

Acute Services Division, Diagnostics, Department of Haematology - Clyde Sector				MP-CGEN-006
MANAGEMENT POLICY – Complaints Policy				
Owner	M. Wight	Reviewer	R. Anderson	Version No - 7
Active Date	27.02.23	Revision Date	See Q-Pulse Record	

COMPLAINTS POLICY

This Document together with Policy and Procedure documents to which it refers, serves to define the Quality Management System of the Department of Haematology, Clyde Sector, NHS Greater Glasgow & Clyde. The document has been compiled to meet with requirements of the Blood Safety and Quality Regulations 2005 (“the principal Regulations”), and subsequent amendments; the United Kingdom Accreditation Service (UKAS); and other National and International Standards, as appropriate. All policies and procedures specified herein are mandatory within the Department of Haematology, Clyde Sector, NHSGGC.

Scope & Purpose of Document

This Policy, and related documents, consistent with local NHSGGC, serves to define Departmental policy and associated procedures for the management of complaints.

This Policy serves to work concurrent with NHSGGC Policy, and hence, does NOT replace NHSGGC Policy for handling complaints.

In addition, this document is prepared consistent with **ISO: 151789, Standard 7.7 –Complaints,**

All Departmental staff are tasked with roles and responsibilities for the management of complaints. Where applicable, specific responsibilities for staff shall be defined within the text.

Document Version Changes

Version 6 is amended to Version 7 – updated ISO reference only.

Document References

- ISO: 15189:2022 – Medical Laboratories – Requirements for Quality and Competence.
- Volume 4, EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Part 1 Chapter 8: Complaints, Quality Defects and Product Recalls
- NHSGGC Risk Policy.
- NHSGGC Complaints Policy.
- NHS Scotland Complaints Handling Procedure (CHP), 2017.

Related Documents

HP-CGEN-005 – Risk & Incident Management Policy
 LI-CGEN-020 – Root Cause Analysis – Investigation Procedures
 QF-CGEN-004 – Complaints Report Form

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1.0 Context setting – NHS Complaints Procedure

New NHS Guidance for Complaints, to complement the National Health Service (Complaints) Regulations 2004 No.1768, which, along with the Health and Social Care (Community Health and Standards) Act 2003, provide the statutory framework for the NHS complaints procedure. The Regulations came into force in July 2004. The intention had been to implement the reformed complaints procedure in full, but following an approach by the Shipman Inquiry, Ministers chose to incorporate a phased implementation of the Complaints Regulations in 2005, allowing full and proper consideration to recommendations made by the Shipman Inquiry.

As far as 'Local Resolution' goes, the Complaints Regulations consolidate and rationalise the requirements set out in the various sets of Directions issued since the NHS Complaints Policy of 1996. This means that 'Local Resolution' remains broadly unchanged for NHS bodies and the new guidance updates information provided in the existing guidance as well as expanding on the Regulations.

The Key objectives of the NHS Scotland Complaints Handling Procedure include:

- Ease of access for patients and service complainants,
- A rapid, simple, and transparent process,
- A system that ensures service improvement following complaints,
- Fairness for both staff and complainants,
- Separation of complaints from disciplinary actions.
- If complaints cannot be resolved immediately by the service provider, the complainant has the right to seek independent review including the appointment, where necessary, of a Trustee (Complaints Convenor) and Review Panel

The NHS Complaints Procedure incorporates two distinct principles:

- **Local Resolution** - The principle objective of local resolution is to provide the fullest opportunity for investigation and resolve of complaints in an open, fair and conciliatory manner. On receipt of complaint, written or verbal, the service provider shall attempt to resolve any issue as quickly as is possible. This process shall include, where possible, an immediate response in person by telephone, to be followed by, investigation based upon local (Trust) policy and procedures.
- **Independent Review** - If complaints cannot be resolved immediately by the service provider, the complainant has the option of seeking further review. This review may involve the collation of a panel to reconsider the complaint.

Further advice on how to complain about NHS Scotland services is detailed in the web link below:

<https://www.mwcscot.org.uk/contact-us>

2.0 NHSGGC Policy

The NHSGGC Complaints procedure seeks to ensure, in accordance with NHS Scotland Complaints Handling Procedure, that complaints are handled thoroughly without delay, with the aim of satisfying the complainant whilst being fair and open with all those involved. The Trust acknowledges that there is a requirement to view complaints positively as a valuable contribution to service development and improvement.

Complainants unhappy with the local response to a complaint, or where they would prefer to discuss the matter with someone not directly involved with the issue, should be directed to contact the Complaints Department. Contact information is available at the web link below:

[Complaints - NHSGGC](#)

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2.1 Definition of a Complaint

A complaint is defined as an expression of dissatisfaction regarding any matter, to include facilities, environment, care and laboratory service provided, and attitude of staff, as provided by NHSGGC. Complaints may be made in person, in writing, or by telephone, to any member of NHSGGC staff.

The procedure extends to cover Clinical Complaints (see below), but does **NOT cover litigation or professional regulation**. Such instances, including complaints made by staff, are covered through the NHSGGC Grievance Policy and Procedure.

2.1.1 Definition of a Clinical Complaint

Clinical Complaints are defined as any complaint relating, in whole, or in part, to action taken in consequence of the exercise of clinical judgement – i.e. any judgement that is made by a member of clinical staff by virtue of their professional knowledge and skill, which a layman could not make.

3.0 Departmental Complaints Procedure

This document is prepared consistent with local policies and procedures, as defined by NHSGGC, and with ISO: 151789, Standard 7.7 – Complaints. This standard requires the Department to maintain a documented procedure (**this document**) for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties.

3.1 General Principles

- Local resolution involves complaints being dealt with quickly and where possible at the source of the complaint. The principle function of local resolution, where possible, and where appropriate, shall be the comprehensive satisfaction of the complainant.
- The aim of the complaints procedure is to enable both parties to address the issues in a non-confrontational manner with the aim of mutual agreement (conciliation).
- If any member of staff receives a complaint from any source, the complainant should be referred to a Departmental Consultant, or the Laboratory, or, Quality Manager. They will complete form (**QF-CGEN-004**) and refer this form to the Quality Manager.
- After receipt of a complaint a folder must be started on the secure 'Clyde Management' drive to store all related paperwork.
- A corresponding NC record must also be launched using the 'Complaints' wizard in Q-Pulse.

3.2 Procedure for Handling Verbal Complaints

- Staff, on receipt of verbal complaints, must always act professionally and shall make every effort to act sympathetically, to understand that the complainant had cause to complain, and offer an explanation, with the purpose of seeking resolution of the complaint. If the complaint cannot be, or is difficult to, resolve, the member of staff should immediately seek the advice of a senior staff member.
- Complainants wishing to record a letter of complaint shall be asked to direct letters to the Technical Services Manager who will complete a departmental Complaints Form (**QF-CGEN-004**).
- Complainants, not wishing to write to Departmental staff and wishing to lodge a formal written complaint to NHSGGC Management, shall be requested to contact The Complaints Team, as defined in Section 2.0.

3.3 Procedure for Handling Verbal Complaints Out of Hours

The procedure for handling verbal complaints out with normal office hours is identical to that of Section 3.2, Procedure for Handling Verbal Complaints, with the exception that complainants seeking to speak to a senior manager:

- For immediate attention, complainants should be directed to contact duty Consultant Medical Staff.

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- Where the complainant is content to wait till normal office hours resume, the complainant shall be requested to contact Technical Services Manager or Sector Manager or Quality Manager, or most senior duty manager.
- As for Section 3.2 above, a departmental Complaints Form (**QF-CGEN-004**) shall be completed by the complaint recipient, and forwarded to the Technical Services Manager.

3.4 Written Complaints

Written complaints should be received or referred to the Technical Services Manager. In this scenario, the Technical Services Manager ensure the completion of a departmental Complaints Form (**QF-CGEN-004**), to be forwarded to the Quality Manager.

3.5 Complaint Acknowledgement and Conclusion

For all written complaints resolved at local level, complainants should be replied to, ordinarily, by letter or e-mail from either the laboratory management team or Technical Services Manager. Where there is no quick conclusion, e.g. when complaint investigation and review is perceived to take longer than one week, a communication will be sent to the complainant.

Following complaint conclusion, a letter shall be written to the complainant, itemising investigations performed, the outcomes of such investigations, and where appropriate, formal apology from the department inclusive of corrective and preventative actions adopted, in the assurance that such cause for complaint should not recur.

Complaints, that cannot be satisfactorily resolved to mutual agreement at departmental level, shall be forwarded / referred to the Complaints Team, as defined in Section 2.0.

3.6 Complaint Review

- All complaints shall be subject to formal review by the Haematology management team and local quality team at their next meeting. This group is responsible for the evaluation of corrective / preventative action implemented at the time of complaint receipt, and subsequent to this, the institution of additional corrective / preventative action as required,
- Technical Services Managers shall, through the departmental meeting programme, meeting minutes, memo's, notice boards, etc, communicate complaints, and where appropriate, control measures, including implemented corrective actions, to departmental staff when appropriate.
- Summary conclusions of complaints shall form a standing agenda item of the Annual Management Review.

3.6.1 Investigation of Complaints - Root Cause Analysis

As further defined in **MP-CGEN-005** (Section 7.5), Root cause analysis is a structured investigation that aims to identify the true cause(s) of a problem, via its contributory factors, and the actions necessary to eliminate it.

The principles are useful in the investigation of any incident but it is particularly important in the formal investigation of a Serious/Significant Incident which requires a more comprehensive and structured approach. A root cause is a fundamental cause which if resolved will eradicate, or significantly contribute to the resolution of the identified problem to which it is attached, both within the local department and more widely across the organisation.

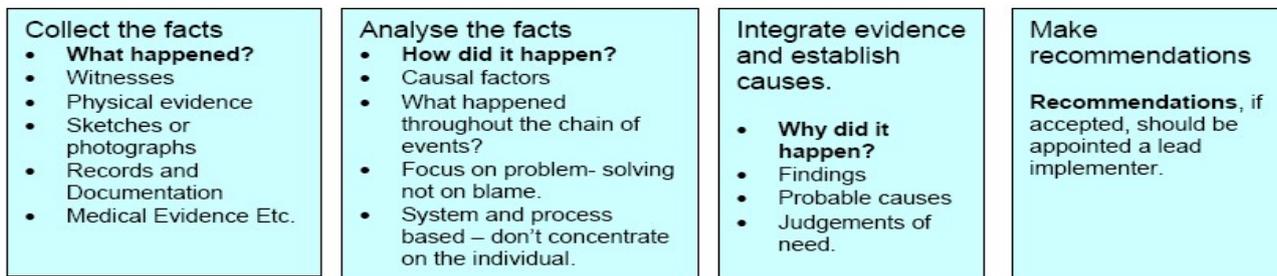
A variety of management 'tools' such as 'cause and effect charts' a 'fishbone diagram' can be applied to this process but the simplest, traditional approach is known as the 'Five Whys' Model. This can be used:

- For general analysis of the cause of any incident
- More formally, usually in a multi-disciplinary team setting, when contributory factors are discussed and in depth causal factors are written down and traced back until a clear understanding of the root cause is reached.

See also – **LI-CGEN-020 – Root Cause Analysis – Investigation Procedures**

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As defined, the Department shall consider Root Cause Analysis for the assurance of an extensive, and systems based investigation process for the management of complaints. The following model demonstrates a typical approach:



4.0 Complaints Reporting

4.1 Departmental Complaints Report Form

A standardised form (**QF-CGEN-004**) operates for the recording and follow up of all departmental complaints. This form records the following information:

- Date of Complaint,
- Name, Designation and Contact Details of the complainant,
- Nature of the complaint, including, if applicable, date and details of incident,
- Acknowledgement written – Yes/No, and Date,
- Investigation(s) performed, Outcome(s) of Investigations, and, Corrective / Preventative Actions,
- Conclusion letter written to complainant – Yes/No, and Date,
- Review at Departmental Quality Group Meeting and HMT - Yes/No, and Date,

4.2 Reporting via Q-Pulse

The Q-Pulse CAPA (Corrective and Preventive Action) Module is used to append completed versions of the departmental complaint form (as defined above in Section 4.1), or to facilitate direct reporting of service complaints, utilising a bespoke “Complaints Report Wizard / Template”.

This approach serves to standardise records and reports for the following:

- Date of Complaint,
- Name, Designation and Contact Details of the complainant,
- Nature of the complaint, including, if applicable, date and details of incident,
- Acknowledgement written – Yes/No, and Date,
- Investigation(s) performed, Outcome(s) of Investigations, and, Corrective / Preventative Actions,
- Conclusion letter written to complainant – Yes/No, and Date,
- Review at Departmental Quality Group Meeting and HMT - Yes/No, and Date,

4.3 Reporting via DATIX (Incident Management System) and Significant Adverse Events (SAE)

For complaints directly relating to the clinical care of patients, staff are instructed to raise complaints via the DATIX on-line Incident Management System and initiate SAE procedures if necessary. For procedural instructions, please refer to **MP-CGEN-005**.