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Volume 1, Issue 1

Bloody Good News

Newfoundland and Labrador Provincial Blood Coordinating Program

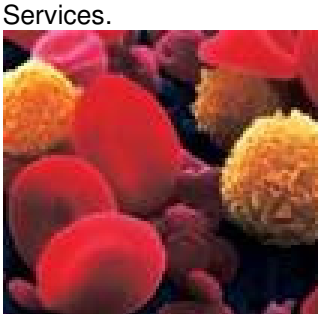
Special Interest Articles:

- Role of Nurses in Transfusion
- Febrile Non-Hemolytic Transfusion Reactions
- Quality Systems

Individual Highlights:

Program Celebrates First Year of Operation

The Department of Health and Community Services approved the establishment of a Provincial Blood Coordinating Program in December 2005. The MISSION of the Provincial Blood Coordinating Program is to develop through leadership and collaboration, the delivery of a safe and cost effective Transfusion Medicine Program for patients within the Health Care Environment of the Province. The keys areas in which the Program focuses its energy are utilization of blood products, surveillance of adverse transfusion reactions, and quality through standardization and implementation of policies that incorporate the CSA Standards for Blood and Blood Components. The Program staff includes Dr. Lucinda Whitman, Medical Advisor, Linda Orr, Utilization Technologist and Marilyn Collins, Program Manager. The Program reports to the Director of Board Services, John Rumboldt at the Department of Health and Community Services.

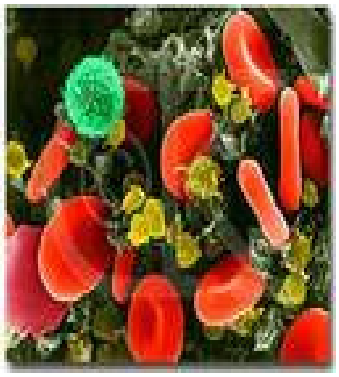


Standards for Blood Transfusion Services

In 2004, the Canadian Standards Association (CSA) developed and published the Z902-04 CSA Standards for Blood and Blood Components. An Expert working group consisting of specialists in the field of transfusion medicine developed these standards. Compliance with the standards will enhance the quality and safety of transfusion medicine and ensure that blood manufacturers and transfusion services follow a consistence approach to standardization.

The Canadian Society for Transfusion Medicine Standards for Hospital Transfusion Services provides a guide specific for hospital blood banks. (Visit CSTM at www.transfusion.ca) Currently all standards are voluntary compliance documents, however Health Canada is moving forward to a regulatory framework based on the CSA Standards. The Canadian Council on Health Services Accreditation provides an accreditation program that assesses the quality of services and is designed based on quality improvement principles while incorporating the CSA Standards. The CSA published ISO Standards for Medical Laboratories; specifically ISO 15189 developed to standardize quality management and technical issues on an international level as it relates to medical laboratories. Visit the CSA online store at www.shopCSA.ca

Blood Product Administration Guidelines



"Thy bones are marrowless, thy blood is cold."
Macbeth,
Act III, Scene IV

The Transfusion Policy Working Group developed the first Policy for Blood Product Administration. The working group consisted of members from nursing and laboratory directly involved in patient transfusion. The Policy was prepared using the CSA and CSTM Standards as a guide to ensure that compliance with the standards was met at all stages of development. The regional health authorities, through the Medical Director and Medical Advisory Committee and the CEO for the region approved the policy for each region. The policy provides work aids that can be posted on the nursing units and referred to when an adverse event is suspected. Pocket cards listing the signs and symptoms of an adverse event and the algorithm for suspected transfusion reactions are available as a two sided card intended for quick reference. Job Aids and pocket cards are distributed when educational in-service sessions are conducted in each region. As a result the incidence of reporting adverse events has increased. The guidelines address such topics as informed consent, ordering blood products, roles of physicians and transfusionists, administration, transfusion of products, adverse event reporting and documentation. The policy will undergo its first revision soon and requests for changes are welcome.

Visit to Regional Health Authorities and Educational Sessions

Can you identify where this picture was taken?

The first year of the operation has been very rewarding with visits to all four Regional Health Authorities who received us most hospitably. It provided an opportunity to meet with senior officials from each of the Regional Health Authorities and offer insight into the Blood Coordinating Program mandate.

Hospital staff attended educational in-services sessions and the feedback was very encouraging. With each visit, we presented information to all available staff from nursing, laboratory and risk management. In Western Region, 49 staff attended sessions on Adverse Event Reporting from Western Memorial. We were unable to visit Stephenville and Port aux Basques at that time and hope to include them in the next visit.

Our visit to three sites in the Labrador Grenfell region brought 69 participants to sessions held over three days.

In March 2007, we visited Central Region on a two-day trip and had 12 participants in Gander and 19 in Grand Falls sites.

There was one visit to the Clarenville site, which included one-on-one training in Reporting IVIG data.

Discussions following the presentations indicated a keen interest in future educational opportunities. We look forward to annual visits with the senior administration of each of the regions as well as the important value of providing continuing education sessions in a variety of blood related topics.

An Educational Half Day held in February included participants from all four regions. Canadian Blood Services and the Association of Registered Nurses of Newfoundland and Labrador also attended. Plans are underway for a full day session for the fall of 2007.

The Nurse's Role in Transfusion Medicine

Nurses have had an important role in patient care for several hundred years. The nurse's role has evolved to include that of managing patients during transfusion as well as offering support and caring to ill patients.

As transfusion programs developed, nurses found themselves in a world of regulations and standards associated with blood product collection, storage and transfusion. Blood Banks or Blood Transfusion Services are responsible for transfusion practice and compliance to standards to ensure safety of the patient and the quality of the product.

Collaboration between BTS and Nursing is pivotal in ensuring guidelines are incorporated into policies and procedures.

Safe transfusion practice is accomplished through staff education. It is important that the Transfusion Committee include nurse educators to ensure nurses receive appropriate orientation, transfusion policy updates and competency assessments. To further promote transfusion safety, nurses also participate in transfusion practice audits identifying deficiencies and recommending corrective action. The nurse is an active team participant who guides safe transfusion practice.

Patient identification remains one of the most frequent causes of adverse events in transfusion medicine.

The Better Safer Transfusion (BeST) Program in Victoria, Australia offers a Post Graduate Certificate Program in Transfusion Practice.

ADHB Nurses

Intravenous Immune Globulin

Canadian Blood Services and Héma-Quebec distribute intravenous Immune Globulin in Canada. IVIG utilization is steadily increasing at an average rate of 11.8% since 1997/98. IVIG represents approximately 16.5% of Canadian Blood Services blood component and plasma proteins budget. The current cost of IVIG ranges between $51to $64 per gram, and an average treatment for a 70kg patient of 1g/kg body weight costs approximately $4000.00.

Newfoundland and Labrador is the third largest users of IVIG in Canada, using 119 grams IVIG per 1000 population.

In an effort to ensure that IVIG is available for patients when needed, a collaborative effort between Canadian Blood Services and the National Advisory Committee on Blood and Blood Products created an Expert Working Group whose mandate was to develop Guidelines for the Administration of IVIG for Hematological and Neurological conditions. These guidelines were recently published in Transfusion Medicine Reviews, Vol 21, No 2, April 2007.

The Newfoundland and Labrador PBCP is a member of the Atlantic Collaborative Working Group on IVIG Utilization. By collecting data and monitoring usage, it is possible to identify areas where utilization may or may not be the treatment of

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"One never notices what has been done; one can only see what remains to be done".
Oscar Wilde

Intravenous Immune Globulin cont'd

Did you know that 3.3 million dollars is spent on IVIG in Newfoundland and Labrador per year?

choice and whether dosing requirements are appropriate. By using the Administration Guidelines and the data collected, it is proposed to develop a standardized approval process for the administration of IVIG in Atlantic Canada. The PBCP released a report for 2006 on IVIG Utilization in NL.

Reactions to IVIG range between 3 and 15 % and are usually mildly or moderately severe. Reducing the infusion rate may minimize further reactions. There are various brands of IVIG and it is important to identify which products are best suited to a patient's condition. Products containing sucrose may affect renal function in certain patients while products stabilized with glucose may influence diabetic patients. Low sodium products may be more suited for patients diagnosed with hypertension, kidney problems or those requiring a low salt diet.

Stay tuned for more on other products in the next edition.

Adverse Transfusion Reactions

Blood administration is not without risk. Although many patients receive blood products without ever having an adverse event, it is important that the signs and symptoms of a transfusion reaction are understood and recognized. Since the Krever Inquiry into the blood system in Canada, staff education and recognition of adverse events has resulted in increased reporting in the health care system. Patient education is just as important so that the patient can recognize and report discomfort and symptoms to health care providers. There are many types of adverse reactions. Each edition of the newsletter will highlight a particular type of reaction as a means to provide awareness and education to the readers.

Febrile Non-Hemolytic Transfusion Reactions

In each newsletter, there will be an item on a different type of Adverse Transfusion Reaction

Febrile Non-Hemolytic Transfusion Reactions (FNHTR) have been reported for many years. FNHTR are typically characterized by an increase in temperature of more than 1^0C and are accompanied by chills, rigors, and a feeling of cold or discomfort. In many cases of FNHTR, there is no increase in temperature. Symptoms may present during the transfusion or up to 2 hours post transfusion. If a patient is receiving multiple components, the reaction may be attributed to the previous component, to the current product being transfused or result from a cumulative effect of the transfused products.

Infrequently transfused patients have an incidence rate of approximately 1% whereas patients frequently transfused demonstrate a frequency of reaction up to 10%.

FNHTR may be the result of antibodies directed to transfused leucocytes or platelets. The antigen-antibody reactions cause the phagocytes to release pyrogens that cause the fever. The presence of cytokines in stored blood products also contribute to FNHTR.

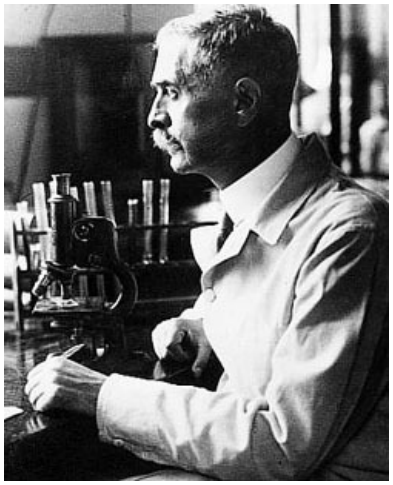
Febrile Non-Hemolytic Transfusion Reactions cont'd

Pre-storage leukoreduction and single donor plateletpheresis have reduced the number of reports of FNHTR. Patients may also have an underlying condition that may cause sporadic temperature increases, thereby making the diagnosis of FNHTR difficult.

The diagnosis of FNHTR is generally one of exclusion as there are no specific tests to confirm the diagnosis. It is important to recognize that fever is also a symptom of a hemolytic reaction which should therefore be excluded.

The transfusion should be stopped. A check should be performed to ensure the right product was transfused to the right patient. The patient's post-transfusion plasma should be checked for hemolysis and a direct antiglobulin test should be performed. Fever is also a symptom of sepsis from a bacterially contaminated component as well as a symptom of Transfusion Related Acute Lung Injury (TRALI). Pre-treatment of the patient with anti-pyretics is often controversial and is not recommended by many as it could mask the presence of fever and the root cause of a more severe transfusion reaction.

Patients exhibiting a fever may be treated with aspirin if there is no history of thrombocytopenia. For those patients with platelet disorders acetominophen or non-steroidal anti-inflammatory agents (NSAIDS) may be used to relieve symptoms. Antihistamines offer no prophylactic support in FNHTR. Patients exhibiting rigors may be treated with meperidine.



This polio researcher was best known for identification of blood groups. Who is he?

CASE STUDY

An 80 yr old female diagnosed with lumbar spinal stenosis. The patient was previously transfused more than 3 months ago. The patient's blood group was O Pos. The patient was not immuno-compromised. The patient was not premedicated prior to transfusion. The patient was receiving Ramipril. The patient's pulse prior to transfusion was 80 and the blood pressure was 105/55. The patient was not transfused under anesthesia. The patient received one unit of red blood cells and half of a second unit when she developed symptoms of a transfusion reaction. The transfusion was stopped. Vital signs indicated a pulse of 62 and blood pressure of 68/33. The patient's blood pressure returned to 115/54 within 10 minutes of stopping the transfusion. The blood product was negative upon culture. The patient was treated with Ringer's lactate. No other interventions were required. The adverse event was not reported to the blood supplier but was reported to PBCP.

1. *What type of reaction was this?*
2. *What was the relationship of the adverse event to transfusion?*
3. *What was the severity of the reaction?*
4. *Did the outcome have major or minor sequalae?*

Each newsletter will contain an interesting case study for you to review. The type of adverse event will be discussed in the next newsletter.

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QUALITY SYSTEMS

Health Canada regulates the manufacturing industry in Canada and this includes blood and blood components. In order to ensure quality objectives are met, personnel from various departments in an organization are responsible for the safety and quality of the products produced. The basic concepts of **Quality Assurance, Good Manufacturing Practices** and **Quality Control** are inter-related.

Quality Assurance is defined as activities that involve quality planning, control, assessment, reporting and improvement necessary to ensure a product or service meets defined standards and requirements.

Good Manufacturing Practice is part of quality assurance that ensures drugs are consistently produced and controlled in such a way to meet quality standards appropriate for intended for use.

Quality Control is defined as operational techniques and activities used to monitor and eliminate causes of unsatisfactory performance at any stage of a process

The International Organization for Standardization (ISO) quality management standards (ISO9001) are applicable for any industry and describe key elements of a quality system or quality system essentials (QSE).

The CSA Standards for Blood and Blood Components are written to enhance the quality and safety of blood collection, processing and transfusion. These standards incorporate applicable quality systems essentials.

Remember Ford Motor Company's logo: "Quality goes in, before the name goes on". This logo captured the essence of a Quality System.

Stay tuned for more on Quality Systems in our next edition.

About Our Program...

If you have a topic that you would like highlighted in our newsletter please feel free to contact us at our e-mail address.

If you would like to share an interesting case that has occurred in your laboratory or clinical setting, please contact us and we will be delighted to print it for you. Just mail the information to us at the address below.

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