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Standards Overload? Understanding the Role of the CSA, CSTM and OLA

By Kathleen Eckert, ART Chairperson Standards Committee, CSTM

Blood Transfusion Laboratories (BTL) and Clinical Transfusion Practice in Ontario and across Canada might be feeling overwhelmed by the many accreditation requirements, standards and guidelines that have emerged in the last few years. Defining standards, regulations and accreditation requirements is essential to understanding the purpose of many of these publications.

A Standard is something considered by an authority or a professional organization to be an approved model or best practice.

A Regulation is a principle, rule, or law designed to control or govern conduct. It is a governmental order having the force of law. Regulations apply standards through the force of law and provide penalties for non-compliance.

An Accreditation Requirement is used to certify a laboratory as meeting all formal official requirements of excellence or best practices. It is usually based on specific standards.

In Ontario, the following 3 specific publications, used to ensure safe transfusion practices within the hospital transfusion service, are available: CSA (Z902-04), CSTM (CSTM Standards for Hospital Transfusion Services v2) and OLA (Ontario Laboratory Accreditation Requirements v4). They are interdependent and yet distinct in purpose.

The CSTM is the national professional organization for Transfusion Medicine in Canada, and therefore it is part of their role to define best practices (standards). CSTM Standards version 6 was used as a basis for the CSA Z902-04 Standards. The CSA (Health Canada initiated) ensures public accountability by including stakeholders outside of the Transfusion Medicine community on their standards committee. The CSA relies on the professionals to continue to define best practices. For this reason, the CSTM continues to review and publish standards focusing specifically on Hospital Transfusion (not the blood suppliers) and referencing each standard to the CSA equivalent. In the current version, the CSTM also reorganized the standards into the twelve Quality Systems Essentials to assist the Hospital Transfusion Service in developing a quality system within their organization. The CSTM Standards will continue to monitor any changes in the CSA standards and will ensure that if a Hospital Transfusion Service is compliant with CSTM standards, they will also be compliant with CSA.

However, CSTM and CSA standards are not regulations or accreditation requirements for hospitals and therefore by definition have no force of law, no certification obligation, and they provide no penalties for non-compliance. Health Canada is developing federal regulations for blood and blood components based on Z902-04, however many of the CSA standards are outside of Health Canada's jurisdiction and will never be referenced in any federal regulations. Accreditation of Ontario laboratories is based on OLA requirements

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which are selected specific standards with which all laboratories must comply. OLA Blood Transfusion specific requirements are based on CSTM and CSA standards, depending on the continuing input from both the professionals and the accountability to the public that both these organizations bring respectively. Understanding the role each organization has and why each organization is continuing to publish, helps those in each individual laboratory as they work to ensure best practices, safe transfusion processes and successful accreditation for their laboratory.

What's New at ORBCoN

By Wendy Owens, Regional Blood Coordinator, ORBCoN Northern and Eastern Ontario Region

In this fourth edition of the ORBCoN Report, the focus is on Standards, Accreditation and Regulations. Many of the projects announced in the last edition of the newsletter are now available to aid hospital health care professionals in complying with the existing requirements in the province of Ontario.

- A web-based tool ("Audit LIVE") to be used by hospitals to perform utilization audits on frozen plasma use
- An e-learning program ("Bloody Easy for Nurses") created by nurses for nurses to provide ongoing training and education related to the handling and administration of blood components
- An online program ("Assessment LIVE") to monitor and document Technologist competency relating to theoretical knowledge in Transfusion Medicine

GREEN means go - Will you be ready?

In August 2008, copies of the Ontario Contingency Plan for the Management of Blood Shortages and accompanying toolkit were mailed out to all hospitals in the province. This plan and toolkit were provided to hospitals in order to encourage and aid hospitals in the development of their own facility specific contingency plan. We are currently in a 'Green' phase which is the time hospitals should be working on their plans to ensure they will be in place should the need arise. The Provincial Blood Programs Coordinating Office (BPCO) with the Ontario Contingency Planning Working Group are planning to hold a mock exercise sometime in the 2009/ 2010 year to test out the Provincial Contingency Plan and determine how it functions with hospital facility plans. The BPCO encourages all hospitals in Ontario to ensure that their plans are developed and in place. Will your site be ready if you get 'the call'?

We want your feedback!

ORBCoN, initiated in 2006, is coming to the end of the first round of funding provided by MOH-LTC. In January of this year, a survey was circulated to hospital personnel asking for feedback on the effectiveness of the Network and the work that has been accomplished over the past three years.

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Ontario Laboratory Accreditation - An Update

By Carol Turner, MLT, ART

Ontario Laboratory Accreditation (OLA) is a conformity assessment program that is accountable to the government regulator. It was developed between 2000 and 2002 for implementation in 2003. OLA is mandatory for Ontario's 229 licensed medical laboratories. All have undergone assessment, and the average laboratory conformance is a remarkable 93.99%; the majority of laboratories were assessed less than 10 major non-conformances and less than 20 minor non-conformances.

Accreditation requirements contain discipline-specific items that focus the assessment on specific discipline activities. The 167 Ontario laboratories licensed for Transfusion Medicine must comply with 86 discipline-specific items – the majority of which are applications from the Canadian national standard CSA Z902. Sixty-four discipline-specific items apply to laboratories that only store and issue blood for emergency use.

The most frequent Transfusion Medicine discipline-specific non-conformances observed:

1. Inventory control: There was a lack of documentation/ evidence that red cells were not held at room temperature longer than 30 minutes and that the temperature had not exceeded 10°C if the cells were to be re-issued.
2. Equipment maintenance ensuring proper performance: There was no evidence/ documentation that equipment was consistently maintained according to CSTM Standards.
3. Instructions for proper specimen and blood product handling: Blood products were not visually inspected before shipment and the inspection documented.
4. There was a lack of documented policies, processes and procedures for the transportation of blood components/products within and outside of the facility.
5. Manuals of other departments relating to transfusion medicine are not consistent with the policies, processes and procedures of the transfusion laboratory.

Reassessments in Ontario licensed laboratories began in September 2008. Updated requirements will apply - 513 requirements and 109 Transfusion Medicine discipline-specific items. One of the notable new discipline-specific items is –that the transfusion service needs to ensure ongoing training for staff involved in blood component/ product administration. A formal program to assess skills in transfusion-related activities needs to be developed and maintained in conjunction with the Departments of Nursing and Medicine.

Hospitals Overcoming Obstacles from OLA Requirements

By Janet Sharun, MLT Thunder Bay Regional Health Sciences Centre

Hospital Transfusion Services have numerous standards they are required to meet set out by OLA, CSA and CSTM. Thunder Bay Regional Health Sciences Centre is a 360 bed teaching and acute care hospital. Meeting these standards is sometimes a difficult task because of overlap with other disciplines or facilities (such as Nursing, Medical, Biomedical, other hospitals and Canadian Blood Services).

Here are a few of our challenges and the solutions to over come the challenges in meeting the required standards.

OLA	Requirement	Solution at our facility
I.B.10 TM110 & TM111	"The evaluation of staff skills of those performing transfusion medicine testing may include, but is not be limited to…" & "Transfusion Services shall ensure on going training for staff involved in blood component/product administration"	Preparing an annual test for staff to complete now with the help of a program "Assessment Live" provided by ORBCoN, results are tracked and documented. A formal program to assess these skills is a bit difficult outside of the lab; Transfusion Ontario does have a link to the Bloody Easy course for nurses and physicians but there is no way to ensure its use. We are working with our education department to have a mandatory quiz tracked by the MedWorxx E-learning tool our facility uses, but there is a huge obstacle in assigning it to the hundreds of nurses on staff. We also attempt to audit some transfusions bi-annually.

Hospitals Overcoming Obstacles from OLA Requirements *continued*

IV.12 & 14	"Shall be records of equipment…" & "Maintenance of laboratory equipment shall ensure proper performance…"	We have been working with our purchasing, receiving, biomedical departments, and distributing company to ensure all information about equipment is received in the laboratory and documentation is continued for the life of the equipment. Prior to purchasing a controlled temperature hood for our Albumin we purchased a low cost temperature recorder and set it to record the temperature of the shelf area every 4 hours.
V.B.1 TM019,TM118, TM119	"The package shipping label of blood components/products for external transport shall be labeled with the following information:"	SWIM manual gave great examples of how to ensure documentation standards are met when blood is shipped to another facility. These forms were used as templates and documentation is enhanced by the use of "canned" texts in our Meditech system
V.B.1 TM021	"~whole blood and red cells are not left at room temperature for longer than 30 min…"	At our facility blood is transported from the blood bank to the operating room refrigerator routinely. To ensure acceptable unit temperature, we have introduced the "Safe-T-Vue®" label on all units issued. The label will go red if the temperature of the unit exceeds 10°C. If a unit is returned to us within 30 min of issue, the temperature of the unit is taken by infrared thermometer and recorded in the Meditech system under the "un-issue" information.

Education and communication with other disciplines is vital in not only meeting standards but also in patient transfusion safety, conservation of blood products and best blood utilization practice.

[i] Ontario Laboratory Accreditation (OLA) Requirements Version 4.1 Released July 2008

Patient Safety & Transfusion of Blood Products

By Veronika Pulley, RN, BA, BScN; ONTraC Blood Conservation Coordinator, Windsor Regional Hospital*

Blood transfusions save lives; but, how do we weigh the risks of transfusion against the benefits? The introduction of testing for HIV and HCV antibodies, along with testing for West Nile Virus shows us that vigilance against transmissible infections in blood transfusions has indeed become very important with regard to patient safety.

The Krever Commission noted that patients have an ethical and legal right to information along with their right to decide. When faced with the need for transfusion of a blood product, patients need to know what are the risks and benefits to receiving a blood product and what are the risks of not receiving a blood product.

In Windsor, much work and effort has gone into the development of a "regional" consent and refusal form for the administration of blood and blood products. In June 2006, educational pamphlets for patients and physicians were developed regarding the risks and benefits of different blood products. Educating nursing staff and physicians was a collaborative event that incorporated the distribution of many literature resources (e.g. articles, data, and educational resources, pamphlets) utilizing recent best practice methodologies.

On discharge from Windsor Regional Hospital, patients are given a copy of their discharge document on which it is noted if they received a blood product during their admission. Patients also receive a fact sheet that describes potential adverse transfusion reactions and the steps to take if an adverse reaction is experienced.

To further promote safety, a 'Regional' Nursing Transfusion Record was designed for documenting on the patient chart. This document is also a resource for the nurses and physicians as it includes best practice guidelines for the transfusion of blood and blood products, parameters for the rate of transfusion, vital signs protocol, signs and symptoms of adverse reactions, and the process to notify the physician and Blood Bank of a reaction. One can also note on a checklist if a valid consent was obtained, the patient armband checked, client education given, and if this was an emergency transfusion.

The 'Regional' Nursing Transfusion Record is currently in use in the 3 hospitals of Essex County, Ontario. Safety for the patient receiving a blood product starts well in advance of any transfusion given and is concluded well after this health care intervention.

Case Report - IV access and Timing of Product Issue

Setting: Emergency room (ER), community hospital
Patient: Patient X - 16 month old male
Background information:
Medical diagnosis – Haemophilia – Factor IX deficiency
Indication – Bleeding
Blood product requested – Factor IX concentrate (FIX)
Description of event:

- 19:10 hrs – Patient X presented (with parents) in ER, with bump on the head (from hitting door frame in the home)
- 21:00 hrs – blood bank staff issued 1 dose of FIX to ER. During this time, ER RN was encountering difficulty gaining IV access on patient X
- 22:05 hrs – ER staff informs blood bank staff that the syringe containing the FIX was accidentally discarded in the sharps container. Patient X only received normal saline used to flush the IV line. A second dose of FIX was issued to ER and given to patient X.

Corrective action taken: incident report was completed by blood bank staff and forwarded to Manager
Outcome: Following receipt of FIX, patient X bleeding stopped and patient X was discharged at 23:40 hrs. It was suggested that patient X wear a helmet to prevent future injury of this nature.
Conclusion: Current standards (CSTM Ver 2, Sept 2007) state "Venous access shall be established as per established hospital policy and procedure". Ontario Laboratory Accreditation requirement (OLA VI.1 TM 064) states "Procedures shall ensure that there is unequivocal identification of both the recipient and the blood component at the time of issue and prior to transfusion". At this facility, there was a policy in place stating that venous access shall be established prior to the issuing of blood or blood products. In this case there was non-compliance with this policy which may have contributed to the accidental discard of the first dose of FIX. In addition, there was failure to follow the procedure for confirming the blood product prior to infusion.
Questions to Ponder:

1. What processes are in place for communication of the standards to personnel outside of the blood transfusion laboratory?
2. What processes are in place to ensure adequate orientation, training and ongoing competency for personnel who administer blood and blood products?

Please refer to our website www.transfusionontario.org March 30, 2009 for a posting of a discussion paper on this case study and compare your answers to the questions posed.

Upcoming Educational Events Calendar

Event	Where	When
North East CBS / ORBCoN 4th Transfusion Medicine Symposium	Ottawa, ON & Videoconference	April 1, 2009
Provincial CBS / ORBCoN Spring Symposium	Toronto, ON	April 17-18, 2009

For a complete list of upcoming events please visit www.transfusionontario.org.

Quote

Never doubt that a small group of thoughtful, committed citizens can change the world.
Indeed, it is the only thing that ever has. *~ Margaret Mead 1902-1978*