

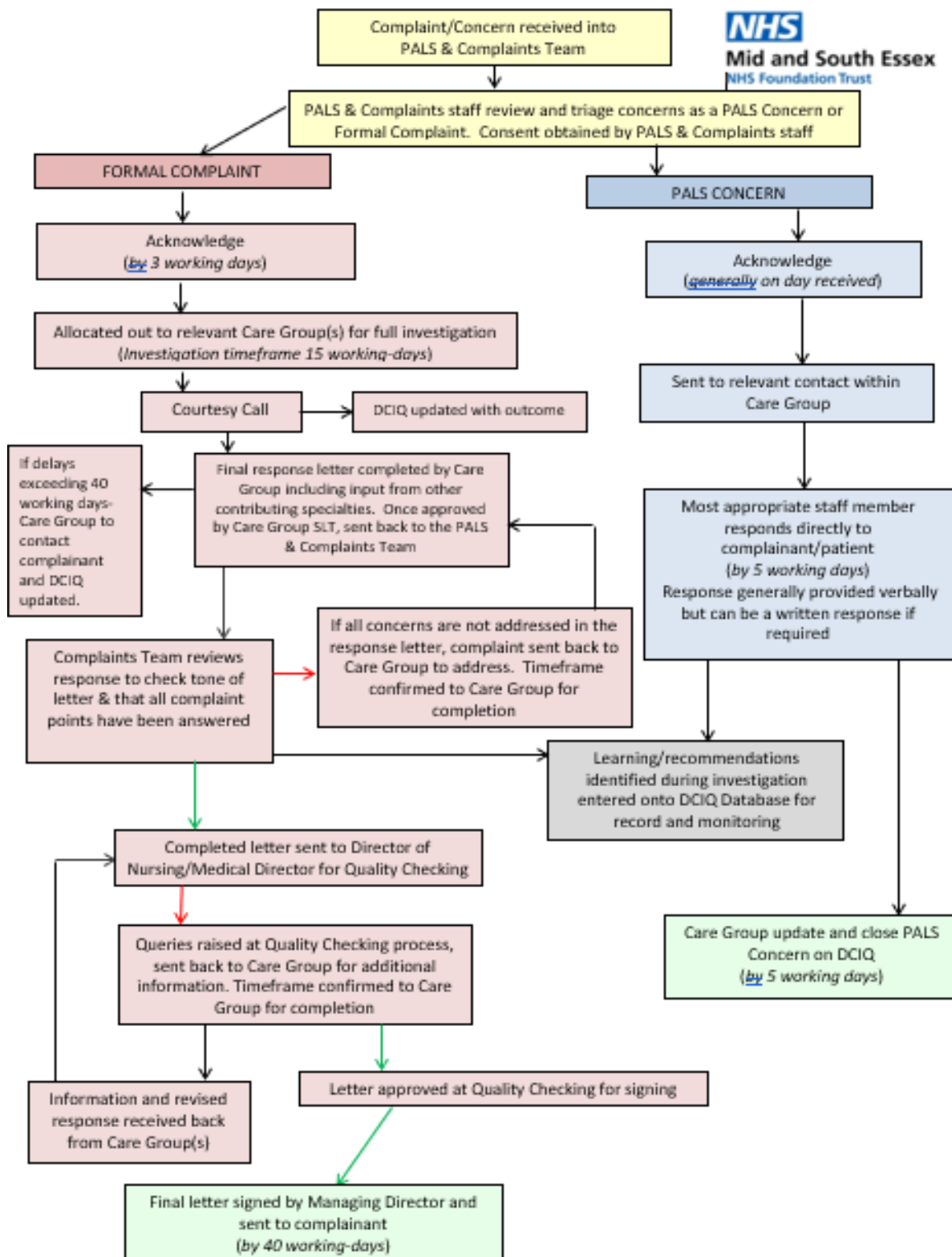
## Policy on the Management of Complaints and PALS

Reviewed by	Approved by	Summary of Changes
<Signature>	<Signature>	Changes from previous version appear in Blue
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May 2025	May 2025	

<b>ASSOCIATED PROCEDURES &amp; FORMS</b>	Identification, Investigation and Control of Non-Conformities [PF-GEN-MP-41] Error and Incident Reporting and Investigation [PF-GEN-MP-39] User and Patient Satisfaction [PF-GEN-MP-2] Quarterly Log of PALS and Trust Complaints [PF-GEN-EXT-36] Consent for Representation letter – [PF-GEN-MF-135] Trust PALS and Complaints Handling Policy [PF-GEN-EXT-86] Complaints and User Feedback [PF-PIP-9]
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<b>LOCATION OF HARD COPIES</b>	

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## 1. Purpose and Scope

The purpose of the Policy is to document the process for managing complaints received from Clinicians, Patients, Staff or other stakeholders in accordance with the requirements of clause 7.7.3 of the ISO 15189:2022 standard.

All complaints are taken seriously by Pathology First, however the way in which they are managed generally depends on where and how they originated. This policy aims to define these processes. Please note that all Complaints, from whatever source, must go to the Quality Team generic e-mail as they are best placed to ensure it is swiftly directed to the correct department / person for investigation and resolution. [The e-mail address is ippl.qualityteam@nhs.net](mailto:ippl.qualityteam@nhs.net)

Where possible complaint trends are investigated as a means of learning from the complaint and prevent any future complaints. Complaints are reported on at Governance and discussed at fortnightly and monthly Governance meetings

Please note that Pathology First will fully investigate all complaints and if this requires taking action with staff such as re-training or performance management etc, it will be undertaken promptly. However staff will be managed internally and their names will never be made public or included in the response to any complaint.

[This policy also deals with PALS \(patient advisory and liaison service\) and Enquiries where patients can ask questions or raise concerns that are not a formal complaint and explains how these are managed by PF and the Trust.](#)

Pathology First strives to ensure that it is an easy process for someone to make a complaint and therefore there is a useful document on the User Handbook around Complaints and User Feedback [PF-PIP-9] as a guide on how to make a complain.

## 2. Responsibility

It is the responsibility of the appropriate Operations Manager to investigate, or delegate the investigation, of any complaints that result from activities within their departments. The investigations and outcomes must be recorded as indicated within this policy and this information must be passed to Quality Team, MSE Governance board, PF Governance group, PCC committee and staff as appropriate to the nature of the complaint.

The Quality Team will act as the channel for ensuring Complaints are handled correctly and quickly, but they are not generally responsible for the investigation or resolution of the complaint. This is managed by the Quality Team using their generic e-mails address – [ippl.qualityteam@nhs.net](mailto:ippl.qualityteam@nhs.net)

If a Complaint is received directly by a department within Pathology First, either from PALS or a clinician etc, it is the responsibility of that department to ensure the Quality Team is made aware so that the complaint can be monitored, trended and reported in accordance with the requirements of the ISO 15189:2022 clause 7.7.2

Pathology First is responsible for patient confidentiality and the maintenance of GDPR. To this end any release of patient information and data is only made to the requesting clinician or their representative unless otherwise

required by the police / Coroner. Any emails between PF and the Trust that contains patient identifiable data must be via nhs.net e-mail accounts. Confidentiality also applies to anyone visiting the site such as contractors or external bodies and they are required to keep any information seen or created during their visit confidential, either via their agreement with PF or via signing a Permit to Work form. This covers the additional clauses in the confidentiality section of the ISO15189:2022 [clause 4.2](#)

The Quality Team (including Trust Quality staff) will report to the Joint Governance Group on the numbers of complaints and any trends noted.

### 3. Definitions

**CAPA** – Corrective Action / Preventive Action

**DCIQ** – The Trust reporting system for Incidents and Complaints and is the latest version of Datix

**GDPR** – General Data Protection Regulations

**MSE** – Mid and South Essex NHS Foundation Trust

**PALS** – Patient Advice and Liaison Service offers confidential advice, support and information on health-related matters. They provide a point of contact for NHS patients, their families and their carers

**PF** – Pathology First

**Subgroup** – Meetings held with senior technical staff and consultant for each department

**Trust** – Refers to MSE Trust but specifically in terms of the JV this will be complaints from Southend or Basildon hospitals and their associated [Primary Care providers](#)

### 4. Records

All records / documentation generated as a result of a process shall be entered onto Q-pulse and where applicable also onto DCIQ

### 5. Process for Raising Complaints or PALS

The Quality Team has oversight of all complaints raised against Pathology First and these are raised through the following channels:

#### 5.1 Complaints / PALS from the Trust / Governance PALS teams

Complaints received from clinicians (hospital medical / nursing staff or GP's) are generally made via the Trust incident reporting systems. These are forwarded to the Quality Team who will direct them to the appropriate manager for investigation.

All complaints logged via PALS or the Trust complaints teams are reported to the relevant Departmental Operations Manager for investigation. Any clarification and resolution can be obtained by contacting the complainant directly but also feedback to the PALS or the Trust complaints teams. Once again it is essential that the Quality team are made aware of any complaints that are being dealt with locally so that they can be recorded and trended.

#### **5.1.1 [Complaints from patients](#)**

[Patient complaints are usually received through PALS or the Trust Complaints team](#)

No written complaint responses received through the Trust will go out directly to the patient on any Pathology First or Synlab headed paper; they should always be returned to the relevant PALS or Trust complaints team for a final response.

### **5.2 [Complaints sent directly to Pathology First and/or the Quality Team](#)**

Complaints raised via the internal incident reporting systems are managed and monitored by the Pathology Governance Lead at the Trust in conjunction with the PF Quality Team.

Complaints provided directly to a department within Pathology First and/or the Quality Team can be either verbal or in written form and shall be logged in the CAPA module of Q-Pulse as a 'Complaint'. Patients, who provide feedback directly to a staff member, will be treated with courtesy and the member of staff will try and provide a satisfactory response. If the member of staff is unable to deal with the enquiry effectively they must pass the enquiry to their supervisor / manager to deal with. Ideally in real time, but certainly immediately after a complaint has been received, it must be forwarded to the Quality Team so that we can ensure it is handled by the correct people in the correct way.

Pathology Consultants may raise complaints or concerns directly with the department Operations Manager, via the subgroup meetings. If the complaint/concern cannot be dealt with in the course of, or immediately following the meeting, then the appropriate manager will need to raise it as a complaint CAPA. These complaints and any actions taken must be brought to the attention of the Quality Team so that they can be reported and trended appropriately.

#### **5.2.2 [Complaints from patients](#)**

Patient complaints may be received directly by staff (usually either in Phlebotomy or via the call centre). These complaints should be recorded on the Complaints section of the CAPA module on Q-pulse and then investigated and resolved by the appropriate manager.

### **5.3 [Complaints from Staff](#)**

Staff are encouraged to talk openly with their line manager at all times to resolve any issues they may have. [This is also the process for raising complaints – however if](#) a member of staff may not feel comfortable making a

complaint to their line manager. In these cases they may do so to the next line of management up, Human Resources, or the Quality Manager. There is also the opportunity to contact the independent Whistleblowing service and details of this can be found on the Speak Up posters displayed on all sites and on Q-pulse [21.1.1a] [and in the policy \[21.1.1\]](#)

## **5.4 Patient Advisor Liaison Service**

### **5.4.1 [PALS received from the Trust PALS team](#)**

The PALS Team are contacted when a patient has a concern about any aspect of the service they have received. This is sent to the Governance team who forward to PF. Any PALS must be investigated and resolution fed back to the Governance team within 5 working days of receipt. If the investigation &/or resolution will take longer than this time period an interim contact must be made back to the patient with a progress report any expected trajectory for resolution.

### **5.4.2 [PALS / Enquiries received directly into PF](#)**

It is not usual to get any PALS or Enquiry direct from a patient, but if this does happen the same process must be followed as in 5.4.1 and the Governance team are made aware of it at the next catch-up meeting.

## **5.5 Complaints received from relatives / representatives of patients**

Special care must be taken when taken a complaint from a relative or representative of the patient. The same process as outlined in section 5.4 will apply in terms of listening to the nature of the complaint and referring all the details to the Quality Team and department manager. However no information can be given to this person about any results or outcomes of the investigation without first ensuring they have the patient's consent to act on their behalf. This can be done in a number of ways and include:

- Evidence that the person has a Lasting Power of Attorney (Health) for the patient
- The return of a completed and signed Consent for Representation letter – [PF-GEN-MF-135]
- The patient being present with their representative at any face to face meeting and indicating that that are happy for the representative to speak on their behalf and have access to results and details of investigations

[Please note – this does not apply when a parent / guardian is complaining on behalf of their child](#)

## **5.6 Complaints from external bodies, suppliers or other Hospitals**

Any complaint provided directly to a department within Pathology First and/or the Quality Team, whether verbal or in written form, shall be logged in the CAPA module of Q-Pulse as a 'Complaint'. If the member of staff receiving the complaint is unable to deal with the enquiry effectively they shall pass the enquiry to their supervisor / manager to deal with.

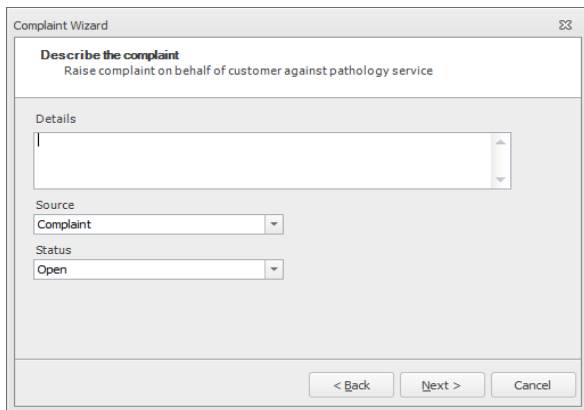
## 6. Receipt of and Recording Complaints on CAPA Module

Complaints, unless they are part of a wider Incident, should be recorded within the CAPA module of Q-pulse. This enables the correct stages to be followed including RCA and Corrective Actions and is the place that the Quality Team will go to to review and trend complaints.

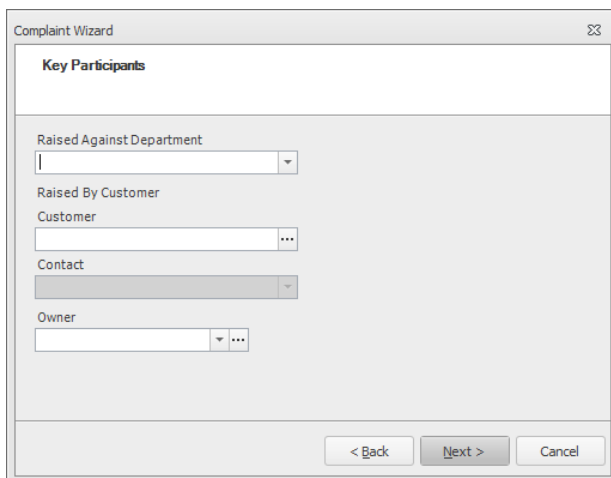
### 6.1 Recording a Complaint

Open the CAPA Module in Q-pulse and create a new entry:

- File
- New
- From Wizard
- Complaint
- Next

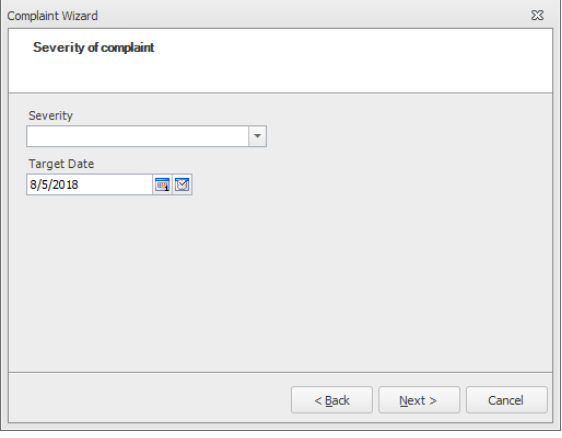


- Record the details of the complaint
- Next



- Complete the details on the second page as above
- Next



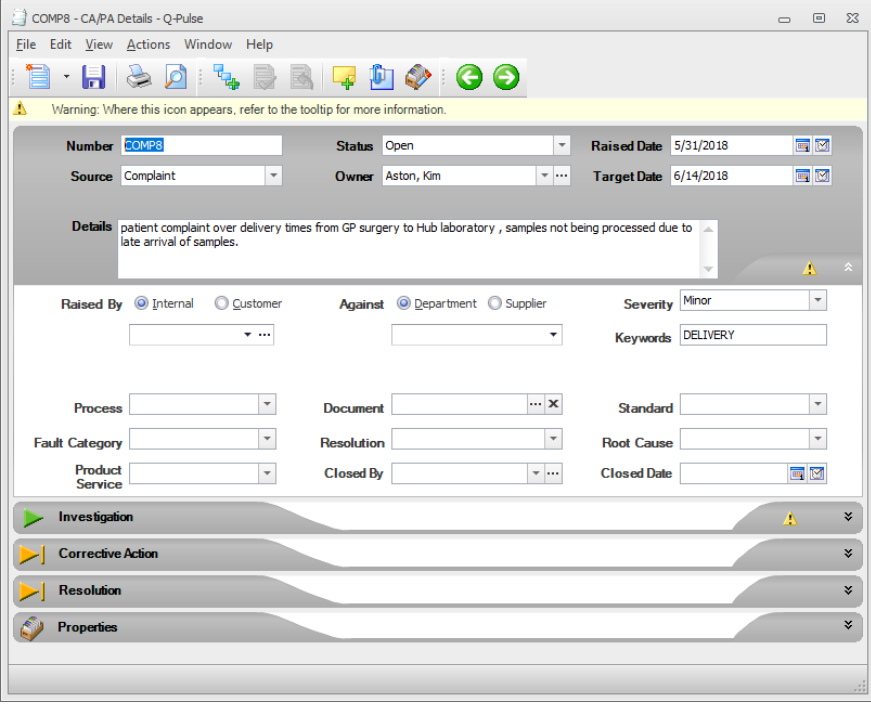


- Record the severity of the Complaint – Minor or Major
- Next
- Finish

This will then create a unique number within Q-pulse CAPA module starting COMP

## 6.2 Recording investigations and results of Complaints on Q-pulse

Enter the COMP number into the search facility in the CAPA module of Q-pulse and the area for investigation etc appears



Complete each section and close in turn ensuring you remember to record the outcome of the complaint within Resolution. Attach any documents or evidence within Properties before closing the whole complaint.

### 6.3 Timescale for responding to Complainants

The timescale for responding to Complainants can vary depending on how and where the complaint is made and also the level of investigation required. At all times we try to follow the same principles and timescales as those in the Trust Complaints Policy.

#### Trust PALS / Enquiries

These need to be completed in **5 working days** and can be answered by phone call or e-mail

#### Trust Complaints

From receipt of email of notification of new complaint the Trust Governance team gets **20 working days** to produce a finalised response. The Governance team ask us for a response within **15 working days** to ensure there is sufficient time to pull all the responses together into the formal letter but that is only really when it is a large complaint covering other disciplines.

Please note that the Trust Complaints Team then get a further 20 working days to quality check it and have it signed by the Managing Director of the site before sending to the patient. The whole process should be complete within 40 working days.

#### Pathology First PALS Enquiries / Complaints

Where these come in directly to PF they are logged onto Q-Pulse and there is no distinction between any of these, as the CAPA section is just Complaints. Q-pulse does not set a target date automatically, but here we defer to be in line with the Trust – so it is **5 working days for PALS** and **15 - 20 days for more formal complaints**

### 6.4 Resolution of Complaints – ISO 15189:2022 7.7.3

The objective of any **type of complaint or PALS** investigation is to achieve resolution of the complaint to the satisfaction of the complainant and also to learn from the event.

The Resolution of Complaints is monitored quarterly by the Quality Team

## 7. Process for Recording and Monitoring Complaint

Complaints information is kept on Q-Pulse as a quarterly updated spreadsheet listing all complaints raised within the Trust against Pathology First. A current, up to date list can be requested and made available for external assessment visits when required. A member of the Quality team manages, liaises and monitors all aspects of complaints.

All complaints are shared with the Trust and anything received directly by PF can also be raised on DCIQ. These are discussed on the fortnightly Governance catch-ups and the monthly Governance meetings. Lessons learnt are also shared between both organisations.

The Quality Manager will regularly feedback on complaints, concerns and compliments to the MSE Governance and Joint Governance Groups and Pathology First Operations and Divisional meetings. All complaints and feedback, including trends shall be monitored through either the Pathology Governance meeting or the Annual Quality Management Review. All actions to be taken shall be documented and timely action taken. This feedback should be cascaded to staff.

Actions taken / suggested following a complaint investigation shall be monitored through departmental meetings, which shall include quality and governance in the agenda. These actions shall be monitored until they are closed.

## 8. References

ISO 15189:2022 standard 7.7 - [Complaints](#)

## Appendix 1 – Complaints and PALS Process

