



**FRAMEWORK FOR APPROPRIATE USE AND
DISTRIBUTION OF SOLVENT DETERGENT TREATED
PLASMA IN CANADA**



FRAMEWORK FOR APPROPRIATE USE AND DISTRIBUTION OF SOLVENT DETERGENT TREATED PLASMA

BACKGROUND:

The National Advisory Committee on Blood and Blood Products (NAC) is an interprovincial medical and technical advisory body to the provincial and territorial health ministries and the blood supplier Canadian Blood Services. NAC provides professional leadership in assisting in identifying, designing and implementing cost-effective blood utilization management initiatives for the optimization of patient care throughout Canada.

In 2011, the Provinces and Territories approved the funding and distribution of solvent detergent treated plasma (S/D Plasma) by Canadian Blood Services for specific patient groups as recommended by the Canadian Agency for Drugs and Technologies in Health (CADTH). Subsequently, the Provincial / Territorial Blood Liaison Committee requested NAC to develop further framework regarding the distribution and handling of S/D Plasma and to collaborate with Canadian Blood Services to identify a suitable mechanism by which S/D Plasma would be routinely available only for the specific patient groups identified.

S/D Plasma is currently licensed in Canada under the name of Octaplasma™. It is virus inactivated solvent detergent treated human frozen plasma with resulting coagulation activity levels similar to those in single-donor fresh frozen plasma. Solvent detergent treatment is not effective against non-enveloped viruses.

RECOMMENDATION:

NAC recommends that Canadian Blood Services retain the inventory of S/D Plasma for all jurisdictions in Canada (with the exception of Quebec) and distribute it to requesting hospitals provided the product request is in accordance with Provincial / Territorial approved recommendations for use developed by CADTH. All requests for S/D Plasma received by Canadian Blood Services will be reviewed against the P/T approved recommendations by Canadian Blood Services Medical Directors. This proposed monitored distribution of S/D Plasma is reflective of the recommendations for use of this product for the specific patient groups identified in the CADTH report.

In an effort to monitor the use of S/D Plasma in adherence to the P/T approved recommendations, hospitals are required to report the disposition of all S/D Plasma units to Canadian Blood Services. Canadian Blood Services will compile all utilization data and report back to the funders, the Provinces and Territories. This utilization monitoring mechanism is intended to mitigate potential escalating costs associated with use of this product outside of the indications for use. Should utilization of S/D Plasma be observed to deviate from the outlined recommendations, the Province or Territory will review the data and follow-up with the respective hospital (s) as appropriate as **approved funding for this product is restricted to the treatment of patients with thrombotic thrombocytopenic purpura (both congenital and acquired), hemolytic uremic syndrome with associated factor H deficiency and clotting factor deficiencies in the absence of a specific clotting factor concentrate product available. These patient populations must also meet the secondary qualifiers as listed on page 3.**

The process by which S/D Plasma is available to patients is supported by the Provincial and Territorial Ministries of Health.



INDICATIONS:

Recommendation:

The following is a direct excerpt from the CADTH report dated May 2011:

The Canadian Agency for Drugs and Technologies in Health's (CADTH's) Panel of Experts recommends that solvent / detergent -treated human plasma (S/D Plasma) be considered for certain patients:

- who require a high volume of transfusions annually because they have:
 - thrombotic thrombocytopenic purpura (TTP)* or,
 - hemolytic uremic syndrome (HUS) with associated factor H deficiency or,
 - clotting factor deficiencies for which specific licensed concentrates may not be readily available (e.g., factor V, factor XI, factor XIII),

- and who (secondary qualifiers):
 - have experienced an allergic reaction to frozen plasma (FP) or,
 - have a pre-existing lung disorder or,
 - need FP but a blood group compatible product is not available in a timely manner.

*In this document, TTP includes both congenital and acquired forms

Frozen plasma (FP) may be interpreted as any plasma product, e.g.: Apheresis Fresh Frozen Plasma (FFPA), Frozen Plasma (FP), Cryosupernatant Plasma, Cryoprecipitate.

An allergic reaction is that which is defined by the Transfusion Transmitted Injuries Surveillance System (TTISS), Public Health Agency of Canada:

Minor – a skin reaction characterized by a transient urticarial or other skin rash with pruritus associated with the transfusion. This reaction may be associated with localized angioedema without respiratory distress.

Severe/Anaphylactic/ Anaphylactoid – in addition to mucocutaneous signs/symptoms there is airway compromise or severe hypotension requiring vasopressor treatment. The respiratory signs/symptoms may be laryngeal (tightness in the throat, dysphagia, dysphoria, hoarseness, stridor) or pulmonary (dyspnea, cough, wheezing/bronchospasm, hypoxemia).



Anaphylactic Shock – in addition to the above mentioned, profound hypotension with loss of consciousness, circulatory collapse or death.

A pre-existing lung disorder is that which is defined as a chronic lung disorder that is symptomatic and requiring treatment. Examples include:

- severe asthma
- severe chronic obstructive pulmonary disease (COPD)

Note: for conditions not specifically listed, consultation with a local transfusion medicine specialist is recommended.

Blood group compatible product is in regard to group AB patients specifically.

DOSING, ADMINISTRATION & MONITORING:

S/D Plasma is available in 200ml bags. Administration, dosing and monitoring should be similar to that of frozen plasma, in adherence with existing local transfusion policies, dependant on the clinical situation.

Transfusion reactions observed in patients being treated with S/D Plasma should be reported as per local standard process.

S/D PLASMA REQUEST APPROVAL PROCESS AND DISTRIBUTION FROM CANADIAN BLOOD SERVICES

As it is recommended that Canadian Blood Services hold the national inventory of S/D Plasma, and in an effort to standardize the process by which this product is distributed to hospitals for transfusion to patients in jurisdictions served by the blood supplier, NAC recommends the request approval process outlined in **Figure 1** and the use of an associated Canadian Blood Services product request form (**Attachment 1 - Example**).

Hospitals will be requested to provide Canadian Blood Services with utilization data on all S/D Plasma units issued and/or transfused within the respective jurisdiction. Canadian Blood Services will compile the data and prepare utilization reports for regular review by the Provincial and Territorial funders.

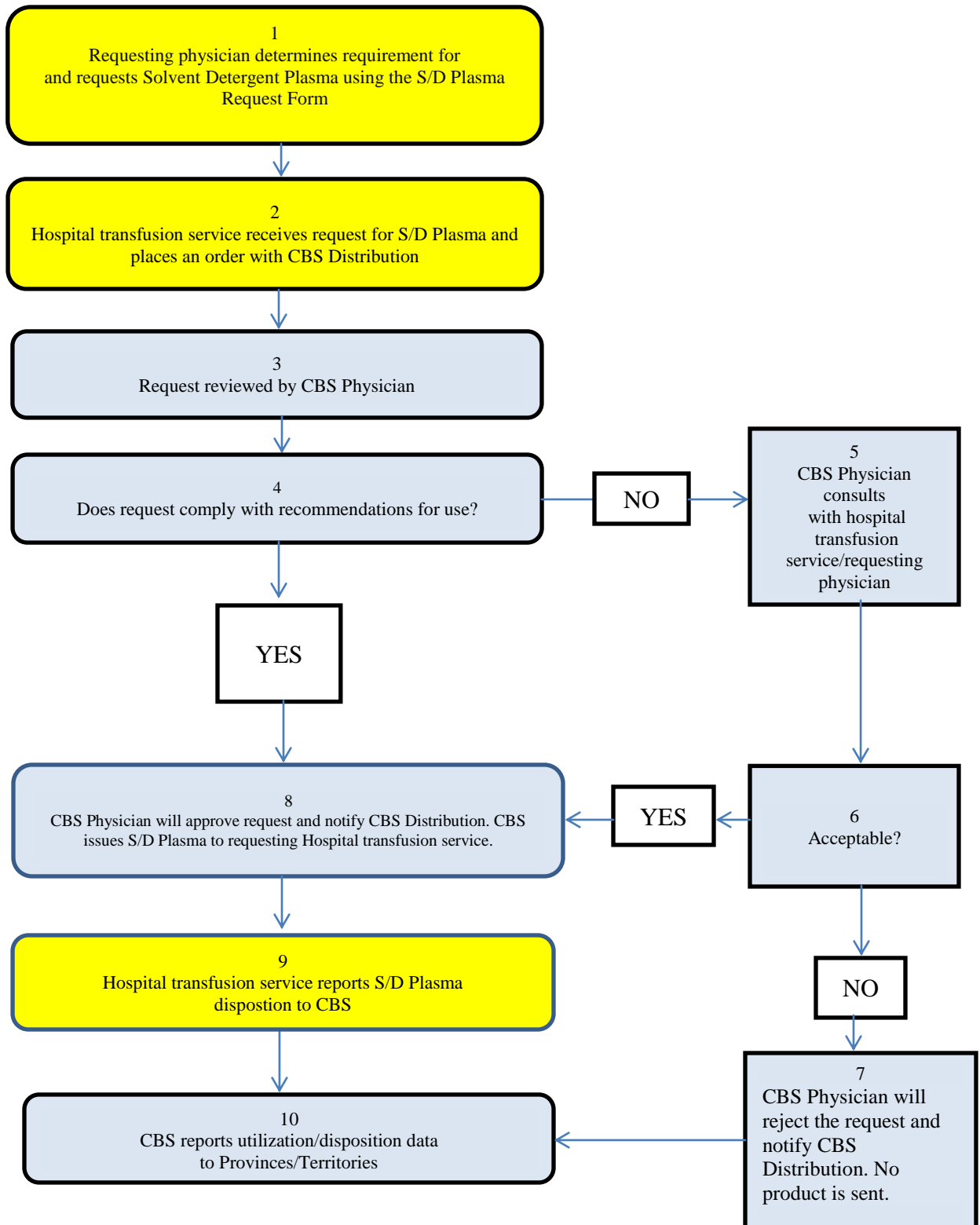


Figure 1 -Request, Approval and Disposition Process for S/D Plasma



REFERENCES & REVIEWED PAPERS

Canadian Agency for Drugs and Technologies for Health, Optimal Therapy Recommendation for the use of Solvent/Detergent-Treated Human Plasma, May 2011.

http://www.cadth.ca/media/pdf/SDPlasma_rec-report_e.pdf

Canadian Blood Services, Circular of Information- Plasma Components, October 2012 edition

[http://www.bloodservices.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/resources/COI/\\$file/COI_CPDPlasmaFFPA23Oct12.pdf](http://www.bloodservices.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/resources/COI/$file/COI_CPDPlasmaFFPA23Oct12.pdf)

Canadian Product Monograph, Octaplasma®, April 10, 2015

http://www.octapharma.ca/fileadmin/user_upload/octapharma.ca/Product_Monographs/CTAPLASMA-PM.pdf

Transfusion Transmitted Injuries Surveillance System, User's Manual. Public Health Agency of Canada, November 2007; page 35.

http://www.transfusionmedicine.ca/sites/transfusionmedicine/files/PDF/TTISS_Users%20Manual%203.0.pdf



Attachment 1 – Example



SOLVENT DETERGENT PLASMA – REQUEST FORM

BOX 1: INFORMATION TO BE PROVIDED BY REQUESTING HOSPITAL

(Send Request to Local Canadian Blood Services Distribution Site)

Requesting Hospital Details:

Hospital Name: Request Date: Hospital Contact Person: Contact # (cell, pager, etc.): Ordering Physician: Contact # (cell, pager, etc.):

Patient Information:

Patient Age Range: Patient Hospital ID# (optional): Sex: Female Male Height: Weight (kg): Blood Group:

Clinical Diagnosis:

Thrombotic Thrombocytopenic Purpura Acquired / Congenital Hemolytic Uremic syndrome Clotting Factor Deficiency Specify: is a licensed factor concentrate available? Yes No Other (specify):

Additional Supporting Information:

Patient has experienced an allergic reaction to plasma Patient has a pre-existing lung disorder Patient is group AB and needs plasma, but a blood group compatible product is unavailable Comments, including additional justification for use:

Proposed Treatment: (for Canadian Blood Services inventory planning only)

Blood Group (if different than above): Start Date of Treatment: Estimated Amount Required per Treatment: Frequency of Treatment: Estimate Length of Treatment*:

E.g.: Amount: 4 units Frequency: Every Week Length of Treatment: for 52 weeks *Requested length of treatment cannot be greater than 12 months. All approvals will expire 12 months from the date of review noted in Box 2.

BOX 2: CANADIAN BLOOD SERVICES USE ONLY: PHYSICIAN DECISION

(Signature and Name of Physician only required for Clinical Diagnosis "Other" in Box 1)

Product Request Classification:

Meets criteria for use: Yes (Approved) No (Rejected) If rejected give details: Name of Physician (print name) or N/A Signature of Physician or N/A Review Date:

All approvals will expire 12 months from the date of review noted above

BOX 3: CANADIAN BLOOD SERVICES PRODUCT DISTRIBUTION USE ONLY

Comments: Date and Time Request Received: Contract Number: Estimated Total Quantity: Expiry Date:

E.g.: How to calculate Estimated Total Quantity: 4 units X Frequency: Every week X Length of Treatment: 52 weeks = 208 For verbal decision record: Name of Physician providing the decision, approved or rejected, Indicate received verbally, initials, date and time. ***All approvals / Contracts will expire 12 months from the date of review noted in Box 2 above.