



NOVA SCOTIA PROVINCIAL BLOOD COORDINATING PROGRAM

Nova Scotia Provincial Blood Coordinating Program (NSPBCP)

Annual Report
April 1, 2009 - March 31, 2010

March 2011



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1.0 Executive Summary

The Nova Scotia Provincial Blood Coordinating Program (NSPBCP) was created in January 2003 to provide leadership and to maximize the safe and appropriate management of blood products and their alternatives for Nova Scotians. Four broad intentions anchor the NSPBCP's promotion of excellence in transfusion medicine: Utilization, Surveillance, Quality Assurance, and Communication & Coordination.

Utilization

The Provincial and Territorial Ministers of Health, except for Quebec, have appointed Canadian Blood Services (CBS) to operate and manage the blood system in Canada. CBS is funded through annual payments from these provinces/territories. The amount of the payment is based on use by the province of blood and blood products, which are administered almost exclusively in hospitals.

The use of blood and blood products has occurred in the absence of any coordinated method for evaluating how appropriately this valuable resource is used. Hospital based health care professionals are not accountable for the costs associated with the use of blood and blood products. The NSPBCP has established a utilization management framework for this expensive and valuable resource. The key objectives of utilization are to optimize appropriate use and to minimize product wastage. In 2009/10 the NSPBCP had initiatives underway related to: Intravenous Immune Globulin (IVIG), Subcutaneous Immune Globulin (SCIG), red blood cells, factor products, octaplex®, recombinant Factor VIIa, massive transfusion, and plasma utilization.

The supply of IVIG is limited and evidence of the effectiveness of IVIG exists for fewer indications than for what it was being used to treat. It is the most commonly used blood product in Nova Scotia and comprises approximately 18% of Nova Scotia's blood budget. With the NSPBCP functioning as the secretariat, the Atlantic Provinces are participating in a collaborative initiative in order to optimize the appropriate use of IVIG within Atlantic Canada. In fiscal year 2009/10, 96.8% of Nova Scotia's use of Intravenous Immune Globulin (IVIG) was within the "labelled" and "unlabelled but indicated" categories. "Unlabelled not indicated" indications decreased from 3.26 g/1000 population in 2008/09 to 2.5g/1000 population in 2009/10.

Red blood cells have a shelf life of approximately one and a half months, out-date wastage occurs when blood has been issued by the supplier to the hospital and it is not used prior to expiration. In-date wastage occurs when the product must be discarded prior to its expiration date. In order to minimize the wastage of this valuable resource the NSPBCP, in collaboration with CBS and the DHAs/IWK, implemented various inventory management strategies to decrease the red blood cell discard rate in Nova Scotia. Each provincial/territorial blood budget is based on the percentage of usage of the total amount of red blood cells (RBC) combined with actual use of blood products. Nova Scotia's RBC percentage of the national decreased from 4.23% to 3.75% from 2006/07 to 2009/10 which resulted in cost savings for Nova Scotia of \$1,913,190.

In response to Health Canada's licensing of octaplex® and its distribution by CBS in July 2008, the NSPBCP convened an expert working group to develop a provincial guideline for this product with the NAC guidelines serving as the reference. Templates for pre-printed orders and data collection tools are under development. The first use of octaplex® occurred in Nova Scotia in February 2009. The NSPBCP categorizes use as labelled or unlabelled and has set a target for 75% of octaplex® use to be appropriate and discards to be less than 80 mL/year. These targets were met as 82% of the use of octaplex® in 2009/10 was labelled, 18% was unlabelled, and 40 mL of octaplex® was discarded.

Recombinant Factor VIIa, also known as NiaStase®, is a genetically engineered protein and is licensed in Canada for hemophilia A/B patients with inhibitors to Factor VIII or Factor IX, respectively. It is used for the treatment of bleeding episodes, including treatment and prevention of those occurring during and after surgery for these patients.

The NAC, in a 2008 publication, reviewed the evidence available for the use of recombinant Factor VIIa in massive bleeding and concluded that rFVIIa should only be considered as a part of a transfusion policy framework for massive bleeding after other supportive measures and treatments have been considered. The Massive Transfusion Working Group expanded their scope to address the use of rFVIIa in massive bleeds.

A target of 90% of rFVIIa use to be according to guidelines was set with a wastage target of less than 10 mg/year and these targets were met based on the rFVIIa utilization data that was received.

A new approach to treating patients requiring massive transfusion has been noted in literature as a result of casualty care in the war in Iraq. An expert working group on Massive Transfusion had existed previously and was reconvened in July 2009. The working group defined massive bleeding as: Bleeding with the anticipation of ongoing blood loss or requiring at least four (4) units of RBCs (adults) or 40 mL per kg (children) in 4 hours and recommended a change in practice which involved introducing plasma and platelets earlier in the treatment for the massively bleeding. The guideline was nearing completion by the end of March 2010 and was presented at the Nova Scotia Trauma Advisory Council Meeting in March 2010.

Surveillance

Nova Scotia participates in two of the Public Health Agency of Canada's surveillance systems: the Transfusion Transmitted Injuries Surveillance System (TTISS) and the Tissue and Organ Surveillance System (TOSS).

The most common adverse reactions occurring in Nova Scotia are febrile non-hemolytic and minor allergic. The incidence of these reactions is within normal parameters in comparison to the incidence rates reported in the literature. The NSPBCP provides education tools to health care professionals such as the Algorithm for Transfusion Reactions which identifies preventative measures such as the administration of antipyretics or antihistamines prior to transfusion.

The NSPBCP convened an Adverse Event Investigation Working Group comprised of representatives from the DHAs/IWK and CBS. A standardized investigation protocol has been developed and as of March 31, 2010 is in draft form. A gap analysis was performed with the *Algorithm for Transfusion Reactions* and the investigation chart has been aligned with this document.

As part of the TOSS initiative, the NSPBCP convened a Tissue and Organ Surveillance System Advisory Group (TOSSAG) comprised of representatives from the Multi-Organ Transplant Program, the Regional Tissue Bank, the Critical Care Organ Donation Program and other key stakeholders. Upon the advice of TOSSAG, the NSPBCP conducted an environmental scan on tissue and organ transplantation activities. The scan identified various items including the existing reporting mechanisms related to adverse transplantation events and sites where tissue transplantation occurs. It was also identified that while the Regional Tissue Bank is a key source of tissue for the DHAs/IWK, tissues are imported from other sources for use in surgical and dental procedures.

Quality Assurance

The NSPBCP received Accreditation Canada reports from the DHAs/IWK and collated the results on Standards for Blood Banks and Transfusion Services, Standards for Laboratory Analyses, and Standards for Laboratory and Blood Services in order to determine the existence of gaps and commonalities. Home Transfusion was identified as an area in which assistance could be provided to support compliance with Home Transfusion requirements contained in the Z902-04 Blood and Blood Components Standards and to standardize the practice of Home Transfusion within Nova Scotia.

The guideline developed by the NSPBCP and distributed in February 2010, dually serves the service care provider, persons employed by an agency able to provide transfusion in the home environment, and the blood transfusion service laboratory personnel, persons employed in laboratories identified as able to prepare and provide blood and blood components for transfusion in the home environment. It states the roles, responsibilities and processes in each area, necessary to achieve compliance to the CSA Z902-04 standards, ultimately supporting standardized practice and enabling safe transfusion in the home environment.

In January 2010, the Canadian Standards Association (CSA) published an updated version of the *CSA Z902, Blood and Blood Components Standard*. The Laboratory Standards Coordinator performed a detailed comparison of the CSA standards Z902-04 to Z902-10 and provided this document to the Provincial Territorial Blood representatives for use in their respective jurisdiction as well as to the Quality Specialists in the DHAs/IWK.

Three hundred and eighty-nine copies of the “Guide to Blood Component and Blood Product Administration” were distributed in October 2009 to the DHAs/IWK. The guide was designed as a quick reference flipchart to aid healthcare providers in the administration of blood and blood products. This project has been developed by the

NSPBCP in collaboration with the Nova Scotia Nurses Transfusion Practice Working Group and the Transfusion Medicine Quality Specialist Working Group. This education tool reflects the Provincial standard for the administration of blood components and blood products serving as a supportive tool to meet Accreditation Canada requirements, while promoting excellence in transfusion medicine.

During the period of April 1, 2009 to March 31, 2010 the Quality Specialists Working Group reviewed and advised on the following items:

- Interchangeability of Fresh Frozen Plasma and Frozen Plasma
- Bar Coding of components created by the Blood Transfusion Service using 128 Bar Coding and International Society of Blood Transfusion (ISBT) 128 Bar Coding
- Patient Notification
- Prothrombin Complex Concentrate order entry build
- 5% IVIG
- Infant Grouping Crossmatch

A framework for conducting an audit to review the documentation and processes developed prior to the NSPBCP's participation was endorsed by the Transfusion Medicine Advisory Group in March 2010. Cape Breton Regional Hospital and Yarmouth agreed to participate in the audit.

Upon receipt of the National Blood Contingency Plan, the NSPBCP conducted a gap analysis and further revisions were made to the Provincial Blood Contingency Plan. The provincial plan was disseminated in Nova Scotia in early April 2010.

The NSPBCP facilitated agreement for the redistribution of red blood cells between hospitals within Nova Scotia effective December 2, 2009.

The NSPBCP provided DHAs/IWK with a Blood Emergency Management Plan (BEMP) template. Effective March 31, 2010, 3 out of 10 of the jurisdictions had implemented their BEMPs and 2 jurisdictions had their BEMP in a draft format.

Communication

The NSPBCP continues to keep stakeholders informed of NSPBCP activities through the bi-annual newsletter, "Blood Counts", the quarterly IVIG Data Collection newsletters, reports and the NSPBCP's webpage on the Department of Health website and has had several publications in the Doctors NS journal.

The NSPBCP supports a consultative and collaborative approach to the development of provincial standards. Working groups with provincial representation and various clinical expert perspectives are established in order to advise the NSPBCP on specific items.

In the past fiscal year the NSPBCP distributed various reports to the members of its various working groups, the CEOs, Vice Presidents, Medical Directors and Laboratory Managers of the DHAs/IWK.

The Nova Scotia Provincial Blood Coordinating Program (NSPBCP) has successfully implemented a web-based program called the *Data Information and Storehouse Initiative* (DaISI). In Nova Scotia this method has replaced Excel spreadsheet and fax data collection processes and Nova Scotia has seen benefits to data quality and improvements to the ease and efficiency for facilities sending immune globulin (Ig) blood product usage data to the NSPBCP.

2.0 Activities of the Nova Scotia Provincial Blood Coordinating Program

The Nova Scotia Provincial Blood Coordinating program was created in January 2003 to provide leadership and to maximize the safe and appropriate management of blood products and their alternatives for Nova Scotians.

In September 2009 a planning session was held with the Provincial Blood Coordinating Program's Advisory Committee to develop a common sense of where the Program stands 5 years post-launch and to get the committee's advice on potential development priorities for the next 3 years.

The Committee offered perspectives on redefining the Mission and Vision statements, as well as the Program's Goal Areas. The revised statements and goal areas are outlined below:

Mission

Promoting excellence in Transfusion Medicine

Vision

Appropriate management and safe administration of blood donor gifts are provided to patients in Nova Scotia

Core Values

Patient safety & population health, accountability & responsibility, leadership, collaboration, and quality.

Four broad intentions will anchor our promotion of excellence in transfusion medicine over the next 3 years.

1. Utilization: To minimize product wastage and optimize appropriate use
2. Surveillance: To reduce preventable adverse events

3. Quality Assurance: To support compliance with transfusion medicine standards of practice
4. Communication and Coordination: To engage, educate and inform stakeholders to support best practice.

2.1 Utilization

The key objectives of Utilization Management activities are to minimize product wastage and to optimize appropriate use of selected blood and blood products. In fiscal year 2009-2010, the NSPBCP was involved with utilization activities for the following:

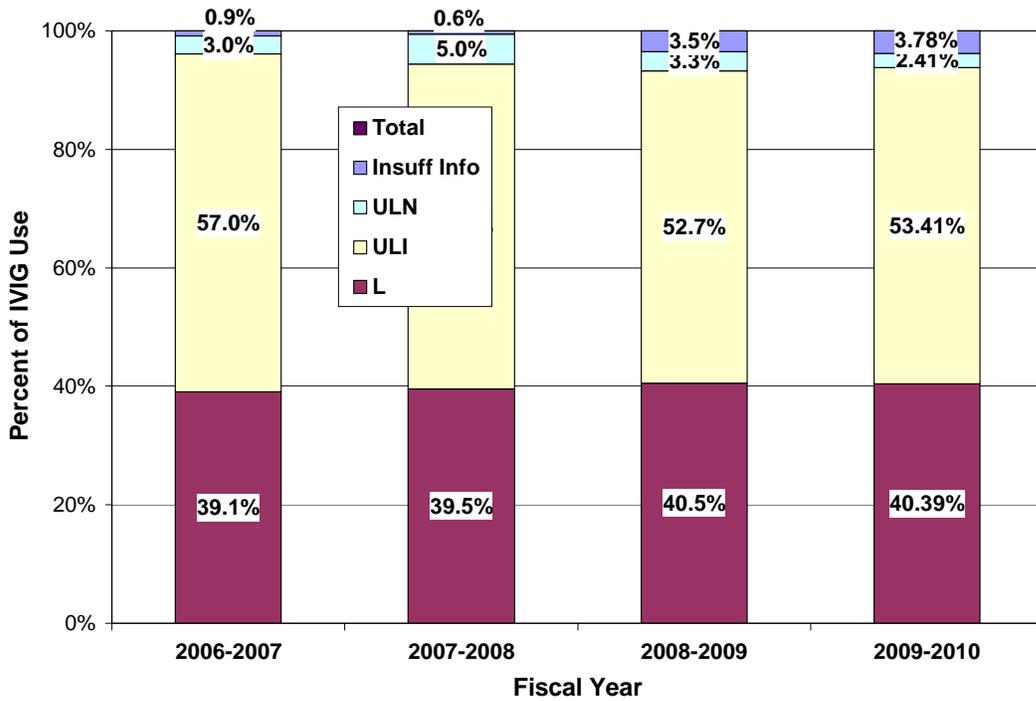
- Intravenous Immune Globulin (IVIG)
- IVIG Atlantic Collaborative
- Octaplex®
- Red Blood Cells
- recombinant Factor VIIa
- Factor Products
- Subcutaneous Immune Globulin
- Massive Transfusion Protocol
- Plasma Utilization
- Indications for Transfusion

2.1.1 Intravenous Immune Globulin (IVIG)

IVIG utilization management activities revolve around two main aspects: optimizing appropriate use and reducing discards. Appropriateness of use is monitored from two perspectives: appropriateness of clinical indications for the use of IVIG and the amount and frequency of dosing. In terms of appropriateness, each clinical indication entered into the Atlantic IVIG Utilization Database is assigned into one of the following categories:

- Labelled (L) – acceptable use
- Unlabelled but indicated (UL-I) - some evidence to support use
- Unlabelled and not indicated (UL-N) - no evidence to support use
- Insufficient information

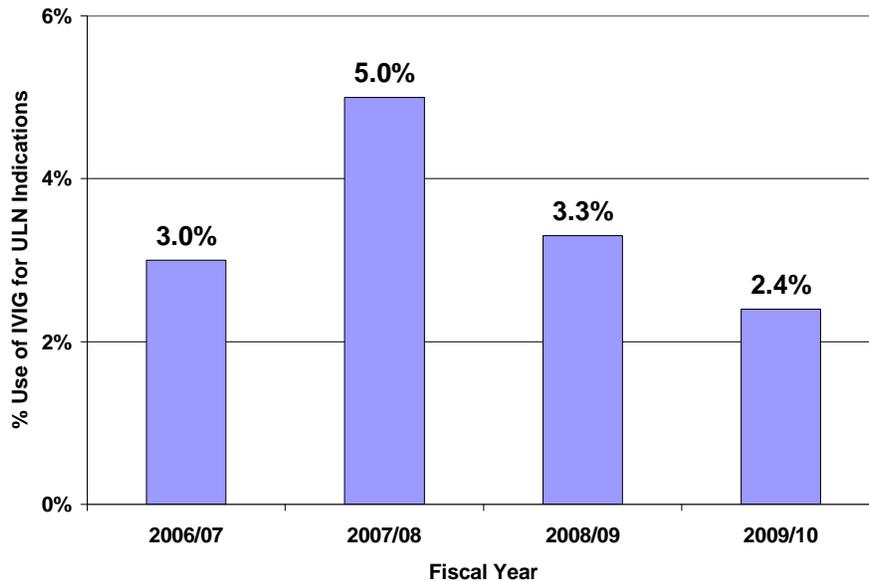
Figure 1: Percent of IVIG Use by Appropriateness Category in Nova Scotia 09/10



As demonstrated in Figure 1, 93.8% of the IVIG used in 2009/10 was used for L and UL-I indications combined. The current target is to increase L and UL-I to 98% by the 2012/13 fiscal year.

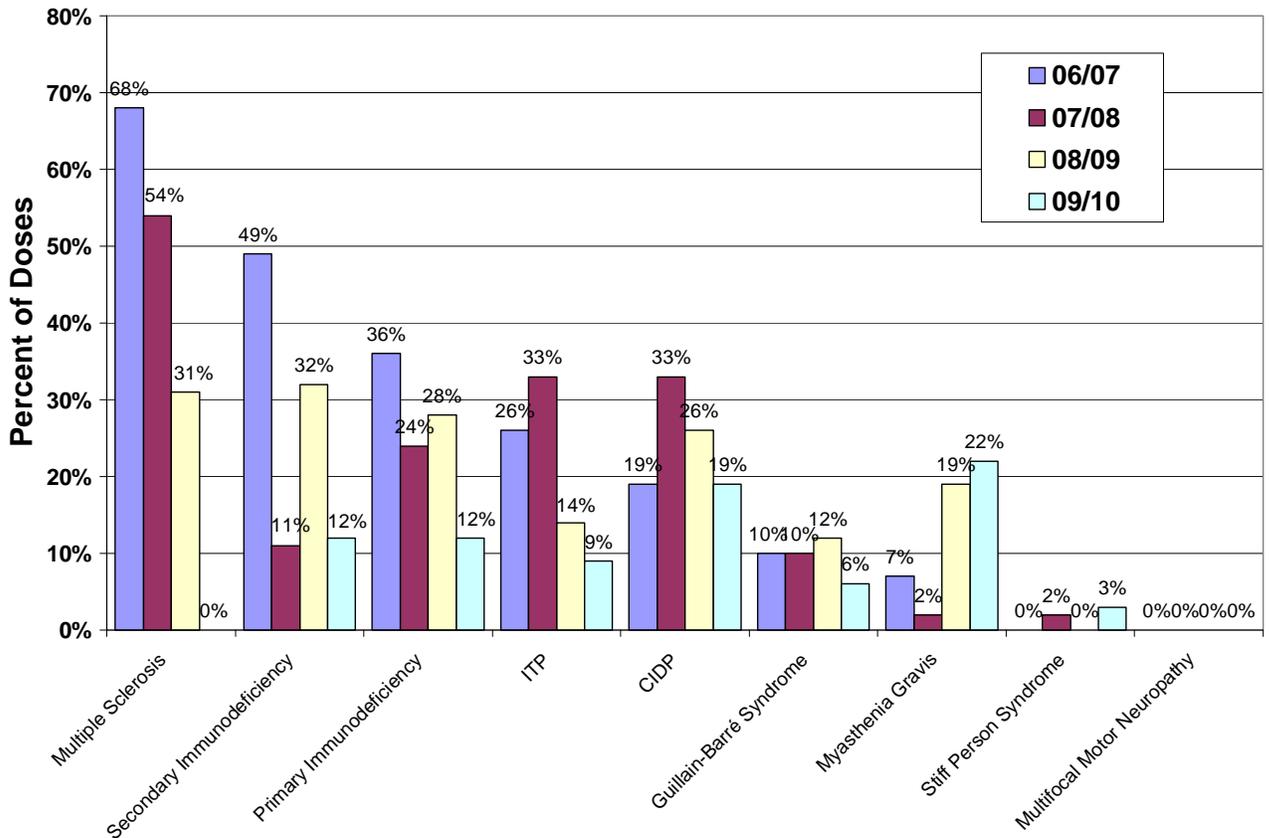
Conversely, the target is to limit the use of IVIG for UL-N indications to two percent or less by 2012/13. Figure 2 shows the proportion of IVIG used for UL-N indications only, with the proportion in 2009/10 at 2.4%.

Figure 2: Proportion of IVIG Used for UL-N Indications in Nova Scotia



While appropriateness of use is evaluated based on the categorization of “labelled”, “unlabelled but indicated” and “unlabelled and not indicated”, the dosing and frequency of administration is also an important measure of appropriateness of use. Figure 3 shows the percent of doses that exceeded the recommended dose or frequency of treatment.

Figure 3: Percent of IVIG Doses Higher or More Frequent than Recommended in Nova Scotia



In addition to utilization, IVIG discards are also monitored. The current goal is to have less than 50 g of IVIG discarded per year in Nova Scotia. Figure 4 shows the grams of IVIG discarded in Nova Scotia for recent fiscal years. Since 2005/06 there has been a steady decline, however in 2009/10 the amount dramatically increased. The reasons for the discards are displayed in Table 1 by jurisdiction, reason and amount.

Figure 4: Total Reported IVIG Discards in Nova Scotia

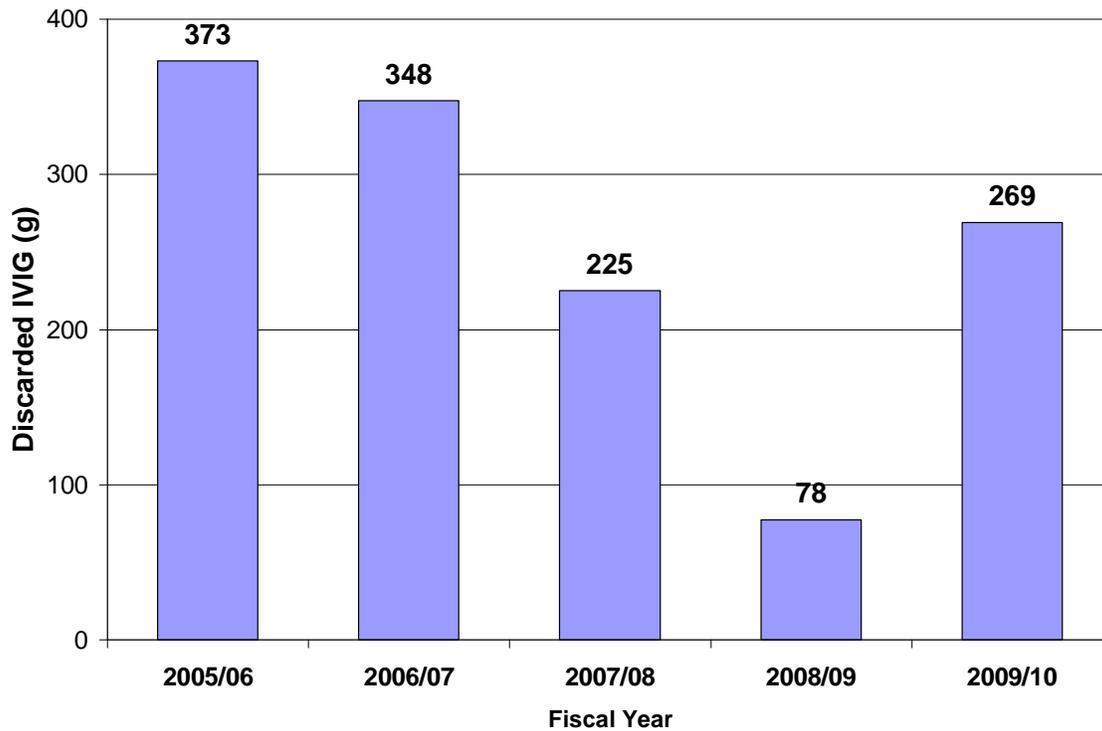
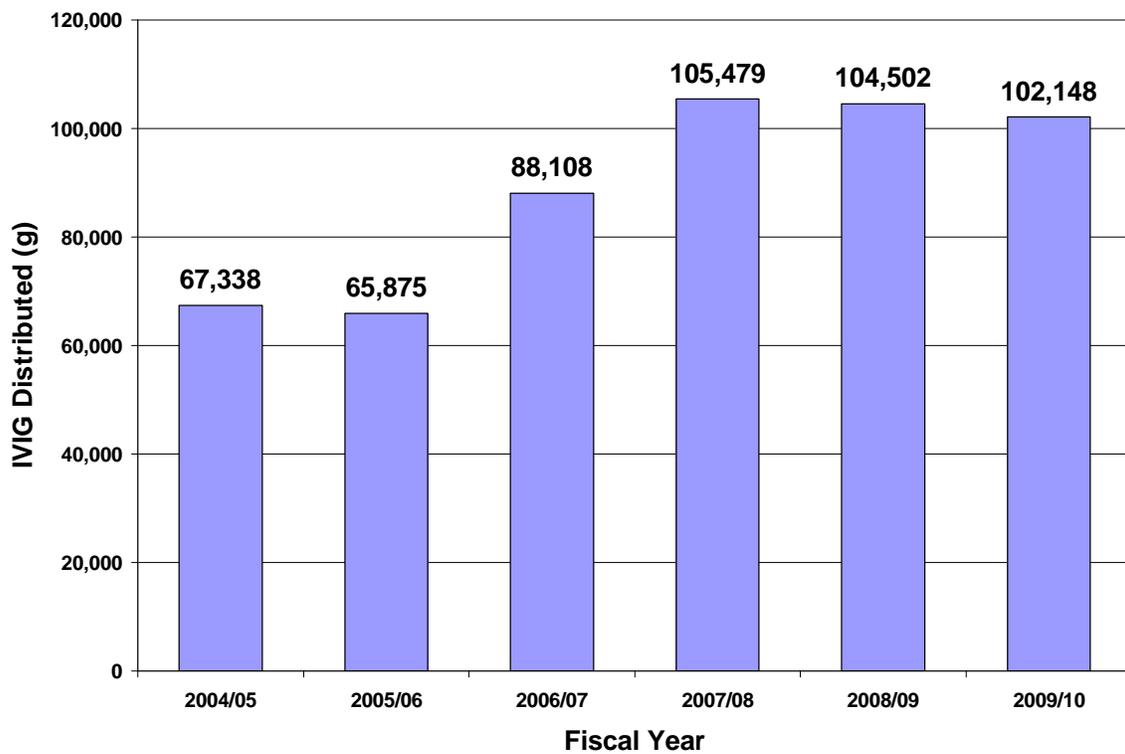


Table 1: Summary of Reported IVIG Discards in Nova Scotia for Fiscal Year 2009/10

District/IWK	Facility	Reason for Discard	Amount (g)
South West Nova Health Authority	Yarmouth Regional Hospital	broken	15
		spiked not transfused	20
Cape Breton Health Authority	Cape Breton Regional Hospital	broken	40
		returned to lab temperature/visually unacceptable	40
	Inverness Consolidated Hospital	incorrectly reconstituted	50
IWK		broken	10
		spiked not transfused/sterility/integrity of product compromised	10
		expired	84

Since 2003, the four Atlantic Provinces have participated in an Atlantic Blood Utilization Strategy (ABUS) with the NSPBCP functioning as the secretariat. IVIG has been the focus of the Strategy and trends in use have been examined using IVIG distribution data from Canadian Blood Services as well as standardized IVIG utilization data elements that have been collected from facilities across all Atlantic Provinces since 2004. An annual report is distributed to the provinces to provide feedback on distribution and utilization. Figure 5 shows the amount of IVIG distributed to Nova Scotia and demonstrates a small decrease in the 2008/09 fiscal year and another in 2009/10.

Figure 5: Annual Distribution of IVIG in Nova Scotia



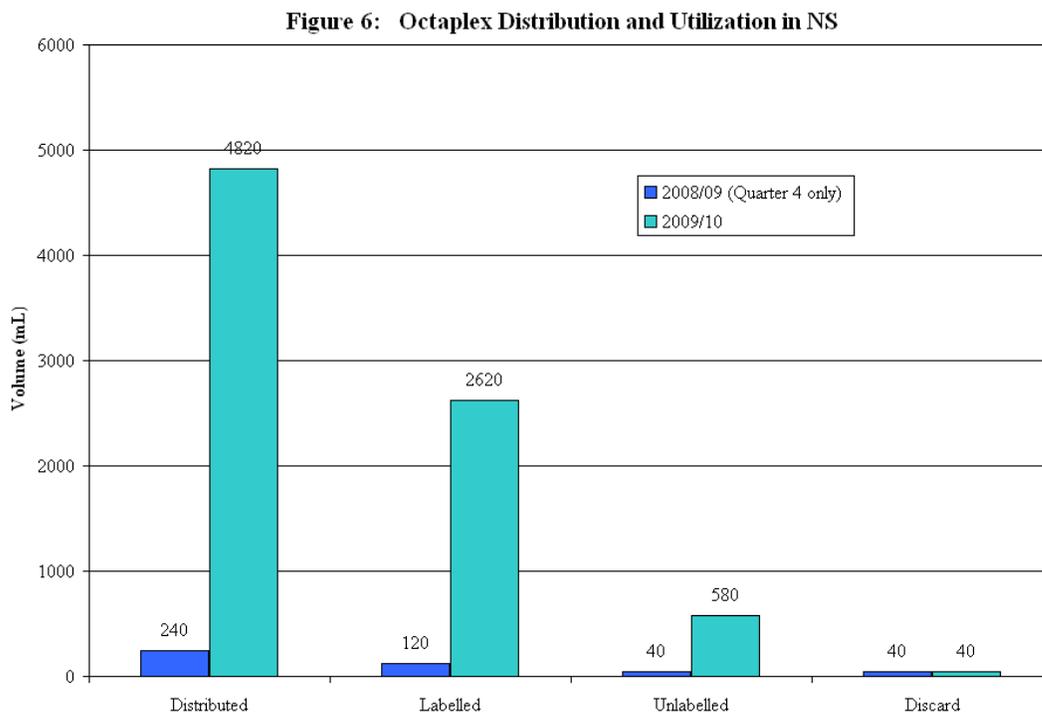
2.1.2 Octaplex®

On May 1, 2007 Health Canada licensed the prothrombin complex concentrate (PCC), octaplex®, for use in Canada. This product is produced by Octapharma Canada, Inc. and effective July 2008 became available for distribution through Canadian Blood Services (CBS). Octaplex® is a human plasma-derived prothrombin complex concentrate that is indicated when rapid correction of prothrombin complex levels is necessary such as major bleeding or emergency surgery when the patient is receiving oral anticoagulants.

The National Advisory Committee (NAC) on Blood and Blood Products developed recommendations for the use of octaplex®. In March, 2009, the NSPBCP convened an expert working group to develop a provincial guideline for this product with the NAC guidelines serving as the reference. The NAC guidelines were promoted until the Nova Scotia guideline was disseminated in February of 2010. A pre-printed order form and data collection tools were also provided and all DHAs/IWK report the use of octaplex® as well as discards to the NSPBCP.

The first use of octaplex® occurred in Nova Scotia in February 2009. The NSPBCP categorizes use as labelled or unlabelled and has set a target for 75% of octaplex® use to be appropriate and discards to be less than 80 mL/year. These targets were met as 82% of the use of octaplex® in 2009/10 was labelled, 18% was unlabelled, and 40 mL of octaplex® was discarded. Figure 6 demonstrates the labelled use, unlabelled use and discards volumes for the past 2 years.

In order for use to be categorized as labelled, the patient must be taking an anticoagulant, have an INR greater than 1.5, and require urgent surgery or invasive procedure within the next 6 hours and/or be massively bleeding. Use was categorized as unlabelled if the product was used in patients who did not meet the above requirements.



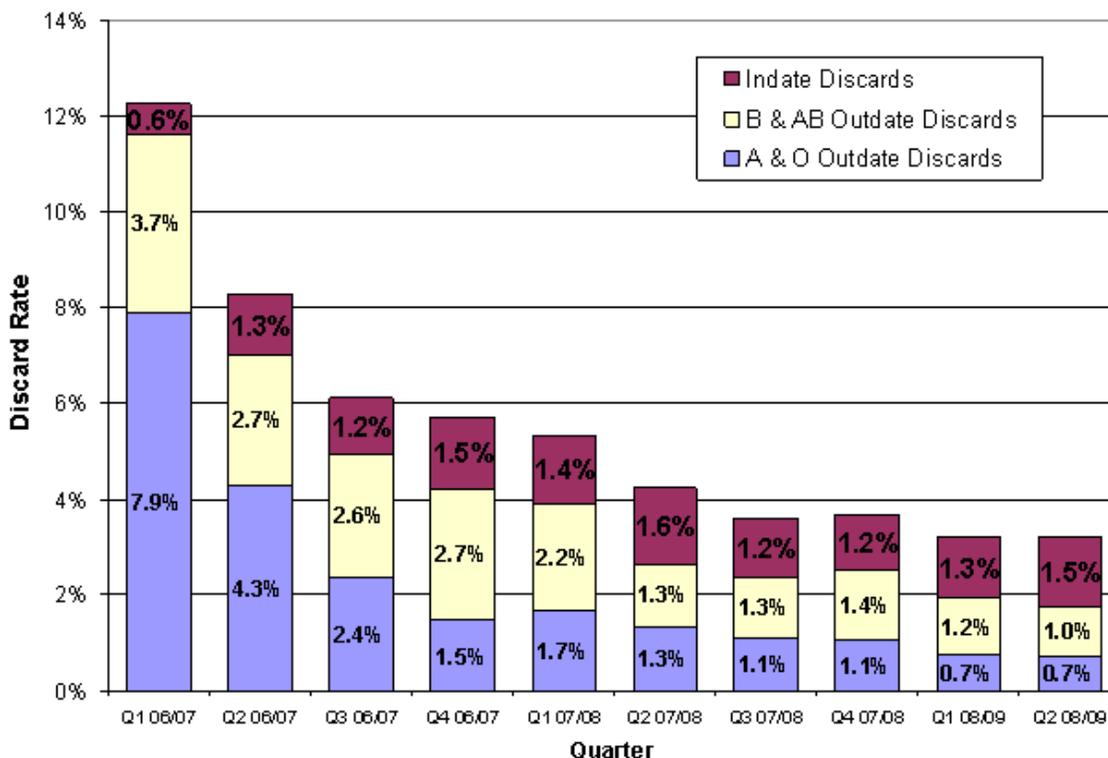
2.1.3 Red Blood Cells

Prior to the 2006/07 fiscal year, yearly red blood cell (RBC) discard rates in Nova Scotia fluctuated between 9 and 11%. During this time, other Canadian provinces were reporting discard rates between 2 and 4%.

In 2006, the Quality Specialists Working Group, CBS and the NSPBCP collaborated to identify strategies to improve RBC inventory management in an effort to reduce RBC discards. Throughout 2006 and 2007, DHAs/IWK gradually implemented these strategies which led to reductions in RBC discards.

Figure 7 shows the quarterly RBC discard rates for quarters in 2006/07 to 2008/09 in Nova Scotia. The discard rate continues to improve into the 2008/09 fiscal year with a discard rate of 3.2% in the second quarter.

Figure 7: Quarterly Nova Scotia RBC Discard Rates



DHAs/IWK report disposition data to CBS on a monthly basis who then provides this information to the NSPBCP. The NSPBCP uses the disposition data to calculate discard rates. During 2008/09 and 2009/10 it was noted that disposition data was absent. As a result the NSPBCP is

unable to provide discard rates for Nova Scotia and for the DHAs/IWK. Strategies are underway in an effort to resolve this gap.

While unable to determine discard rates the NSPBCP is able to monitor the distribution of red blood cells to Nova Scotia. Figure 8 demonstrates a 7.4% decrease from 06/07 to 07/08 followed by 1.4% increase and 1.1% decrease.

Each provincial/territorial blood budget is based on the percentage of usage of the total amount and as a result of the decreased distribution Nova Scotia's percentage decreased from 4.23% to 3.75% from 2006/07 to 2009/10.

Figure 8: RBC Distribution

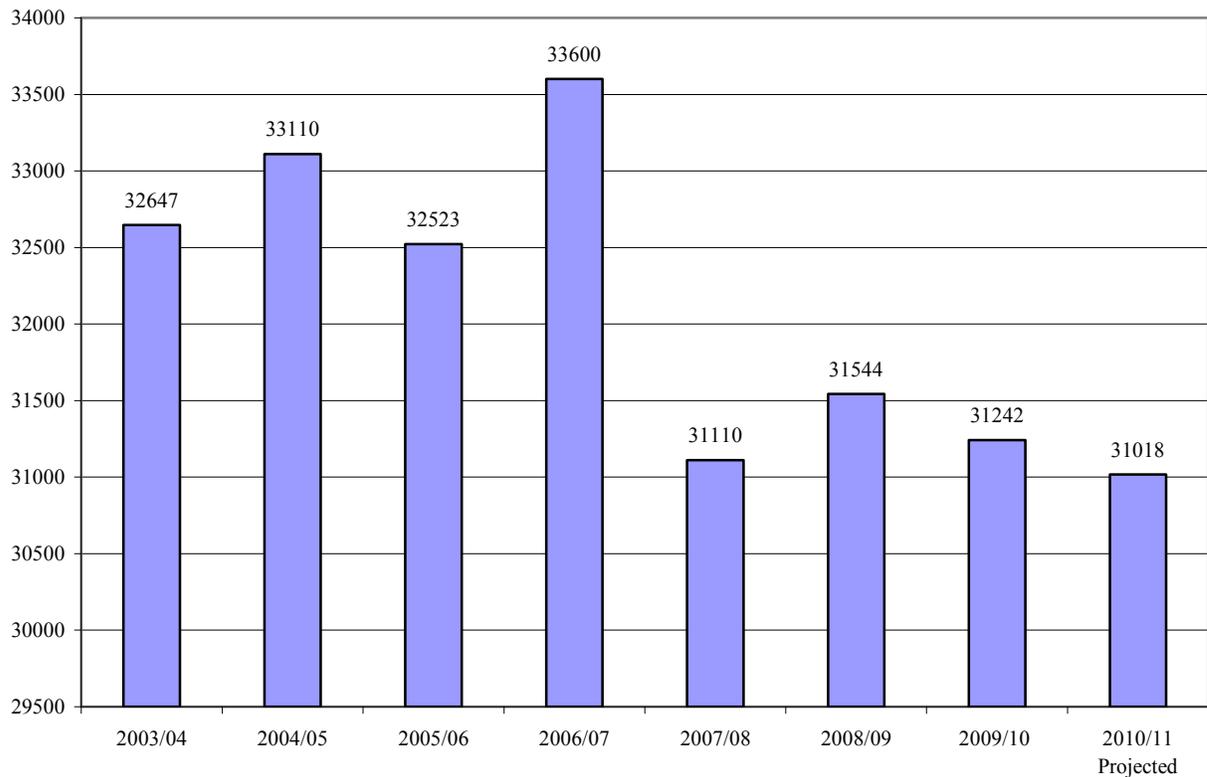


Table 2: Nova Scotia Impact of reduction in RBCS 2006/07 to 2009/10

	2006/07	2007/08	2008/09	2009/10
Actual RBCs	4.23%	3.89%	3.79%	3.75%
Budget RBCs	4.19%	4.23%	3.89%	3.79%
Actual funding Transfusable Products & Stem Cells (\$)	18,067,517	16,843,007	17,060,154	17,375,259
Budget funding- Transfusable Products & Stem Cells (\$)	17,882,359	18,324,946	17,531,854	17,519,968
Savings/(cost overrun) (\$)	(185,158)	1,481,939	471,700	144,709

Source: CBS

Notes:

1. RBC utilization is used to determine funding for the Transfusable Products and Stem Cells programs. Therefore savings above relate to these programs only.
2. Savings experienced in a given fiscal period are due to a decrease in Nova Scotia's share of RBC utilization as a percentage relative to the other provinces/territories.

2.1.4 Recombinant Factor VIIa (rFVIIa)

Recombinant Factor VIIa, also known as NiaStase[®], is a genetically engineered protein and is licensed in Canada for hemophilia A/B patients with inhibitors to Factor VIII or Factor IX, respectively. It is used for the treatment of bleeding episodes, including treatment and prevention of those occurring during and after surgery for these patients.

The NAC, in a 2008 publication, reviewed the evidence available for the use of recombinant Factor VIIa in massive bleeding and concluded that rFVIIa should only be considered as a part of a transfusion policy framework for massive bleeding after other supportive measures and treatments have been considered. The Massive Transfusion Working Group expanded their scope to address the use of rFVIIa in massive bleeds.

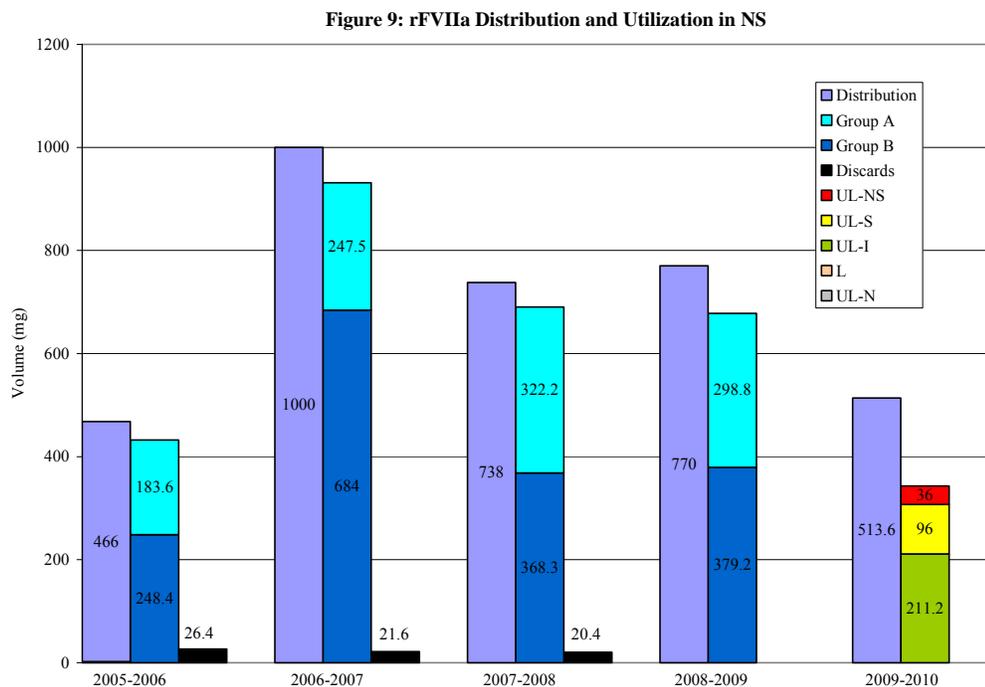
In 2009-10, the NSPBCP developed detailed criteria in order to classify the use of rFVIIa as labelled (L); unlabelled – indicated (UL-I); unlabelled – not indicated (UL-N); unlabelled – supported (UL-S) by the framework and unlabelled – not supported (UL-NS) by the framework. These categories are explained in further detail in Appendix 1. In previous years, the utilization of rFVIIa was classified into two groups – Group B or Group A. Group B is the equivalent of labelled and unlabelled-indicated while Group A is the equivalent of unlabelled supported and unlabelled not supported.

A target of 90% of rFVIIa use to be according to guidelines was set with a wastage target of less than 10 mg/year and these targets were met based on the rFVIIa utilization data that was received. Table 3 displays the amount

of rFVIIa used. For patients who received the product due to factor deficiencies (211.2 mg), the use was classified as unlabelled but indicated. The 36 mg categorized as unlabelled - not supported was administered to six patients. One patient received rFVIIa prophylactically prior to a procedure where it was anticipated that bleeding would occur and the patient refused transfusion based on religious beliefs. The remaining 5 patients received rFVIIa prior to other corrective measures/hemostatic interventions being implemented.

Table 3: Use of rFVIIa

FY	Appropriateness	Utilized (mg)	% total mg
2009-2010	UL-I	211.2	62%
	UL-S	96	28%
	UL-NS	36	10%
Total		343.2	100%



2.1.5 Factor Products

Pre-printed order forms for ordering clotting factor products for adults and children with various clotting disorders were under development. As a result of further exploration it was identified that patients with factor deficiencies are issued a “Factor First” card. These cards are kept on their person and provided to clinicians in the event that emergency treatment is

required. For this reason, the development of the Pre-Printed order forms has been deferred.

2.1.6 Subcutaneous Immunoglobulin (SCIG)

In 2008, the Provinces and Territories approved the inclusion of SCIG as a regular product within Canadian Blood Services' plasma protein products portfolio. In September, 2008 the Atlantic Collaborative IVIG Utilization Working Group expanded the mandate of ABUS to include SCIG. The expansion involved the collection of SCIG utilization data and the development of an Atlantic guideline for the use of SCIG.

The Atlantic Guidelines for Subcutaneous Immune Globulin was distributed in September 2009. In 09/10, all SCIG use was appropriate as it was for the treatment of primary immune deficiencies and was within recommended dosing guidelines. No discards of SCIG were reported in any of the Atlantic Provinces in 09/10.

2.1.7 Massive Transfusion Protocol

A new approach to treating patients requiring massive transfusion has been noted in literature as a result of casualty care in the war in Iraq. An expert working group on Massive Transfusion had existed previously and was reconvened in July 2009. The working group defined massive bleeding as: Bleeding with the anticipation of ongoing blood loss or requiring at least four (4) units of RBCs (adults) or 40 mL per kg (children) in 4 hours and recommended a change in practice which involved introducing plasma and platelets earlier in the treatment for massively bleeding. The guideline was nearing completion by the end of March 2010 and was presented at the Nova Scotia Trauma Advisory Council Meeting in March 2010.

2.1.8 Plasma

In January 2009, the Program Advisory Council (PAC) was advised that as of the third quarter of fiscal year 2009/10, a 14% increase in the national utilization of AB plasma was noted. PAC requested the NSPBCP review the utilization trends for plasma use, in particular AB plasma, in order to determine if a new transfusion ratio as referred to in the Massive Transfusion Guideline could be supported.

The NSPBCP formed an Ad Hoc committee to review the plasma utilization in Nova Scotia and to determine if a massive transfusion protocol of 1:1:1 could be supported. In Nova Scotia, overall plasma increased by 31.3% in 2008/09 with AB plasma increasing by 62%. The primary cause of the increase in AB plasma use was due to one hospital thawing a unit of AB plasma to have on hand as the transfusion service was not staffed during the overnight hours. This resulted in a 504% increase in AB plasma utilization at this hospital. CBRH and SSRH also had increase in 2008/09 (77.8% and 48% respectively). The hospital where the unit of AB plasma was prepared for the overnight hours implemented 5 day expiration of thawed plasma in January 2010 and the use of AB plasma decreased in the remaining 3 months of the 2009/10 fiscal year. Patients with thrombotic thrombocytopenia purpura (TTP) did not impact the volume of AB plasma use in the province. Plasma data for 2009/10 shows a decrease in plasma utilization by 2.5% and a decrease in the AB plasma by 1.3% for the entire year. The Plasma Ad Hoc Committee felt that the introduction of plasma early in the treatment of the massively bleeding patient could be sustained.

2.1.9 Indications for Transfusion

The NSPBCP is developing a provincial standard for the *Indications for Transfusion*. This guideline will contain the adult and pediatric indications for appropriate blood and blood product transfusion and will be applicable during the Green Phase of the Provincial Blood Contingency Plan. As of March 31, 2010 a literature review has been completed with the development of a draft document.

3.0 Surveillance

The key objective of surveillance is to reduce preventable adverse events related to blood transfusion.

Three keys strategies were identified that would support the reduction of preventable adverse events: Avoid transfusion, minimize the risks of transfusion and respond appropriately to adverse reactions. Each of the strategies and their related activities will be discussed in the following section.

3.1 Avoid Transfusion

Avoiding unnecessary transfusion is key in minimizing any risks related to blood transfusion. Various strategies have been developed by the NSPBCP and implemented at the DHAs/IWK to support informed consent related to blood transfusion.

3.1.1 Develop Patient Information Tools

The NSPBCP in collaboration with the Nova Scotia Nurses Transfusion Practice Working Group (NSNTPWG) revised the existing patient education pamphlet. The revised pamphlet emphasizes important questions for patients to ask themselves before receiving a transfusion, therefore promoting self-advocacy. Additionally, the revised pamphlet refers patients to Nova Scotia Healthlink 811 in the event of an adverse reaction to a transfusion received as an outpatient. Information on alternatives to transfusion was developed in collaboration with Canadian Blood Services and the QEII Health Sciences Centre Perioperative Blood Management Program. As of March 31, 2010, the draft document was finalized.

3.2 Minimize risks of transfusion

3.2.1 Identify current and potential risks to patients and develop strategies to minimize the risks

Nova Scotia participates in the Public Health Agency of Canada (PHAC) Transfusion Transmitted Injuries Surveillance System (TTISS). This surveillance system, using non-nominal data, monitors all adverse reactions associated with transfusion. 100% of DHAs/IWK report adverse reactions to the NSPBCP.

The most common adverse reactions occurring in Nova Scotia are Febrile Non-Hemolytic and Minor Allergic. The NSPBCP provides education tools to health care professionals such as the Algorithm for Transfusion Reactions which identifies preventative measures such as the administration of anti-pyretics or antihistamines prior to transfusion.

The literature shows that Acute Hemolytic Transfusion Reaction (AHTR) resulting from an ABO incompatible unit as a result of a patient

identification error is the most frequent severe reaction and the leading cause of death associated with transfusion⁵ and 80% of AHTR related deaths occur as a result of ABO incompatibility due to an error. These errors are often associated with incorrect patient identification, sample errors, and administration errors⁶. Recognizing this potential risk, strategies have been developed to promote positive patient identification, and strict adherence to blood administration policies. Continuing education provided to healthcare professionals emphasizes this potential risk and our data shows, there have been no deaths in Nova Scotia related to ABO incompatibility due to an error. An article in the July 2009 edition of the NSPBCP's newsletter provided a case study on positive patient identification; encouraging healthcare providers to ensure patient armbands are in place and checked as per administration policies. Educating patients to ensure their own armbands are being checked by the healthcare provider is an important strategy being considered to promote prevention and maximize patient safety.

Table 4: Components distributed in Nova Scotia in 2009*

Blood Components	Number of units distributed	
	N	Percent per year
Red Blood Cells	30763	68.29
Fresh Plasma	1597	3.55
Apheresed Fresh Frozen Plasma	4285	9.51
Platelets	2914	6.47
Apheresed Platelets	1204	2.67
Cryosupernatant/Cyroprecipitate	4284	9.51
Total	45047	100

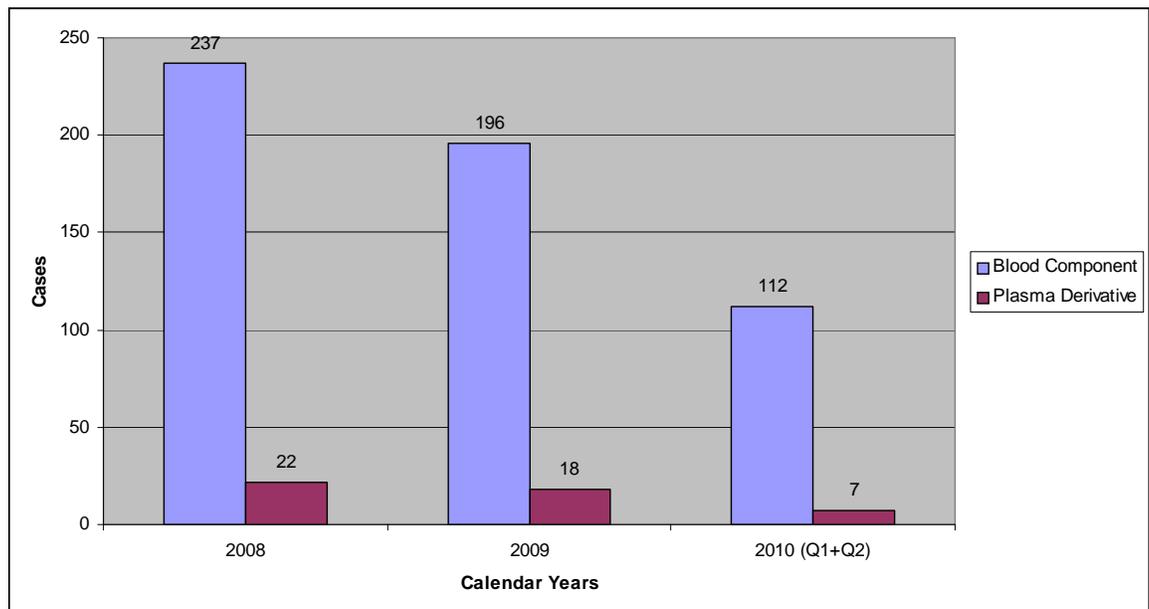
*Disclaimer: Transfused data not available at this time. Based on CBS distribution data to obtain a view of incidence rates in Nova Scotia

Table 5: Incidence Rates for 2009 Calendar Year in Nova Scotia for blood components*

ATEs	Incidence Rate
Delayed Hemolytic Reaction	1:45047
Febrile Non-Hemolytic Reaction	1:469
Hypotensive Reaction	1:6435
Minor Allergic Reaction	1:653
Possible TRALI	1:45047
Severe Anaphylactic/Anaphylactoid	1:15016
TACO	1:7508

*Note: Transfused data not available. Incidence rates calculated based on CBS distribution data.

Figure 10: Overall Picture of Transfusion Reactions 2008, 2009, and 1st 2 quarters 2010*



*TTISS data based on calendar year

Table 6: Transfusion Reactions 2008, 2009, and 1st 2 quarters 2010* for blood components

Type of Transfusion Reaction	2008	2009	2010
Acute Hemolytic Reaction	Less than 5		
Delayed Hemolytic Reaction	Less than 5	Less than 5	
Delayed Serological Transfusion Reaction (new alloantibodies)	16	8	6
Febrile Non-Hemolytic Reaction	126	96	59
Hypotensive Reaction	60	69	35
Severe Anaphylactic/Anaphylactoid	Less than 5	Less than 5↑	
TACO	17	6	Less than 5
TAD	Less than 5	Less than 5↓	Less than 5↑
TRALI	Less than 5		
Possible TRALI	Less than 5	Less than 5↓	
Unknown	Less than 5		
Other Transfusion Reaction	Less than 5	Less than 5↑	Less than 5↓
Total	237	196	112

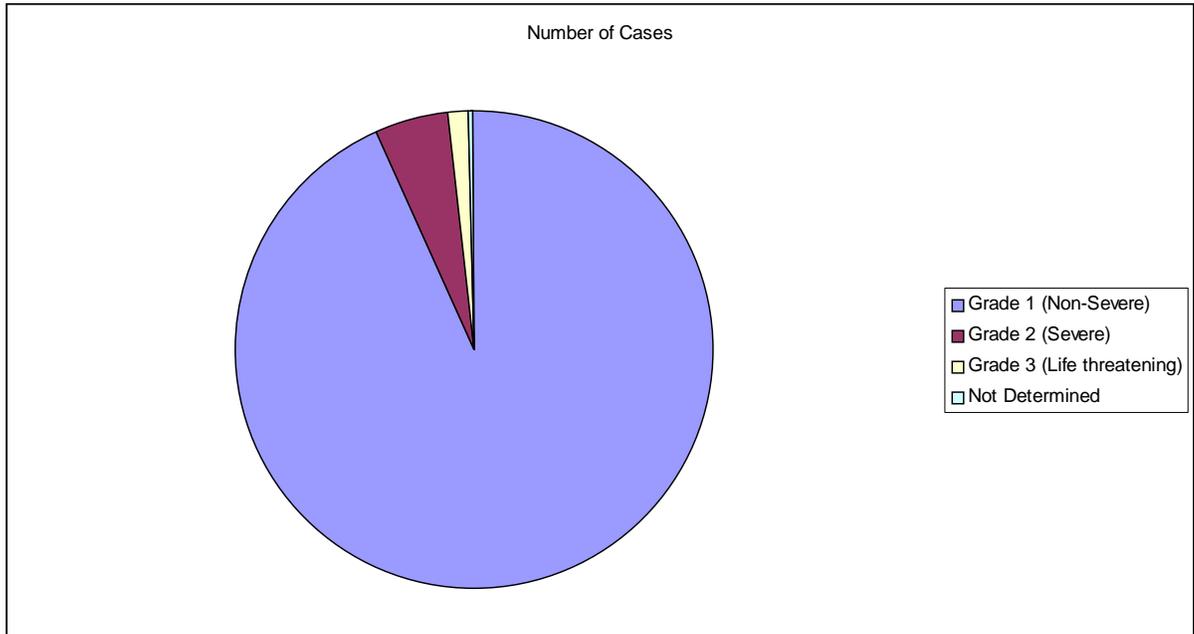
Note: TTISS data is based on calendar year. Reactions are listed as “Less than 5” if there were less than 5 of the related reaction reported within the calendar year. The arrow ↑ indicates the number of reactions is increased from the previous year, while the arrow ↓ indicates the number of reactions is decreased from the previous year. If there is no arrow present this indicates that the number of reactions is unchanged from the previous year.

Table 7: Transfusion Reactions 2008, 2009, and 1st 2 quarters 2010* for blood products

Type of Transfusion Reaction	2008	2009	2010
Acute Hemolytic Reaction			Less than 5
Delayed Hemolytic Reaction	Less than 5	Less than 5 ↓	Less than 5 ↓
Delayed Serological Transfusion Reaction (new alloantibodies)	Less than 5		
Febrile Non-Hemolytic Reaction	Less than 5	7	
Hypotensive Reaction	Less than 5		
IVIg Headache	Less than 5	Less than 5	Less than 5
Minor Allergic Reaction	7	Less than 5	Less than 5 ↓
TACO		Less than 5	
TAD			Less than 5
Unknown	Less than 5		Less than 5
Other Transfusion Reaction	Less than 5	Less than 5 ↓	Less than 5 ↓
Total	22	18	7

Note: TTISS data is based on calendar year. Reactions are listed as “Less than 5” if there were less than 5 of the related reaction reported within the calendar year. The arrow ↑ indicates the number of reactions is increased from the previous year, while the arrow ↓ indicates the number of reactions is decreased from the previous year. If there is no arrow present this indicates that the number of reactions is unchanged from the previous year.

Figure 11: Severity from 2008 to 2010 (Q1+Q2)



3.2.2 Establish working group

The adverse reactions to transfusions are submitted by the DHAs/IWK to the NSPBCP and the NSPBCP enters into a database developed by the Public Health Agency of Canada (PHAC). The output capabilities of this database were very limited and queries could not be generated. In order for the NSPBCP to obtain data from the database the NSPBCP had to develop IT tools. PHAC recognized that this functionality needed to be provided and the NSPBCP validated the PHAC tool.

The NSPBCP relies on data reported by the DHAs/IWK to CBS in order to calculate incidence rates of transfusion reactions. Various strategies have been implemented to address the gaps in the data.

As a result of both of these challenges the development of a working group has been temporarily deferred until these issues are resolved.

3.2.3 Supports compliance with transfusion medicine standards of practice related to blood administration

In collaboration with healthcare professionals, the NSPBCP Nursing Policy and Procedure for Blood, Blood Component and Plasma Derivative Administration was developed to guide the DHAs/IWK in creating and implementing blood administration policies in each district. 100% of the DHAs/IWK have implemented a blood administration policy in their district. As of March 31, 2010 the revision of this document was underway by the NSPBCP in collaboration with the Nova Scotia Nurses Transfusion Practice Working Group and the Transfusion Medicine Quality Specialist Working Group. With the release of the CSA Standards Z902-10 in 2010, it was identified that a review of the implications of the current/new version of the standards was required therefore presented a delay in the policy revision to ensure this review was completed.

A home transfusion guideline was developed in collaboration with provincial stakeholders. The guideline, distributed February 2010, supports standardized practices within the home setting related to administration, identification of transfusion reactions, and patient notification of the receipt of transfusion.

3.3 Respond appropriately to Adverse Reactions

3.3.1 Implement strategies to support the identification, reporting and classification of adverse reactions

As a strategy to support the identification and reporting of adverse reactions to transfusion the NSPBCP hosts an annual Adverse Event meeting. In fiscal year 2009/10 the event occurred on November 4, 2009 at the Marriott Harbourfront with approximately 60 participants in attendance.

3.3.2 Develop and distribute provincial adverse reaction investigation standard and toolkit

Recognizing the importance of evidence required for appropriate classification of an adverse event, the NSPBCP convened a Adverse Event Investigation Working Group comprised of representatives from the DHAs/IWK and CBS. A standardized investigation protocol has been developed and as of March 31, 2010 is in draft form. A gap analysis was performed with the *Algorithm for Transfusion Reactions* and the investigation chart has been aligned with this document.

3.3.4 Tissue and Organ Surveillance

The Public Health Agency of Canada (PHAC) is implementing a national Tissue and Organ Surveillance System (TOSS) to increase the safety of organ and tissue transplantation through the identification, analysis and timely response to potential, actual and emerging threats; specifically adverse events from tissue and/or organ transplantation. Nova Scotia is participating as one of three pilot sites in this system.

The TOSS initiative provided the opportunity for the Department of Health to determine the most appropriate model for tissue and organ surveillance in Nova Scotia. It was determined that surveillance of adverse events for tissues and organs should be channeled through a provincial program, and the Nova Scotia Provincial Blood Coordinating Program was chosen for this initiative.

National activities April 9, 2009-March 31, 2010:

- Collaboration with other pilot provinces as members of TOSS Data Working Group to determine the required data elements for adverse transplantation events in tissues

Provincial activities April 9, 2009-March 31, 2010:

- Tissue and Organ Surveillance System Advisory Group (TOSSAG) established
- Environmental scan framework developed and approved by TOSSAG
- Health care professional surveys developed and approved by TOSSAG.
- Completion of TOSS Environmental Scan and survey

Findings from the TOSS survey:

- 48 responses (9 tissue transplanting surgeons; 4 organ transplant surgeons; 2 hospital administrators; 33 other physicians and dentists)
- Responses from 8 of the 10 regions (9 DHAs plus the IWK)
- 100% of respondents to the organ transplanting surgeon and tissue transplanting surgeon survey indicated they discuss the risks of transplant with their patients
- 66.7% of respondents from the other physicians/dentists group do not discuss the risks of tissue transplant with their patients
- 70% of respondents from the other physician/dentist group indicate they are advised when their patient receives a transplant
- 100% of tissue transplanting surgeons consider malignancy transmission, infection (bacterial/fungal/viral), and graft failure to be the most serious types of possible transplantation adverse events
- 100% of organ transplanting surgeons considered graft failure, malignancy transmission, and infection/disease transmission to be the most serious types of possible transplantation adverse events
- Both groups of physicians involved in tissue and organ transplantation also considered package failure, aseptic compromise of the organ/tissue and storage temperature failure as “serious adverse transplantation reactions”
- For hospital administrators, the question asking if their facility had a registry for tracking tissue from a unique tissue identifier (tissue ID) to the recipient, 1 of the 2 (50%) respondents indicated they did have a tracking system in place
- For the tissue transplanting physicians group they indicated they follow patients from 3 to greater than 24 months. The organ group indicated they all follow patients for greater than 24 months
- When the respondents were asked what steps they would follow if a patient presented with a suspected serious adverse transplantation reaction, most indicated they would notify the Regional Tissue Bank or the transplanting surgeon or transplant team
- 68% of respondents (excluding the organ transplanting surgeon group) responded that the institution they are associated with have a patient safety reporting system

- 100% of respondents to the organ transplanting surgeon survey responded that the institution they are associated with have a patient safety reporting system
- 96.9% of respondents (excluding the organ transplanting surgeon group) responded that they do not follow a written procedure for reporting a serious adverse transplantation reaction
- 77.8% of tissue transplanting surgeons, 25% of organ transplanting surgeons, 100% of hospital administrators, and 92.7% of the other physician/dentist group reported they were not aware of the Health Canada Regulations titled “Safety of Cells, Tissues and Organs for Transplantation”
- Common themes emerged from the last question of the surveys which asked “What features are important for developing a surveillance system?” They were:
 - Easy, simple to use reporting
 - Clear guidelines
 - Ability to collect and extract data
 - Awareness of the system
 - Regular reports

Recommendations from the TOSSAG June 2010 meeting:

1. Facilitate the development of physician education tools to assist family physicians in identifying adverse events related to organ and tissue transplantation.
2. Develop an algorithm, provincial standard and provincial guideline for the reporting of adverse events that meets key stakeholder requirements.
3. Facilitate the development of patient education tools to assist recipients in identifying adverse events related to tissue and organ transplantation.
4. Perform a gap analysis on Multi-Organ Transplant Program (MOTP), Regional Tissue Bank and Critical Care Organ Donation standards of practice related to adverse event reporting and provide advice on addressing any existing gaps.
5. Provide education to health care professionals/physicians on the algorithm, provincial standard, and provincial guidelines for the reporting of adverse events.
6. Provide education to health care professionals/physicians on signs and symptoms of an adverse transplantation reaction
7. Develop standardized information to be provided to physicians/patients following tissue transplantation

8. Develop standardized elements for obtaining informed consent for organ and tissue transplantation.
9. Identify US tissue products imported to Nova Scotia for various procedures *and work toward a more efficient tracking and traceability system.*
10. Explore the development of an adverse events form for MOTP with lists of possible adverse outcomes
11. Elaborate on existing Adverse Outcome forms to include signs and symptoms of adverse reactions for existing tissue outcome forms
12. Develop detailed guidelines as to how/when to contact recipients if they are potentially involved in an adverse reaction relating to their transplant
13. Work with the Department of Health Promotion and Protection to develop reporting mechanisms to TOSS.

4.0 Quality Assurance

The key objective of this component is to support compliance with transfusion medicine standards of practice with the areas of focus being: Accreditation Canada/Z902 Standards, Laboratory Information Systems in Blood bank, Emergency Planning and Weak D testing.

4.1 Accreditation Canada/Z902 Standards

In 2005, the Canadian Council on Health Services Accreditation (CCHSA), in partnership with the Canadian Standards Association (CSA), developed an accreditation program to assess compliance with requirements for biomedical laboratories, blood banks, and transfusion services consistent with CSA standards.

Effective 2008, the accreditation of laboratory and blood standards became a required component of Accreditation Canada's (formerly CCHSA) accreditation program. Over the past several years, the NSPBCP has developed approximately one hundred Standard Operating Procedures (SOPs) to assist DHAs/IWK in achieving compliance with the Z902 Standards for Blood and Blood Components. As of March 31, 2010 nine of the ten DHAs/IWK underwent Accreditation Canada review which included the new requirements. Feedback obtained from the Provincial Laboratory Managers indicated that the Blood Transfusion Services were well positioned for the review. The NSPBCP collated the results from the DHAs/IWK and identified Home Transfusion as an area in which assistance could be provided to support compliance with Home Transfusion requirements contained in the Z902-04 Blood and Blood Components Standards and to standardize the practice of Home Transfusion within Nova Scotia.

The initial step in the development of the Home Transfusion guideline was to acquire and review existing documents. An environmental scan was performed and resulted in the review of three protocols:

1. *Continuing Care Branch Home Transfusion Therapy Protocol (March 5, 2002)*
2. *Home Care Nova Scotia Home Blood Transfusions (undated)*
3. *Home Care Nova Scotia Northern Region (July 1999)*

The documents were assessed for compliance with CSA Z902-04 Blood and Blood Components Standard. The Continuing Care Branch Home Transfusion Therapy Protocol was identified as being the document most compliant with Z902-04 requirements and was therefore selected as the template for the necessary revisions.

Revisions were performed respectful of current standards; CSA Z902-04 Blood and Blood Components, the 24th edition of AABB Standards for Blood Banks and Transfusion Services; which evolved to the 25th edition during document development; as well as Transport Canada's Transport of Dangerous Goods and any others as appropriate.

With a template chosen and standards to direct the revision, key teams and individuals provided feedback on content and processes. Feedback was obtained from the Victorian Order of Nurses: the provider of the service in Nova Scotia and Blood Transfusion Services personnel.

The end product, distributed February 2010, is a guideline that dually serves the *service care provider*, persons employed by an agency able to provide transfusion in the home environment, and the *blood transfusion service laboratory personnel*, persons employed in laboratories identified as able to prepare and provide blood and blood components for transfusion in the home environment. It states the roles, responsibilities and processes in each area, necessary to achieve compliance to the CSA Z902-04 standards, ultimately supporting standardized practice and enabling safe transfusion in the home environment.

In January 2010, the Canadian Standards Association (CSA) published an updated version of the *CSA Z902, Blood and blood components standard*. The Laboratory Standards Coordinator performed a detailed comparison of the CSA standards Z902-04 to Z902-10 and provided this document to the Provincial Territorial Blood representatives for use in their respective jurisdiction as well as to the Quality Specialists in the DHAs/IWK.

Three hundred and eighty-nine copies of the "Guide to Blood Component and Blood Product Administration" were distributed in October 2009 to the DHAs/IWK. The guide was designed as a quick reference flipchart to aid healthcare providers in the administration of blood and blood products. This project has been developed by the NSPBCP in collaboration with the Nova Scotia

Nurses Transfusion Practice Working Group and the Transfusion Medicine Quality Specialist Working Group. This education tool reflects the Provincial standard for the administration of blood components and blood products serving as a supportive tool to meet Accreditation Canada requirements, while promoting excellence in transfusion medicine.

4.2 Laboratory Information Systems-Blood bank

Medical Information Technology, Inc. (MEDITECH) was selected to provide the application system software for Nova Scotia hospitals (with the exception of the facilities managed by the Capital Health Authority and the IWK Health Centre). The development of the application is performed by Hospital Information Technology Services of Nova Scotia (HITS-NS) based on the direction provided by the DHAs.

The role of Acute and Tertiary Care Provincial Programs is to set and monitor standards that are provincial in nature. A Provincial program acts in an advisory capacity to Nova Scotia's Health System. It was recognized that as a Provincial Program there was an opportunity for the NSPBCP to support the development of applications and processes that would insure compliance of transfusion medicine standards. The DHAs supported the involvement of the NSPBCP in this process and subsequently a process has been established whereby the NSPBCP facilitates the development of recommendations to HITS-NS through the Quality Specialists Working Group.

During the period of April 1, 2009 to March 31, 2010 the Quality Specialists Working Group reviewed and advised on the following items:

- Interchangeability of Fresh Frozen Plasma and Frozen Plasma
- Bar Coding of components created by the Blood Transfusion Service using 128 Bar Coding and International Society of Blood Transfusion (ISBT)128 Bar Coding
- Patient Notification
- Prothrombin Complex Concentrate order entry build\
- 5% IVIG
- Infant Grouping Crossmatch

A framework for conducting an audit to review the documentation and processes developed prior to the NSPBCP's participation was endorsed by the Transfusion Medicine Advisory Group in March 2010. Cape Breton Regional Hospital and Yarmouth agreed to participate in the audit.

4.3 Emergency Planning

The Nova Scotia Provincial Blood Coordinating Program (NSPBCP) established the Blood Emergency Response Team (BERT) in 2004 as a mechanism to review emergent threats to the blood supply and to develop a response plan in order to minimize the impact to the health system. This team is comprised of members from Canadian Blood Services, the DHAs/IWK Health Centre, the Department of Health and the Provincial Blood Coordinating Program.

Nova Scotia's Blood Emergency Response Team (BERT) and DHAs/IWK requested that the NSPBCP develop a provincial blood contingency plan to ensure a consistent and coordinated response within Nova Scotia. The NSPBCP convened a working group, conducted an ethics session and liaised with key contacts within the Nova Scotia Department of Health (NSDoH) to ensure congruency with pandemic and Health Services Emergency Management plans. The NSPBCP presented the plan to the Senior Leadership Team (SLT) at the NSDoH and received endorsement to proceed with provincial consultations.

Upon receipt of the National Blood Contingency Plan, the NSPBCP conducted a gap analysis and further revisions were made to the Provincial Blood Contingency Plan. The provincial plan was disseminated in Nova Scotia in early April 2010.

The NSPBCP facilitated agreement for the redistribution of red blood cells between hospitals within Nova Scotia effective December 2, 2009.

The NSPBCP provided DHAs/IWK with a Blood Emergency Management Plan template. Effective March 31, 2010 3 out of 10 of the jurisdictions had implemented their BEMPs and 2 jurisdictions had their BEMP in draft.

4.4 Weak D Testing

In the fall of 2008 the Rh Program disclosed discrepant D typing on a patient; one facility reported the patient as Rh Positive and the second facility reported the patient as Rh negative. Both facilities reproduced their initial results and it was highlighted that variable testing and interpretation techniques exist in Nova Scotia.

The IWK and Rh program are developing a policy for the reporting and interpretation of D typing. The Quality Specialist Working Group has been advised of this initiative and supports the standardization of D typing and interpretation.

5.0 Communication and Coordination

The key objective of this component is to engage, educate, and inform stakeholders in order to support best practices in transfusion medicine.

5.1 Strategic Communications

The NSPBCP continues to keep stakeholders informed of NSPBCP activities through the bi-annual newsletter, “Blood Counts” (published in July and January), the quarterly IVIG Data Collection newsletters, reports and the NSPBCP’s webpage on the Department of Health website.

Additionally, when the NSPBCP is introducing a new initiative to physicians an article is submitted to the Doctors NS journal. The December 2008/January 2009 DoctorsNS publication contained an article titled “New approval process in place for IVIG requests” authored by the NSPBCP’s Utilization Management Coordinator. See Appendix 2.

5.2 Stakeholder Engagement

The NSPBCP supports a consultative and collaborative approach to the development of provincial standards. Working groups with provincial representation and various clinical expert perspectives are established in order to advise the NSPBCP on specific items. Some of the working groups that have been established include: Atlantic Collaborative IVIG Working Group, Adverse Event Investigation Working Group, Patient Services Working Group.

5.3 Feedback mechanisms

In the past fiscal year the NSPBCP distributed various reports and guidelines to the members of its various working groups, and the Vice Presidents and CEOs of the DHAs/IWK.

Report	Distribution Date	Distribution to:
NSPBCP Annual Report April 1, 2008 - March 31, 2009	February 3, 2010	CEOs DHAs 1-9/IWK VPs of Medicine DHAs 1-9/IWK VPS Patient Care DHAs 1-9/IWK Laboratory Managers DHAs 1-9/IWK Program Advisory Council Members Transfusion Medicine Advisory Group Members NS Nurses Transfusion Practice Working Group Members Transfusion Medicine Quality Specialists Working Group Members
IVIG Utilization in the Atlantic Provinces FY 2008/09	February 3, 2010	CEOs DHAs 1-9/IWK VPs of Medicine DHAs 1-9/IWK VPS Patient Care DHAs 1-9/IWK Laboratory Managers DHAs 1-9/IWK Program Advisory Council Members Transfusion Medicine Advisory Group Members Atlantic Collaborative IVIG Working Group NS Nurses Transfusion Practice Working Group Members Transfusion Medicine Quality Specialists Working Group Members
Red Blood Cell (RBC) Discards Report Q1 06/07 to Q2 08/09	February 15, 2010	CEOs DHAs 1-9/IWK VPs of Medicine DHAs 1-9/IWK VPS Patient Care DHAs 1-9/IWK Laboratory Managers DHAs 1-9/IWK Transfusion Medicine Advisory Group Members Transfusion Medicine Quality Specialists Working Group Members
NSPBCP Guidelines for Home Transfusion	February 18, 2010	CEOs DHAs 1-9/IWK VPs of Medicine DHAs 1-9/IWK Laboratory Managers DHAs 1-9/IWK Program Advisory Council Members Victoria Order of Nurses
NS Provincial Blood Contingency Plan	April 9, 2010	CEOs DHAs 1-9/IWK VPs of Medicine DHAs 1-9/IWK Laboratory Managers DHAs 1-9/IWK Transfusion Medicine Quality Specialists Working Group Members
Guidelines and Toolkit for Massive Transfusion in Nova Scotia	November 30, 2010	CEOs DHAs 1-9/IWK VPs of Medicine DHAs 1-9/IWK Medical Directors BTC DHAs 1-9/IWK Laboratory Managers DHAs 1-9/IWK Transfusion Medicine Advisory Group Members NS Nurses Transfusion Practice Working Group Members Transfusion Medicine Quality Specialists Working Group Members

In January 2009 the NSPBCP received approval from the DHAs/ IWK to unmask the names of the DHAs/IWK in reports.

5.4 Data collection processes

The HITS-NS Service Delivery Manager conducted an IT/IM review of the NSPBCP based on the COBIT model. In general the review was positive with some recommendations including moving databases from Microsoft Access. As a strategy to introduce better ways to obtain quality data, the Nova Scotia Provincial Blood Coordinating Program (NSPBCP) has successfully implemented a web-based program called the Data Information and Storehouse Initiative (DaISI). In Nova Scotia this method has replaced Excel spreadsheet and fax data collection processes and Nova Scotia has seen benefits to data quality and improvements to the ease and efficiency for facilities sending immune globulin (Ig) blood product usage data to the NSPBCP.

Work is underway to expand this approach to Ig data collection into New Brunswick, Newfoundland and Prince Edward Island. This expansion has resulted in a revised Privacy Impact Assessment, performance of a Threat Risk Assessment and revision to our data sharing agreements with the other Atlantic provinces.

The NSPBCP is pursuing extracts/linkages with DHA health information systems. In collaboration with the HITS NS Service Delivery Manager the NSPBCP has implemented activities to support compliance with Bill 89 (incorporated data auditing capability in some of our technologies (i.e.: DaISI has been upgraded to audit data access to a large degree) and upgrade to new technologies (i.e.: Microsoft SQL Server 2008) with better auditing and encryption capabilities.

References

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6. Transfusion Clinical Biology (2001;8:278-281)Transfusion and risk of infection in Canada: Update 2006. Pediatrics & Child Health, 2006;11(3), 158-162

Appendix 1 Recombinant Factor VIIa Classification

Labelled – Indicated (L)

rFVIIa is indicated (labelled) in hemophilia A/B patients with inhibitors to FVIII or FIX, respectively, for the treatment of bleeding episodes.

Unlabelled - indicated (UL-I) = patients with a diagnosis of:

- Congenital Factor VII Deficiency –
 - a. Prevention of bleeding in surgical interventions or invasive procedures in patients with congenital FVII deficiency
 - b. Treatment of bleeding episodes
- Hemophilia A/B with Factor VIII/IX Inhibitors
 - a. prophylactic use
- Acquired Hemophilia/Inhibitors –
 - a. May be indicated for patients who are severely bleeding, i.e. for patients in an acute crisis.

Unlabelled – not indicated (UL-N)-

rFVIIa is administered to patients to treat a factor deficiency other than Congenital Factor VII Deficiency, Acquired Hemophilia/Inhibitors or Hemophilia A/B with Factor VII/IX Inhibitors.

Unlabelled - supported by the framework (UL-S)

- Patient is massively bleeding
- Corrective measures have been taken prior to administration of FVIIa
 - a. 5 units of red blood cells
 - b. Plasma
 - c. Tranexamic Acid or DDAVP

Unlabelled - not supported by the framework (UL-NS)

- rFVIIa was the early intervention for the massively bleeding patient
- the patient was not massively bleeding and rFVIIa was used to correct a coagulopathy before a procedure.
- rFVIIa was given to the patient because they are Jehovah's Witnesses only.
- rFVIIa was administered to reduce a patient's INR