Ontario
Trillium Gift of Life Network

Clinical Process Instruction Manual

Preparing for a Health Canada Inspection Process Instruction

Policy:

Every three years Health Canada conducts an inspection of each organ procurement organization (OPO) to determine their compliance to the *2007 Safety of Human Cells, Tissues and Organs for Transplantation (CTO) Regulations*. This is an important review of TGLN's (Trillium Gift of Life Network) clinical and operational processes. For a successful inspection outcome, preparation is needed in getting ready. The Quality Department leads the preparation work and the subsequent inspection process activities.

Process:

Inspection Activities

1. A summary of the Health Canada inspection activities are shown on the timeline displayed in Exhibit 1. Each activity will now be described.

Clinical Charts

2. A Health Canada inspection's scope includes all of the clinical charts from the date of the previous inspection, three years prior.
   - 2.1. Quality requests from Information Systems a list of all donor clinical charts in which there was at least one organ donated, that got transplanted.
   - 2.2. The list of donor clinical charts needs to include the following information, as a minimum:
     - TGLN #
     - date of donation
     - adult vs. pediatric
     - names of organs donated
   - 2.3. The above list is given to Health Canada in advance of the inspection, so that they can select the cases to be reviewed.
   - 2.4. Quality develops a list of all donor clinical charts that involved the exceptional distribution process. This chart list is also provided to Health Canada for their review and selection of representative cases.

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3. Serology testing comprises an important diagnostic tool to determine donor suitability.
   3.1. TGLN employs a range of serology labs across Ontario to perform the required infectious disease testing, to serve all donor hospitals.
   3.2. Each lab performs one or more serology tests to serve the local geography on infectious disease testing.
   3.3. Each serology test requires a Health Canada specified, licensed test kit to be used.
   3.4. Health Canada confirms that serology labs used the required licensed test kit(s).

Errors, Accidents, and Adverse Reaction Records

4. Health Canada requires all OPOs to maintain records of donation cases in which:
   - donation processes not followed, as documented
   - unexpected events occurring in donation cases, which preclude donation.
   - recipient complications arise post-transplant that may be donor-derived.

   4.1. The errors and accidents events follow a methodology maintained by Health Canada's Inspectorate. The adverse reaction events follow a different methodology maintained by Health Canada's Marketed Health Products Division.
   4.2. TGLN Quality maintains separate binders for errors / accidents and for adverse reactions. Each binder has a series of tabbed sections for each case which display the following information as a minimum:
      - initial notification correspondence to Health Canada concerning the error, accident or adverse reaction.
      - notification correspondence to transplant programs
      - 15 day follow-ups
      - corrective action plan as required
      - case close-out notification correspondence to Health Canada
      - response correspondence from Health Canada, either asking additional questions or approving the case close-out.
   4.3. Health Canada confirms that the documentation maintained conforms to their expectations.

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Quality System

5. Key areas of scrutiny in a Health Canada inspection include elements of the quality management system.
   5.1. The methodology involved in the creation, deletion and revision of controlled documents is scrutinized, including the key aspects of:
      - approvals of controlled documents
      - reading and understanding of documents before publishing
      - archiving of controlled documents
   5.2. The area of records is reviewed for the key attributes of:
      - availability of required documents
      - identification of clinical records with a TGLN donor case identification number
      - retention of records for the prescribed durations
   5.3. The internal auditing process is reviewed to determine its effectiveness. Key attributes of the internal auditing process include:
      - scheduled internal audits, at a minimum of bi-annually conducted
      - audit scope including all areas of the Health Canada *CTO Regulations*
      - independency of the auditors used in the audit process
      - resolution of the audit findings

Packaging and Labelling

6. The packaging and labelling processes are reviewed to ensure:
      - appropriate packaging materials are used
      - correct information is displayed on the interior label, exterior label and packaging insert

Facilities

7. The facility which TGLN includes requirements that include:
      - temperature and humidity criteria

- access security criteria
- equipment maintenance records
- qualification of supplies used during recovery

Training

8. Clinical staff training records are required to demonstrate the appropriate expertise involved in the donation process, including:
    - orientation
    - competency
    - continuing education

Inspection Methodology

9. The Health Canada inspection process is a review of documented records. Interviews with staff are only required to clarify the records presented.

10. Preparation activities to improve the efficiency of the inspection process, include the following:
    - identification of key staff who can respond to subject matter questions
    - creation of a file of records to respond to process questions
    - identification of a TGLN representative who can help facilitate the responses to Health Canada questions

11. During the inspection process, the TGLN representative performs the following activities:
    - provides answers to questions
    - facilitates the response to questions from TGLN process experts
    - gathers records as required in response to Health Canada questions
    - consults with TGLN senior management regarding the inspection process

12. At the conclusion of the inspection, the TGLN representative performs the following activities:
    - gathers the potential non-conformances identified
    - reviews the Exit Notice published by Health Canada displaying the audit results

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- facilitates the response to Health Canada non-conformances
- implements the action plan to close out the non-conformances
- creates a binder of records to demonstrate the close-out of each identified non-conformance

Records:

- No Records

References:

- Document and Data Control, QSP-5-1
- Corrective and Preventive Action, QSP-14-1
- Quality Records, QSP-16-1
- Internal Auditing, QSP-17-1
- Donor Medical and Social History – Organ or Combined Organ & Tissue, CPI-9-207
- Donor Assessment – Combined Organ and Tissue, CPI-9-208
- Infectious Disease Testing – STAT, CPI-9-211
- Infectious Disease Testing – Non-STAT, CPI-9-213
- Microbiology Testing, CPI-9-214
- Exceptional Distribution, CPI-9-217
- Facility Management, CPI-90-420
- Equipment Maintenance, CPI-9-426
- Error / Accident, CPI-9-804
- Unexpected Serious Adverse Reaction, CPI-9-805
- Employee Training Files – Clinical Staff, CPI-9-903

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Exhibit 1: Sample Health Canada Inspection Preparation Timeline

Health Canada Inspection Preparation Timeline

LEGEND:
Not Started
In Progress
Completed

Timeline / Task / Quality Staff	Calendar				
	Month 1	Month 2	Month 3	Month 4	Month 5
1. Document Control					
a) Organize document approvals					
b) Organize R&U records					
c) Organize iTx R&U records					
d) Organize annual document review					
e) Organize document folder revisions					
f) Obtain on-call Training Records from last 2 doc revisions					
g) Update uncontrolled documents binder (Calvin)					
2. Clinical Charts					
a) Select and review Pediatric charts					
b) Create chart lists for 2013/2014/2015					
c) Re-review CSA requirements for donor assessment					
d) Review of iTx template					
3. EXD charts					
a) Select EXD charts					
b) Review EXD charts					
c) Ensure ExD sign off compliance					
4. Testing					
a) Organise Test Kit licensing					
5. EA/AR Binder					
a) Ensure 2013-2014 compliance					
b) Ensure 2015 to date compliance					
c) Review EA/AR procedures (David)					
6. Internal Audits					
a) Organize lab audit evidence					
b) Organize audit reports and evidence					
c) Develop 2013, 2014 & 2015 audit schedule and logs					
d) Organize audit checklists (Print Blank Checklists)					
7. Training and Education					
a) Select best training records per function					
b) Obtain updated "on-call" staff list					
8. Records					
a) Prepare a new tub					
b) Fill tub with records					
9. Ext. HC Compliance					
a) Organize responses from HC inspection					
b) TGLN responses to non-conformances					
10. Inspection Preparation					
a) Prepare and conduct training					
b) Identify response team					