2011 - 01
Volume 5, Issue 1

Bloody Good News

Newfoundland and Labrador Provincial Blood Coordinating Program

Special Interest Articles:

- Blood Warmers
- How New Blood Products Enter the Blood Supply

Individual Highlights:

Annual Provincial Reports on IVIG Utilization, Adverse Events and Blood Component Utilization

The Provincial Blood Coordinating Program (PBCP) staff has been working diligently to finalize our annual reports.

This will be our third set of reports that provide provincial insight into the blood program in Newfoundland and Labrador. The data collected by the Transfusion Safety Officers provides the PBCP with statistics that have the potential to identify where we spend our health care funds to the best of our collective responsibility.

As health care providers, we must all assume some element of accountability for the utilization, administration and product loss of these expensive products. The blood program in NL accounts for approximately $25 million dollars of the health care budget. The ever increasing demand for quality health care for the first wave of baby boomers and an already aging population, as well as increased diagnosis of long term illness, will continue to require increased financial resources to better manage health care in NL and Canada.

The Regional Health Authorities (RHAs) Chief Executive Officers, VP of Medical Services, Risk Managers, Directors of Laboratories and Nursing, Transfusion Committee Chairs and the Transfusion Safety Officers will receive copies of these reports. Please take the time to review these reports and direct your questions to the Program. The staff of the PBCP will be visiting the RHAs throughout the year to provide in service education to staff related to utilization and transfusion activities.

Auditing Transfusion Related Practices

The Provincial Blood Coordinating Program is in the process of developing audit tools to assist in assessing compliance to various blood component and blood product guidelines.

Auditing processes provide valuable information as a snapshot of routine daily activities. They also provide data that may influence or change current practices leading to efficiencies and better utilization of valuable resources.

The first audit tool will evaluate the Utilization of Intravenous Immune Globulin Request Approval Process and the IVIG Administration Guidelines as IVIG use continues to increase throughout the province of NL as well as the remainder of Canada.

The first draft of the audit tool was circulated to a small group and is going through its first draft revision. The audit tool will review the request approval form for completeness and accuracy in requesting products, reviewing the indications for use of IVIG to ensure the product use is for licensed indicated conditions as well as identify prescribing practices and explore the reasons for product wastage and product discards.

The audit tool will be available to the Regional Health Authorities by April 2011.

The next audit tool to be developed will be for compliance to the Inter Hospital Transfer Program as we continue to experience unusually high rates of outdated red blood cells in certain regions of the province.

Other audit tools to be developed will focus on compliance to blood administration guidelines, reporting adverse events. These tools will help identify gaps in information gathering that prompt repeat requests for complete reporting.

Pathogen Reduction

Dr Ken Jenkins serves as Vice President Medical Services with Western Health, in Corner Brook, NL.

Dr. Jenkins served 20 years with the Canadian Forces in several roles including operational flight surgeon, Wing/Base Surgeon in Goose Bay, NL and Ottawa, ON, Senior Medical Officer in Geilenkirchen, Germany, Command Surgeon for the Air Force and Wing Commander at 9 Wing Gander. He served as Honorary Colonel for 103 SAR Squadron in Gander, NL from 2006-2010.

Dr. Jenkins is a member of the Transfusion Medical Advisory Group for the PBCP.

"I'm so optimistic I'd go after Moby Dick and take the tartar sauce with me".

Hilary Hinton "Zig" Ziglar Nov 6, 1926 to present American author, salesperson and motivational speaker

At our recent Transfusion Symposium in November 2010, one of the topics presented was "Reducing Pathogenic Risk", so we thought we would share some aspects of this presentation with you.

As we are aware blood components are capable of carrying pathogens, some of which include HIV, HCV, Malaria and West Nile Virus just to name a few. Blood donations are routinely tested for many known pathogens but there are still pathogens for which there are no tests available on a large scale. There are many existing pathogens as well as re-emerging pathogens, and blood suppliers have applied many mitigation strategies to date to reduce known pathogens. Some of these include bed side leukoreduction, leukodepletion processes, sample diversion pouch on blood collection systems, bacterial testing, buffy coat production process and irradiation.

There are now several Industry leaders who have developed or are in the process of developing systems whereby pathogen reduction occurs by the exposure of blood components to ultraviolet light and chemicals, detergents, dyes and visible light. The nucleic acids found in bacteria, parasites and viruses are modified by exposure to these agents thus preventing replication of the pathogens in the blood components.

However, not all blood components can be treated with all methods. The components are impacted by these treatments, however the therapeutic quality of the components continue to meet acceptable standards.

Pathogen reduction technology will eventually become the standard as improvements continue to be made to existing technologies and new opportunities arise to improve the safety of the blood supply.

Blood Warmers

Knowledge and appropriate use of blood warmers are required in sustaining quality in transfusion medicine services. Blood warmers are designed to warm blood safely and administer blood at routine and low flow rates.

The blood warming devices in transfusion medicine vary depending on the heating system used to increase the temperature of blood being transfused to core body temperature.

The warming device must be approved by the FDA and meet CSA standards for use. According to the CSA standards, a visible thermometer and temperature alarm device are required as well as regular calibration and validation of the blood warmer. The warming device must be properly maintained in accordance with the manufactures and hospital policy as part of quality system controls for transfusion equipment.

Routine transfusions seldom require blood warmers as they are small volume transfusions and rarely cause physiologic instability. Blood warmers are necessary for massive transfusions. Their use helps prevent hypothermia, complications of hypothermia, hemolysis and / or other damage to the red blood cells being transfused. Occasionally, blood warmers are required in patients with a potent cold agglutinin and exchange transfusion of an infant. Blood warmers are commonly used in Surgery, Intensive Care Units and Emergency Rooms.

Blood warmers should be cautiously used, as they are not without risk. There is a potential for the warmer to malfunction, overheat or have mechanical failure. This could cause thermal injury to the red blood cells and if improperly warmed cause bacterial growth, potentially harming the recipient of the blood component.

Due to the variety of blood warmers available, they should be used according to the manufacturer instructions.

Healthcare professionals and consumers are encouraged to report any product adverse incidents to the manufacturer and/or Health Canada at http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/index-eng.php

New Blood Products in 2010

There are always new and exciting blood products introduced into our laboratory inventory. In October of this year Berinert® (C1 esterase inhibitor, Human), now a licensed product in Canada, was made available from Canadian Blood Services.

This product is indicated for the treatment of acute abdominal or facial attacks of hereditary angioedema (HAE). In hereditary angioedema C1 esterase inhibitor (C1-INH), a naturally occurring blood protein is present in low levels or the protein does not function properly. Low or non-existing C1-INH can cause spontaneous episodes of swelling in the body as well as pain and discomfort. This disease can be fatal if the swelling occurs in the throat area.

Berinert® prepared from a large pool of human plasma contains C1-INH, which replaces the missing or malfunctioning protein in patients with HAE. By increasing the level of functioning C1-INH in a patient, swelling can be alleviated or prevented during an HAE episode or prior to a surgery. Berinert® is administered intravenously at 20 U/kg and at a rate of 4 mL/minute.

For further information with regard to this product, the full product monograph should be read and is available at http://www.cslbehring.ca .

There are also products introduced that help simplify preparation and reduce the volume and the number of vials that are needed for a larger dose.

Humate P® Antihemophilic Factor (Human) and von Willebrand Factor Complex (Human) high strength became available in January and Humate P® medium strength is now available in 1000 and 2000 IU. Humate P® is approved by Health Canada for the indication in von Willebrand disease to prevent excessive bleeding during and after surgery for both adult and pediatric patients.

Kogenate ® FS antihemophilic Factor (Recombinant) is now available in a 3000 IU vial. Gammagard liquid (Immune Globulin Intravenous) 10% solution is now available in 30g/300ml size.

Niastase RT® (rFVIIa) is a new formulation that will replace the Niastase® formulation and makes treatment more convenient and accessible. Niastase RT® is available in 1, 2 and 5 mg vials and stable at a wide temperature range including room temperature (2°-30°C) until product expiry.
It is important to remember that when these products are introduced, that the product monograph is read so that all medical professionals are aware of the implications these products will have on patients.

Introducing New Blood Products into the Blood Supply

Have you ever asked how blood products enter the health care system?

There is a very well designed mechanism to ensure that the health care of Canadians incorporates new drugs and blood products into its treatment options.

Health Canada works with various levels of government, health care professionals, research, and manufacturers to provide a regulatory environment for many products. Blood products are considered Schedule D drugs and must be approved for use by Health Canada through the Biologics and Genetics Therapies Directorate (BGTD). The products regulated by BGTD include blood and blood products, viral and bacterial vaccines, gene therapy products, tissues, organs and xenografts, which are manufactured in Canada or elsewhere.

Before a product receives approval for use, the manufacturer must provide scientific evidence indicating the safety, quality and efficacy of the product in order to determine that the benefits outweigh the risks.

The pathway includes pre-clinical studies, clinical trials, regulatory product submission (New Drug Submission – NDS), a submission review by the Health Products and Food Branch. If it is determined that the product is beneficial, a Notice of Compliance (NOC) or a Drug Identification Number (DIN) is issued to the manufacturer.

Blood and blood products do not require a DIN. Canadian Blood Services (CBS) is one of the manufacturers of blood products in Canada and must follow this process.

The next stage in the process is public access which includes labeling, public databases, price review and funding. The product label contains important information for consumers. The Common Drug Review process assesses new drugs for possible coverage by various Federal and Provincial / Territorial drug benefit plans. The Canadian Agency for

Upcoming Events:

- CSTM Annual Conference
  May 12-15, 2011
  Toronto
- Massive Transfusion Consensus Conference
  June 9-11, 2011
  Toronto
- CSMLS LABCON 2011
  June 10-13, 2011
  Toronto

Introducing New Blood Products into the Blood Supply

The **National Advisory Committee on Blood and Blood Products** is a group of Canadian experts with interests and expertise in the field of Transfusion Medicine. The members provide advice on issues affecting transfusion medicine within the hospital environment. They assist in providing information to the Provincial and Territorial Ministers of Health on cost effective utilization management of blood products that optimize patient care.
Visit NAC at
http://www.nacblood.ca

Drugs and Technologies in Health (CADTH) assess a drug's cost effectiveness by conducting evidence based clinical and pharmaco-economic reviews.

The Provinces and Territories are responsible for the management and funding the health care system which includes managing publicly funded drug formularies and in some instances limiting coverage for particular cases.

Once CBS receives approval or NOC, the Provinces and Territories decide on the funding approach.

In some cases, Health Canada will permit access to some drugs or products not authorized for sale in Canada through the Special Access Programme (SAP).There are guidelines for accessing these products in order to provide care on a case-by-case basis. The manufacturer makes the final decision whether or not to supply the drug. In some cases the cost of the drug may not be covered by insurance.
Health Canada through its many branches monitor the product's safety and effectiveness for the life cycle of the product's use in Canad and may require recall or withdrawal of the product if it fails to meet standards or provide the desired effect. Adverse events should be reported
to the National Adverse Reaction Centre.

Through international collaboration, the Health Products and Food Branch (HPFB) continue to participate and contribute to the global harmonization of drug regulation.

Case Study #11

An 85-year-old female hematology patient required a blood transfusion during her chemotherapy treatment. The patient was immune-compromised and had received previous transfusions within the past three months. The patient's ABO and Rh group was A positive.

The patient's vital signs were stable prior to the start of the transfusion. Two hours into the transfusion of A positive Irradiated red blood cells, the patient presented with shortness of breath, hypoxemia, increased jugular venous pressure and her blood pressure increased from 120/78 to 134/74.

The transfusion was stopped. A chest x-ray was ordered, diuretics, antibiotics, and supplementary oxygen was administered. The diuretics were effective.

1. Classify type of reaction

2. What was the relationship of the adverse event to the transfusion?

3. What was the severity of the reaction?

4. What was the outcome of the adverse event?

Case Study #10 Interpretation

1. *Type of Reaction – Severe/Anaphylactic Reaction*
2. *Relationship of adverse event to transfusion – Probable*
3. *Severity of the reaction –Grade 2 (Severe)*
4. *Outcome –Minor*

Each newsletter will contain an interesting case study for you to review. The type of adverse event and answers to the questions will be provided in the next edition of the newsletter.

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We're on the Web!
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http://www.health.gov.nl.ca/health/bloodservices/index.html