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Volume 3, Issue 1

Bloody Good News

Newfoundland and Labrador Provincial Blood Coordinating Program

Special Interest Articles:

- Adverse Event Education Day
- TSO Breaks Ground
- Blum Award Recipient

Individual Highlights:

Adverse Event Education Day / TSO Conducts Grand Rounds

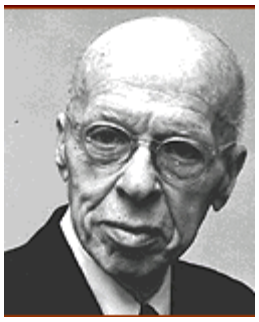
Our third Adverse Event Education Day was held November 21, 2008. The program for the day included a presentation by Ms. Cindy Hyson, Manager of Transfusion Transmitted Injuries Section of the Public Health Agency of Canada. Cindy's presentation placed adverse event reporting in perspective for those who are the front line reporters. Linda Orr presented case studies representative of data reported to the program and some of the challenges encountered in receiving incomplete data. The event was well attended with representation from each of the regional health authorities.

Barbara Chaulk is the Transfusion Safety Officer for the Western Regional Health Authority. On October 31, 2008, Barb as she is favorably known conducted Medical Grand Rounds to 31 attendees of whom 18 were physicians at Western Memorial Hospital in Corner Brook. Her topic was "Transfusing is Risky Business". The highlights of her presentation were: Risks due to Human Error (included a recent newspaper report of a death); Risks with Platelet Transfusion (included a newspaper report of a death); Transfusion Reactions and their Symptoms; Risks & Complications of Massive Transfusions; Iron Overload – Detection, Cause, Complications, Treatment and a Case Study; Alternatives to Transfusing; and Responsibilities of Physicians, Nurses and Laboratory Staff to Reduce the Risk. Congratulations to Barb for taking on this initiative to raise awareness of Transfusion Safety.

New Products – Privigen® and Vivaglobin® (Subcutaneous IG)

Privigen® is a new IgG intravenous immune globulin, that will be available from Canadian Blood Services in 2009. Developed by CSL Behring for the treatment of Primary Immune Deficiency (PID) conditions, Secondary Immune Deficiency (SID) conditions and chronic Immune Thrombocytopenia Purpura (ITP), it is prepared from large pools of human plasma. Privigen® is supplied as a sterile, ready-to-use 10% protein liquid preparation for IV administration. A four-step process used during manufacturing reduces the risk of virus transmission. A new feature of Privigen® is room temperature storage. Privigen® can be stored up to 25°C until expiry, therefore it is readily available for administration. As Privigen® contains no preservatives; unused product should be discarded upon completion of the infusion. With the addition of L-proline as a stabilizer, formation of IgG dimers (which affect product tolerability) is decreased by 30% compared to other IgG products formulated with glycine. The usual dose of Privigen® for PID and SID conditions is 0.2g to 0.8g/kg body weight administered every 3 to 4 weeks. Patient response to therapy should be monitored by serum IgG trough levels. The usual dose for chronic ITP patients is 1g/kg body weight for two consecutive days. The recommended initial infusion rate of Privigen® for all patients is 0.5 mg/kg/min or 0.005 ml/kg/min. If the infusion is well tolerated, the rate for PID and SID patients may be gradually increased to a maximum of 8 mg/kg/min and for chronic ITP patients to a maximum of 4 mg/kg/min. Privigen® should not be infused with other preparations. The most common adverse reaction reported by patients was headache. Privigen is available in 5g (50ml), 10g (100ml) and 20g (200ml) bottles. See product insert for contraindications.

New Products – Privigen® and Vivaglobin® (Subcutaneous IVIG)



Do you know this Mt. Sinai surgeon who developed the citrate method of blood transfusion?

Vivaglobin® Immune Globulin Subcutaneous (SCIg), a new product from CSL Behring, is administered subcutaneously in patients with primary immune deficiency. Supplied as a sterile liquid, it is a 16% protein solution containing at least 96% IgG and contains no preservatives. SCIg must not be mixed with other products. SCIg is administered weekly by subcutaneous injections in the abdomen, thighs, upper arms and/ or lateral hip. SCIg should not be injected into a blood vessel. Patients should start treatment with Vivaglobin® one week after receiving a regularly scheduled IVIG infusion. It is recommended that the initial dose be calculated by multiplying the previous IGIV does by 1.37, then dividing this dose into weekly doses based on the previous IGIV treatment interval. The recommended weekly dose is 100 to 200 mg/kg body weight. A target serum trough level is at least 500mg/dL.

SCIg can be administered in the home setting provided protocols have been put in place that comply with the CSA Z902-04 standards for home transfusion. Patients require training by hospital staff prior to infusing the product themselves. Patients must also be aware of and report any / all adverse events should they occur. Equipment such as infusions sets, syringes and pumps may require funding through third party insurance depending upon how the program is funded within the regional health authorities for each province. It is important that serum IgG levels are monitored regularly so that the patient receives the intended benefit.

The product is available in single use vials in 3mL, 10mL and 20mL vials.

IVIG Utilization Management – Product Discards

Newfoundland and Labrador continues to be a high volume user of IVIg, third nationally and first within the Atlantic region. With a manufacturer's cap of five percent over fiscal year (FY) 2007/08 national purchases, an annual growth rate of ten percent and a limited global supply, future shortages of IVIg may become a reality. Therefore, it is imperative to address the discard rate of IVIg.

The rate of discarded product varies considerably across the country.This indicates that product management and utilization practices also vary and asks what the differences are in IVIg management across the provinces and territories.

As the cost of IVIg is dependant upon various conditions, i.e. market cost and availability of the product and the market value of the Canadian dollar, the amount of product discarded has a impact on provincial costs.

One of the reasons for discarding product was breakage. The question should be asked whether transporting product from the lab to the floor in a tray or basket, reduce the amount broken. Product spiked but not transfused was another reason for discarding reconstituted IVIg. Why? Did the patient experience an adverse reaction? Did the physician adjust the dosage after the product was reconstituted? Another reason for discarding product was incorrect reconstitution of the IVIg. Review of the directions prior to reconstitution may eliminate this situation. As IVIg usually has an expiration date of greater than one year when received at the hospital, careful product management, with an emphasis on stock rotation, should prevent product loss due to expiration. Redistribution of near outdate product from a smaller site to a larger utilization site will also reduce product expiration.

As a member of the four province Atlantic Collaborative IVIg Utilization Working Group, the Newfoundland and Labrador Provincial Blood Coordinating Program submits utilization data quarterly that captures product discards based on eleven discard reasons and six locations where IVIg administration occurs.

Regional Health Authorities are continually challenged to reduce the amount of IVIg discarded in an effort to avert any future product shortages.

"Leadership is practiced not so much in words as in attitude and in actions".

Harold Geenan, Chairman, International Telephone and Telegraph Corporation

The Risk Manager's Role in Transfusion Medicine

The patient is at the centre of risk management as it relates to transfusion of blood components and blood products. The outcome of clinical events and the management of those risks, affect the transfusion chain. The transfusion chain consists of many elements from donor to recipient and forms the basis of hemovigilance. Risk management is part of the overall quality system within the hospital setting of which hemovigilance and surveillance are components. It involves the collection of information, monitoring and evaluation of the effects of transfusion, whether expected or unexpected, desired or undesired.

The Risk Manager, a key participant in Transfusion Committee reports on transfusion events, outcomes of events whether adverse or favorable and the impacts on processes and procedures. The Risk Manager should have a good understanding of the classifications of severity of adverse events as well differentiating incidents, errors and accidents as defined in the Adverse Event Users' Manual. Corrective and preventive measures may be required or those already in place may need to be reinforced through further education or review of policies and procedures. The Risk Manager should use the data published by the Public Health Agency of Canada to support its actions in an effort to promote safe transfusion practice. By creating an effective network of physicians, nurses, laboratory and administrative staff who have a positive attitude toward error management, data can be collected, analyzed, evaluated and shared thus enhancing the transfusion chain while at the same time promoting surveillance and good quality management practices. The Risk Manager is more likely to identify changes in transfusion practice through the error management system as well as recognize trends that may signal pending risks. The Risk Manager can also positively influence practice by reporting on events that clearly demonstrate that the changes made, have reduced the potential for adverse events to occur. Hemovigilance is a good approach to risk management.

A French decree in January 1994 declared hemovigilance as an essential part of transfusion safety and defined as:

"All the surveillance procedures, starting with the collection of blood and its components up to and including the follow-up of transfused patients, which aim to collect and assess information concerning the unexpected or adverse effects due to the use of labile components and to prevent their taking place."

CSTM Blum Award

Marilyn Collins, Provincial Program Manager, was the recipient of the 2008 Edna Blum Award presented by the Canadian Society for Transfusion Medicine. Her peers recognized Marilyn for her commitment to the Society. She has served three 2-year terms as Eastern Director on the CSTM Board during which time she piloted the development of a manual for the CSTM Editorial Board and website. Later as a member of the CSTM Standards Committee, she was involved in the development of the "*CSTM Standards for Hospital Transfusion Services*", version 2. Marilyn continues to serve on the CSTM Standards committee for another term. She is currently a member of the Board of Directors (Eastern) with the Canadian Society of Medical Laboratory Scientists.

CSTM will celebrate 30 years as a society whose mission is to promote and support best practices in Transfusion Medicine in Canada. This special event will take place in Ottawa from June 4-7, 2009. Make your reservation soon to be a part of this milestone in Transfusion Medicine. See link: ----------→

To join the Society visit: http://www.transfusion.ca/new/downloads/Eng-CSTM-member-brochure-05.pdf

CSTM will celebrate its 30th Anniversary in Ottawa, June 2009. Visit: http://www.transfusion.ca/new/meetings/2009/index.html

Hypotensive Transfusion Reaction

The hypotensive transfusion reaction results in a precipitous drop in systolic and/or diastolic blood pressure of greater than 30mm Hg. and may be accompanied by facial flushing, GI symptoms, dyspnea, hypoxemia, bradycardia, syncope and nausea. The reaction usually presents within minutes of the start of the transfusion. Treatment usually consists of stopping the transfusion, administering a bolus of normal saline and providing circulatory support. There are many theories associatied with this type of reaction. Transfusing blood components through negatively charged bedside leukocyte reduction filters appears to generate production of labile vasoactive proteins such as bradykinin (BK). Defects in BK metabolism, either inherent or drug induced (ACE inhibitors), interfere with the normal degradation of BK allowing an accumulation of BK in the blood. As BK is degraded effectively in the lungs, use of the heart-lung machine during CABG surgery is also thought to be a cause of a hypotensive reaction. To reduce the number of hypotensive reactions, it is advisable to use pre-storage leukocyte reduced blood components. For patients receiving ACE inhibitor therapy, it is recommended to discontinue the medication 24-48 hours prior to transfusion.

Answer from Issue 3
Do you know the viral researcher who co-discovered HIV and went on to identify the virus that causes human T-cell leukemia?
Robert Gallo

Case Study #5

This case involved an 82-year-old female immuno-compromised by lymphoma and chemotherapy. The patient was not pre-medicated but had been transfused within the past three months. Approximately 50ml. Gammagard S/D had been infused between 1745h and 1840h when patient exhibited signs of an adverse reaction: hypertension (BP 110/70 pre, 165/88 post), ↑ temp (37.3 pre, 39.0 post), ↑ pulse (72 pre, 100 post), chills & rigors, SOB, anxiety, confusion, wheeze, stridor and cyanosis. The transfusion was stopped and the patient was treated with antihistamines, steroids, antipyretics, diuretics, vasopressors, bronchodilators, Ativan, Ventolin, Lasix, supplemental O^2 and transferred to ICU. The patients vital signs were relatively stable by 2400h.The patient succumbed to a cerebral hemorrhage three days later. The adverse reaction was reported to the PBCP and the Atlantic Regional Adverse Reaction Centre, Halifax.

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 #4 Interpretation

1. *Transfusion Associated Circulatory Overload (TACO)*
2. *Relationship of adverse event to transfusion – probable*
3. *Severity of the reaction – Grade 2 (severe)*
4. *Outcome – Minor or no sequelae*

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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