New CSA Z902-15: What does this mean for hospitals?

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Disclosure

Commercial Interests

• Grants/Research Support
  – Glaxo-Smith Kline

• Consulting
  – Genzyme, Boehringer-Ingelheim

• Education Support
  – CSL Behring, Grifols

None specifically related to today’s lecture
Objectives

• Identify current changes to CSA Z902-15
• Identify impact on hospitals and transfusion services
First off, a brief history...

• A nationwide public health calamity ….late 1970s and the 1980s
• The national blood supply was contaminated with two infectious viruses, HIV & Hepatitis C
• Public inquiry to fully clarify the tragic events of the 1980s to reaffirm public confidence in the system and ensure that the Canadian blood system will be able to deal with future challenges
• 1998 - A national blood service
• Independent and able to make decisions in best interest of the blood supply system
• A national integrated database to manage donors and donations
• 1994 – CSTM prepared a brief to Krever
  – Need for National standards in all areas of TM (i.e. testing, record keeping, proficiency, etc)
  – Emphasis on education rather than legislation
  – Importance of communication between blood supplier and hospitals
Health Canada

- 1997 – Health Canada Expert Working Group tasked to develop standards for blood
- 1998 – Licensing framework for blood establishments
- Regular meetings with Expert Advisory Committee on Blood Regulation to provide medical, scientific, and ethical advice to assist regulatory decision making

- 2004 – CSA Standards for Blood and Blood Components Z902-04
  - Krever - intent to have regulations specific to blood

• 2003 CSTM Annual Meeting
  – The CSA Z902 standards were coming
  – Decision to revise and align with CSA Z902 but to focus on Hospital Transfusion Services

• 2004
  – CSTM Standards for Hospital Transfusion Services version 1.0 released
CSA Standards Z902

- To maintain and enhance the safety, efficacy and quality of blood collection, storage, processing and transfusion
- Sets out the minimum criteria for acceptable performance and may be exceeded in practice
The CSA Standards Process

- Technical Committee membership from blood centres, transfusion service, government, patient groups
- Voted and approved by Technical Committee
- Public review of new drafts, and users can suggest improvement of the standard anytime
- Any changes must be supported by sound rationale
Highlights from Z902-15

Annex A (informative)
Summary of significant changes in the third edition

Notes:
1) This Annex is not a mandatory part of this Standard.
2) This Annex was developed as a reference aid for locating revised clauses and tables in this Standard.

• Highlight 9 changes that may affect the hospital transfusion service
4.3.6.2
Personnel training procedures shall include mechanisms to ensure ongoing training of all clinical staff involved in the administration of blood components.

- Ensure that clinical staff (e.g. RN, anesthesiologists, perfusionists, etc.) who hang blood have been trained.
- Does not refer to the practice of medicine or the ordering of blood
4.6.1.6
Operating procedures shall be reviewed and updated at least every two years by a knowledgeable individual who has authority to make necessary changes.

- Changed from annual to every 2 years
- Consistent with AABB standards
7.6.2.3

Frozen plasma and fresh frozen plasma shall be thawed at 30 to 37°C. The maximum storage time for thawed plasma before transfusion shall be as follows:

a) **5 days** if plasma was collected in a closed system and maintained at 1 to 6°C

b) 24 h at 1 to 6°C if collected in an open system

- Refer to CBS Circular of Information
  - FP – 5 days
  - Cryosupernatant – 24 hrs (but soon to be 5 days)
  - Apheresis FFP – 24 hrs
Sheffield et al. Transfusion 2012;52:493-502
10.6.2
If computerized crossmatch is used, two determinations of the recipient’s ABO type shall be made, the first on the current sample and the 2nd by
a) Testing of a second current sample
b) Comparison with previous records
c) Retesting of the same sample

10.6.3
Retesting shall only be done in situations where positive patient identification technology is used at the time of specimen collection
Out of 6051 clinical service errors in 6 years
- 2.7% samples not labeled (1 in 37)
- 2.5% samples labeled with wrong patient identification (1 in 40)

Maskens et al. Transfusion 2014;54:66-73
10.10.5
A blood component that has been returned to the transfusion service shall not be re-released unless:

a) For RBCs, at least one sealed segment
b) Documentation and visual inspection
c) Temp monitoring or not outside a controlled environment for more than 60 min
d) Blood bag closure is undisturbed
4 RBC are ABO/Rh matched, pooled and split

Sterility testing and unit spiking *

- Control (C) unit remains in storage
- Test (T) unit is exposed 6 times to RT, each time for 30 min (total = 3 hours) during 42d of storage

- Control (C) unit remains in storage
- Test (T) unit is exposed 3 times to RT, each time for 1 hour (total = 3 hours) during 42d of storage

Ramirez-Arcos et al. Vox Sang 2013; 105:100-7
Units reached 10.7°C at 30 min 14.2°C at 60 min

No difference in quality of RBCs

Fig. 2 Yersinia enterocolitica growth and endotoxin production over 42 days following multiple 30- and 60-min RT exposures. Graphs show average ± SD CFU/ml of Y. enterocolitica (a) obtained in two independent experiments, each performed in duplicate in control or test RBC units, which have been exposed to RT for 30 min (grey) or 60 min (black). Graphs show endotoxin units (EU) detected during growth of Y. enterocolitica in RBC units (b).

Fig. 3 Serratia marcescens growth and endotoxin production over 42 days following multiple 30-min and 60-min RT exposures. Graphs show average ± SD CFU/ml of S. marcescens (a) obtained in two independent experiments, each performed in duplicate in control or test RBC units, which have been exposed to RT for 30 min (grey) or 60 min (black). Graphs show endotoxin units (EU) detected during growth of S. marcescens in RBC units (b).
11.2.1
An operating procedure shall be in place for obtaining informed consent of the recipient prior to the transfusion and shall include
a) Description of blood component or **blood product**
b) Risks and benefits
c) Alternatives if appropriate

- Blood product has been included in the requirement for informed consent
Fibrin Sealants – Frequently Asked Questions for Physicians

1. What are fibrin sealants?
   - Fibrin sealants are topical hemostatic products used in various procedures. The currently available fibrin sealants at Sunnybrook are Evicel®, Tisseel® and Artiss® - plasma cryoprecipitate-based sealants that contain human fibrinogen and thrombin and Surgiflo® - a thicker hemostatic matrix that contains human thrombin.

2. Is it a blood product?
   - Yes. These products contain human-derived blood products. As with blood transfusion, the donors have been screened for viral infections such as Human Immunodeficiency Virus (HIV), Hepatitis C (HCV) and Hepatitis B (HBV). In addition, the human-derived blood products in fibrin sealants have undergone additional virus inactivation and virus removal steps during the manufacturing process which are considered effective for enveloped viruses such as HIV, HCV, HBV, and for the non-enveloped Hepatitis A virus (HAV). The measures taken may be of limited value against non-enveloped viruses such as parvovirus B19, and theoretically, Creutzfeldt-Jakob disease (CJD) and variant-CJD.

3. Is consent required?
   - Yes. Patients should be informed that it is a blood product and that the risk of viral transmission is exceptionally low, but not zero, because the product is derived from blood donors. They should also be informed of the risk of allergic reactions.
11.2.2
A process shall be in place to ensure that inpatients who receive blood components or blood products receive notification of the transfusion

- Notification for inpatients only
- Outpatients or their caregivers should be aware that they are coming to the hospital for a transfusion
11.6
The transfusion service **should** have a written policy indicating who should receive cellular blood components selected to reduce the risk of CMV transmission

- No longer “shall” for CMV risk reduction
- Recognizes that leukoreduction does reduce the risk of CMV transmission
Record Retention

- Tables 4 and 5
- Changes from indefinite to 50 years maximum.
- Record retention requirements for
  - An establishment that transfuses blood
  - An establishment that washes, pools or irradiates blood
  - Additional requirements not covered by the federal regulations
If you have a suggestion for CSA...

- Contact inquiries@csagroup.org with the following information:
  a) Standard designation (number);
  b) relevant clause, table, and/or figure number;
  c) wording of the proposed change; and
  d) rationale for the change

- (Include “Proposal for change” in subject line)
Summary

• Ensure that your transfusion service is compliant with the CSA Z902-15 Standards
  – Get involved → make a suggestion to CSA.

• Certain sections are now referenced in the Blood Regulations

• Be prepared as Health Canada has now started inspections of transfusion services