

Saskatchewan Transfusion Committee Resource Book

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Developed by:

Saskatchewan Transfusion Medicine Working Group

Transfusion Committee Resource Book Sub-Committee

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Preface

The development of this Resource Book for Saskatchewan Transfusion committee members was commissioned by the Saskatchewan Transfusion Medicine Working Group (TMWG). The document will assist the committee members understand the role of a hospital transfusion committee (TC) in the current health care environment.

The initial section (pp. 5-9) of this resource book is intended as an orientation for new members of a Transfusion Committee. It provides valuable background information on the blood system in Canada and helps to define the purpose of Transfusion Committees, which may be new information for these individuals.

The second section of this document is designed to be used as a reference guide for all Transfusion Committee members for items related to the mandate of the committee. Throughout this section, resources and tools are provided to support Transfusion Committee activities.

Acknowledgements

Ontario Regional Blood Coordinating Network (ORBCoN) has granted permission to the Saskatchewan Transfusion Medicine Working Group (TMWG) to use their Transfusion Committee Handbook and Transfusion Committee Toolkit as resources. Ontario Regional Blood Coordinating Network (ORBCoN) is funded by the Ontario Blood Programs Coordinating Office of the Ministry of Health and Long-Term Care to provide educational resources to Ontario hospitals to ensure blood is utilized appropriately and safely. Thank you to the Ontario hospitals that contributed their resources to create these documents. We also wish to extend our gratitude to ORBCoN, which has allowed Saskatchewan to edit and use the resources.

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Saskatchewan Transfusion Committee Resource Book Subcommittee

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Welcome to your Transfusion Committee

Why are you here?

The Transfusion Committee (TC) needs input from the physicians and nurses that order and administer blood for patients as well as from laboratory representatives who are responsible for the service that provides blood for transfusion. The responsibility for ensuring that blood transfusion occurs safely at a hospital lies, in part, with the TC. You have been asked to participate on this committee because you can provide valuable expert knowledge from your area of specialty on how well the transfusion service meets your needs as well as those of your patients.

What is the mandate of the Transfusion Committee?

- To ensure blood is ordered appropriately and administered safely
- To ensure wastage of blood components and products is minimized
- To review reports of adverse reactions, incidents and complaints and make recommendations for their prevention to improve patient safety
- To provide health care professionals in your facility with current information and education relating to blood transfusion

What do you need to know about the blood system?

Where does blood come from?

The majority of blood for transfusion is collected as whole blood from volunteer donors in Canada by Canadian Blood Services (CBS) and, in Quebec, by Héma-Québec (HQ). The whole blood is processed into blood components (red cells, platelets, plasma and cryoprecipitate) for distribution to hospitals for transfusion to patients. Some components are collected through a process called apheresis which results in the collection of specific components like platelets and plasma. CBS and HQ are tasked with screening these volunteer donors to ensure the blood collected will provide the most benefit to the recipients while minimizing the risks. This includes screening each donor using a questionnaire and interview and testing the collected blood for pathogens that could be transmitted to the recipient. Both CBS and HQ must adhere to strict regulatory requirements mandated by Health Canada to ensure the blood supply is as safe as possible for all Canadians.

In addition, CBS and HQ purchase other blood products that are manufactured by pharmaceutical companies. Examples include coagulation factor concentrates used primarily for hemophiliac patients, immunoglobulins (IG) such as Intravenous Immune Globulin (IVIG), RhIG and Hepatitis B IG and blood derivatives such as albumin. The majority of these products are produced from human blood that may be collected from paid donors and is sourced from companies based in the United States and Europe. These products require complex manufacturing processes and are often costly.

Who pays for blood in Canada?

CBS and HQ are funded by the Provincial and Territorial Ministries of Health to collect, process and distribute blood components to hospitals in Canada and to purchase the required quantity of manufactured blood products from the various pharmaceutical suppliers licensed to provide products in Canada.

The funding formulas for each province are currently based on the use of red blood cell (RBC) units and the amount of manufactured products issued to hospitals within each province.

Are there any 'rules' to follow relating to the handling and use of blood in Canada?

There are accepted standards for the collection, testing, processing, storage, transportation, issuing, administration and tracking/documentation of blood for transfusion. These standards were developed by subject matter experts in the field of transfusion medicine.

- Canadian Standards Association National Standard for Blood and Blood Components CSA Z902-10
- Canadian Society for Transfusion Medicine Standards for Hospital Transfusion Services version 3 (2011)

Hospitals are monitored for compliance to these standards through Accreditation Canada and, in Saskatchewan, through the Diagnostic Quality Assurance Program (a division of the College of Physicians and Surgeons of Saskatchewan). Consequences of non-compliance can include the loss of hospital accreditation and loss of laboratory license.

Health Canada takes an active role in ensuring the quality and safety of the Canadian blood supply. For this reason, the blood suppliers and manufacturers have been heavily regulated by Health Canada for many years. A new federal law governing product safety from "vein-to-vein" has been published by Health Canada (the "*Blood Regulations"*), and will come into force on October 23, 2014. Hospital transfusion services and "walking donor" programs will then be regulated by Health Canada (Health Products and Food Branch). While many hospital transfusion services will meet the requirements of the new legislation because of ongoing laboratory accreditation, there will be new formalities required like authorizations, licensing, registration, and inspections by Health Canada. The extent of the requirements will depend on the level of services provided by a given transfusion service.

Do these Standards cover Transfusion Committees?

Yes, there are specific standards that outline the requirements of TCs, including the need for Terms of Reference for the committee, membership of the committee and frequency of meetings.

A list of the standards relating to the TC appears in appendix A of this handbook.

What will you need for your committee meetings?

You should be provided with your TC's Terms of Reference. A generic version and examples provided by Saskatchewan hospitals are found in the appendices of this resource book (refer to Appendix B).

What will be discussed at Transfusion Committee meetings?

- > Agendas may include discussions about
- Blood utilization and wastage
- > Development and approval of guidelines for ordering blood and/or blood products
- Policies to improve the use and provision of blood for transfusion including informed consent
- > Audits on blood utilization and administration
- > Adverse reactions that are reported during or following a blood transfusion
- > Incidents and errors or 'near misses' related to blood for transfusion
- > New products offered through CBS or HQ
- Dissemination of transfusion information and education, staff training and competency
- Contingency/emergency planning

Within this resource book, you will find brief outlines of each section that may be discussed at a TC meeting and suggested tools that may support committee members in fulfilling their role. Example agendas are provided in the agenda section of this resource book.

Special Roles on the Transfusion Committee

Chairperson

The chairperson's role on the TC is to:

- > Ensure Terms of Reference are developed, approved and provided to all members
- Schedule meetings to ensure the committee meets at least quarterly
- > Set agendas to ensure the committee can fulfill its mandate
- > Encourage all members to participate equally in discussions and provide their opinion
- Ensure committee members are provided with the data and tools required to enable them to develop recommendations
- > Arrange for minutes to be distributed
- > Ensure that action items are reviewed and completed
- Liaise between the Medical Advisory Committee (MAC) and the TC including bringing recommendations forward to MAC
- > Assist the members in understanding the accountability associated with the TC
- > Maintain awareness of members about the ethical aspects of their decision making
- > Provide an opportunity for all members to declare a conflict of interest at any time

Secretary

The secretary's role on the TC is to:

- > Record attendance at each meeting
- Record and distribute minutes of each meeting, ensuring action items and decisions and recommendations are documented within the minutes
- > Distribute background documents for discussion to committee members as required
- > Assist the chairperson in scheduling meetings as required

Transfusion Safety Officer and the Transfusion Committee

Some hospitals have created a position for a healthcare professional, with either a Nursing or Laboratory background, whose focus is to improve patient safety relating to blood transfusion. This person is often tasked with developing policies and procedures for patient identification and blood administration, reviewing blood utilization, dealing with adverse reactions and incidents related to blood transfusion, and delivering educational programs. If the hospital has a Transfusion Safety Officer, they should be a member of the TC.

Transfusion Safety Officers will often perform audits and present data to the TC in order to develop recommendations to improve performance and prevent errors and incidents. These activities can also be performed by either nursing or laboratory personnel, but having someone dedicated to this role is often more effective.

Remember you are vital to your Transfusion Committee

Your input can ensure that patients at your hospital receive safe and effective blood transfusion therapy only when it is truly needed. You will become more familiar with your hospital's guidelines for ordering and administering blood, the benefits and risks associated with it, as well as contributing to recommendations to prevent errors and improve patient safety. As a participating member on the TC, you will also become more knowledgeable on blood and any new practices related to the use of blood or its alternatives. Blood is a precious resource that requires effective management to ensure an adequate and safe supply for all Canadians. Your active participation on your TC plays an important role in meeting this mandate.

We are confident that you will find your participation on the TC rewarding and we thank you for your valuable time.

For further resources and information on Transfusion Medicine: http://www.health.gov.sk.ca/transfusion-medicine

The Saskatchewan Transfusion Resource Manual is located at the following link: <u>http://www.health.gov.sk.ca/sk-transfusion-resource-manual</u>

Agendas

Saxena S.(2013) 2nd edition, "The Transfusion Committee: Putting Patient Safety First," which outlines both the importance and the components of an agenda. A summary of the section related to agendas is found below. These points can be used as a reference and as a tool when developing an agenda.

- Purpose and specific objectives clearly defined
- Create and distribute in advance in order to provide an opportunity to add agenda items, do 'homework', prepare to present data and make decisions
- Serves as a reminder notice to the actual meeting
- Notifies members of meeting date, time and location
- Brief description of specific issues/items and identifies who is bringing them forward
- Label each agenda item "action" or "information"
- Use to show compliance with standards
- Meeting handouts distributed in advance with the agenda provides members the time to review the material and contribute (often achieved by email).

Agenda Example #1

MEMORANDUM

DATE: _____, 2013

TO: Members, RQHR Transfusion Committee

FROM: Dr. (Chairperson of TC)

RE: RQHR Transfusion Committee Meeting

A meeting of the above mentioned committee has been scheduled for Wednesday, _____, 2013 at 1600 hours at the ______.

AGENDA

- 1. Approval of Agenda
- 2. Chairperson (Dr)
- 3. Massive Transfusion Protocol (Dr)
- 4. Consent Health Canada Audit (Manager Transfusion department background)
- 5. Membership (Dr)
- 6. New Business
 - 6.1
 - 6.2
 - 6.3

Distribution to members of Transfusion Committee:

- 1. (Transfusion Med. Physician) 2. (Medical Director of Lab. Technology) 3. Nurse Educator
- 4. Transfusion Manager & Supervisor 5. Transfusion Safety Manager 6. Perfusionist
- 3. Medical representatives: Anesthesiology
 - Medicine Obstetrics/Gynecology Cancer Services Surgery Family Medicine Critical Care One will be designated as "Chair, TC"

Agenda Example #2

Agenda

Meeting called by:	
Date & Time:	
Meeting Location:	
Please Bring:	
Participants:	
AD hoc:	

Transfusion Committee								
Agenda Item	Desired	Person	Time					
	Outcomes	Responsible	Allotted					
1. Acceptance of Agenda	Approval	All	2 min.					
2. Minutes of Previous Meeting	Approval	All	5 min.					
3. Product Presentation	Presentation		30 min.					
4. Review of Policies:	Review	All	35 min.					
 5. Business arising from minutes: a) Terms of Reference b) SAP c) Contingency planning 	Update		5 min.					
6. New Business								
a) Blood Sampling b) Octaplasma (new product)	Discussion		10 min.					
7. Round Table Discussion	Additional items	All	10 min.					
 8. Reports: a) Blood Adverse Reaction report b) CBS Hospital Disposition Quarterly Reports 	Review	All	10 min.					
9. Date of Next Meeting								
10. Adjournment								

Agenda Items for the Transfusion Committee Blood Utilization and Wastage Review

Blood utilization review includes review of: blood inventory management; blood ordering practices; blood administration practices; and review of standardized protocols such as massive transfusion.

Blood inventory management can include supply issues from the blood supplier, blood wastage rates and inventory levels.

Review of blood ordering practice can be achieved by examining the appropriateness of orders, for example using a crossmatch-to-transfusion ratio to determine if many more units are ordered for certain procedures or by certain physicians than are actually transfused.

Review of blood administration practice can involve monitoring of informed consent for transfusion, review of blood issuing and infusion to ensure compliance with hospital policies and procedures.

Why should a Transfusion Committee monitor blood product utilization and wastage?

- > To improve patient care and safety
- > To ensure efficient and effective use of the blood products in your facility
- > To reduce the cost to the healthcare system due to unnecessary transfusion
- > It is a requirement by Canadian Standards Association (CSA Z902-10) 1
- > It is a requirement of the CSTM standards for Hospital Transfusion Services²

Some reasons why utilization reviews are necessary at your facility:

- > Identify cases of over-transfusion or under-transfusion
- Reduce unnecessary patient exposure to blood products and prevent associated adverse events

Examples of tools available to help review blood product utilization:

- ✓ Saskatchewan hospitals submit disposition and inventory data to Canadian Blood Services Hospital Component Disposition and Inventory Reporting System. Data submitted to CBS is collated in a data warehouse, and then made available to hospitals by accessing their own graphs at any time through the web based reporting system see figure 1 for an example of graphs provided.
- ✓ Crossmatch-to-Transfusion ratio (see figure 2)

Figure 1:

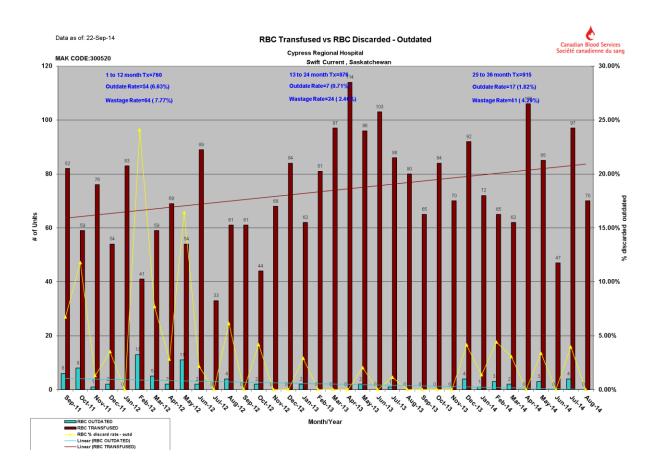


Figure 2: Example of Crossmatch to Transfusion Ratio Graphs by Physician and Department

OVERALL DATA <mm yy=""></mm>										
		CT								
Physician	Department	Crossmatched	Transfused	Ratio						
Jones	Surgical	4	0	4:0						
Smith	Hematology	4	1	4:1						
Jones	Surgical	3	2	3:2						
Smith	Hematology	2	1	2:1						
Johnson	Ortho	3	3	1:1						
Edwards	Ortho	4	0	4:0						
Martin	OBS	20	2	10:1						
Total		40	9	40:9						

BY PHYSICIAN <mm yy=""></mm>							
Physician	Crossmatched	CT Ratio					
Jones	7	2	7:2				
Smith	6	2	3:1				
Johnson	3	3	1:1				
Edwards	3	1	3:1				
Martin	20	2	10:1				
Total	39	10	39:10				

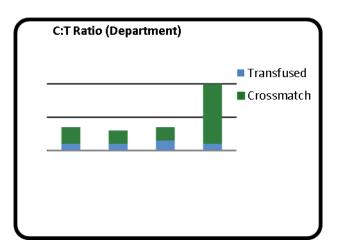
BY DEPARTMENT <mm yy=""></mm>							
Department	Crossmatched Transfused CT Ration						
Surgical	7	2	7:2				
Hematology	6	2	3:1				
Ortho	7 3		7:3				
OBS	20	2	10:1				
Total	40	9	40:9				

For organizations that do not use a just-intime (JIT) electronic crossmatch system, monitoring the number of units crossmatched to the number of units transfused, may be a helpful quality indicator.

- 1. Determine the group for analysis. Some examples are:
 - Patient group
 - Department
 - Physicians
- 2. Establish the timeframe for analysis: e.g. a month, 3-months or a year.
- 3. Tally the number of crossmatched units and determine how many of those units were actually transfused.

These ratios will assist organizations in identifying possible inefficiencies to the crossmatching process with regard to resources and personnel required. The review of C:T ratios also identifies differences in utilization practices by peer and department.

The literature demonstrates that a good C:T ratio is between 1.5 (3:2) and 2.5 $(5:2)^{3,4}$



Development of Guidelines

Why Transfusion Guidelines?

Transfusion practice can vary widely by facility, clinical service and individual physician.

Guidelines can help support clinical decisions about appropriate use of blood components and products. ^{5,6}

Establishing facility guidelines for transfusion will help to reduce inappropriate transfusions and increase patient safety.⁷

Development of guidelines

Ensure that they are:

- Evidence based
- > Appropriate for your facility
- > Easy to comprehend
- > Easy for clinicians to access
- > Developed with both clinical and laboratory input

Why review and monitor?

Medical research is being done every day to help improve therapies for patients and increase patient safety. Transfusion Medicine is always evolving and practices are continually improving. The committee should be monitoring and reviewing their current practices based on:

- > New evidence (i.e. Restrictive Transfusion Strategies)
- Increased use of alternatives to transfusion in the management of anemia, i.e.
 Erythrocyte Stimulating Agents (ESAs)
- New initiatives and programs, such as the Saskatchewan Immune Globulin (IVIG) Utilization Management Program

Examples of guidelines:

- ✓ Guidelines to Novel anticoagulants i.e. Dabigatran ("Pradaxa") and Bleeding patients Guidelines are found on the following link: <u>http://www.health.gov.sk.ca/dabigatran%E2%80%90guideline</u>
- ✓ National Advisory Committee on Blood and Blood Products- Guidelines Guidelines are located on the following link: <u>http://www.nacblood.ca/resources/guidelines/</u>
- Blood Product Administration Guidelines refer to Bloody Easy version 3 published by ORBCon refer to link http://transfusionontario.org/en/cmdownloads/categories/bloody_easy/
- ✓ Saskatchewan Immune Globulin (IVIG) Utilization Management Program Guidelines

Bloody Easy version 3

Indications for Transfusions -RBC

Hemoglobin	Recommendation
>100 g/L	Likely inappropriate except in exceptional circumstances
70-100 g/L	Likely to be appropriate if there are signs or symptoms of impaired oxygen delivery
<70 g/L	Likely to be appropriate
<60 g/L	Transfusion highly recommended -Young patients with low risk of ischemic cardiovascular disease can sometimes tolerate greater degrees of anemia

Recommendations for RBCs – Bloody Easy version 3⁶

Adult patients:

In non-urgent situations, it is recommended to:

- Order one unit at a time, then reassess need for more
- Transfuse during daylight time (shown to be safer)
- Usually infuse over 2 hours, depending on the ability to tolerate but always within 4 hours of issue from blood bank

Pediatric patients:

- 15ml/kg of RBCs should raise the Hgb by 20g/L
- Start slow (1ml/kg/h, up to 50ml/h) for the first 15 minutes
- Than usual rate is 5ml/kg/h, up to 150ml/h

Refer to Bloody Easy version 3 for further recommendations on other blood products, i.e. platelets.⁶

Policies for Blood Transfusion

Why should Transfusion Committees determine Transfusion Policies?

Policies, processes and procedures describe the purpose and objectives of the organization, how processes are anticipated to function, how they work together, how to perform the processes, areas of risk or control, what their requirements are, how to implement them and how to measure or evaluate them.⁸

Many of the standards mandating the existence of a TC with defined Terms of Reference and minimum meeting intervals also charge the TC with defining or approving transfusion policies.¹

The clinical perspective in addition to the laboratory perspective is critical in obtaining the safest and most practical policies for transfusion activities. The members of the TC can help provide this input on behalf of, and preferably in collaboration with, members of their own departments. Review, revision and approval of these policies should be documented in the TC minutes, creating a record of the transfusion policy identification, development and approval process. It is also ensures a transparent process to clinical areas, departments, administration and auditors.

What types of policies should Transfusion Committees consider?

Some of the key policies related to transfusion at your hospital (or group of hospitals if you have a regional TC model) that should be developed or reviewed by the TC are:

- > Informed consent for transfusion and protocol for refusals
- Pre-transfusion testing orders: group and screen versus crossmatch, computer/electronic crossmatch, maximum surgical blood order schedules
- Medical indications for blood products and ordering practices
- > Patient identification for specimen collection and blood product administration
- Administration practices and guidelines/monographs for adults and neonates and pediatric patients where appropriate
- > Massive transfusion protocol
- > Transfusion adverse event identification, intervention, reporting and monitoring
- Non-conformance/error reporting, complaints, corrective and preventative measures, monitoring and evaluation from the laboratory, clinical areas and other pertinent departments
- Management and performance of audits
- > Lookback/Traceback for reported transfusion transmitted infections
- > Introduction of new blood products
- Blood shortage management
- > Staff training and on-going competency for handling blood components/products

Saskatchewan Transfusion Medicine Working Group (TMWG) and RHAs have developed some tools to assist hospitals with development of transfusion related policies:

- 1. Saskatchewan Transfusion Resource Manual
- 2. Blood Transfusion Information for Patients Hand Book
- 3. Saskatchewan Hospitals Transfusion Adverse Event Report form
- 4. Bloody Easy 3 hardcopy version copies may be obtained from the Intra-Regional Transfusion Safety Managers
- 5. Informed Consent Reference cards and sheets obtained from the Intra-Regional Transfusion Safety Managers

The regular review of policies and procedures for accuracy, currency and relevance is another important aspect of policy and procedure development.

"Policies, processes and procedures are the cornerstones to safe transfusion practice."

Audits

What are audits?

The general definition of an audit is the inspection and examination of a process or quality system to ensure compliance with requirements for an organization, function, process, product or step.⁹ A function of the hospital TC is to assess and review the results of audits of transfusion practices at the hospital. Auditing can improve an organization's effectiveness and efficiency by leading to recommendations that promote continuous quality improvement of transfusion practice. As part of the audit process, it is essential that the findings of audits, including any corrective action implemented, be documented.

Why should audits be done?

- The Canadian Standards Association Standards for Blood and Blood Components (CSA Z902-10) requires that each facility perform periodic reviews and audits. These internal audits should be performed annually at a minimum, to verify the continuing effectiveness of the quality system.¹⁰
- The Canadian Society for Transfusion Medicine Standards for Hospital Transfusion Services states that the transfusion service must establish an internal audit program to ensure quality of processes and procedures.¹¹

The Laboratory Quality Assurance Program of the College of Physicians and Surgeons of Saskatchewan has been granted the authority under the Medical Laboratory Licensing Act and Regulations to administer a quality assurance program for medical laboratories. The purpose of auditing and accrediting a laboratory is to evaluate and ensure compliance with the established standards and to provide recommendations for improvement. ¹²

http://www.cps.sk.ca/CPSS/Programs and Services/Laboratory Quality Assurance. aspx?LabQualityCCO=4

What kinds of audits should the Transfusion Committee get involved with?

- Blood utilization review is an example of an audit that is used to identify the appropriate use of blood components and products at your facility.
- Regular evaluations of blood ordering and transfusion practices should be conducted. Specific areas that are important to address are: ordering, distribution, handling, dispensing, and administration of blood components and blood products.
- Additional auditing categories may include: policies and procedures, facilities management, training/personnel qualifications and competency, quality assurance, complaints/deviations, error/accident trends, adverse events, testing and lookback/traceback.¹³
- > Informed consent for blood/blood components transfusion audits
- Bedside check audits

The format of any audit/review process must be established by each institution. A blood utilization review must include the criteria for appropriate blood utilization. Each review can be conducted either prospectively or retrospectively and data collection can be performed manually or by accessing laboratory information systems.

Review of Adverse Reactions to Blood Components/Products

What types of reactions/events should be discussed at your Transfusion Committee meetings?

A transfusion is an important component of numerous patient therapies. The process, however, has potential serious risks. A Transfusion Reaction Algorithm is available in the Saskatchewan Transfusion Resource Manual. The algorithm is a resource to assist healthcare workers recognize and manage transfusion reactions. The contact information for the provincial Transfusion Medicine Consultants is located on the algorithm. Please refer to Appendix F.

Saskatchewan has developed an adverse event report form to be completed if a recipient of blood, blood components, or plasma protein products experiences an adverse event. The information is provided to the Transfusion Transmitted Injuries Surveillance System (TTISS) database. TTISS is a national surveillance and monitoring system run by the Public Health Agency of Canada (PHAC) for reporting of adverse reactions to blood, blood components, or plasma protein products. The data are used to help identify and mitigate risks related to transfusion of these products in Canada.

In Saskatchewan, serious adverse events are also reported to the RHA Patient Safety Department (sometimes known as "Risk Management") for reporting to the Saskatchewan Ministry of Health. An example of a reportable serious adverse event would be a hemolytic reaction due to the administration of ABO-incompatible blood or blood products. Further explanation is found in the Saskatchewan Transfusion Resource Manual, Adverse Event Reporting. Blood Easy version 3 Risk Chart* for receiving Blood and blood components⁶:

Risk of Event	Event			
1 in 20	Febrile non-hemolytic transfusion reaction per pool of platelets			
1 in 100	Minor allergic reactions (urticaria)			
1 in 300	Febrile non-hemolytic transfusion reaction per unit of RBC (1'donor exposure')			
1 in 700	Transfusion-associated circulatory overload per transfusion episode			
1 in 7,000	Delayed hemolytic transfusion reaction			
1 in 10,000	Transfusion-related acute lung injury (TRALI)			
1 in 10,000	Symptomatic bacterial sepsis per pool of platelets			
1 in 40,000	ABO-incompatible transfusion per RBC transfusion episode			
in 40,000 Serious allergic reaction per unit of component				
1 in 60,000	Death from bacterial sepsis per pool of platelets			
1 in 153,000**	Transmission of hepatitis B virus per unit of component			
1 in 250,000Symptomatic bacterial sepsis per unit of RBC				
1 in 500,000 Death from bacterial sepsis per unit of RBC				
<1 in 1,000,000	Transmission of West Nile Virus			
1 in 2,300,000	Transmission of hepatitis C virus per unit of component			
1 in 4,000,000	Transmission of Chagas disease per unit of component			
1 in 4,300,000	Transmission of HTLV per unit of component			
1 in 7,800,000	Transmission of human immunodeficiency virus (HIV) per unit of component			

- * All of these risk frequencies are likely to have quite wide confidence intervals.
- ** Where time permits, consider hepatitis B vaccination in prospective transfusion recipients, especially for those requiring repeated infusions, of blood or blood products (<u>www.phac-aspc.gc.ca:Immunization</u> Guide, part 4, pg. 194).
- Appendix E: Resources developed by the Saskatchewan Transfusion Medicine Working Group regarding major evaluated risks of blood transfusion.

Figure 3: Example of the types of Adverse Events recorded over a set period of time. Headings adapted from the Serious Hazards of Transfusion (SHOT) Summary Report 2011¹⁴

Month / Adverse Event Type												
	Adverse	e Events	Caused by	y Error	Possibly / Probably Preventable				May not be Preventable		ntable	
					BR							
<year></year>	IBCT	HSE	I&U	Anti-D	ATR	HTR	TA/GvHD	TACO	TRALI	TAD	PTP	TTI
Jan	1 plt											
Feb								2 fp	1 plt			
Mar			2 fp						1 plt			
Apr		2 plt										
May												
Jun			3 fp					1 fp/1rbc				
Jul						1 IVIG						
Aug								1 fp				
Sep												
Oct								2 fp				
Nov												
Dec												
Totals	1	2	5			2		7	2			

Key: IBCT Incorrect blood component transfused; HSE Handling and storage errors; I&U Inappropriate/unnecessary; Anti-D Errors related to RHIG; BRATR Bacterial related adverse transfusion reaction; HTR Hemolytic transfusion reaction; TA/GvHD Transfusion associated graft versus host disease TACO Transfusion associated circulatory overload; TRALI Transfusion related acute lung injury TAD Transfusion associated dyspnea; PTP Post transfusion purpura; TTI Transfusion transmitted infection

Figure 4: Type of Reaction by Category

Oversight of transfusion practices and adverse events requires active participation of physicians, nursing, laboratory, administrators and other healthcare providers to ensure prevention of adverse events and to identify appropriate corrective actions. Review of adverse reactions can aid in identifying sentinel events, near miss errors and potential product related issues. Implementation and subsequent monitoring of corrective actions can improve patient safety related to transfusion.⁷

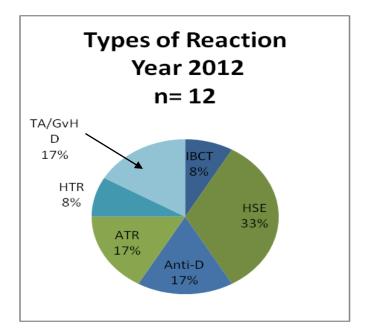
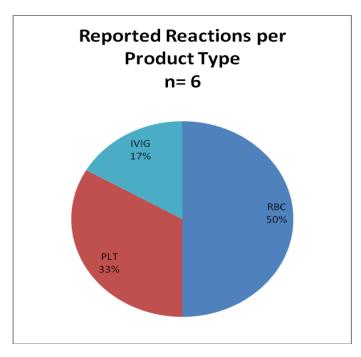


Figure 5: Reactions by Component/Product



Figures 4 and 5 demonstrate other examples of Adverse Reaction Summary Reports.

Review of Errors and Incidents Related to Blood Transfusion

Why does the Transfusion Committee need to review errors and incidents?

The Canadian Standards Association for Blood and Blood Components (CSA Z902-10) requires that any incidents, such as errors, accidents and deviations from normal operating procedures be identified, investigated, evaluated and corrective action taken when required.¹⁵ TCs are involved with the development and maintenance of policies and procedures involving the transfusion of blood components and products, and should be closely involved with all the steps involved with the error management process.

Saskatchewan Laboratory Accreditation requirements state that the process for formulating corrective action must include an investigation to determine the underlying root causes of the problem. Corrective action shall be appropriate to the magnitude of the problem and risks encountered.¹² A system must be in place within the transfusion service/laboratory to check adverse event information and recommendations for future transfusions for subsequent transfusions.¹⁶

In his primer for healthcare executives written for the Medical Event Reporting System for Transfusion Medicine (MERS-TM), Marx explains that it is through the lessons of our everyday errors that we can design our work environment to be less error prone and more error tolerant.¹⁷ Reporting of actual errors as well as "near miss" incidents should be encouraged in a blame-free, non-punitive environment. The subsequent investigation and analysis should take a systems based approach, focusing on all relevant contributing factors. Serious errors usually occur as a result of multiple contributing factors. Near-miss event provide an opportunity for learning in the absence of serious harm.

The investigation of serious errors will usually be performed by trained individuals belonging to the Safety/Quality and Risk Management departments (valuable members of any TC). The following provides a brief summary of the type of the information a TC may be asked to review.

Root Cause Analyses (RCA)

- Is a quality-improvement tool that helps individuals and organizations determine the contributing factors that led to an incident. ¹⁸
- Is based on the belief that problems are best solved by attempting to address, correct or eliminate the root causes, as opposed to addressing the obvious symptoms. By directing corrective measures at the root cause(s), it is more probable that problem reoccurrence will be prevented.

Root Cause Analysis (RCA) Procedure

This brainstorming exercise will provide the group with a better understanding of the process itself and will also help to determine what the root causes of any problem are.

- 1. Define or describe the problem/issue
- 2. Gather data and evidence
- 3. Brainstorm the major <u>categories</u> of causes of the problem and write the categories of causes as branches from the main arrow
- Brainstorm all the <u>possible causes</u> of the problem and write each idea as a branch from the appropriate category – causes can be written in several places if they relate to several categories
- 5. Identify the most effective solutions
- 6. Determine corrective action and preventative measures
- 7. Implement and verify the corrective and preventative actions and measures
- 8. Monitor the process for compliance (did the preventative measures work?)

Fishbone Diagram, (Cause-and-Effect Diagram), Ishikawa Diagram

The fishbone diagram is a tool that helps to identify many possible causes for an incident or problem and can be used to structure a brainstorming session with the TC in addition to staff performing the procedure. It immediately sorts ideas into useful categories. See figure 6 using the problem 'wrong blood in tube' as an example.

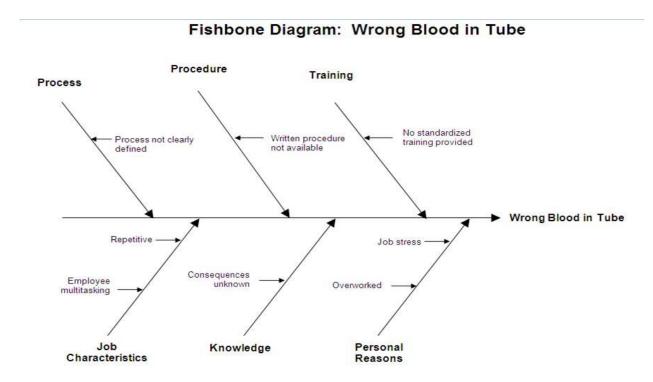


Figure 6: Fishbone Diagram (Cause-and-Effect Diagram).¹⁹

Root cause analysis does not need to be complex or difficult. Charles Vincent proposes six categories of contributing factors to be considered following any error: work environment factors, environmental factors, team factors, task factors, knowledge, organizational factors and individual factors. Categorizing the events that contributed to an error enables a systematic approach to determining root cause.²⁰

Additional tools that may be useful to the transfusion committee include:

<u>Pareto diagram</u> – a type of graph that is useful in ranking data by the number of occurrences for each problem.

<u>Flow chart</u> – a schematic diagram used to trace a process from start to finish and is very useful in determining the root cause of a problem.

<u>Scatterplot</u> – a graph that is used to show the relationship between two measured variables and is useful in determining a cause and effect correlation.

Review of New Blood Components and Products

New blood components or blood products are introduced in Canada on the advice of the National Advisory Committee (NAC) on blood and blood products. The NAC is a medical advisory body that has representation from all provinces and territories and provides advice on blood and blood products to the provincial and territorial Ministries of Health (MOH) that provide funding for the blood system in Canada. NAC also develops and publishes guidelines and recommendations on the use of blood products (see <u>www.nacblood.ca</u>)

The MOH considers the recommendations made by NAC when determining whether a new blood product will receive funding to be supplied to hospitals in Canada.

What role does the Transfusion Committee play in approving new blood components or products?

The TC at each hospital should:

- > Determine if the new blood component or product will be used at their facility
- > Develop and approve evidence based clinical guidelines for use of the product
- > Develop and approve in-house administration policies and procedures
- > Determine the quantity to keep in stock and availability of the new product
- > Educate staff (medical and nursing) about the new product and appropriate use

Another role for the TC is to audit the use of the product once it has been approved and it has been implemented to ensure it is being ordered and used appropriately.

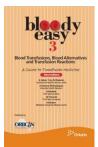
Education about Blood Transfusion

Blood transfusion involves personnel from diverse backgrounds with different levels of knowledge and understanding. In order to properly and safely accomplish their role in transfusion each individual needs to be trained to the appropriate level. Any person(s) involved in any step in the transfusion process must meet the competency requirements set out in the standards.

The Canadian Standards Association Standards for Blood and Blood Components (CSA Z902-10) states that each facility shall create, maintain, and document a formal competency assessment program. Competency shall be assessed following training and at regular and routine intervals thereafter.²¹

The Diagnostic Quality Assurance Program of the CPSS states that there shall be documentation of staff training at hire and with each procedural change in the transfusion services.

Bloody Easy 3: Blood Transfusions, Blood Alternatives and Transfusion Reactions. A Guide to Transfusion Medicine Third Edition



This educational tool provides practical information on Transfusion Medicine in a concise booklet format. It is designed to enhance knowledge of physicians, nurses, and technologists on the clinical use of blood transfusions and blood alternatives. *Bloody Easy 3* – available from inter-regional transfusion managers or download at

http://transfusionontario.org/en/cmdownloads/categories/bloody_easy/

Bloody Easy Blood Administration. A Handbook for Health Professionals



This booklet is ideal for nurses or health care professionals administering blood. It provides an overview of blood and blood products, the risks associated with them, and how they should be administered. In addition, it describes the types of transfusion reactions that may occur. This booklet is available in both English and French by downloading from the below link. http://transfusionontario.org/en/cmdownloads/categories/bloody-bloody/

Resource Manual for Medical Directors of Transfusion Medicine



This Resource Manual for Medical Directors of Transfusion Services provides support and guidance to physicians responsible for transfusion medicine services in the Province of Ontario. It provides a framework outlining sound transfusion laboratory practice, and seeks to advocate for appropriate current practices in the use of both labile blood components and manufactured products. This booklet is available by downloading from the link below. http://transfusionontario.org/en/cmdownloads/categories/resource-manual-for-medical-directors-of-transfusion-medicine/

Disaster and Contingency Planning Related to Blood Transfusion

Blood and blood components play a vital role in the provision of healthcare to patients. Unexpected events can occur that may result in a reduction in service by the transfusion service. Hospitals need to have contingency plans in place to mitigate the impact and risk to patients should this occur. Examples of the type of situation that could result in a reduction of service by the transfusion service include:

- Facility catastrophic event such as fire, flood or earthquake causing building or building system failure
- Local disaster resulting in overwhelming requests for provision of blood and/or blood products, such as multi-vehicle accident, airplane or train accident
- > National event resulting in a severe shortage of blood and/or blood products

Local or Regional Disaster Plans

Most hospital laboratories will have plans in place to address events that would require displacement of laboratory services and large local disaster scenarios affecting a large number of patients. The TC should be familiar with these plans and review them periodically to ensure patient care will be addressed adequately in relation to the provision of blood components and products.

National Blood Shortage Events

A National plan for the management of Blood Shortages was developed by a working group of the NAC. It was released in 2010 and recently revised and re-released in January 2012.²² The Saskatchewan Transfusion Working group developed a Saskatchewan Regional Health Facilities Blood shortage management plan in January 2010. To locate the current version follow <u>http://www.health.gov.sk.ca/transfusion-medicine</u>.

What does this mean for the Transfusion Committee?

Each hospital should have a plan developed to guide healthcare professionals through the response that will be required should a National Blood Shortage ever occur. Hospitals will need to take steps to reduce the demand for the affected blood component, inform staff and patients that may be impacted as a result of delayed or deferred treatment, maintain communication with CBS as well as the Ministry of Health and Long-Term Care. This type of event would greatly impact the transfusion service and its ability to provide service within the hospital therefore, it is in the best interest of the TC to be familiar with and review the Hospital Emergency Blood Management Plan.

What role would Transfusion Committee members have to play during a blood shortage?

Each hospital should develop their own plan, addressing their own needs should a blood shortage ever occur. Saskatchewan's Transfusion Medicine Working Group has developed a template to assist health regions and health facilities with the development of their own blood shortage management plans in a manner that is consistent with the national plan, and in effect, consistent with those of health providers in other provinces and territories.²³ TC members should be familiar with the hospital plans that relate to the management of blood resources in a disaster or critical shortage situation. Following a disaster or critical shortage of blood resources, the TC should review the events and determine if the plan was effective.

Committee Members' Code of Conduct

In addition to the Terms of Reference of a committee, committee members should abide by a code of conduct that will ensure ethical and timely decision making and professional conduct. The following was extracted from the ORBCoN Transfusion Committee Toolkit released in 2008.

Confidentiality:

Members will consider issues non-confidential unless otherwise advised. Members will observe confidentiality when asked to do so.

Professional Responsibilities:

- Members will familiarize themselves with the issues before them
- Members will actively participate on the committee
- In accordance with conflict of interest guidelines, members will not use their position as members of the committee for private gain (see Appendix C for an example of conflict of interest guidelines and Appendix D example of Conflict of Interest Attestation and Disclosure Form)

Behavior:

- Members will be honest and trustworthy
- Members will respect others right to privacy
- Members will avoid harm to others
- Members will focus on the issues and respectfully express both assenting and dissenting views with the understanding that all views are valued
- Members will speak freely, but not monopolize the dialogue
- Members will engage in productive inquiry that values each other's experiences

Ethical Decision Making

Situations may arise where "doing the right thing" is not clear. These situations may be referred to as ethical dilemmas, which are not always easily identified. If you or your committee encounters any of the warning signs listed below, there is a significant possibility that there is an ethical dilemma to be resolved:

- A sense of discomfort when the situation is viewed through the lens of being published in a newspaper or viewed on television
- > Wanting to proceed in the right direction, but confronting barriers
- Receiving information you wish you didn't have
- An uneasiness caused by competing values (loyalty versus disclosure; safety versus financial prudence)
- Conflict in the group or committee from different perspectives, values, culture and professions
- A unique situation that has not been faced before. Policies and standards of practice do not apply
- > An intuitive, gut feeling that something isn't right

The most prepared organizations have ethics policies and an established decision framework to guide them with these difficult decisions. The goal of having a framework to guide decision making is to develop a common approach that can be applied to situations where existing policies and processes do not provide sufficient guidance. Some organizations also have ethics specialists that assist teams in reaching the best, most transparent decisions.

What is ethical decision making?

Ethical decision making is a disciplined reflection on how to make decisions about what should be done in a particular situation. Ethical decision-making usually involves four related questions²⁴:

- > What should we do? (What options are good or right in this context?)
- > Why should we do it? (Exploring the values and reasons that support each option.)
- How should we do it? (What plan of action best aligns with these values and reasons?)
- Who should do it? (Who is responsible for making the final decision and enacting and communicating it?)

Hospital care is a public service, thus the benefits of hospital care should be accessible to all members of the community. In order to meet the needs of the community, hospital resources must be prioritized and allocated wisely, on the basis of fair and publicly-defensible reasons and procedures. While a health care professional's first duty is to the patient, both managers and clinicians also have a responsibility to promote fair access to health care resources prudently.²⁵

Open, collaborative and transparent discussion with committee members, each providing their experience and knowledge is often a most efficient method to address situations that may present as an ethical dilemma.²⁴

Additionally, committee members should not hesitate to ask for outside assistance and input from non-committee members like staff, volunteers, patients and their families in order to make the best decision in a difficult situation.

References

- Canadian Standards Association, CAN/CSA-Z902-10 A National Standard on Blood and Blood Components. Standards Council of Canada; Mississauga, Ontario (CSA Z902-10 February 2010, 4.4).
- 2. Canadian Society for Transfusion medicine Standards for Hospital Transfusion Services; Ottawa, Ontario. (Ver 3 February 2011,1.8).
- 3. Zumberg, M. (2007) Blood Bank/Transfusion Committee Tutorial: The Shands Transfusion Committee. Retrieved June 14 2012, from University of Florida ,Graduate Medicine Education web site: http://gme.med.ufl.edu/files/2009/07/transfusion committee tutorial zumberg.ppt
- Novis. David A., Renner .Stephen, Friedberg. Richard, Walsh. Molly K., and Saladino. Andrew J. (2002). Quality Indicators of Blood Utilization. Archives of Pathology & Laboratory Medicine: February 2002, Vol. 126, No. 2, pp. 150-156. <u>http://www.archivesofpathology.org/doi/full/10.1043/0003-</u> 9985%282002%29126%3C0150:OIOBU%3E2.0.CO;2
- 5. Stevenson H, et al. Clinical Guide to Transfusion (3rd ed.); Toronto, Ontario Canadian Blood Services, 2006.
- Callum JL, et al. Blood Easy: Blood Transfusions, Blood Alternatives and Transfusion Reactions: A Guide to Transfusion Medicine (3rd ed); Toronto, Ontario. Ontario Regional Blood Coordinating Network: 2011.
- 7. Saxena S. The Transfusion Committee: Putting Patients Safety First; Bethesda (MA): AABB Press 2013.
- Roback JD (Ed). AABB Technical Manual (17th ed.). Bethesda, (MA): AABB Press 2011: p 16.
- 9. Walters, LM. Introducing the Big Q: A Practical Quality Primer. Bethesda, Maryland; AABB Press 2004: p 162.
- 10. Canadian Standards Association, *CAN/CSA-Z902-10 A National Standard on Blood and Blood Components*. Standards Council of Canada; Mississauga, Ontario (CSA Z902-10 February 2010, 4.6.3).
- 11. Canadian Society for Transfusion Medicine Standards for Hospital Transfusion Services; Ottawa, Ontario. (Ver 3 February 2011, 8.1).
- 12. The Laboratory Quality Assurance Program of the college of Physicians and Surgeons of Saskatchewan. http://www.cps.sk.ca/CPSS/Programs_and_Services/Laboratory_Quality_Assurance.asp x?LabQualityCCO=4
- 13. Walters, L.M. Introducing the Big Q: A Practical Quality Primer. Bethesda, Maryland; AABB Press 2004: p 179.
- 14. Annual SHOT Report 2011. Retrieved August 28, 2012 from <u>www.shotuk.org/wp-</u> <u>content/uploads/2012/07/SHOT-ANNUAL-REPORT</u>.
- 15. Canadian Standards Association, *CAN/CSA-Z902-10 A National Standard on Blood and Blood Components*. Standards Council of Canada; Mississauga, Ontario (CSA Z902-10 February 2010, 4.6.2).
- 16. Saskatchewan Transfusion Resource Manual. Transfusion Medicine Working Group; Saskatchewan (September 30, 2011, Guideline 17#).

- 17. Marx D. Patient Safety and the Just Culture: A Primer for Health Care Executives. MERS-TM <u>http://www.mers-tm.net/support/marx_primer.pdf</u>
- 18. Root cause analysis. Retrieved August 23, 2012 from <u>http://www.patientsafetyinstitute.ca/english/toolsresources/rca/pages/default.aspx</u>
- 19. Fishbone Diagram procedure. Retrieved August 10, 2012 from <u>http://asq.org/learn-about-quality/cause-analysis-tools/overview/fishbone.html</u>
- 20. Vincent C. Clinical Risk Management: Enhancing Patient Safety. BMJ Books 2001
- 21. Canadian Standards Association, *CAN/CSA-Z902-10 A National Standard on Blood and Blood Components*. Standards Council of Canada; Mississauga, Ontario (CSA Z902-10 February 2010, 4.3.3).
- 22. National Plan for the Management of Shortages of Labile Blood Components. National Committee on Blood and Blood Products and Canadian Blood Services. Jan 18, 2012. www.nacblood.ca/resources/shortages-plan/National-shortages-plan-Jan-2012-final.pdf
- 23. Saskatchewan Regional Health Facilities Blood Shortage management Plan. Saskatchewan Transfusion Working Group. Jan. 29, 2010. http://www.health.gov.sk.ca/adx/aspx/adxGetMedia.aspx?DocID=b8257fab-528b-4904-a8ad-0e335934483e&MediaID=3664&Filename=blood-shortage-managementplan-jan-2010.pdf&l=English
- 24. Frolic A with Hamilton Health Sciences Clinical Ethics Committee. Hamilton Health Sciences Ethics Framework. ; Jan 2010.
- 25. CMA Code of Ethics sections 43 and 44 http://www.cma.ca/index.cfm/ci_id/2419/la_id/1.htm
- 26. Accreditation Canada, "Driving Quality Health Services", August 2012, retrieved August 22, 2012 www.accreditation.ca/en/
- 27. Canadian Society for Transfusion Medicine, *Standards for Hospital Transfusion Services;* Ottawa, Ontario. (v3 February 2011).
- 28. Laboratory Quality assurance Policy Manual, College of Physicians and Surgeons of Saskatchewan, LabQA; Saskatchewan. (2013 edition).
- 29. Transfusion Committee Handbook. Ontario Regional Blood Coordinating Network; Ontario (V1 August 31, 2012).
- 30. Transfusion Committee Toolkit. Ontario Regional Blood Coordinating Network; Ontario (V! March 25, 2008).

Appendices

Appendix A: Standards Relating to Transfusion Committees in Canada

Accreditation Canada

Accreditation Canada is a not-for-profit, independent organization accredited by the International Society for Quality in Health Care (ISQua). They provide national and international health care organizations with an external peer review process to assess and improve the services they provide to their patients and clients based on standards of excellence.²⁶

Accreditation Canada requirements (Draft, June 2012) that apply to Transfusion Committees include:

19.1 The organization has a transfusion committee that provides consultation and support on transfusion practices and activities. Guidelines: The committee helps to define blood transfusion policies to the local clinical activities; ensures that regular evaluations of blood transfusion practices are conducted; sets criteria for the evaluation of ordering practices, usage, administration policies and the ability of services to meet recipient needs; recommends corrective measures if necessary; disseminates transfusion medicine information and education; evaluates reports of adverse transfusion events and transfusion errors within the facility as well as relevant federal and provincial or territorial reports on adverse transfusion events; and reviews available alternatives to allogeneic blood transfusion and makes appropriate recommendations on their use.

Canadian Society for Transfusion Medicine (CSTM) Standards for Hospital Transfusion Services

The Canadian Society for Transfusion Medicine is a multidisciplinary society which promotes and supports the best practice in Transfusion Medicine in Canada through education, communication and partnerships. It is through this mandate that the Standards for Hospital Transfusion Services were developed. These standards are intended to be incorporated into Canadian hospitals' policies, processes and procedures.²⁷

CSTM Standards (v3 Feb 2011) that apply to Transfusion Committees include:

1.8: A transfusion committee shall be established to:

- a) identify transfusion policies as appropriate to local clinical activities
- b) identify criteria for blood component and blood product utilization
- c) ensure regular audits of transfusion practices are performed, reviewed and appropriate corrective action taken

- d) identify inappropriate use of blood components and blood products and facilitate corrective action
- e) identify available alternatives to allogeneic blood transfusion and development of recommendations on their use
- f) ensure the dissemination of transfusion medicine information and education
- g) review reports of adverse reactions and errors in the facility, as well as relevant governmental reports on adverse transfusion events
- 1.9: The transfusion committee shall:
 - a) involve key members of the transfusion community, including physicians, nurses, transfusion service staff, and executive management
 - b) meet at least quarterly
 - c) The transfusion committee may operate regionally
- 2.2: The TS medical director shall attend all transfusion committee meetings or send a designate who is a physician

Canadian Standards Association (CAN/CSA) Z902 National Standard for Blood and Blood Components

The Canadian Standards Association (CSA) is a not-for-profit, nonstatutory, voluntary association engaged in standards development and certification activities. These standards were developed through a consensus of volunteer experts involved in the Canadian Blood System with varied viewpoints.¹

CAN/CSA Z902-10 (Feb 2010) Standards that apply to Transfusion Committees include:

4.4: The transfusion service shall have a transfusion committee with documented terms of reference (defining, for example, its membership, scope of activity, and meeting frequency). The role of the committee shall be to provide consultative and support services with relation to transfusion practices and activities. The committee membership shall include key stakeholders, including physicians, nurses, transfusion staff, hospital administration, and other personnel as needed. It shall meet at least quarterly. The purpose of the transfusion committee shall be to:

- a) help define blood transfusion policies as appropriate to the local clinical activities
- b) ensure that regular evaluations of blood transfusion practices are conducted
- c) set criteria for the evaluation of ordering practices, usage (including the discarding of blood and blood components), administration policies, and the ability of services to meet recipient needs
- d) recommend corrective measures, if necessary
- e) disseminate transfusion medicine information and education
- evaluate reports of adverse transfusion events and all transfusion errors within the facility, as well as relevant federal and provincial or territorial reports on adverse transfusion events

g) review available alternatives to allogeneic blood transfusion and make appropriate recommendations on their use

Laboratory Quality Assurance Program - College of Physicians and Surgeons of Saskatchewan

The Laboratory Quality Assurance Program (LabQA) of the College of Physicians and Surgeons of Saskatchewan has been granted the authority under the Medical Laboratory Licensing Act and Regulations to administer a quality assurance program for medical laboratories.

The LabQA Program is an accreditation program that provides the framework for continuous improvement in laboratory services, through a peer review process.

Laboratory quality assurance policy manual (2013 edition) requirements that apply to Transfusion Committees include:

Transfusion Medicine Policy #1- Standards of Transfusion Medicine Practice

All Transfusion Medicine laboratories shall adhere to the most current CSTM and CSA Z902 standards and the following province-specific policies.²⁸

Appendix B: Example of Terms of Reference of a Transfusion Committee

Example #1 – Generic Version

<Hospital Name> Transfusion Committee

Terms of Reference

1.0 OVERVIEW

Each hospital in Saskatchewan is required to be a member with a transfusion committee^{1,2} with documented terms of reference. The committee shall review policies and activities to ensure that blood utilized in that facility occurs safely and effectively. The transfusion committee functions can be accomplished through another existing committee (such as pharmacy and therapeutics committee). The transfusion committee can function as a regional committee.

2.0 MANDATE

The mandate of the committee is to provide consultative and support services with relation to transfusion practices and activities. The purpose of the committee is to:

- Help define blood transfusion policies as appropriate to local clinical activities
- Ensure that regular evaluations of blood transfusion practices are conducted
- Set criteria for the evaluation of ordering practices, usage (including wastage/discards) and administration policies
- Ensure the transfusion service and clinical team is able to meet the needs of recipients
- Recommend corrective action/measures as required
- Disseminate information and education related to blood transfusion
- Evaluate reports of adverse transfusion events and errors within the facility, as well as relevant reports from other jurisdictions (provincial, national)
- Review available alternatives to allogeneic blood transfusion and make recommendations on their use

3.0 ACCOUNTABILITY

The transfusion committee should report to the Medical Advisory Committee <or similar committee>

4.0 MEMBERSHIP

The transfusion committee is required to involve key physician and nurses involved in the use of blood for transfusion, transfusion service staff and executive management.

The medical director responsible for the transfusion service must attend transfusion committee meetings. If unable to attend, a designate can be sent in their place but this designate must be a physician.

The transfusion committee must have a chairperson named and this person should ideally not be the medical director responsible for the transfusion service.

5.0 TERMS OF MEMBERSHIP

Each member of the committee shall have a term of <insert length of term> years with an option to renew at the end of each term. Rotation of terms should occur to ensure new members can gain experience from those that have participated on the committee for at least two years.

6.0 MEETING FREQUENCY

Meetings of the transfusion committee must occur at least quarterly.

- 6.1 Meetings
 - 6.1.1 The TC membership shall include key stakeholders, including physicians, nurses, transfusion staff, hospital administration, and other personnel as needed.
 - 6.1.2 A secretary will be appointed to record and distribute minutes of meetings, decisions and recommendations
- 6.2 Review of Terms of Reference
 - 6.2.1 The committee shall have terms of reference defining its membership, scope of activity and meeting frequency.

7.0 CONFIDENTIALITY AND CONFLICT OF INTEREST

In the participation on the transfusion committee, members may have access to information of a confidential nature. Members must not disclose confidential information obtained during the course of their role in the transfusion committee and must take all reasonable steps to avoid and declare, if necessary, any conflict of interest.

Example #2 – Terms of Reference

SUNRISE HEALTH REGION

Administration – General Administration - Committees

Page 40 of 2

Subject: Regional Transfusion Committee Terms of Reference	Number: 110.030
Approval: Executive Director of Health Services	Distribution: Administration Manual All Sunrise Health Region sites and the following affiliates: St. Anthony's Hospital St. Paul Lutheran Home St. Peter's Hospital Developed by: Regional Transfusion Committee
Implementation Date: February 25, 2005	Review: (mmyy) Initial

POLICY:

The Region shall have a Regional Transfusion Committee formed with membership appointed by, and accountable to, the Sunrise Health Region's Executive Director of Health Services.

PURPOSE:

The purpose of the Regional Transfusion Committee is to oversee all aspects of blood transfusion practice including policy/procedure development, maintaining and reviewing transfusion practices in order to promote high standards of patient care through the safe application and effective use of blood products throughout Sunrise Health Region facilities.

TERM & MEMBERSHIP:

The Regional Transfusion Committee shall be a permanent regional committee.

Members shall include the following:

- Executive Director of Health Services Ex Officio
- Medical Staff Representative
- NUM Surgery Yorkton Regional Health Centre (YRHC)
- NUM Medicine/Hemodialysis Yorkton Regional Health Centre (YRHC)
- RN St. Peter's Hospital
- RN Kamsack Hospital/Nursing Home
- Transfusion Supervisor Yorkton Regional Health Centre (YRHC)
- Chemotherapy / Infusions Department Yorkton Regional Health Centre (YRHC)
- Health Records Representative Yorkton Regional Health Centre (YRHC)
- Nurse Educator
- Director of Diagnostics
- NUM Emergency/ICU Yorkton Regional Health Centre (YRHC)

Additions or changes to membership will be at the recommendation of the Committee Chairperson. As needed, the Committee Chairperson may call upon other individuals to sit as advisory members.

FREQUENCY OF MEETINGS:

Conducted quarterly or more frequently at the call of the Director of Diagnostics, chairperson.

FUNCTION:

- 1. To develop standard request/consent/transfusion forms throughout the region.
- 2. To develop policy and procedures for the administration of blood and blood products. To be reviewed yearly and revised as necessary.
- 3. To develop policy and procedures for detecting, managing, reporting and evaluating transfusion reaction. To be reviewed yearly and revised as necessary.
- 4. To provide information and develop procedures for the use of new products.
- 5. To oversee and evaluate in-service programs for health care providers in transfusion medicine.
- 6. To ensure standard documentation in the health record of the administration of blood components.
- 7. To evaluate the utilization of blood products.
- 8. To evaluate blood bank performance in such areas as timeliness of response, productivity, and outdating of products.
- 9. To develop indicators to assess the application, effective use and administration of blood products.
- 10.To evaluate blood bank and facility policies for dispensing and handling blood products.
- 11.To review the use of unmatched blood.
- 12.To provide direction regarding the use of blood received from facilities other than Canadian Blood Services.
- 13.To review the timeliness and adequacy of delivery of blood components from Canadian Blood Services.

Example #3 – Terms of Reference

Terms of Reference- Regina Qu'Appelle Health Region

TRANSFUSION COMMITTEE

PURPOSE

To provide a means for reviewing the quality, provision and utilization of Transfusion Medicine Services within the Regina Qu'Appelle Health Region (RQHR).

FUNCTIONS

- a. To review the quality initiatives of Transfusion Medicine Services with specific reference to quality audits, incident reports and review of external inspections.
- b. To review adequacy of supply and utilization of blood components, plasma fractionation products, surgical bone, human tissue and substitutes.
- c. To consider and make recommendations regarding alternatives to homologous blood utilization including, but not limited to, autologous/directed donations, intra-operative red cell salvage, peri-operative erythropoietin, and plasma substitutes.
- d. To develop and/or review internal audits of blood transfusion and tissue practice in the RQHR and external reports where applicable.
- e. To monitor the frequency and type of any transfusion/tissue reactions reported.
- f. To consider any complaints or suggestions for Blood Transfusion Services from staff or patients.
- g. To review and assist in the development of educational material for physicians, staff and patients.

RELATIONSHIPS

The Transfusion Committee reports to the Regina Qu'Appelle Health Region Department Head Council and makes recommendations to it. Subjects for consideration may be received from the Department Head Council, medical/technical specialists in the Blood Transfusion Laboratories, or any member of the Transfusion Committee.

MEMBERSHIP

Medical representatives from Departments of:

Anesthesiology Medicine Obstetrics/Gynecology Cancer Services Surgery Family Medicine Critical Care * One will be designated as "Chair, Transfusion Committee" Medical/Scientific Representatives from Blood Transfusion Laboratories:

Director Laboratory Services Head, Transfusion Medicine Services Technical Specialists from Transfusion Medicine Services Hematologist ** One will be designated "Secretary, Transfusion Committee"

Other Members

Quality Improvement Clinical Education Clinical Administration

Appendix C: Example of Conflict of Interest Guidelines

A conflict of interest is any situation where your decision or opinion could be influenced by:

- a. your personal interest, or
- b. those of a close friend, family members, business associate, corporation or partnership in which you hold a significant interest, or a person to whom you owe an obligation

Conflict of interest arises when a reasonably well informed person could perceive that a decision was made or advice was given that would promote your personal interests or those you have some relationship with as listed above.

If you feel you have a conflict of interest at any time, you must disclose this to the chairperson of the committee and ask to be excused from the discussion / decision. If you are not aware of any conflict until after the discussion or decision has been made, you are still required to disclose your conflict immediately. Some committees require a conflict of interest form be signed. Alternatively, the disclosure of conflict of interest can be added as a standing agenda item and recorded in the committee meeting minutes.

Appendix D: Example of a Transfusion Committee Conflict of Interest Form

RHA Facility Name Facility Address

Transfusion Committee Conflict of Interest Disclosure

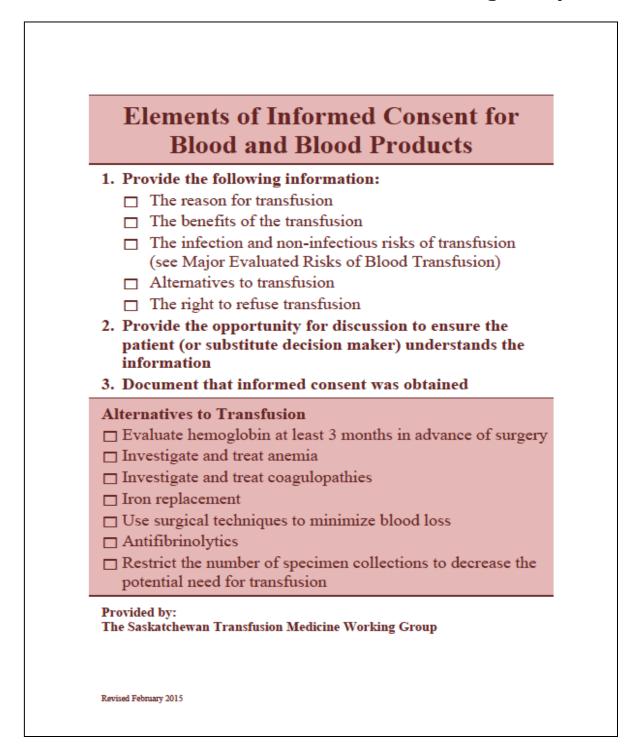
Ι,_____,

Printed Name

Hereby disclose the following potential conflict(s) of interest:

Saxena, S and Shulman, IA. The Transfusion Committee: Putting Patient Safety First, AABB Press, Bethesda Maryland. 2006pg56-57

Appendix E: Physician Resources provided by Saskatchewan Transfusion Medicine Working Group



Major Evaluated Risks of Blood Transfusion

Infectious Complications	Frequency of Risk
Human Immunodeficiency Virus (HIV)	1 in 8,000,000
Hepatitis C Virus (HCV)	1 in 6,700,000
Malaria	1 in 4,000,000
Human T-cell Lymphotropic Virus (HTLV)	1 in 2,500,000
Hepatitis B Virus (HBV)	1 in 1,700,000
West Nile Virus (WNV)	< 1 in 1,000,000
Bacterial contamination of red blood cell unit	1 in 250,000 (symptomatic)
	1 in 500,000 (death)
Bacterial contamination of platelet pools	1 in 10,000 (symptomatic)
Bacterial containination of platelet pools	1 in 60,000 (death)

Non-Infectious Complications	Frequency of Risk
ABO-incompatible transfusion	1 in 40,000 per transfusion episode
Anaphylaxis	1 in 40,000 units
Transfusion-related acute lung injury (TRALI)	1 in 12,000 units
Delayed hemolytic transfusion reaction	1 in 7,000 units
Febrile non-hemolytic transfusion reaction	1 in 300 units (RBC)
	1 in 200 units (platelets)
Transfusion-associated circulatory overload (TACO)	1 in 100 per transfusion
	episode
Allergic reaction (minor)	1 in 100 units

Provided by:

The Saskatchewan Transfusion Medicine Working Group

References:

Bloody Easy 3, 2011; ORBCoN Updated Risks of Transfusion 2014; CBS Circular of Information Nov. 2014 (Pooled/aph. platelets)

Revised February 2015

Reference Bloody Easy 3, 2011

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ORBCoN Updated Risks of Transfusion

2014

NON-INFECTIOUS COMPLICATIONS	ESTIMATED RISK OF EVENT
	(UPDATED 2014)
Minor allergic reaction (hives, urticaria)	1 in 100
Transfusion-associated circulatory overload (TACO)	1 in 100
Febrile non-hemolytic transfusion reaction per unit of RBC	1 in 300
Delayed hemolytic transfusion reaction	1 in 7,000
Transfusion-related acute lung injury (TRALI) per unit of	1 in 12,000
component transfused	
ABO incompatible transfusion per unit of RBC	1 in 40,000
Serious allergic reaction per unit of component transfused	1 in 40,000
INFECTIOUS COMPLICATIONS	ESTIMATED RISK OF EVENT
	(UPDATED 2014)
Bacterial contamination per platelet concentrate	1 in 3,000
Bacterial sepsis per platelet concentrate	1 in 10,000
Death from bacterial sepsis per platelet concentrate	1 in 60,000
Symptomatic bacterial sepsis per unit of RBC	1 in 250,000
Death from bacterial sepsis per unit of RBC	1 in 500,000
Parvovirus B19 per unit of component	1 in 5,000 to 20,000
West Nile Virus	< 1 in 1 million
	No cases reported in Canada since
	2003
Hepatitis B Virus per unit of component	1 in 1.7 million
HTLV per unit of component	1 in 2.5 million
Chagas disease per unit of component	1 in 4 million No cases reported in
	Canada in last 5 years
Malaria per unit of component	1 in 4 million
	No new cases reported in Canada in
	over 10 years
Hepatitis C Virus per unit of component	1 in 6.7 million
HIV per unit of component	1 in 8 million
Variant Creutzfeldt-Jacob Disease (vCJD)	Rare - No cases reported in Canada
Babesiosis	Rare - 1 case reported in Canada in 2000

References:

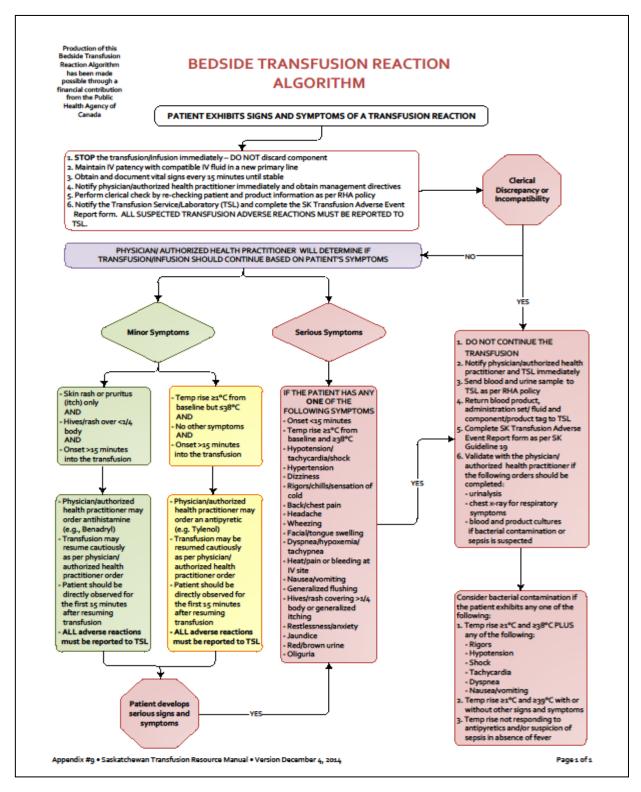
- MacDonald NE, O'Brien S, Delages G. Transfusion and risk of infection in Canada: Update 2012. Canadian Pediatric Society Infectious Disease and Immunization Committee. Pediatr Child Health; 17(10) e102-e111.
- O'Brien SF et al. Current incidence and residual risk of HIV, HBV and HCV at Canadian Blood Services. Vox Sanguinis 2012;103:83-6.
- Canadian Blood Services Circular of Information on Red Blood Cells, leukocytes reduced (LR). July 2013. <u>www.blood.ca</u>

Version date January 31, 2014

Permission granted from ORBCoN

Reference http://transfusionontario.org/en/cmdownloads/categories/transfusion/

Appendix F: Bedside Transfusion Reaction Algorithm



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