A Toolkit for the Introduction of a New Blood Product

Prepared by

Ontario Regional Blood Coordinating Network

Central
ORBCoN Office
416.480.6100 ext. 89433

Northern and Eastern
ORBCoN Office
613.798.5555 ext. 19741

Southwest
ORBCoN Office
905.525.9140 ext. 22915

www.transfusionontario.org
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Additionally, we would like to recognize the efforts of the Toolkit Working Group for the *Introduction of a New Blood Product*, whose efforts and feedback are sincerely appreciated:

Dr. Jeannie Callum, Director of Transfusion Medicine and Tissue Banks, Sunnybrook Health Sciences Centre
Ms. Sheila Chase-Weekes, Production Manager, Canadian Blood Services
Dr. Allison Collins, Pathologist and Deputy Chief of Laboratory Medicine, Peterborough Regional Health Centre
Ms. Mary Lynn Hall, Blood Conservation Co-Coordinator, North Bay General Hospital
Ms. Kathleen McShane, Transfusion Safety Officer/Blood Conservation Coordinator, The Hospital for Sick Children
Mr. David Rupert, Senior Technologist, Woodstock General Hospital

Finally, we acknowledge the funding support provided by the Ministry of Health and Long-Term Care (MOHLTC) through the Blood Programs Coordinating Office (BPCO).

Abbreviations and Definitions

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<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>BPCO</td>
<td>Blood Programs Coordinating Office</td>
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<td>CBS</td>
<td>Canadian Blood Services</td>
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<td>CSA</td>
<td>Canadian Standards Association</td>
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<td>CSTM</td>
<td>Canadian Society for Transfusion Medicine</td>
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<td>IS</td>
<td>Information Systems</td>
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<td>MOHLTC</td>
<td>Ministry of Health and Long-Term Care</td>
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<td>OLA</td>
<td>Ontario Laboratory Accreditation</td>
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<td>ORBCoN</td>
<td>Ontario Regional Blood Coordinating Network</td>
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<td>QMP-LS</td>
<td>Quality Management Program-Laboratory Services</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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<td>TC</td>
<td>Transfusion Committee</td>
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<td>ISBT</td>
<td>International Society of Blood Transfusion</td>
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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. The network consists of three regions, which at the time of publication of this report, paralleled the geographic divisions developed by Canadian Blood Services, located in Toronto (Central), Ottawa (Northern and Eastern), and Hamilton (Southwest).

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.

ORBCoN's mandate is to communicate with hospitals about blood issues in conjunction with Canadian Blood Services, improve patient safety through education, and standardize best practices, in addition to improving blood utilization and inventory management. The network is a support system for existing structures, aiding in the overall enhancement of blood transfusion services.

This toolkit is one of several initiatives aimed at providing standard resources for health care professionals. It will act as a guideline for those implementing new blood products and incorporating them into existing inventories. This resource is offered as a guidance document, rather than a prescriptive one. Your project plan 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 product without overtaxing their limited resources.

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

Having a detailed plan to implement a change like introducing a new blood 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\textsuperscript{1} and OLA\textsuperscript{2}. Additionally, this quality component has been identified as one of the top ten nonconformances by AABB\textsuperscript{3}, which cites failure to abide by change control policy as a major issue found in AABB assessments.

\textsuperscript{1} Canadian Standards Association, “CAN/CSA Z902 Blood and Blood Components”, Mississauga ON: C SA, 2010, 4.7.1 and 4.7.2.
A Toolkit for the Introduction of a New Blood Product

Change is frequently stressful, especially in busy environments like hospitals\(^4,5\) that experience a steady stream of change for various reasons like 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.

1. What Information Should We Gather Before the Blood 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, along with 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\(^8\). This Baxter manufactured item was 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

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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 (NAC) recommended guidelines and ORBCoN (Ontario Regional Blood Coordinating Network) resources. To easily access published literature, use a search engine such as Pub Med\(^9\) (http://www.ncbi.nlm.nih.gov/pubmed/) or Google Scholar\(^{10}\) (http://scholar.google.ca). 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 of the product. Thus, they 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 at all.

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 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 on going 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. Newer IVIg products did not replace current IVIg products, but rather, became part of the regular supply


• 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
• Is there a facility that will participate in a blood product 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 facility to be used up before its outdate?
• 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 department
• If the product requires reconstitution or pooling, which department will 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 for this product at your hospital, recommended dosage, infusion guidelines and contraindications for this blood product will be outlined in the Clinical Guidelines document. Outline special dosing for unique conditions, 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 may be outlined in this document as well.
c) Develop the In-House Blood Product Monograph/Blood Administration Guidelines
The new blood product monographs (blood administration guidelines) provide guidance to the individual ordering and administering the product. The monograph will 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 additional supplies required. Patient monitoring guidelines are also found 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 may be particularly involved if new methodology 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 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. Link the information 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\textsuperscript{11} and CSA\textsuperscript{12} standards.

Laboratory staff may require a brief assessment after training to comply with standards such as OLA\textsuperscript{13}, CSA\textsuperscript{14} and CSTM\textsuperscript{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.

RN\textsuperscript{s} 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

\begin{footnotesize}
12 Canadian Standards Association, “CAN/CSA Z902 Blood and Blood Components”, Mississauga ON: CSA, 2010, 4.3.2.1, 4.3.3.1, 4.3.4
15 Canadian Society for Transfusion Medicine, “Standards for Hospital Transfusion Services”, Ottawa ON: CSTM, 2011, 6.2.7d)
\end{footnotesize}
adverse events and how to document pertinent information in the computer and on the patient’s chart. As previously described, the Canadian requirements indicate an assessment of competency for all individuals involved with blood 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

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” routine. The informed consent process should be reinforced when the staff members are trained for this new blood product.

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.

3. What Should We Do After the Blood 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. It is advantageous to audit the data prospectively in order to modify any practice issues, forms and procedures that require revision in a timely manner. 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 and OLA 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 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 product procedures, policies and guidelines must be reviewed on an annual basis. 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 accumulated over the year. If any of the product storage, handling or administration steps have changed before the annual review, the current documents should be revised as soon as possible.

Three basic checklists are provided here to facilitate the construction of a tracking system by your facility. 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 Product is Introduced

From the Blood Supplier (Canadian Blood Service—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 requirements
- Dosing information and product half life
- Ancillary supplies
- Preparation information
- Product handling and waste information
- In services for hospital staff

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 Product is Introduced

- Determine inventory levels
- Determine storage capacity
- Determine the clinical urgency when the product is required
- Develop clinical guidelines
- Develop the 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
- Transition the inventory (new and old products)
- Transfusion Committee approval
C. Post-Implementation Checklist: What We Need to Do After a New Blood 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 annually?
- Reviewed for currency and completeness?
- Subject to user feedback?
5. References (Bibliography)

### A. Pre-Implementation Tasks:
**What We Need to Know Before a New Blood Product is Introduced**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Most Responsible Person</th>
<th>Planned Completion Date</th>
<th>Actual Completion Date</th>
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<tbody>
<tr>
<td><strong>From the New Blood Product Supplier (E.g. Canadian Blood Service—CBS)</strong></td>
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<tr>
<td>Obtain as much information as possible about the new blood product</td>
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<td>(include an itemized summary)</td>
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<tr>
<td>Proposed implementation date</td>
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<tr>
<td>CBS and/or other product codes (e.g. ISBT)</td>
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<tr>
<td>Ordering, shipping and storage instructions</td>
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<td><strong>From the Blood Product Manufacturer</strong></td>
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<td>Product monographs</td>
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<td>Educational material (including in-services)</td>
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<td>Product sizes</td>
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<td>Storage requirements</td>
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<td>Dosing information and product half life</td>
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<td>Ancillary supplies</td>
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What We Need to Know Before a New Blood Product is Introduced

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<th>Planned Completion Date</th>
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<tr>
<td><strong>From the New Blood Product Manufacturer, continued</strong></td>
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<tr>
<td>Preparation information</td>
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<td>Product handling and waste information</td>
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<tr>
<td><strong>Other Sources</strong></td>
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<tr>
<td>Published literature on the product</td>
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<td>National Advisory Committee (NAC) recommended guidelines</td>
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<td>Staff and stakeholders</td>
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<td>Investigation of ISBT codes, if required</td>
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### B. New Blood Product Planning Tasks: What We Should Do Before a New Blood Product is Introduced

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<th>Activity</th>
<th>Most Responsible Person</th>
<th>Planned Completion Date</th>
<th>Actual Completion Date</th>
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<tbody>
<tr>
<td>Consult with your TC to:</td>
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<tr>
<td>• Inform</td>
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<td>• Obtain feedback/expertise</td>
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<tr>
<td>Determine Inventory Levels:</td>
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<tr>
<td>Current product</td>
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<td>New blood product</td>
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<tr>
<td>Determine Storage:</td>
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<tr>
<td>Temperature</td>
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<td>Capacity</td>
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<td>Determine the Clinical Urgency (when product is required)</td>
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<td>Develop Clinical Guidelines</td>
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<tr>
<td>Develop the In-House Blood Product Monographs/ Administration Guidelines</td>
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<td>Develop the Laboratory SOPs</td>
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<tr>
<td>Input the New Product and Order Codes into the IS</td>
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## B. New Blood Product Planning Tasks: What We Should Do Before a New Blood Product is Introduced

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<tr>
<td><strong>Train/educate:</strong></td>
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<td>MLTs and laboratory staff</td>
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<td>Nurses and clerical staff</td>
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<td>Physicians</td>
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<tr>
<td><strong>Investigate the Possibility of a Redistribution Program</strong> (for the new blood product)</td>
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<td><strong>Transition the Inventory:</strong> Reduce and/or phase out current inventory</td>
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<tr>
<td><strong>Ramp up new blood product inventory</strong></td>
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<td><strong>Transfusion Committee Approval of the Plan</strong></td>
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</table>
## Post-Implementation Tasks:
### What We Need to Do After a New Blood Product is Introduced

<table>
<thead>
<tr>
<th>Activity</th>
<th>Date of Review</th>
<th>Performed by</th>
<th>Clinical Area/Chart Identifier</th>
<th>Compliance (Y/N*): *if ‘N’, explain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor the Guidelines by Chart Review</td>
<td>All orders outside the guidelines have been reviewed</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Other orders have correct indications</td>
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<td></td>
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<tr>
<td></td>
<td>Correct dose</td>
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<tr>
<td></td>
<td>Complete and accurate documentation</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Informed consent has been obtained</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adverse events have been charted (see next section)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Monitor Adverse Events</strong></td>
<td></td>
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<tr>
<td></td>
<td>Adverse events are documented and reported</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Adverse events are reviewed</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Adverse events are investigated, as appropriate</td>
<td></td>
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<tr>
<td></td>
<td>Adverse events are presented to the TC</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Post-Implementation Tasks:
### What We Need to Do After a New Blood Product is Introduced

| Activity                          | Date of Review | Performed by | List Document Reviewed | Compliance (Y/N*):  
|-----------------------------------|----------------|--------------|-------------------------|---------------------
| Re-Evaluate SOPs, Guidelines and Policies |                |              |                         | *if ‘N’, explain     |
| Documents are reviewed annually   |                |              |                         |                     |
| Documents are current and complete|                |              |                         |                     |
| Documents are subject to user feedback |            |              |                         |                     |
XXX Hospital/Health Centre

BLOOD PRODUCT ADMINISTRATION GUIDELINES (Monograph)

<table>
<thead>
<tr>
<th>Blood Product Name:</th>
<th>Approved by: xxxxx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cryosupernatant Plasma (CSP)</td>
<td>Date Approved: xxxxx</td>
</tr>
<tr>
<td>Other Names:</td>
<td>Effective Date: xxxxxx</td>
</tr>
<tr>
<td>• CSP</td>
<td>Version #: V 2</td>
</tr>
<tr>
<td>• Cryo-poor plasma (CPP)</td>
<td>Document #: xxxxxx</td>
</tr>
<tr>
<td>• Plasma - cryoprecipitate reduced</td>
<td></td>
</tr>
<tr>
<td>• Cryo-depleted plasma</td>
<td></td>
</tr>
</tbody>
</table>

### 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)
- Bleeding patients on warfarin who require an invasive procedure before vitamin K can reverse the warfarin

### 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

### 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
For warfarin reversal: 5 – 8 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 24 hours in a monitored refrigerator

DISCLAIMER NOTE: This template for 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:** 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.

#### ABO Compatibility of Plasma Products

<table>
<thead>
<tr>
<th>Compatible Plasma Product ABO</th>
<th>Recipient’s ABO</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>O, A, B, AB</td>
</tr>
<tr>
<td>A</td>
<td>A, AB</td>
</tr>
<tr>
<td>B</td>
<td>B, AB</td>
</tr>
<tr>
<td>AB</td>
<td>AB</td>
</tr>
</tbody>
</table>

Rh type is not a concern for plasma products.

### Administration, Method

**Infusion Rate** - Prescribed by the physician, 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

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### Adverse Events

Risk of transfusion reactions range from 1 in 20 for FNHTR with the administration of a pooled platelet product to 1 in 7,800,000 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)