.

Acting fairly and proportionately

- Complainants must not be discriminated against or victimised. Care and treatment for patients and families must never be prejudiced by any complaint, regardless of outcome.[6]

[6] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 16.

- St Helena (and everyone working within it) has a duty to be honest, open, and truthful in all dealings with patients, carers, and the public. Nevertheless, St Helena recognises the stress that complaints can sometimes place on staff and will support them, including with safe and supportive spaces to share and reflect on lessons learnt. The above notwithstanding, organisational and personal interests must **never** be allowed to outweigh our duty to be honest, open, and truthful.

Putting things right

- Staff should establish with the Complainant at the outset the outcome they are looking to achieve; be this an immediate remedy for a problem, an explanation or apology, a full investigation potentially leading to disciplinary action, a legal claim, or a change to the organisation's policies, procedures or operation.[7] So far as is proper and practicable, we should always strive to provide the outcome Complainants desire.

Seeking continuous improvement

- St Helena should not merely accept concerns and complaints fairly and openly; it should actively welcome them as an important source of feedback and 'an early warning of failures in service delivery.' Every concern or complaint is an opportunity to improve the quality of care for other people.[8]
- Appropriate action must be taken without delay to respond to any failures identified by a complaint or the investigation of a complaint. Actions taken should be documented on the record using the Actions form to demonstrate that the organisation has learnt from it. Where actions are taken, these should be evidenced rather than merely asserted.

---

[7] Healthwatch England (2014), "Suffering in Silence," p. 6.

[8] 'Learning from complaints is a powerful way of helping to improve public service, enhancing the reputation of a public body and increasing trust among the people who use its service. Public bodies should have systems to record, analyse and report on the learning from complaints. Public bodies should feed that learning back into the system to improve their performance' PHSO 2008).

- The RIG shall have principal responsibility for monitoring complaints, looking for trends, and identifying areas of risk. It will bring these to the attention of other clinical governance subgroups as required. The RIG will produce quarterly reports for the CGCG.
- The RIG will also enforce compliance with complaints handling standards, having principal operational responsibility for ensuring investigations are timely and adequate, and actions mandated in response to concerns and complaints are monitored and completed.

Being Responsive and Caring

- At all times, staff should deal with concerns and complaints sensitively, positively, and empathetically; ensuring that the Complainant knows that they are being listened to and taken seriously and that we understand the outcome they are seeking. The Complainant should never be made to feel that they are a burden, inconvenience or nuisance to staff. Staff must avoid presenting the process of making a formal complaint as intimidating, confrontational or onerous.
- St Helena should be sympathetic to Complainants who wish to 'stop the clock' on a complaint while dealing with illness, trauma or bereavement, unless to do so would prejudice a disciplinary process, jeopardise patient or staff safety, or entail a breach of statutory or regulatory duties.[9]

Concerns Procedure

1. A concern may be raised with any member of staff. Concerns received via *iWantGreatCare* or any other survey or feedback mechanism should be handled separately but logged and supervised by the Quality Assurance and Audit Group. Complaints received by these mechanisms should be logged on Sentinel at the discretion of the Director Care or the Head of Quality & Compliance.

[9] Healthwatch England (2014), "Suffering in Silence," p. 6.

2. When receiving a concern in person, staff should ask for the full details and take written notes if required. They should be sure to record the following:
    - The name of the person raising the concern.
    - The date received.
    - The name and position of the person receiving the concern.
    - A brief description of the concern. This should be verified with the Complainant.
    - The outcome or response the Complainant is seeking, including whether they want any feedback. If they do want feedback staff should record;
        i. Whether the Complainant wants a verbal or written response.
        ii. Any contact details that may be necessary.
        iii. Any special communication requirements or other needs the Complainant might have.
        iv. If the concern involves an external provider, whether the Complainant consents to having their personal information passed to them.
3. If the Complainant is raising a concern that has affected them or a person for whom they care who is in receipt of St Helena services, they should be asked whether they wish to make a formal complaint. If they choose to make a complaint, the complaints procedure should be followed from this point on (go to page 10).
4. The person raising the concern should be informed that their concern will be logged and raised with the appropriate manager. They should be informed of the timescale within which they can expect to receive feedback (if it has been requested).
5. Once the details of the concern have been taken, the concern must be logged on Sentinel within one working day.

Investigating the Concern

1. From this point on, the concern will be treated in the same manner as an incident (see Incident Management Policy and Procedure [013] and the Serious Incident Management Policy and Procedure [014]).
2. If the Complainant has requested feedback, this should be given in the preferred form where practicable at the conclusion of any investigation or, if no investigation is required, within five working days. If the concern is referred to the RIG, the RIG will determine the appropriate response.
3. The RIG should manage investigations, ensuring that they are completed promptly, and that Complainants receive timely notifications. Compliance figures and exceptions will be reported to the RIG at each meeting.
4. Feedback to the Complainant should detail any findings and any actions that have resulted from raising the concern, as appropriate.

Complaints Procedure

1. A complaint may be raised with any member of staff, verbally or in writing.
2. If the Complainant wishes to make a verbal complaint, the following details should be recorded in all instances;
    - The name of the person making the complaint.
    - The Complainant's contact details.
    - The date received.
    - The name and position of the person receiving the complaint.
    - A full description of the complaint, which the Complainant should be asked to sign off for accuracy (where appropriate and practicable).
    - The outcome or response the Complainant is seeking, including whether they want a response and, if so, in what form.
    - Any special communication requirements or other needs the Complainant might have.
    - If the concern involves an external provider, whether the Complainant consents to having their personal information passed to them.

3. Complaints received by post must be logged by whomever receives them.
4. All complaints will be reported in the first instance to the Director of Care (DoC) with the appropriate line manager copied in.
5. For all formal complaints, the DoC will nominate A) a named case handler who will be the Complainant's point of contact throughout the complaint; B) an Investigation Lead. This may be the same person if needed.
6. All Complainants should receive a phone call from the DoC or nominated deputy within 3 working days of receipt to confirm the details of the case and to offer them an initial face-to-face meeting at a mutually convenient time and place. This should be within 10 working days, unless inconvenient to the Complainant. Delays longer than 10 days must be documented on the complaint record.
7. The phone call should be followed up, no later than 3 days after receipt of the complaint, by sending the Complaints Pack to the Complainant. This should be documented on the record. This pack consists of a written acknowledgement from the DoC (or deputy) and should include the following (if established):
    a. A point by point summary of the complaint confirming the specific questions or concerns raised by the Complainant.
    b. The resolution sought.
    c. An outline of the process that will be followed.
    d. The name and contact details of the case handler.
    e. A copy of this policy and procedure.
    f. Any other pertinent information.
    g. If accepted, details of the initial face to face meeting with the case handler.
    h. The date by which they should expect to receive a report.
8. Progress investigating a complaint will be reported at each subsequent RIG meeting until the complaint is closed. At the discretion of its Chair, an extraordinary meeting of the RIG may be convened to discuss the complaint at any stage of the process.
9. On completion of the investigation, the report and subsequent response letter will be reviewed by the DoC and RIG prior to being sent to the Complainant.

10. Investigations should be carried out as promptly as possible, with a written report being sent to the Complainant no later than 28 working days after receipt of the complaint (or, if requested by the Complainant, a telephone call).
    - Where investigations breach their deadlines, the Investigation Lead must document the reason on the record and any extension must be approved by the Complaint Owner. Breaches will be reviewed by the RIG.
    - Where the 28 day deadline is likely to be breached, or is breached, the Complainant must be given an explanation and a revised completion estimate. All exceptions to the deadline and revised deadlines must be documented on the record.
    - The RIG will monitor compliance and exceptions.
11. The full response must follow the template provided in Appendix 3 on page 30.
12. The Complainant will be invited to confirm if they are satisfied with the outcome. The deadline for this will be 20 working days, after which, if no response is received, the complaint will be closed, and the Complainant recorded as satisfied. The Complainant will also be offered a face to face meeting with their case handler or a member of the Senior Leadership Team, should they wish it.
13. If the Complainant requests a face to face meeting, this will be an opportunity for the case handler to further explain the investigation findings (if necessary) and to explore with the Complainant any requests, concerns or objections they might have. Further requests should be treated favourably wherever possible and referred to the RIG if required (in the event of such a referral, the clock will be stopped). At the conclusion of the meeting, the Complainant will be invited to confirm if they are satisfied with the results of the investigation. If they are satisfied, the complaint will be closed. Note that the Complainant must be reassured that they do not need to decide at this meeting and may take 10 working days to consider their response. If this deadline passes without response, the complaint will be closed, and the Complainant will be recorded as having been satisfied with the resolution.

14. If the Complainant is not satisfied with the outcome, they may request that their complaint is reviewed by the Patient and Family Services Committee of the Board of Trustees at their quarterly meeting or earlier, if necessary, by the Chair of the Committee. The Complainant should be given the opportunity to speak to the Committee or individual Trustees if they request. The Committee Chair should then write to the Complainant outlining their findings. If the Complainant remains dissatisfied, they should be given advice and assistance to refer their complaint to the NHS Suffolk and North East Essex Integrated Care Board (ICB) for their review. The complainant may also ask us to refer their complaint to the Parliamentary Health Service Ombudsman (PHSO) for review, although they should be informed that the PHSO may not accept the referral.
15. If the complaint is referred to the ICB or PHSO, St Helena will cooperate fully with any ensuing investigation and will comply with any requirements that may result.
16. When complaints are upheld or partially upheld, the RIG should send a summary to the appropriate team to ensure lessons are learned and that any action plan is completed. The RIG will approve all actions and ensure compliance. Staff members should be supported to reflect on their practice as required.
17. Complaints will be seen primarily as an opportunity to learn rather than a reason to apportion unfair blame. However, the DoC, in consultation with the RIG and senior colleagues where necessary, will determine whether a complaint merits invoking the disciplinary process against any member of staff. The Complainant shall be informed of the disciplinary process and, at the discretion of the RIG, its outcome.

Reporting

- Complaints and concerns will be reported from the RIG to the CGCG in its submission to the 1st draft Quarterly Quality Report. This will be an anonymised summary of each complaint, findings, whether the Complainant

was satisfied, and any actions resulting from it. The RIG will also report quarterly compliance figures.

- The CGCG will report to the PFS Committee and to the ICB and CQC using the final draft of the Quarterly Quality Report.
- St Helena must provide to the CQC,[10] by no later than 28 days beginning on the day after receipt of the request, a summary of
    - All complaints made
    - Responses made to such complaints
    - Any further correspondence with the complainants in relation to such complaints, any other relevant information in relation to such complaints as the Commission may request.

Security

Access to complaints is restricted to only those people with a legitimate purpose in accessing them. Certain complaints may be further restricted, and access granted as appropriate. Parties to a complaint may not be permitted access to the record except with the approval of the Clinical Director. All accesses and amendments to records are logged.

Associated Policies and Procedures

- Duty of Candour Policy [012]
- Clinical Incident Management Policy and Procedure [013]
- Serious Incident Management Policy and Procedure [014]

Compliance with Statutory Requirements

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 16.

[10] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 16.

Responsibilities/Accountabilities

Title	Accountability
Director of Care	Overall responsibility for compliance with this policy in Patient & Family Services
Line Managers	Responsible for ensuring their staff comply with this policy.
All staff	To understand this policy and their responsibility for receiving complaints.

Staff Training Requirements

Training on this policy should be conducted by the Learning & Development Officer annually.

Monitoring (Including Audit) and Frequency of Review

Compliance with this policy will be monitored through an annual audit managed by Quality Assurance and Audit Group and reported to the Risk and Incident Group and upward to the Clinical Governance and Compliance Group

This document shall be reviewed every three years.

Data Protection

Does this Policy require sign off from the Data Protection Officer?	No

References:

1. **Care Quality Commission** (2014) “Complaints Matter” http://www.cqc.org.uk/sites/default/files/20141208_complaints_matter_report.pdf (accessed 05/08/2016)

2. **Health and Social Care Act 2008** (Regulated Activities) Regulations 2014: Regulation 16. Receiving and acting on complaints, http://www.cqc.org.uk/content/regulation-16-receiving-and-acting-complaints (Accessed 05/08/16)

3. **Healthwatch England** (2014) "Suffering in Silence. Listening to consumer experiences of the health and social care complaints system," http://www.healthwatch.co.uk/sites/healthwatch.co.uk/files/hwe-complaints-report.pdf (accessed 05/08/2016)

Equality Impact Assessment Initial Screening Tool

Document Reviewer(s):	Clinical Policies and Procedures Review Group	Date Assessment Completed:	06/04/2023

Assessment of possible adverse impact against any minority group			
Could the document have a significant negative impact on equality in relation to each area below?	Response		If yes, please state why, and the evidence used in your assessment
	Yes	No	
1. Age		X	
2. Sex		X	
3. Disability		X	
4. Race or Ethnicity?		X	
5. Religion and Belief?		X	
6. Sexual Orientation?		X	
7. Pregnancy and Maternity?		X	
8. Gender Reassignment?		X	
9. Marriage and Civil Partnership?		X	

- You need to ask yourself:
- Will the document create any problems or barriers to any community or group?
- Will any group be excluded because of this document?
- If the answer to either of these questions is yes, you must complete a full Equality Impact Assessment.

Assessment of positive impact			
Could the document have a significant positive impact by reducing inequalities that already exist?	Response		If yes, please state why, and the evidence used in your assessment
	Yes	No	
1. Promote equal opportunities		x	

2. Eliminate discrimination		X	
3. Eliminate harassment		X	
4. Promote positive attitudes towards disabled people		X	
5. Encourage participation by disabled people		X	
6. Consider more favourable treatment of disabled people		X	
7. Promote and protect human rights		X	

On the basis of the information/evidence/consideration so far, do you believe that the document will have a positive or negative adverse impact on equality?

Positive	Please rate (delete as applicable) the level of impact					Negative
			NIL			

Is a full equality impact assessment required? No

Appendix 1 – Investigation Procedure

Investigation Procedure

Appointing an Investigation Lead

Upon receipt of a complaint, the DoC will decide whether an investigation is needed. Where it is, the first act will be to appoint an Investigation Lead. In cases where the complexity of the complaint appears to merit it, the DoC may appoint a team to assist the Investigation Lead, but this will be exceptional. Throughout the remainder of this section, 'Investigation Lead' should be taken to mean either an individual or team.

Any team should comprise staff with the requisite knowledge to provide appropriate scrutiny during the process but should not include anyone directly involved in the incident. The DoC may also procure external consultants where necessary.

The role of the Investigation Lead is to ascertain the facts, assess the evidence and report their findings. They should aim to be impartial and examine the facts and evidence logically. It is essential to remember that the Investigation Lead is neither an advocate for the Complainant, nor a spokesperson for St Helena.

Defining the Terms of Reference

The DoC and/or the Head of Quality and Compliance (HQC) will produce Terms of Reference (TOR) for investigations. Investigation Leads may request TOR be amended if there is a sufficient reason. This may include where the investigation brings new matters to light or where the Complainant raises additional concerns.

Once it has been decided a complaint requires investigation, the TOR will be included as part of the Sentinel action to the nominated Investigation Lead. This action must be sent within 48 hours of the decision to investigate. The TOR must broadly define the questions the investigation should answer and specify the known or suspected Care Delivery Problems (CDPs). Broadly, TOR should require the investigation team to produce a clear report establishing the plain facts of the incident and answering the following questions:

- What happened?
- What were the consequences?
- Which, if any, processes or procedures were not followed?
- Which, if any, processes or procedures were deficient?
- Which, if any, equipment was at fault?
- Who, if anyone, was at fault?
- What was the underlying cause?
- What, if anything, should be done to prevent a similar re-occurrence?

By addressing each of these questions in turn, it should be possible for the Investigation Lead to get at the root of the complaint and contrast what did happened with what should have happened. Generally, this will need to be done for each CDP identified.

Reports are a legal record. Remember that your investigation will form the basis of St Helena's response to the incident and could be shared externally. It may be read by patients, family members, legal authorities, and others outside St Helena. It should provide all the information needed to understand what happened. Nobody reading it should need to ask you further questions to understand it. It should not use shorthand and people involved should be clearly identified. A useful rule of thumb is that reports should be written as if to be read by someone who does not work here. The HQC can advise on this.

It is important to remember that the investigation should be a synthesis of the available evidence, not merely a summary of 'he said but she said'. The goal is to reconcile contradictions, eliminate ambiguities, and account for discrepancies to arrive at as an authoritative account as is possible. Where contradictions and discrepancies cannot be resolved they must be acknowledged.

Conducting the Investigation

Before commencing the investigation, the Investigation Lead should consider whether any of the following is necessary.

- Speaking to the Complainant to further clarify their concerns and their perception of where service fell short of their expectations. It may also be necessary to manage their expectations.
- Notifying service leads/managers of the investigation.
- Notifying any interested external parties of the investigation.
- If working with a team, discuss the TOR, any Root Cause Analysis (RCA) tools to be used, set goals and deadlines, and a programme of work to meet them.

The Investigation Lead should consider the specifics of the complaint when determining how to devise a robust investigation that addresses all the relevant issues. Where there are no concerns about individual or collective practice and no contention over the facts of the incident, a low level, 'desk-based' investigation may be sufficient. Where the complaint is more complex, the facts are unknown or disputed, or individual practice has been questioned, a more thorough investigation with fact finding will be required. The format for such an investigation is discussed below.

Initial evidence collection

It is essential that the Investigation Lead identifies and secures all relevant evidence as soon as possible. They should begin by drawing up a list of all the likely sources of documentation on the incident. These will include:

- SystmOne records for the relevant admission
- Call logs
- Administrative records
- Witness statements/interviews
- Training records
- Duta rotas
- Manufacturers' product reports
- Current policies/procedures

If there is any possibility that documentation might be relevant, it should always be secured, even if it turns out later not to have been useful. It is far preferable to secure

evidence and then to not need to use it than to need evidence that one has neglected to collect.

It may be necessary to secure physical evidence, such as equipment or medicines, or to photograph the relevant location. Evidence must be secured as soon as possible after any complaint or incident. ‘Secured’ means preserved in such a way that it cannot be altered from its state at the time of the incident. Items should be removed from situ or, where this is not practicable, photographed in sufficient detail. Dated copies of records should be taken if necessary, to preserve their integrity. Items must be stored in areas with limited and controlled access. Medicines involved in incidents or complaints must not be stored in the Drug Room.

Staff statements

Where statements are required, the Investigation Lead must take them in person or require them to be sent by secure email. It is then the responsibility of the Investigation Lead to add them to the appropriate sub-form on complaint record. Witnesses must not be permitted access to the complaint record, as this may prejudice the investigation. The HQC can offer support on securing records. Statements taken in person should be agreed with the person giving them who should be asked to sign them. Staff should be asked to sign statements directly under the last line to ensure confidence. For staff completing them by email, the email itself will be regarded as the signature. Scanned, signed originals and emails must be attached to the Sentinel record as evidence.

To conduct a successful interview, it is important to:

- Understand the needs of the person and the background to the complaint
- Know the questions you want to ask in advance
- Know when specialist support is needed
- Let the interviewee know in advance what you are likely to ask, so they can prepare, and explain that you would like to record the conversation with their permission
- Give the interviewee the option of having a witness of their choice present

- Hold the interview in a private place and avoid interruptions
- Ask the interviewee to recount their version of what happened and the problems with care they think occurred. Avoid interrupting when they first give their account
- Ask the individual what they think could have prevented the incident, focusing on the conditions and events preceding it
- Use open-ended questions to elicit information
- Ask clarifying questions to fill in missing information. Allow staff to tell the story as they see it. Don't correct them or prompt them with contradictory accounts
- Reflect to the interviewee the information obtained. Correct any inconsistencies.

Compiling a Chronology/using an RCA tool

Once the information has been collected, it can be used to compile a chronology of events leading up to, during, and immediately after the incident. This chronology is an investigatory tool and does not from part of the report. It should, however, be included as an appendix to help those who review the report.

Problem exploration and drawing conclusions from evidence

Once all the evidence has been gathered and a timeline constructed, the Investigation Lead should begin the process of applying RCA to the CDPs that have been identified during the course of the investigation. The two tools commonly used for this are the '5 Whys' technique and the contributory factors grid (fish bone analysis).

The Investigation Lead will use this analysis to draw up any recommendations they have to reduce or eliminate the potential for similar occurrences. Potential points of failure include:

- Human error or inappropriate behaviour by staff.
- The poor application of resources (e.g. too late, incomplete, insufficient prioritisation).
- Procedural or administrative problems.
- Services not able to deliver the requirement.
- The organisation failing to understand or accept its responsibilities.

The report should be:

- Complete: Does the response cover all the relevant aspects of the complaint and address all the required issues?
- Relevant: Does everything in the response contribute to an understanding of the conclusion reached by the Investigation Lead or explain any recommendations made?
- Logical: Does the response present a reasoned and understandable progression from complaint to conclusion?
- Balanced: Is the response impartial, factual, and measured? Does the report deal with the issue from the viewpoint of the Complainant, but also establish the right context for the actions of the organisation?
- Robust: Does the response make sense and present a coherent argument in support of the Investigation Lead's conclusions and recommendations?

Ratification of investigation report and action plan

Once complete, the Investigation Lead will record their draft report and action plan on Sentinel, notifying the DoC and the HQC. Once the report and recommendations have been approved, the DoC will send them to the Complainant, less any necessary redactions and anonymisation. Where deemed necessary, reports and recommendations will also be reviewed by RIG before they go to the Complainant.

Staff who are involved in complaints

Line managers will support staff who are subject to a complaint, acting as an intermediary between they and the Investigation Team. The Being Open principles require staff members to be kept as informed as possible about the nature of the complaint and the progress of the investigation, insofar as the investigation is not prejudiced. Staff members asked to be interviewed may request the presence of their line manager, a disinterested colleague, legal counsel, or a union representative. In the case of allegations of serious or potentially criminal activity, staff will be advised to seek legal counsel.

St Helena will always seek to take a supportive rather than punitive approach to investigating complaints and will always operate a fair blame culture.

Where a draft report makes criticisms of staff, the DoC will ensure that they can respond and, where appropriate for that response to be included in the final report.

Sharing Learning internally and externally

If the complaint relates to a Serious Incident or is otherwise subject to the interest of Commissioners or the Care Quality Commission, it will be sent to them by the Director of Care. Other stakeholder who may also need a copy include:

- HM Coroner
- The Health and Safety Executive
- The Police

The above list is not exhaustive and external stakeholders may be identified as the event occurs or is investigated.

Any meetings held to provide feedback from investigations and share learning should be minuted.

Action Plans

All actions resulting from a complaint must be recorded on the relevant Sentinel record using the Actions function and completion will be monitored by the RIG. Each action must specify:

- The action to be taken
- The CDP or issue the action addresses
- Any resource requirements
- The Action Sponsor
- The Action Owner
- The deadline
- The required documentation to evidence completion.

Actions should always be SMART: Specific, Measurable, Agreed, Realistic, and Time-scaled.

Care must be taken in the phrasing of actions. A useful rule of thumb is that an action must include a verb and a noun. It must also be obvious when an action would be complete (time-bound). An action should also be singular, not several tasks wrapped up in one. The text of an action should be self-contained: it should make sense if read in isolation from the rest of the report.

Examples of good actions:

- Please **repair** (verb) the **front wall** (noun)
- Please **summarise** (verb) this **report** (noun) in the IPU team meeting and **report back by deadline** (time-bound).

Examples of poor actions:

- “Medical team training re: processes” Too vague.
- “Please could you look at the processes that led to this error. Can you ring and apologise to the patient and his wife and ascertain any issues that were not addressed.” Multiple tasks in one.
- “Please keep this under review.” Keep **what** under review? When would this action be complete?

Appendix 2 – Example agenda for Investigation Team meeting

This is a list of items that would likely be needed on the agenda of Investigation Team meetings. If there are several meetings during an investigation, items 2-4 are unlikely to be needed for all of them.

For Investigation Leads acting alone, these items are useful prompts for structuring your activity.

		Lead for any actions
1	Expected attendees and any apologies	
2	Incident overview: • Details of the incident • Immediate actions taken • Support required for patient, family, and staff	
3	Patient Background: • How long known to services • Diagnosis • Teams involved in care	
4	Review of assessments and care: • Were care plans in place, adequate and have they been updated following the incident? • Were risk assessments in place, adequate and have they been updated following the incident? • Was care of the appropriate standard?	
5	Findings: • What are the findings of the review?	Chair
6	Actions required: • What recommendations does the Team have?	Chair
7	Any other issues to be discussed: • Is there anything else to be discussed or actioned in relation to this incident? • Do any other agencies need to be aware of the findings?	Team

Appendix 3 – Root Cause Analysis Methodology for Investigating Complaints