

Final Report

Provincial Survey of the Impact of Standard #Z902 “Safety of Blood and Blood Components” on Transfusion Medicine Laboratories in Ontario Hospitals

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EXECUTIVE SUMMARY

1.0 Introduction (see page 1 for details)

A province-wide survey of Ontario hospitals was performed in 2001 to determine how the introduction of proposed National Standards for Blood Safety would impact hospital Transfusion Medicine (TM) laboratories. Although the questions in the “Impact Survey” were based on the first Draft Standards for Blood Safety (2000), the content of the revised Standard Z902 – Safety of Blood and Blood Components has not significantly changed; hence, the results as presented are still applicable. The highlights from the survey are summarized below.

2.0 Impact Study response rate (see page 2 for details)

- 108 of 161 hospitals with a TM laboratory responded (67.1 %):
 - 9 teaching hospitals;
 - 51 community hospitals;
 - 48 small hospitals.

3.0 Hospital Demographics (see pages 2-3 for details)

- 32.4% of responding hospitals reported having multiple sites;
- Responses represent an estimated cumulative total of 22, 632 active beds;
- General medical patients are treated in all hospitals;
- Surgical patients are treated at most community and teaching hospitals;
- Specialty services (neonatal, ICU, burns, and nephrology) are located predominantly in teaching hospitals.

4.0 Laboratory Testing (see page 4 for details)

- Grouping, screening, and crossmatching are performed by all teaching and community hospital TM laboratories;
- The extent of other serological testing performed in hospital TM laboratories is variable across hospital types.

5.0 Laboratory Information Systems (LIS) (see pages 4-7 for details)

- All teaching hospitals have a LIS as well as a TM module (LIS-TM);
- 98% (50/51) of community hospitals have an LIS, and 84.3% of these have a LIS-TM;
- 72.9% (35/48) of small hospitals have an LIS, and 12.5% of these have a LIS-TM;
- Overall, only 46.3% (50/108) of hospitals have a matching LIS and LIS-TM;
- 24.5% (23/94) of the hospitals with a LIS system have multiple hospital sites, and 60.9% (14/23) of these multi-site hospitals have their LIS networked to allow for inter-site electronic communication;
- 12 different LIS-TM are used across hospitals, with Meditech the most common (49.1%);
- Hospital LIS-TM systems are used to inventory fractionated products by 42.6% of hospitals; to do electronic crossmatching by only 2% of hospitals; and to control appropriate issuing of CMV seropositive and non-irradiated blood in very few hospitals.

6.0 Transfusion Committees (see pages 8-9 for details)

- Only 48.1% (52/108) of hospitals have a Transfusion Committee;
- Only 59.6% (31/52) of Transfusion Committees have formal Terms of Reference;
- Overall, Transfusion Committees tend to meet at least 4 times per year;
- Activities that Transfusion Committees take on are variable across hospitals;
- 100% of hospitals with Transfusion Committees consider their activities useful.

7.0 Quality Management (see pages 9-17 for details)

- Most hospitals use the AABB (99.1%) and CSTM (84.3%) Standards;
- Only 19.4% (21/108) of hospitals have a QA Specialist; and in 15 (71.4%) of the hospitals, they are responsible for QA in other laboratory areas in addition to the TM Service;
- Only 50% of hospitals have a Quality Policy Statement in place, with an additional 11% under development;
- Quality System Essentials (QSEs) are frequently lacking with only 8.3% of hospitals having all 16 QSEs assessed in the survey and 33.4% have fewer than 8 QSEs in place. The following QSEs are missing in at least 50% of hospitals:
 - Process analysis;
 - SOP critical control points identified;
 - Workflow defined for development of critical procedures;
 - Process validation for procedures;
 - Identified procedure distribution locations.
- Only 23.2% (25/108) of hospitals have all 8 required criteria present in their SOP format. The criteria most frequently missing from the SOP format are:
 - Staff categories responsible for performing steps;
 - Unique # identifying document and revisions.
- Written policies and procedures are frequently lacking with only 8.3% (9/108) hospitals having policies and procedures in place for all 12 laboratory functions assessed in the survey and 5 hospitals (4.6%) have them in place for only 2 laboratory functions. The laboratory functions with policies and procedures most frequently missing are:
 - Validation of blood transportation;
 - Blood shortages;
 - Recall of blood products;
 - Use of equipment.
- Only 57.4% (62/108) of hospitals have a specific policy in place for the rejection/acceptance of samples when the phlebotomist's signature is missing; of these hospitals, 53.7% reject the sample (rejection is most frequent in teaching hospitals);
- Only 34.3% (37/108) of hospitals have some form of competency assessment performed on staff; of these, most hospitals do not assess competency in all procedures;
- The format of competency assessment programs varies widely across hospitals;
- Status of components of an Error Management System:
 - Laboratory Management is kept informed of errors in 92.6% of hospitals;
 - Error reports are documented by most hospitals (85.2%);
 - Corrective action reports are generated in 59.3% of hospitals;
 - Only 50.9% of hospitals take preventative action;

8.0 Informed Consent (see pages 17-19 for details)

- 50% of hospitals use a general hospital consent form which does *not* mention transfusion;
- 19.4% of hospitals use a general hospital consent form that clearly mentions transfusion;
- 22.2% of hospitals have a consent form specific for transfusion;
- 30% to 40% of community and small hospitals do not have written information for patients to inform them about transfusion risks. All teaching hospitals provide written information.

9.0 Patient Written Notification of Transfusion (see pages 19-22 for details)

- Only 35.2% (38/108) of hospitals provide written notification of transfusion to patients;
- Hospitals that provide notification usually do so during the patient's hospital stay (68.4%).

10.0 Lookbacks and Tracebacks (see pages 22-23 for details)

- The following information is traceable in all hospitals: blood products; fractionated products; recipient's name, ABO group and Rh type; donor unit # or lot #; product Rh type, date of issue; and date of transfusion;
- The following information is *not* traceable in some hospitals: visual inspection of product (43.2%); time infusion starts (18.9%); time infusion is complete (18.9%); and presence/absence of adverse effects (13.5%).

11.0 Blood Administration (see pages 23-27 for details)

- Only 44.4% of hospitals have blood administration policies and procedures based on current practices, and only 25.9% of hospitals revise them annually;
- Blood administration policies and procedures are usually prepared jointly by nursing and laboratory staff (77.8%);
- The following deficiencies are present in more than 50% of hospitals:
 - Monitoring transfusion practices (63.9%);
 - Trend analysis (73.2%);
 - Education related to blood administration (57.4%).

12.0 Training (see pages 27-29 for details)

- Training is documented in 77.8% of teaching hospitals but in less than 50% of small and community hospitals;
- Training is in need of updating and support in 77.7% of teaching hospitals, 58.8% of community hospitals, and 58.3% of small hospitals;
- Training requires additional resources in 88.9% of teaching hospitals, 68.8% of small hospitals, and 62.7% of community hospitals.

13.0 Transfusion Reactions (see pages 30-31 for details)

- Laboratory manuals and nursing policy and procedure manuals do not contain adequate information to guide follow-up of suspected transfusion reactions in 75.9% and 68.5% of hospitals respectively;
- The processes for reporting transfusion reactions vary across hospitals.

14.0 Collection, Transportation, and Storage of Blood (see pages 31-34 for details)

- 25% (27/108) of hospitals collect blood on-site, mainly for autologous donation programs;
- Deficiencies related to QSEs in hospitals collecting blood include: written information about risk of disease; absence of deferral donor registry at donation site; and process for counseling or referral for donors with positive test results;
- Various manufacturing activities are performed on blood in the hospital setting;
- 77.8% (84/108) of hospitals transport blood to various locations using coolers; of these, 51.2% do not validate the coolers to ensure appropriate temperature and only 49.1% have instructions in place for the packaging of coolers using gel and ice packs.

15.0 Special Programs (see page 35 for details)

- Only 2 hospitals have Walking Donor Programs and policies and procedures are in place;
- 16 Ontario hospitals (14.8%) have Home Transfusion Programs but none of these hospitals have all of the required QSEs in place for such a program.

16.0 Equipment (see pages 36-38 for details)

- There are 237 refrigerators used by the 108 hospitals to store blood; 94.8% of these refrigerators meet required standards of continuous temperature monitoring and recording;
- 141 freezers are used to store blood products (no freezer in 10 small hospitals); temperature monitors are lacking in 39 (27.7%) freezers and recorders are absent in 52 (36.9%) freezers;
- Contrary to the Standards, 64.8% of refrigerators and 32.4% of freezers are used to store donor/patient samples and reagents along with blood products;
- The estimated cost to replace equipment that does not meet the Standards is estimated at \$1.8 million for responding hospitals and approximately \$2.7 million province-wide.

17.0 Facilities (see pages 38-39 for details)

- Many facility deficiencies are present in hospital laboratories including:
 - Component processing not separate from testing (54.6%);
 - More bench space (50.0%) and overall lab space (35.2%) needed;
 - A separate area for donor interviews required (41.7%);
 - Cracks/open joints are present in floors and walls (25%).

18.0 Staffing (see pages 39-40 for details)

- 50% of teaching hospitals include lab assistants/clerks as part of the staffing model;
- only 4.6% of hospitals have staff that work only in Transfusion Medicine;
- 70.4% of hospitals have insufficient staff to comply with the Standards.

19.0 Impact Study Conclusion

Overall there were a number of areas where hospitals are not in compliance with the proposed Standards. The major deficiencies are: lack of development and implementation of quality management programs (SOPs, document control, training, competency assessment, and error management); absence of Transfusion Committees; lack of appropriate equipment; and insufficient staffing.