Ontario
Trillium Gift of Life Network

Clinical Process Instruction Manual

Patient Safety Disclosure Process Instruction

Policy:

Trillium Gift of Life (TGLN) works collaboratively with its stakeholder partners, including transplant programs, hospitals, laboratories, tissue banks, and others, as they inform patients and/or substitute decision makers about events impacting on their or their loved one's health care. TGLN's stakeholder hospitals are obligated to disclose certain patient safety related incidents to patients and/or substitute decision makers under the *Public Hospitals Act* and its regulations. TGLN will participate at a hospital's request with respect to incidents that may have impacted on patient safety (harmful, no harm or near miss), where disclosure is deemed necessary or advisable.

For issues that may be contentious or perceived to be of concern to the Minister, Senior Leadership will ensure that both the TGLN Board Chair and the Ministry of Health and Long-Term Care are notified.

TGLN supports discretionary disclosure, where appropriate, in which information may be provided to a patient and/or substitute decision maker regarding an occurrence or event that occurred in which the organization wants to be transparent and accountable.

Senior Leadership supports its staff through the disclosure process by providing necessary emotional, psychological, education and practical support.

Process:

1. A TGLN employee believes or becomes aware that there has been an event that may have impacted patient safety (harmful, no harm or near miss) where disclosure may be deemed necessary or advisable. The employee will advise his/her manager who, in turn, will advise the VP, Clinical Affairs and the Director of Quality of the situation.

2. The Director of Quality will be responsible for investigating events and will make a recommendation to the VP, and the Clinical Affairs as to whether disclosure is warranted with the patient's health care professional (HCP) at the stakeholder hospital.

3. The VP, and the Clinical Affairs will make the determination if disclosure is recommended or otherwise and will bring this matter to Senior Leadership, for approval. Senior Leadership will determine who within TGLN will notify the patient's most responsible HCP where disclosure is recommended.

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4. If the HCP believes that disclosure is necessary or advisable and requests TGLN's participation in disclosure, the appropriate TGLN representative will participate, as requested. TGLN management may also request that an appropriate TGLN representative be included in the disclosure process where the event impacting the patient was caused by or was within the control of TGLN. Senior Leadership will respect the decision of the HCP as to whether a TGLN representative will be included in the disclosure process. TGLN's Director of Quality will be consulted and kept informed throughout the investigation and disclosure process.

5. Where a TGLN representative has been asked to participate in disclosure, Senior Leadership will designate a person to represent the organization. Furthermore, others involved in the patient's care and investigation and resolution of the incident may be asked to also be present for the conversation. A dialogue between the TGLN representative and the HCP will occur to ensure that the mutual disclosure policies of each organization will be respected.

6. Where the HCP decides to involve a TGLN representative in the disclosure process, the TGLN representative and the HCP will identify who should be most responsible for leading the disclosure conversation and who else should be present during the conversation. Typically, the patient's HCP will be the lead person for the disclosure. The disclosure lead should possess the following attributes: be most knowledgeable about the occurrence, have an existing relationship with the patient, be able to explain next steps and be someone with whom the patient or substitute decision maker is comfortable.

7. The TGLN representative will support the HCP in initiating a disclosure conversation as soon as reasonably possible after a patient safety incident is recognized. Where appropriate, disclosure may be initiated with the patient's family or his/her substitute decision maker depending on the condition of the patient (e.g. pediatric patient).

8. The disclosure lead will focus the conversation on known facts and provision of further clinical care and emotional support, as required by the patient/substitute decision maker and his/her family. The TGLN representative will fully document the events having an impact on patient safety, and related disclosure conversations. This documented file will be sent to the Director Quality for storage in the quality department files.

   A sample disclosure checklist that could be used as a tool in this process is shown in Appendix 1. Likewise, process details that might be used in the disclosure planning and execution are shown in Appendix 2.

9. Prior to participating in disclosure, or during the disclosure process, if the issue is contentious and may be of concern to the Minister, the TGLN representative will advise Senior Leadership, who

in turn will ensure that both the TGLN Board Chair and the Ministry of Health and Long-Term Care are notified.

10. The TGLN disclosure representative will provide on-going communication and a summary of the patient safety incident and its subsequent investigation and disclosure with VP, Clinical Affairs and the Director Quality.

TGLN Discretionary Disclosures

11. There may be circumstances where an event has occurred at TGLN or involving TGLN staff that, despite not being subject to the disclosure requirements to which hospitals are subject, a TGLN employee believes it is appropriate or advisable to disclose to the patient and/or substitute decision maker. For example, a TGLN employee may wish to disclose to a substitute decision maker an event or error on his/her part for which the employee wants to be transparent and accountable.

12. The TGLN employee will consult with his/her manager and steps 1 to 3 of this process instruction will be followed. A strategy will be developed for the disclosure that is consistent with the principles and processes in this process instruction. This process instruction will allow for disclosure independent of the HCP or hospital. Senior Leadership may decide to consult with its legal counsel.

13. Prior to participating in disclosure, or during the disclosure process, if the issue is contentious and may be of concern to the Minister, the TGLN representative will advise Senior Leadership, who in turn will ensure that both the TGLN Board Chair and the Ministry of Health and Long-Term Care are notified.

Provision for Healthcare Provider Support & Education

14. The appropriate member of Senior Leadership will support its staff through the disclosure process by providing emotional, psychological and practical support. Education, training and related resources will also be provided to staff that are required to participate in the disclosure process. Where appropriate and beneficial, TGLN will support affiliated healthcare providers where there is a joint disclosure conversation.

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Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Disclosure File	——	TGLN Disclosure Representative	TGLN Disclosure Representative	10 years

References:

- *Canadian Disclosure Guidelines, Canadian Patient Safety Institute*
- *Regulation 965, Public Hospitals Act*

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Appendix 1: Checklist for Disclosure Process

(Adapted from the *Canadian Disclosure Guidelines*, Canadian Patient Safety Institute)

- Determine if immediate transplant patient/donor family/substitute decision maker care needs are met.

Disclosure Process Plan

- Gather known and agreed upon facts regarding the event impacting patient safety.
- Identify the most responsible health care provider (HCP) at the stakeholder organization involved in care of transplant patient/donor family/substitute decision maker.
- Determine with the HCP who will be present at the meeting(s) and who will:
    - Lead discussion during the meeting;
    - Be the contact person for the patient/family/substitute decision maker;
    - Support the health care providers involved in the incident;
    - Coordinate the disclosure process.
- Plan when the initial disclosure will occur and to whom disclosure will be made (patient or substitute decision maker).
- Establish what information will be shared and how to conduct an effective disclosure conversation.
- Locate a private location to hold disclosure meetings, free of interruption.
- Be aware of your emotions and the emotions of the HCP and other providers involved in the process, seek support if required.
- Anticipate the patient's/donor family's/substitute decision maker's emotions and ensure appropriate support is available.
- Anticipate which support persons (e.g. family, friends, spiritual representatives) will be required during the meetings with the patient.

Initial Disclosure

- Introduce participants to transplant patient/donor family/substitute decision maker and reason for attending the meeting.
- Use language and terminology that is appropriate for the transplant patient/donor family.
    - If translation services are required, ensure it is readily available.
- Describe the known and agreed upon facts of the event impacting patient safety and its outcome known at the time.
- Describe the steps that were and will be taken in care of the transplant patient/donor family/ substitute decision maker.
- Avoid speculation or blame.
- Apologize using the words "I'm sorry".
- Inform the transplant patient/donor family/substitute decision maker of the process for analysis of the event and what the patient can expect to learn from the analysis, and the projected timelines.

    - Provide the opportunity for the transplant patient/donor family/substitute decision maker to ask questions and clarify if information was understood.
- Invite transplant patient/donor family/substitute decision maker to discuss the event from their point of view.
- Be sensitive to cultural and language needs.
- Review what was discussed and document what was said and actions decided upon for moving forward.
- Offer to arrange subsequent meetings if required, and provide key contact information.
- Offer practical, emotional support, if needed.
- Reimburse reasonable expenses related to attending disclosure process, as appropriate.
- Facilitate further investigations and/or treatment if required.

Subsequent and Post-Analysis Disclosure

- Continue practical and emotional support as required for transplant patient/donor family/ substitute decision maker, loved ones and providers.
- If corrective actions initiated, ensure that corrective actions are completed and changes to practice reinforced.

Document

- Time, place and date of disclosure meetings
- Names and relationships of all attendees
- Facts presented
- Offers of assistance and response
- Questions raised and answers given
- Plans for follow-up with key contact information

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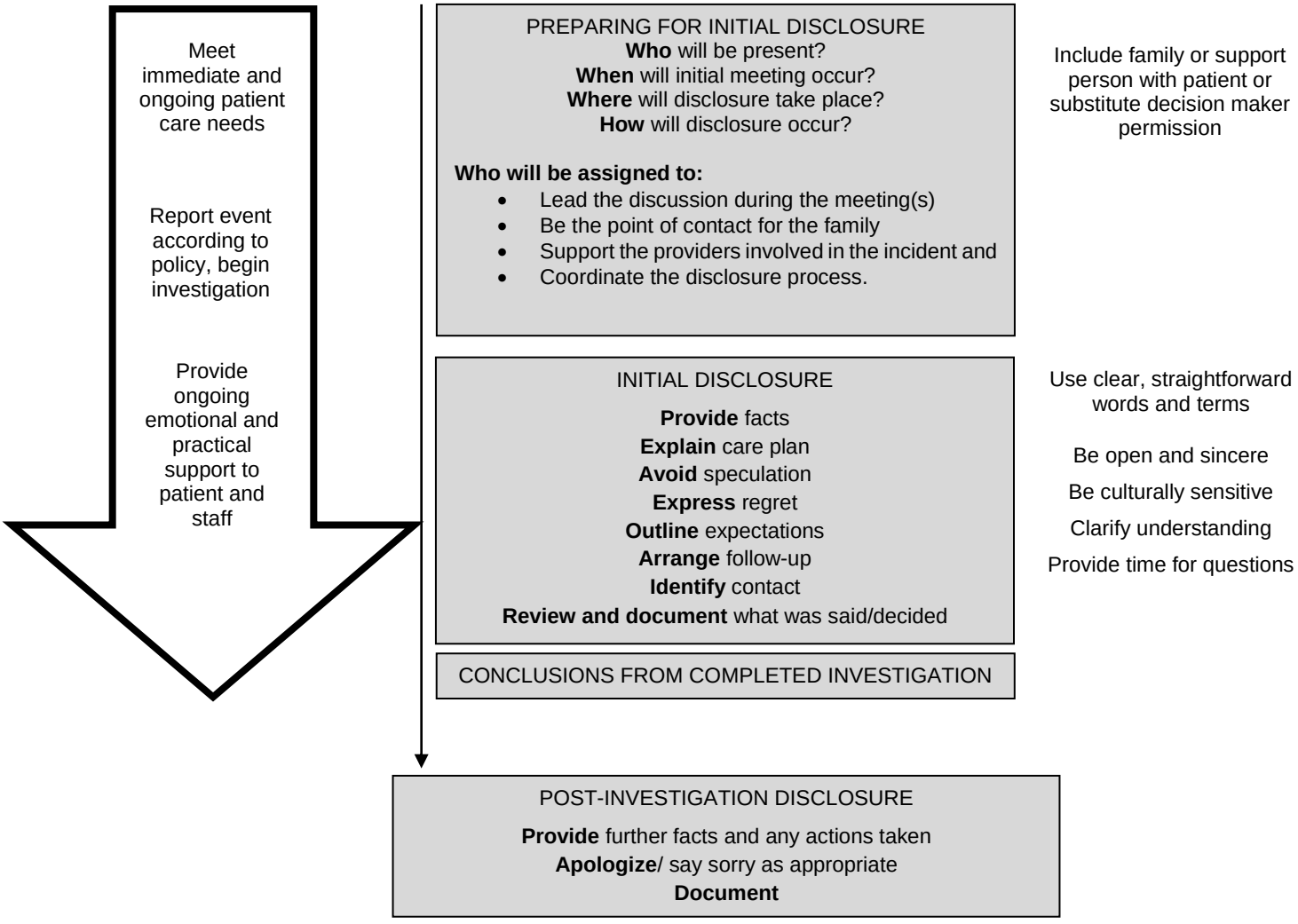
Appendix 2: The Disclosure Process*



*Adapted from Canadian Patient Safety Institute's Canadian Disclosure Guidelines