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Bloody Good News

Newfoundland and Labrador Provincial Blood Coordinating Program

Special Interest Articles:

- Fibrogammin ® P: A Treatment for a Rare Bleeding Disorder
- Improvements in the Provincial Red Blood Cell Outdate Rate

Individual Highlights:

A New Year Begins – Welcoming Change in 2013

As the New Year begins, we reflect on the many achievements of the past year and strike new objectives for the year approaching. We begin the New Year saying farewell to one of our employees – Cheryl Jacobs, who is embarking upon a new aspect in her nursing career, as patient navigator in Palliative Care. Cheryl has worked hard over the past three years to develop and finalize the Best Practice Resource Manual for Nurses. Cheryl developed many documents with the Nursing Working Group and has advanced the appropriate utilization of blood and blood products throughout her time with the Program. We wish Cheryl the best of luck in her new career path.

Daphne Whalen-Brake assumed the role of Transfusion Practice Coordinator Jan. 21, 2013.

We are also going to bid farewell to Sharon Linehan early in the New Year as Sharon will be returning to a position at Eastern Health. Sharon has been successful in her endeavors to reduce red cell component wastage through the inventory management project. After discussions throughout the Regional Health Authorities, Sharon worked to develop minimum and maximum inventory and reorder levels for various hospitals.

The search for a successor for Sharon is underway and an announcement will be forthcoming.

'Quality Consciousness'

Quality care is a fundamental part of Transfusion Medicine, yet despite our best efforts transfusion therapy is not without risk. Complications continue to be reported throughout the transfusion process, ranging from mild to life threatening, and occur within minutes, days or weeks post transfusion.

Healthcare providers in Transfusion Medicine need to be aware of and understand the importance of quality in Transfusion Medicine to establish, maintain and improve the quality and safety of transfusions for all recipients. As healthcare providers, we need to develop a 'Quality Consciousness'. Consciousness, according to Stedman's Medical Dictionary, 28th Edition, is defined as "*a state of being aware or perceiving physical facts or mental concepts; a state of general wakefulness and responsiveness to environment".* Thus, 'quality consciousness' of Transfusion Medicine would involve an increased awareness of oneself and the transfusion medicine environment (collection, processing, issuing, administration areas). It involves an increased awareness of transfusion standards, policies, standard operating procedures, best practice guidelines, possible adverse events and hemovigilance programs. It also involves aligning the quality practices, goals and vision of your facility with transfusion medicine quality practices, goals and vision. Attention should be focused on each transfusion procedure to ensure compliance, safety and quality care in Transfusion Medicine.

Education, awareness and self-reflection encourage healthcare providers to demonstrate increased personal judgment, skill and competency; attributes that contribute to improved patient outcomes and reduced transfusion events. Quality consciousness can involve a shift in healthcare providers' attitudes, an increased awareness of their own and others contribution to Transfusion Medicine, and lead to changes in transfusion practice, improvement in Transfusion Medicine and therefore, safe, quality transfusion care.

Pierre Charles Alexander Louis was the founder of medical statistics. Noting that there was no reliable data, he felt that medicine could become a science if there were sufficiently large numbers of observations that would lend the data to numerical analysis. His data collection led to analysis using statistical tables, which supported several publications.

His influence attracted foreign students and his numerical method was appreciated in the United States where the collection of detailed data and statistical analysis was growing and became a guideline for medical research.

Not everyone in Paris recognized his importance. He continued teaching at hospitals and became a member of the Academy of Medicine. In 1832, he became president of the Society for Medical Observation in Paris and as a result a similar society was formed in Boston.

From this developed the concept of the clinical-case conference.

Fibrogammin ® P: A Treatment for a Rare Bleeding Disorder

Factor XIII Deficiency is a rare inherited autosomal recessive bleeding disorder affecting one in several million people. Diagnosis is often based on the results of a Factor XIII assay laboratory blood test and a detailed review of the individual's family history. Individuals with this disease generally have less than 2% of the normal amount of Factor XIII, and as this level decreases the severity of the disease increases. Classical presentations of Factor XIII Deficiency are associated with severe bleeding (umbilical cord, joint, mucosal), spontaneous intracranial hemorrhages, poor and delayed wound healing, and spontaneous and recurrent miscarriages. The plasma derived FXIII concentrate Fibrogammin® P is one available treatment often used to control and prevent bleeding associated with Factor XIII Deficiency.

Fibrogammin® P is a concentrate of blood coagulation Factor XIII derived from human plasma. This fibrin-stabilizing factor is composed of total protein, human albumin, glucose and sodium chloride. It helps to strengthen and stabilize fibrin to prevent clot breakdown. Fibrogammin® P is supplied in lyophilized vials as a dry white powder and solvent solution, which requires reconstitution for use. It is available in a 250 and 1250 International Unit vial size.

Currently, Fibrogammin® P is an unlicensed product within Canada and is not commercially available. This product is only available by physician request through Health Canada's Special Access Programme.

The therapeutic indications for Fibrogammin® P include:

- Congenital deficiency of Factor XIII and resulting hemorrhagic susceptibility;
- Hemorrhages and wound healing disturbances;
- Hemorrhagic predisposition caused by acquired Factor XIII deficiency; and
- Supportive therapy in case of disturbances in wound healing.

Fibrogammin® P is contraindicated in individuals with hypersensitivity to the components of Factor XIII. Antihistamines and corticosteroids may be administered prophylactically in the case of patients with known allergies. In addition, caution should be exercised in recipients with recent thrombosis due to the fibrin stabilizing effect of Factor XIII.

The dosage (International Units/ Kilogram) and frequency of the administration of Fibrogammin® P should be individualized and based on body weight, laboratory values and patient clinical conditions. Fibrogammin® P administration requirements are:

- Administer at room temperature;
- Slow intravenous infusion at a rate not exceeding 4mLs/ minute;
- Infuse through separate intravenous line;
- Do not mix with other medications; and
- Follow facility guidelines.

It is recommended that treatment be monitored closely in patients receiving Fibrogammin® P with a Factor XIII assay. Any unused product is discarded as per facility policy. Patients are monitored for potential adverse reactions. The shelf life of Fibrogammin® P is 3 years stored at +2 to +8˚C. Do not use after the expiry date noted on the package or container.

Due to the lifelong risk of bleeding and severity associated with Factor XIII Deficiency, preventative treatments which include regular infusions of Fibrogammin® P are recommended as a prophylactic treatment.

Treatment of acute bleeding episodes require higher doses of Fibrogammin® P than for prophylactic treatment. Laboratory confirmation of the diagnosis is made by normal results of the coagulation screening and Factor XIII assays. The condition can also be defined by a clot solubility test.

For patients who receive repeated Fibrogammin® P treatments, it is important they be monitored for the development of inhibitors to Factor XIII by their clinical presentation and laboratory tests.

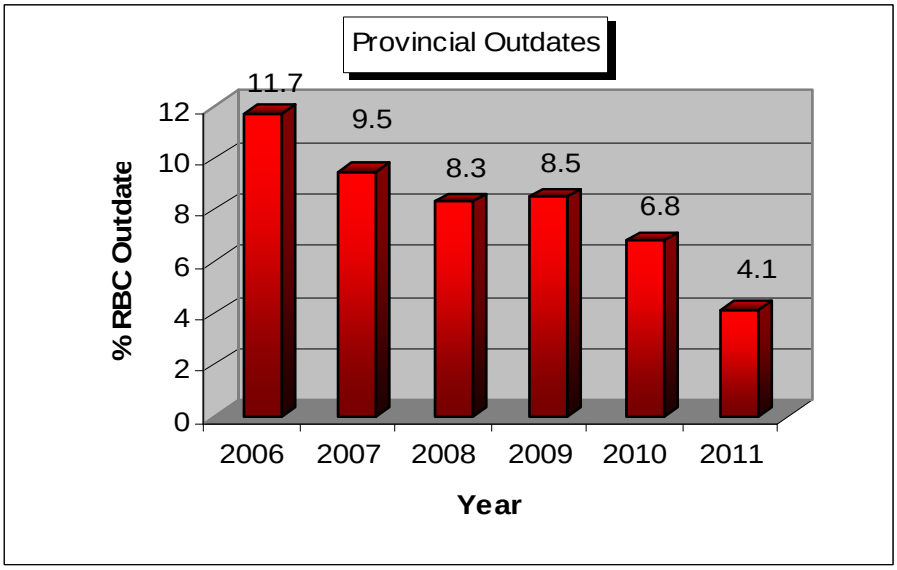
"We now accept the fact that learning is a lifelong process of keeping abreast of change. And the most pressing task is to teach people how to learn."

Peter Drucker

1905-2005

Improvements in the Provincial Red Blood Cell Outdate Rate

Congratulations to all laboratory technologists for their hard work in making positive changes to the inventory management practices. As a result of these changes, we have experienced a decrease in the provincial red blood cell outdate rate.



Improvement in our outdate rate can be attributed to a variety of inventory management practices made by facilities across the province. Facilities increased the number of Inter-Hospital Transfers of soon to be outdated red blood cell units and added compiling an expiry list to the daily task batch. Education for laboratory staff contributed to increased awareness of the importance of this resource to the residents of Newfoundland and Labrador. Good inventory management practices and appropriate utilization of blood components and blood products is essential for a safe and cost effective Transfusion Medicine Program.

It was great to see all facilities work together to improve the outdate rate. In the past six years, the NL outdate rate has decreased from 11.7% in 2006/07 to 4.1% in 2011/12. We have made progress, but there is room for improvement. We will continue to work with the facilities that continue to experience inventory management challenges. Once these challenges have been addressed, we hope to see further reductions in the outdate rate.

Fibrinogen Concentrate

Haemocomplettan® P is a human derived fibrinogen concentrate hemostatsis treatment. It is distributed by Canadian Blood Services under the name RiaSTAP® through Health Canada's Special Access Programme. RiaSTAP® is indicated for the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency which comprises afibrinogenemia and hypofibrinogenemia. It is available in single-use vials containing 900-1300 mg of lyophilized fibrin concentrate, 400-700 mg human albumin, 375-660 mg L-arginine hydrochloride, 200-350 mg sodium chloride and 50- 100 mg sodium citrate. RiaSTAP® should be stored at 2-25˚ Celsius and is stable up to the expiration date indicated on the vial label.

The recommended dosage (mg/Kg body weight) should be individualized and depend on the extent of bleeding, plasma fibrinogen level and body weight. When the baseline fibrinogen level is not known, the recommended dose is 70 mg/Kg body weight. RiaSTAP® administration requirements are:

- Intravenous infusion at room temperature at a rate not to exceed 5mLs/ minute;
- Administer through separate infusion site;
- Do not mix with other medications;
- Do not use after expiry date;
- Recipient fibrinogen level monitoring during treatement is recommended (target fibrinogen level of 100 mg/dL should be maintained); and
- Administer under Physician supervision.

RiaSTAP® is contraindicated in recipients who have a known hypersensitivity to RiaSTAP® or its components. It should not be used during pregnancy. Safety and efficacy has not been studied in labor and delivery, nursing mothers and the geriatric population. Documented warnings and precautions include adverse reactions, thrombosis, allergic reactions, and transmissible infectious agents. Precautions should be taken when recipients are on a controlled sodium diet due to the high sodium content found in RiaSTAP®.

For additional information, please refer to your facility policy and the manufacturer's product insert prior to administration of this product.

Case Study #17

A 43 year old female patient with a medical diagnosis was ordered a unit of packed red blood cells. The patient's blood group was A positive and it was unknown whether she received prior transfusions within the past three months or had previous pregnancies. No pre-medication was administered prior to the patient being transfused and the patient's vital signs were stable.

Approximately 2 hours and 35 minutes into the red cell transfusion, the patient's temperature increased from 37.9ºC to 39.4 ºC. The patient's pulse, respirations and blood pressure remained stable.

The transfusion was stopped. Antipyretics were administered to the patient and blood and product cultures were ordered. The cultures performed on the patient and the product were negative. The patient's symptoms resolved with the interventions.

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 #16 Interpretation

1. Type of Reaction – Transfusion Associated Circulatory Overload (TACO)

2. Relationship of adverse event to transfusion – Possible

3. Severity of the reaction –Grade 1 (Non-Severe)

4. Outcome –Minor (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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