

Quality Process Instruction Manual

Complaint Process Instruction

1.0 Purpose:

To describe the methodology for responding to complaints.

2.0 Scope:

This process instruction applies to:

- Trillium Gift of Life Network (TGLN)

3.0 Responsibilities:

Director Quality is responsible for:

- logging, clarifying and performing a preliminary investigation for all appropriate external customer complaints (real and potential) brought to Quality's attention
- conducting critical incident reviews, verifying the effectiveness of solutions and communicating them to the affected staff
- managing the Corrective/Preventive Action Report and Lessons Learned Log processes

Clinical and Operations Management are responsible for:

- responding directly to minor complaints from external stakeholders regarding his/her department
- facilitating incident reviews of internal/external stakeholder complaints that affect his/her function
- advising Director Quality of any critical incidents

Employees are responsible for:

- advising the appropriate manager/director of any complaints or critical incidents received from external/internal stakeholders

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4.0 Process

General

- 4.1 To provide a relevant term of reference, a complaint will be defined as an “expression of dissatisfaction made to TGLN related to its or stakeholder services or its complaints handling process itself, where a response or a resolution is explicitly or implicitly expected”.
- 4.2 Complaints received at TGLN are generally from external stakeholders and they can be categorized in the following groupings:
- clinical-organ/tissue/hospital program
 - donor family
 - funding program (i.e. Prelod, TPPR)
 - public
 - internal – infrastructure (i.e. phone system)
- 4.3 To resolve all forms of complaints received, five methodologies are employed, which include:
- Manager Review
 - Incident/Case Review
 - Critical Incident Review
 - External Stakeholder Complaint Review
 - General Review – External Stakeholders

Complaint Resolution Methodologies

Manager Review

- 4.4 Low level types of complaints are received from external stakeholders by both department’s staff and management. Low level complaints are straight forward issues that can be resolved solely by the functional manager/director, for which the risk to TGLN is low.

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- 4.5 The complaint is directed to the appropriate functional manager/director.
- 4.6 The complaint is resolved by the functional manager/director and the resolution communicated to the external stakeholder.
- 4.7 Features of this resolution process include:
- complaint is generally not logged
 - an initial response is provided to the external stakeholder within 2 business days
 - the time required to resolve the complaint is dependent on the issue received
 - the format of the response to the external stakeholder is generally in the format of the complaint received
 - the incident is detailed on the Lessons Learned Log. This log is used to document the investigation conducted and the Lessons learned Log process is managed by the Quality Department. For more information on the Lessons Learned Log, please refer to the *Nonconformance Procedure, QSP-13-1*.
 - no follow-up response to the external stakeholder is generally provided after the resolution has been communicated
 - senior management is advised of any complaint at the discretion of the manager who conducted the incident/case review
 - Director Quality is advised of the complaint if a trend of similar issues has been identified by the functional manager/director

Incident/Case Review

- 4.8 Medium level types of complaints are received from external stakeholders by both department staff and management. Medium level complaints are less straight forward issues that need other departmental staff/management involvement, in addition to the functional manager/director, to resolve. These complaints represent some moderate risk to TGLN and therefore they are treated more formally.

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- 4.9 The complaint is directed to the appropriate functional manager/director.
- 4.10 The functional manager/director solicits input from other knowledgeable staff/management. The complaint is resolved and the resolution is communicated by the functional manager/director to the external stakeholder.
- 4.11 Features of the incident/case review process include:
- complaint is logged on the *Lessons Learned Log*
 - an initial response is provided to the external stakeholder within 2 business days
 - the time required to resolve the complaint is dependent on the magnitude of the issue received
 - the format of the response to the external stakeholder is generally in the format of the complaint received
 - the incident is detailed on the Lessons Learned Log. This log is used to document the investigation conducted and the Lessons Learned Log process is managed by the Quality Department. For more information on the Lessons Learned Log, please refer to the *Nonconformance Procedure, QSP-13-1*.
 - no follow up response to the external stakeholder is generally provided after the resolution has been communicated
 - Senior Management is advised of any complaint at the discretion of the manager who conducted the incident/case review

Critical Incident Review

- 4.12 A critical incident is a reactive situation when one or more of the following outcomes result:
- recipient safety is at risk
 - incorrect organ allocation/loss of organ
 - systemic breakdown in a clinical process(es)

Critical incidents represent the potential of significant risk to TGLN and as a result they are processed with a rigorous methodology. The process involved

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in resolving a critical incident is detailed in *Critical Incident Process Instruction, QPI-14-1*.

- 4.13 Features of the critical incident review process instrument include:
- Director Quality spearheads the critical incident review process. All potential critical incidents are screened by the Director Quality for validity
 - all valid critical incidents are logged on the *Corrective/Preventive Action Log*
 - all valid critical incidents are documented on a *Corrective Action Report*
 - a kick-off meeting to initiate the fact gathering may be conducted within 2 working days after the critical incident has been identified and communicated to Director Quality
 - an initial response is generally provided to the external/internal stakeholder within 2 business days after the complaint has been received by the Director Quality
 - the time required to resolve the complaint is dependent on the magnitude of the issue received
 - the format of the response to the stakeholder is generally in the format of a *Corrective Action Report* with a cover letter
 - the methodology used to investigate the critical incident is the corrective action process that is further detailed in the *Corrective/Preventative Action Procedure, QSP-14-1*
 - follow up may be provided to the stakeholder after the *Corrective Action Report* has been published
 - Senior Management is advised of all valid critical incidents

Prevention of Critical Issue Review

- 4.14 In cases where critical issues can be predicted, managers/directors are responsible for their identification to the Director Quality.
- 4.15 Each proactively identified critical issue is investigated and resolved using the preventive action report process, as detailed in the *Corrective/Preventative Action Procedure, QSP-14-1*.

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- 4.16 The features of preventive critical issue review process include:
- Director Quality spearheads the critical incident review process. All potential incidents are screened by the Director Quality for validity
 - all critical incidents are logged on the *Corrective/Preventative Action Log*
 - all critical incidents are documented on a *Corrective/Preventive Action Report*
 - the time required to resolve the complaint is dependent on the magnitude of the issue received
 - the methodology used to investigate the critical incident is the preventive action process, that is detailed in the *Corrective/Preventive Action Procedure, QSP-14-1*
 - Senior Management is advised of all valid critical incidents

External Stakeholder Complaint Review

- 4.17 During organ or tissue donation recoveries, complaints might surface between staff from different external stakeholders, regarding their interaction with one another. In these situations, TGLN management will perform the following tasks to help bring resolution to the complaint:
- perform a preliminary investigation with TGLN staff involved in the matter, to better understand the specifics of the complaint
 - advise the appropriate management of both the external stakeholder organizations that there were issues raised during the donation case that need to be resolved. TGLN management will advise that their role in this matter is that of an information provider and an advocate for the complaint resolution to avoid a future re-occurrence.
 - provide contact information of appropriate TGLN manager(s) whose staff were involved in the case to both organizations, so that any additional facts of the complaint can be made to them
 - follow-up with the management of both organizations involved in the matter within 8 weeks to ensure that the complaint has been closed out to both parties' satisfaction

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General Review – External Stakeholders

- 4.18 For all other types of external stakeholder complaints received which don't fit any of the three previously mentioned categories, the complaint should be routed to the Director Quality. The features of this review process include:
- Director Quality determines appropriate staff/management to get involved
 - all complaints will be logged on the *Corrective/Preventive Action Report*
 - the methodology used in the investigation is detailed in the *Corrective/Preventive Action Procedure, QSP-14-1*
 - Senior Management is advised of all external stakeholder complaints, that meet this category

Complaint Feedback

- 4.19 Quality will act as the point of contact for any external stakeholder who wants to provide feedback on his/her complaint resolution satisfaction.

5.0 Records

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Lessons Learned Log	QSF-13-1	Director Quality	Quality Department	16 years
Corrective / Preventative Action Report	QSF-14-1	Director Quality	Quality Department	16 years

6.0 References:

- Non-Conformance Procedure, QSP-13-1
- Corrective/Preventative Action Procedure, QSP-14-1
- Critical Incident Process Instruction, QPI-14-1