ORBCoN

Ontario Regional Blood Coordinating Network

Introducing a New Blood Component or Product to Your Hospital

Central	Northern and Eastern	Southwest
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Abbreviations and Definitions

BPCO	Blood Programs Coordinating Office
CBS	Canadian Blood Services
CSA	Canadian Standards Association
CSTM	Canadian Society for Transfusion Medicine
IQMH	Institute for Quality Management in Healthcare
IS	Information Systems
ISBT	International Society of Blood Transfusion
MOHLTC	Ministry of Health and Long-Term Care
NAC	National Advisory Committee for Blood and Blood Products
ORBCoN	Ontario Regional Blood Coordinating Network
PATB	Provincial Agencies Trillium Gift of Life Network/Blood & Specialized Programs
SOP	Standard Operating Procedure
TC	Transfusion Committee

Introduction

The Ontario Regional Blood Coordinating Network (ORBCoN) was implemented by the Blood Programs Coordinating Office (BPCO), of the Ministry of Health and Long-Term Care (MOHLTC) in 2006. In 2016, the BPCO changed its name to Provincial Agencies Trillium Gift of Life Network/Blood and Specialized Programs (PATB). ORBCoN consists of three regional offices, which parallel the geographic divisions developed by Canadian Blood Services, located in Toronto (central Ontario), Ottawa (northern and eastern Ontario), and Hamilton (southwest Ontario).

ORBCoN's mandates include communicating with hospitals about blood issues in conjunction with Canadian Blood Services, improving patient safety through education, and standardizing best practices, in addition to improving blood utilization and inventory management processes. The network is a support system for existing structures, aiding in the overall enhancement of blood transfusion services. ORBCoN's stakeholders include: medical directors working in hospital transfusion services, laboratory and quality managers, medical laboratory technologists (MLTs), medical laboratory assistants/technicians (MLA/Ts), nurses, transfusion safety officers, physicians ordering blood products and patients.

This toolkit is one of several initiatives aimed at providing standardized resources for health care professionals. It will act as a guideline for those who wish to introduce new blood products as licensed by Health Canada and made available through Canadian Blood Services, or new blood components, and incorporate them into existing inventories. This document refers to both components and products, so when the term product appears, it refers to both components and products. This resource is offered as a guidance document, rather than a prescriptive one. Your processes/procedures for introducing a new blood product will still be subject to:

- Current requirements and standards
- Your own policies and procedures
- Your organizational governance

Purpose and Rationale

The purpose of developing a toolkit to facilitate the introduction of new blood products is to support Ontario hospitals in the transition of making new blood products available within their organizations. This toolkit includes checklists and suggestions to assist in the examination of key aspects prior to implementation, during implementation and afterwards. By sharing these tools, duplication of effort across the province is reduced so hospitals can manage an effective evolution to the new blood component or product.

It is important to bear in mind that the intent of this toolkit is to use it in a multi-disciplinary, multiple departmental environment. Crucial decisions involved in implementing a new blood product at your organization should not be made in isolation and should have review and input from both the laboratory and clinical areas.

Having a detailed plan to implement a change like introducing a new blood component or product, is an example of quality practice in action. This plan is a key element of change control and change management as described by CSA[1] and IQMH[2].

Additionally, this quality component has been identified as one of the top ten nonconformances by AABB[3], which cites failure to abide by change control policy as a major issue found in AABB assessments.

Change is frequently stressful, especially in busy environments like hospitals[4,5] that experience a steady stream of change for various reasons including safety, efficiency, process improvement, reducing risk and improving patient care. However, the flow of operations must be as seamless as possible during the changeover and patient safety must be protected. A sound implementation plan decreases the stress level for all, minimizes change fatigue[6,7] and minimizes errors during the transition.

This toolkit provides a starting point at which to begin the process, with tips provided all the way through to the post- implementation evaluation phase.

1. Canadian Standards Association, "CAN/CSA Z902 Blood and Blood Components", Mississauga ON: C SA, 2015, 4.7.1 and 4.7.2.
2. Institute for Quality Management in Healthcare, "Medical Laboratory Accreditation Requirements v7.1", Toronto ON: IQMH, 2017, II.A.2e.
3. AABB "The Top 10 AABB Nonconformances". AABB News; 13,7 (July 2011), pp3-4.
4. P. Garside. "Are We Suffering From Change Fatigue?", Quality and Safety in Healthcare-BMJ, London England: 2004, pp. 89-90.
5. R. MacIntosh et al. "Overcoming Change Fatigue: Lessons from Glasgow's National Health Service", Journal of Business Strategy/ Emerald Group Publishing, Bingley UK: 2007, pp. 18-24.
6. Stander, Cobus. http://www.itnewsafrica.com/2009/07/cure-change-fatigue-with-a-healthy-dose-of-change- management/ "Cure Change Fatigue with a Healthy Dose of Change Management", IT News Africa, accessed January 15, 2018.
7. R. MacIntosh et al. pp. 18-24.

1. What Information Should We Gather before the Blood Component or Product is Introduced?

Collect as much information as you can before you begin to stock the product. Ask the supplier of the blood product, (for example, Canadian Blood Services-CBS), to provide as much information as possible about the new blood product, including implementation dates, product codes and shipping and storage instructions. Take note that CBS is not always the supplier of a blood product as in the case of a fibrin sealant product, TISEEL®. This product is not distributed by CBS.

A further point about product codes is that sometimes organizations must lobby for ISBT 128 labelling codes from the International Society of Blood Transfusion (ISBT), particularly when CBS is not involved in the product distribution. An organization itself may generate a need for a product code when a blood product must be manipulated to meet a patient's special requirement. To date, ISBT codes are only used for "human blood, cellular therapy products, tissues, organs, as well as those plasma derivatives for which ABO is relevant"[8]. Therefore not all human blood products (e.g. albumin) will require an ISBT code.

The blood product manufacturer can supply information about the product including:

- Product monographs
- Literature searches and references
- Educational material
- Product sizes
- Storage requirements
- Dosing information and product half life
- Ancillary supplies
- Preparation information
- Product handling and waste information
- In services for hospital staff

8. ICCBBA, "ISBT 128 Standard Technical Specification". ICCBBA, San Bernardino CA, June 2017.

Other sources of information include published literature on the product, both from the research and operational point of view, and where applicable, the National Advisory Committee on Blood and Blood Products (NAC) and ORBCoN resources. To easily access published literature, use a search engine such as Pub Med[9] or Google Scholar[10] Determine what already might be developed by searching for existing guidelines in other provinces, states and countries.

Consultation with large centres that will have a big turnover of the new product may prove to be useful as they will consume the largest volume and will most likely be the first to discover additional tips for reconstitution, administration, adverse events and challenges. Also consider consulting with organizations with specific areas of expertise to determine product use for particular patient populations. For example if you require information for your pediatric population, a good source of information would be pediatric specialty facilities like children's hospitals.

Your transfusion service may be approached to introduce a new infusion product, where upon further investigation, is determined to be a non-blood product and thus, does not require the extensive tracking that a transfusion service provides. Therefore this new product, which may or may not be replacing or augmenting an existing blood product, does not fall under the auspices of transfusion medicine and should be directed to another department like pharmacy.

Manufacturers may also provide in-services to staff about the new blood product and will supply kits for demonstration and practice purposes. Additionally, begin to engage staff and stakeholders to obtain their input and assistance in this new blood product implementation.

2. What Should We Do before the Blood Component or Product is Introduced?

a. Set Inventory Levels and Determine Issue/Storage Capacity

You are about to start receiving and using a new blood product. How do you decide how much product to stock initially and on an ongoing basis? Some things to consider in setting your inventory levels are:

- Consult with your Transfusion Committee (TC) both to inform them of the new product and to obtain their input on introducing this product and establishing appropriate stock levels
- Are you presently using any product for the same purpose? If so, you can use your current administration history of this product as a guide to determine stock levels for the new blood product
- What is the dose for an average sized adult and/or child? Consider stocking a particular number of doses to meet your predicted needs, and adjust accordingly
- Will this new product be replacing a previous product, or will it be used in conjunction with the old product? If the new product is replacing a previous one, the stocking levels will be higher than if it is to be used in conjunction with another existing product. E.g. When first introduced, fibrinogen concentrates did not replace the use of cryoprecipitate
- What will be the urgency of the request? If there is a 24 hour window to fulfill the request, your hospital may not need to keep an inventory of the product at all and order it as required
- What is the distance from the blood supplier? If you are located in close proximity to your blood supplier you may decide to order the product on demand rather than maintaining a stock

9. US National Library of Medicine - National Institutes of Health. "Pub Med", *National Center for Biotechnology Information*, Bethesda MD: http://www.ncbi.nlm.nih.gov/pubmed/, accessed January 15, 2018.
10. Google. Google Scholar: http://scholar.google.ca/, accessed January 15, 2018.

- How long is the shelf life of the new product? If the shelf life is short, stocking smaller supplies with more frequent deliveries will decrease the chances of product wastage
- Do you currently have a redistribution strategy in place or is there an organization that will participate in a blood product/component redistribution program, to minimize product waste? For example, if they are a high user of this product and your organization only uses it occasionally, can you ship short dated product to the other organization to be used up before its outdate? What will your preset redistribution date be? E.g. 6 months before expiry?
- What are the stock levels at the blood supplier? They may have a small supply of stock initially, so each hospital may only be able to carry minimal amounts
- What is the turn-around time required to obtain the product from the supplier?
- What is the clinical urgency when the product is required? Will you have a window period of several hours in which to obtain the product , or will the need be immediate? The more immediate the need, the more likely it is that at least a minimum stock of the blood product be maintained in your transfusion medicine laboratory
- If the product requires reconstitution or pooling, which department will assume this responsibility (laboratory, nursing, pharmacy)? If the product is requested infrequently, perhaps the laboratory would be best positioned to assume this responsibility
- Determine the product's storage requirements and your storage capacity. If storage space is a challenge, then more frequent orders of small amounts of product might be your only option. Don't forget to account for the storage of any ancillary supplies if necessary. Do you require more refrigerator space? Sometimes the supplier will offer free storage units
- What do your users estimate the future utilization of this product will be?
- Are there contraindications for this product that may impact a significant proportion of your patient population? If so, this may reduce the amount of stock you will be required to carry

b. Develop Clinical Guidelines

Include current major clinical users (or intended users) at your institution when reviewing the literature and commercial information about the new blood product. Depending on the use of the product, some groups to consult with are:

- Trauma
- Obstetrics
- Anesthesia
- Cardiac
- Surgical
- Critical Care
- Others, depending on the indication of the product (e.g. Neurology, Surgery, Pediatrics, Immunology, Hematology, Nephrology, Dialysis)

Factors such as acceptable clinical indications, recommended dosage, infusion guidelines and contraindications for this blood product should be outlined in the Clinical Guidelines document. Outline special dosing for unique conditions such as neonates, children and other situations as described in the resource literature, especially where applicable at your organization. The authorization process for using the new product outside of the hospital defined guidelines should be outlined in this document as well.

The guidelines are linked to order sets, so updates to both regular order sets, which may be computerized, and downtime order sets should be developed, revised and validated.

c. Develop In-House Blood Product Blood Administration Guidelines/Monographs

The new blood product monographs (blood administration guidelines) provide guidance to the individual ordering and administering the product. The monograph should outline items pertaining to the product like a description of the product and what it is used for, the size of the vial/bag, how and where to order it, precautions and contraindications, dose calculations, patient preparation for infusion, how to prepare and infuse it including compatible solutions (if any) and any additional supplies that are required. Patient monitoring guidelines should also be listed in this document. An example of a template and monograph can be found in appendix 4.

Of course, numerous stakeholders are involved in developing these documents. For example, nursing practice will need to be involved if new administration methodology (such as new pump instructions) and/or ancillary supplies are implemented. In many organizations, these new practices would be trialed in house first before the product was introduced to patients.

d. Develop Laboratory Standard Operating Procedures (SOPs)

The SOPs will contain pertinent product information such as product ordering instructions, storage and monitoring, product expiry information, inventory management including minimum/maximum stock levels, situations where physician/hematologist approval is required, product preparation information; computer codes and inventory receipt/issuing instructions.

e. Add Information Systems (IS) Product and Order Codes

Ensure your IS system accepts the new component/product codes and ordering codes/sets on both the laboratory and clinical side. Determine if multiple codes are required for different sizes or doses of the new product.

f. Train and Educate

Hospital staff will require training on this new blood product, including medical laboratory technologists, nurses, physicians and some clinical clerical staff. This can be accomplished in several ways. First get the message out that a new product is coming through the use of posters, email and your intranet. Some hospitals actually insert a link in their in house monographs that takes the user to a short educational presentation with audio. Relevant information should be linked to the Clinical Guidelines and Monographs, and keep the message as brief as possible. Identify high volume users of the product. They may be trauma specialists, anesthesia, obstetrics, cardiac surgeons and intensivists, for example. You may want to consider using some case based learning in addition to some sort of competency assessment as indicated in the CSTM[11] and CSA[12] standards.

Laboratory staff may require a brief assessment after training to comply with standards such as IQMH[13], CSA[14] and CSTM[15], under the umbrella of change training requirements. MLTs must know the indications of the product, inventory and storage requirements, any preparation required, accompanying computer tasks and be aware of how to locate clinical and infusion instructions.

RNs and some clerical staff will require knowledge about how to process an order. In addition, all staff who administer the product must know how to infuse the product and monitor the patient, store and handle the product, be aware of

11. Canadian Society for Transfusion Medicine, "Standards for Hospital Transfusion Services v4", Ottawa ON: CSTM, 2017, 2.14.
12. Canadian Standards Association, "CAN/CSA Z902 Blood and Blood Components", Mississauga ON: C SA, 2015, 4.3.2.1, 4.3.3.1, 4.3.4
13. Institute for Quality Management in Healthcare, "Medical Laboratory Accreditation Requirements v7.1", Toronto ON: IQMH, 2017, I.B.10, I.B.11.5
14. Canadian Standards Association, "CAN/CSA Z902 Blood and Blood Components", Mississauga ON: C SA, 2015, 4.3.1.1
15. Canadian Society for Transfusion Medicine, "Standards for Hospital Transfusion Services v4", Ottawa ON: CSTM, 2017, 6.2.7d

adverse events and how to document pertinent information in the computer and on the patient's chart and report them to the Transfusion Medicine Laboratory. As previously described, the Canadian requirements indicate an assessment of competency for all individuals involved in the administration of blood components and products is necessary.

g. Transition Your Inventory

Establish the date to accept this new blood product. If this product is replacing a previous product (E.g. recombinant Factor VIII products replacing human derived Factor VIII products in the 1980s):

- Plan to phase out the old product
- Reduce your inventory of the current product by reducing the amount ordered
- Consider redistributing the old product to other sites that have the capacity to use it (contact your regional ORBCoN office for assistance)

If the new product is augmenting the supply of an existing product (E.g. PCC products: Beriplex® is being supplied by CBS in conjunction with the current PCC product, octaplex®):

- Do not exhaust the supply of the old inventory, as this product will still be used
- However, the stock levels may have to be substantially reduced
- Assess the required stock amounts of each product when you are determining your inventory levels

h. Informed Consent

This new blood product must be added to the library of the blood products falling under your "Informed Consent" policy. The informed consent process should be reinforced when staff members are trained for new blood products.

i. Transfusion Committee (TC) Approval

Of course, before you implement the product, your plan will be presented to your TC for their input, suggestions and approval if possible. They can also assist in connecting with the specialty groups that may use the product to give their feedback and suggestions. Any change request information should be documented.

3. What Should We Do After the Blood Component/Product is Introduced?

a. Monitor Compliance with the Guidelines

Select a proportionate number of charts to review for a defined period of time. The number of charts and the length of review time will depend on the volume of the product and number of patients receiving the product. For example, based on your inventory estimates, if only 1 – 2 patients per month receive 1 – 3 doses of the new product, you may elect to review all patient charts for a 12 month period. If 5 – 10 patients use the product every week, you may choose to do a weekly review for 4 months. If it is feasible, it is advantageous to audit requests prospectively in order to modify any practice issues, forms and procedures that require revision in real time. Items to be reviewed will include verification that:

- All orders outside of the guidelines are authorized
- Other orders have a correct indication
- Correct dose is ordered and administered
- Documentation is complete and accurate
- Informed consent is obtained
- Adverse events are reported, reviewed and if warranted, investigated

This documented, detailed review of patient charts provides evidence of meeting CSA[16] and IQMH[17] requirements that specify the performance of regular audits of activities within the laboratory and clinical areas. Additionally, report this audit to your TC as a quality indicator.

b. Monitor Adverse Events

As with any blood component/product, adverse events must be monitored. Document, report and review all adverse events with the new blood product, and include them in your regular adverse event report to your TC.

c. Re-evaluate Guidelines, SOPs, Policies

All laboratory and clinical blood component/product procedures, policies and guidelines must be reviewed at least every two years (CSA[18] and IQMH[19]). The evaluation will include a review assessing that the content of the policies and procedures is current and up to date, the completeness of the documents, in addition to incorporating pertinent user feedback. If any of the product storage, handling or administration steps have changed before the scheduled 2-year review, the current documents should be revised as soon as possible.

16. Canadian Standards Association, "CAN/CSA Z902 Blood and Blood Components", Mississauga ON: CSA, 2015, 4.6.3
17. Institute for Quality Management in Healthcare, "Medical Laboratory Accreditation Requirements v7.1", Toronto ON: IQMH, 2017, II.A.2
18. Canadian Standards Association, "CAN/CSA Z902 Blood and Blood Components", Mississauga ON: C SA, 2015, 4.6.1.6
19. Institute for Quality Management in Healthcare, "Medical Laboratory Accreditation Requirements v7.1", Toronto ON: IQMH, 2017, V1.3 TM 140

4. New Blood Component or Product Implementation Guidance Checklists ☑

Three basic checklists are provided to aid your hospital in the development of a tracking system. You will be able to track your organization's progress with moving forward in your implementation journey. A more formalized model of working documents (forms) incorporating these tasks, along with areas to record the most responsible person (MRP), proposed completion dates and actual completion dates are provided in appendices 1-3.

A. Pre-Implementation Checklist: What We Need to Know before a New Blood Component/Product is Introduced

From the Blood Supplier (Canadian Blood Services—CBS):

- ☐ Obtain as much information as possible about the new blood product
- ☐ Proposed implementation date
- ☐ CBS product codes
- ☐ Ordering, shipping and storage instructions

From the Blood Product Manufacturer:

- ☐ Product monographs
- ☐ Educational material
- ☐ Product sizes
- ☐ Storage and shipping requirements
- ☐ Dosing information and product half life
- ☐ Ancillary supplies
- ☐ Preparation information
- ☐ Product handling and waste information
- ☐ In services for hospital staff
- ☐ Possible adverse reactions

Other Sources:

- ☐ Published literature on the product
- ☐ National Advisory Committee (NAC) recommended guidelines
- ☐ Staff and stakeholders
- ☐ Investigation of ISBT codes, if required
- ☐ Consultation with other centres

B. Product Planning Checklist: What We Should Do before a New Blood Component or Product is Introduced

- ☐ Determine inventory levels
- ☐ Determine storage capacity and requirements (room temperature, refrigerated or frozen)
- ☐ Determine the clinical urgency when the product is required
- ☐ Develop clinical guidelines
- ☐ Develop the in-house product monograph/administration guidelines
- ☐ Develop laboratory SOPs
- ☐ Input the new product code and order sets into the IS system
- ☐ Train/educate:
  - ☐ MLTs and laboratory staff
  - ☐ Nurses and clerical staff
  - ☐ Physicians
- ☐ Investigate the possibility of a redistribution program for the new blood product (contact your regional ORBCoN office)
- ☐ Plan transition of the inventory (new and old products) if applicable
- ☐ Transfusion Committee approval
- ☐ Determine if the Medical Advisory Committee (MAC) approval is required

C. Post-Implementation Checklist: What We Need to do after a New Blood Component or Product is Introduced

Monitor the Guidelines by Chart Review

- ☐ All requests outside the guidelines have been reviewed
- ☐ Orders have correct indications
- ☐ Correct dose
- ☐ Complete and accurate documentation
- ☐ Informed consent has been obtained
- ☐ Adverse events have been reported

Monitor Adverse Events

- ☐ Adverse events are documented and reported
- ☐ Adverse events are reviewed
- ☐ Adverse events are investigated, as appropriate
- ☐ Adverse events are presented to the TC

Re-evaluate SOPs, Guidelines and Policies

Are the documents:

- ☐ Reviewed at least every 2 years?
- ☐ Reviewed for currency and completeness?
- ☐ Subject to user feedback?

5. References (Bibliography)

1. AABB "The Top 10 AABB Nonconformances". AABB News; 13,7 (July 2011), pp3-4.
2. Canadian Blood Services. *Circular of Information; Plasma components AFFP, FP CPD, Crypsupernatant CPD, Cryoprecipitate CPD)*. Ottawa ON: July 2017.
3. Canadian Society for Transfusion Medicine. *Standards for Hospital Transfusion Services v4*. Ottawa ON: CSTM, 2017.
4. Canadian Standards Association. *CAN/CSA Z902 Blood and Blood Components.* Mississauga ON: Canadian Standards Association, 2015.
5. Garside, P. "Are We Suffering From Change Fatigue?" *Quality and Safety in Healthcare-BMJ*, London, England, 2004;13:89-90.
6. Google. Google Scholar: http://scholar.google.ca/, accessed January 15, 2018.
7. ICCBBA, "ISBT 128 Standard Technical Specification". ICCBBA, San Bernardino CA, June 2017.
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9. Institute for Quality Management in Healthcare *Medical Laboratory Accreditation Requirements v7.1*. Toronto ON:IQMH, 2017.
10. Stander, Cobus. http://www.itnewsafrica.com/2009/07/cure-change-fatigue-with-a-healthy-dose-of-change-management/ "Cure Change Fatigue with a Healthy Dose of Change Management", IT News Africa, accessed January 15, 2018.
11. US National Library of Medicine - National Institutes of Health. "Pub Med", *National Center for Biotechnology Information*, Bethesda MD: http://www.ncbi.nlm.nih.gov/pubmed/, accessed January 15, 2018.

Appendix 1

Pre-Implementation Tasks:
What We Need to Know before a New Blood Component or Product is Introduced

Activity	Most Responsible Person	Planned Completion Date	Actual Completion Date
From the New Blood Component/Product Supplier (E.g. Canadian Blood Service—CBS)			
Obtain as much information as possible about the new blood product (include an itemized summary)			
Proposed implementation date			
CBS and/or other product codes (e.g. ISBT)			
Ordering, shipping and storage instructions			
From the Blood Product Manufacturer			
Product monographs			
Educational material (including in-services)			
Product sizes			
Storage requirements			
Dosing information and product half life			
Ancillary supplies			

Appendix 1

Pre-Implementation Tasks:
What We Need to Know before a New Blood Component or Product is Introduced

Activity	Most Responsible Person	Planned Completion Date	Actual Completion Date
From the New Blood Component/Product Manufacturer, continued			
Preparation information			
Product handling and waste information			
Other Sources			
Published literature on the product			
National Advisory Committee (NAC) recommended guidelines			
Staff and stakeholders			
Investigation of ISBT codes, if required			

Appendix 2

New Blood Product Planning Tasks:
What We Should Do before a New Blood Component or Product is Introduced

Activity	Most Responsible Person	Planned Completion Date	Actual Completion Date
Consult with your TC to: • Inform • Obtain feedback/expertise			
Determine Inventory Levels:			
Current product			
New blood product			
Determine Storage:			
Temperature			
Capacity			
Determine the Clinical Urgency (when product is required)			
Develop Clinical Guidelines			
Develop the In-House Blood Product Monographs/ Administration Guidelines			
Develop the Laboratory SOPs			
Input the New Product and Order Codes into the IS			

Appendix 2

New Blood Product Planning Tasks:
What We Should Do before a New Blood Component or Product is Introduced

Activity	Most Responsible Person	Planned Completion Date	Actual Completion Date
Train/educate:			
MLTs and laboratory staff			
Nurses and clerical staff			
Physicians			
Investigate the Possibility of a Redistribution Program (for the new blood product)			
Transition the Inventory: Reduce and/or phase out current inventory Ramp up new blood product inventory			
Transfusion Committee Approval of the Plan			

Appendix 3

Post-Implementation Tasks:
What We Need to Do after a New Blood Component or Product is Introduced

Activity	Date of Review	Performed by	Clinical Area/Chart Identifier	Compliance (Y/N*): *if 'N', explain
Monitor the Guidelines by Chart Review				
All orders outside the guidelines have been reviewed				
Other orders have correct indications				
Correct dose				
Complete and accurate documentation				
Informed consent has been obtained				
Adverse events have been charted (see next section)				
Monitor Adverse Events				
Adverse events are documented and reported				
Adverse events are reviewed				
Adverse events are investigated, as appropriate				
Adverse events are presented to the TC				

Appendix 3

Post-Implementation Tasks:
What We Need to Do after a New Blood Component or Product is Introduced

Activity	Date of Review	Performed by	Clinical Area/Chart Identifier	Compliance (Y/N*): *if 'N', explain
Re-Evaluate SOPs, Guidelines and Policies				
Documents are reviewed annually				
Documents are current and complete				
Documents are subject to user feedback				

Appendix 4

XXXXX Hospital/Health Centre

BLOOD PRODUCT BLOOD ADMINISTRATION GUIDELINES/MONOGRAPHS

Blood Product Name: Cryosupernatant Plasma (CSP)	**Approved by: xxxxx** **Date Approved: xxxxx** **Effective Date: xxxxxx**	**Page 1 of 3** **Document #: xxxxxx** **Version #: V 2**

Classification/Indications	CSP is prepared from slowly thawed Frozen Plasma (FP) that is centrifuged to separate the insoluble cryoprecipitate from the plasma portion. The remaining plasma is frozen. It is a source of plasma having reduced levels of von Willebrand Factor (vWF) and Factor VIII. It may be used for: • Replacement of multiple coagulation factors, except for Factor VIII and vWF • Treatment of Thrombotic Thrombocytopenia Purpura (TTP) • Treatment of Hemolytic Uremic Syndrome (HUS)
Precautions/Contraindications	Do not: • Use for consumptive coagulopathies (e.g. DIC) • Use for single coagulation factor deficiencies • Administer to patients with known anti-IgA antibodies • Use to treat hypovolemia • Use ABO incompatible plasma products • Use for urgent warfarin reversal
Supplied	The mean volume is 282 ± 37 mL (no less than 100 mL) Can be stored for 12 months at -18°C or colder ABO of the blood donor is indicated on the bag label
Dosage	Depends on the clinical condition and size of the patient To augment the concentration of clotting factors: 10 - 15 mL/Kg Pediatric infusions: 10 – 20 mL/Kg
Reconstitution/Stability	Thawing process takes about 20 - 30 minutes Transfuse thawed product within 4 hours Thawed product can be stored at 1 – 6°C for 120 hours in a monitored refrigerator

DISCLAIMER NOTE: This template for Component or Product Monograph has been prepared solely as an example of the type of information that may be included in a document of this nature. It must not be used for the content on Cryosupernatant Plasma, even as a reference document.

Blood Product Name: Cryosupernatant Plasma (CSP)	**Effective Date: xxxxxx**	**Page 2 of 3**

Compatibilities/ Incompatibilities	Only 0.9% sodium chloride is permitted to be added to this product or to be infused through the same tubing Compatible Red Blood Cells (RBCs), platelets and other blood components and 5% albumin may be added at the physician's discretion Do NOT add: • Medications/drugs • D5W (5% Dextrose in water) • Lactated Ringers or any other calcium containing solution
Administration, Identification and ABO Compatibility	Positively identify, as per the policies and procedures, (before administration): • The potential recipient • The product order/dose • The product Verify that informed consent has been obtained **Plasma Products-ABO Compatibility** **Patient ABO Group** — **Compatible Donor ABO** O — O, A, B, AB A — A, AB B — B, AB AB — AB Rh type is not a concern for plasma products
Administration, Method	**Infusion Rate** - Prescribed by the physician or practitioner, but infusion times usually run from 30 to 120 minutes. Transfuse slowly where possible for the first 15 minutes (50 mL/hour) **Administration Set** - A standard blood administration set (170 – 260 microns) is used **Gravity, minibag, buretrol and infusion pumps** - Are all acceptable methods of infusion. Do not administer by IV push, IM or SC **Dilution** - Do not dilute this product **Monitoring** - Monitor the patient as per the policies and procedures, but minimum criteria are assessing vitals: • Before the transfusion • 15 minutes after commencement of transfusion • At the end of the transfusion • During any transfusion reactions

DISCLAIMER NOTE: This template for Component or Product Monograph has been prepared solely as an example of the type of information that may be included in a document of this nature. It must not be used for the content on Cryosupernatant Plasma, even as a reference document.

Blood Product Name: Cryosupernatant Plasma (CSP)	Effective Date: xxxxxx	Page 3 of 3

Adverse Events • **Stop the transfusion** • **Notify physician** • **Treat patient symptoms** • **Notify Transfusion Medicine** • **Follow the Transfusion Reaction/ Adverse Event Policy**	Risk of transfusion reactions range from 1 in 20 for FNHTR to 1 in 21,000,000 for transmission of HIV. A list of the most commonly described transfusion reactions is supplied below: 1. Allergic Reaction 2. Bacterial Contamination 3. Anaphylactic Reaction 4. Transfusion Associated Acute Lung Injury (TRALI) 5. Transfusion Associated Circulatory Overload (TACO) 6. Acute Hemolytic Transfusion Reaction 7. Febrile Non-Hemolytic Transfusion Reactions (FNHTR) 8. Hypotension (Bradykinin Mediated) 9. Delayed Hemolytic Transfusion Reactions 10. Post Transfusion Purpura 11. Transfusion-Related Alloimmune Thrombocytopenia 12. Other transfusion transmitted infections (virus, parasite and prion)

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Appendix 5

XXXXX Hospital/Health Centre

BLOOD COMPONENT OR PRODUCT ADMINISTRATION GUIDELINES/MONOGRAPHS

Blood Product Name: Fibrinogen Concentrate (Human) Other names: RiaSTAP	**Approved by: xxxxx** **Date Approved: xxxxx** **Effective Date: xxxxx**	**Page 1 of 3** **Document #: xxxxxx** **Version #: V 2**

Classification/Indications	RiaSTAP is a pasteurized, lyophilized, preservative free fibrinogen concentrate derived from human plasma. The product is reconstituted with sterile water and also contains human albumin, L-arginine hydrochloride, sodium chloride and sodium citrate. It is used for the treatment of congenital fibrinogen deficiency in: • Afibrinogenemia • Hypofibrinogenemia
Contraindications	There is a risk of thrombosis when patients are treated with this product, particularly with high and/or repeated dosing. Use with caution in pregnant and nursing women, neonates and pediatrics and the elderly due to insufficient safety studies. There are no known drug interactions. Do not use: • In patients who are hypersensitive to the drug or any of the components in the formulation
Supplied	Supplied in single dose vials of 1 g fibrinogen with 50 mL of sterile water for reconstitution. This unconstituted product is stored at 2-25°C (refrigerator or room temperature) and has a shelf life of 60 months. Do not freeze or expose to the light.
Dosage	Once reconstituted, the injection will contain approximately 20 mg/mL. Dosage is dependent on the patient's fibrinogen level and clinical condition. Suggested target is 1 g/L of fibrinogen for minor bleeding and 1.5 g/L for major bleeding. Maintain levels until hemostasis is reached. INITIAL DOSE: in normal weight adults: 3,000 – 4,000 mg or 70 mg/kg SUBSEQUENT DOSES if fibrinogen level is known: Dose in mg = [(Target level g/L – Measured level g/L) ÷ 0.017] x Patient weigh (kg). Can round to the nearest thousand.

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Blood Product Name: Fibrinogen Concentrate (Human) Other names: RiaSTAP	**Effective Date: xxxxxx**	**Page 2 of 3**

Reconstitution/Stability	Reconstitute as follows: 1. Bring vials to room temperature before reconstituting 2. Reconstitute with the 50 mL of sterile water diluent provided 3. Remove cap from lyophilized product to expose central portion of stopper 4. Clean stopper surface with antiseptic and allow to dry 5. Using a transfer device or syringe, transfer the full 50 mL of diluent (sterile water) into the product vial 6. Gently swirl the product vial until the product is fully dissolved. Usually takes 5-10 minutes. Do not shake the vial as it creates foaming Inspect product. It should appear clear and colourless to slightly opalescent. Discard if particulate matter is present or if it is discoloured. Store reconstituted product at room temperature for a maximum of 8 hours. Do not refrigerate or freeze. Product should be administered as soon as possible.
Compatibilities/ Incompatibilities	Only reconstitute with the sterilized water diluent provided. Do not mix or infuse with any other product, solution or drug. The sodium content may exceed 200 mg per treatment, so use with caution in patients with sodium restrictions.
Administration/Identification	Positively identify and/or confirm, before product administration: • The recipient • The product • The order and dose • Informed consent has been obtained ABO and Rh is not a concern with this product. No transfusion medicine testing (e.g. group and screen, crossmatch) is required.
Administration, Method	Product should be at room temperature. Use a separate injection site and do not mix with any other substances. Administer product intravenously. Do not exceed 5 mL per minute (100 mg/minute). Discard any partially used product. Observe and monitor at least: • Before the infusion • During infusion • At the end of infusion • During any reactions to the product

Blood Product Name: Fibrinogen Concentrate (Human) Other names: RiaSTAP	**Effective Date: xxxxxx**	**Page 3 of 3**

Adverse Events • Stop the infusion • Notify physician • Treat symptoms • Notify TM laboratory • Follow transfusion reaction policy	Although rare with this product, the most common reactions are allergic ones (rash) and generalized reactions such as chills, fever, nausea and vomiting. More serious, but rare events include: • Anaphylaxis • Thrombotic events: myocardial infarction, pulmonary embolism, deep vein thrombosis and arterial thrombosis

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