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Bloody Good News

Newfoundland and Labrador Provincial Blood Coordinating Program

Special Interest Articles:

- Recipient Notification of a Recall
- Transfusion Associated Circulatory Overload (TACO)

Individual Highlights:

Transfusion Triggers

Every blood transfusion carries unknown risks, costs and can be problematic for inventory levels if used unnecessarily. Transfusions have been associated with an increased mortality rate and increasing the duration of a patients stay in hospital. Every year in the USA twenty-four million blood components are transfused resulting in more than 10% of extended hospital stays that require a procedure. In 2011 there were 69 fatalities reported from transfusion recipients in the USA with thirty (equaling 43%) being attributed to their transfusion. With many potential risks associated with blood transfusions, TRALI was the highest, causing 43% of fatalities in the USA between 2007-2011; with hemolytic transfusion reactions coming in second with 23%. With this being said, best transfusion practices should be implemented to keep blood loss at a minimum, improve blood usage and conservation and to improve patient outcome.

Physicians are often faced with the decision whether to transfuse their patient. This decision can cause some anxiety as there are no defined criteria to state when the moment is right to begin transfusing. Physicians often use hemoglobin levels as triggers to begin transfusions, but there is no laboratory value that indicates there is an absolute need for transfusion without considering other factors.

Ten trials have been published up to 2000 investigating transfusion triggers and what hemoglobin levels can be tolerated. One study at Texas Heart Institute TX, USA included two groups of people. One group of patients received blood transfusions post operatively when their hemoglobin fell below 80g/l and the second group received blood transfusions post operatively when their hemoglobin level fell below 90g/l. There was no difference seen post operatively between the two groups and patient outcomes were not affected in the group with the lower hemoglobin of 80g/l. Four randomized trials of patients were also studied to see if a hemoglobin level of 70-80g/l could be tolerated as opposed to patients of hemoglobin levels of 90-100g/l. These patients were in either ICU, undergoing cardiothoracic surgery, hip fracture repair or acute upper gastrointestinal hemorrhage. The results showed that the clinical outcomes were similar for those receiving blood transfusions at the 70-80g/l hemoglobin range and those at 90-100g/l range.

When using hemoglobin levels as a transfusion trigger the patient's health history must also be considered by a physician. Post- operative mortality is greatly increased if patients have cardiovascular disease. When data was reviewed it was noticed that patients with pre-existing heart disease had a lower survival rate when placed in a restrictive transfusion strategy group (receiving transfusions at a lower hemoglobin level). This theorizes that patients with heart disease and those critically ill will probably benefit from higher hemoglobin concentrations. The New England Journal of Medicine reported upon an analysis of the Center for Medicare Services that included seventy-nine thousand patients greater than sixty- five years of age; these patients were all hospitalized for acute myocardial infraction. Those that had hematocrit values less than 33% and received blood transfusion(s) had decreased mortality rates.

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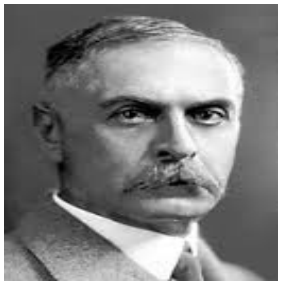

Karl Landsteiner (1868-1943) discovered human blood groups in 1901. He was awarded the Nobel Prize for Physiology or Medicine for his discovery that “under normal physiological conditions, when blood serum of a human was added to normal blood of another human, the red corpuscles in some cases coalesce.”

Lansteiner’s discovery of red cell agglutination led to identification of three blood types, A, B and O. One year later, colleagues discovered group AB.

Prior to the discovery of blood groups, therapeutic blood transfusion was rarely practiced due to the risks, or transfusion, including deaths that had occurred following early transfusions.

In 1937, along with his colleague Alexander Weiner, Landsteiner discovered the Rhesus factor, thereby markedly increasing the safety of blood transfusion.

Recipient Notification of a Blood Component Recall

Blood Transfusions are not without risk. Most of the risks are associated with an adverse event to the transfusion. However, other risks such as manufacturing incidents may occur from time to time.

In 2009, the World Health Organization published a report on the development of a conceptual framework designed to provide a method to organize patient safety data and information for aggregation and analysis. While the framework is not yet a classification system, much work is underway by the working group.

The CSA Standards, Z902-10 clearly state that facilities must have policies and procedures in place to ensure recall of blood components is rapid and complete.

The Canadian Patient Safety Institute (CPSI) published guidelines in 2011 that address “honest and effective communication between healthcare providers and their patients”.

Canadian Blood Services (CBS) is the manufacturer and distributor for blood components in Canada, except for Quebec.

From the moment a donor enters a clinic, processes are regulated by various activities and controls to ensure the safety of the blood components produced.

On occasion, there are events that require the recall of blood components from the hospitals that have received these components. In some instances, these components or blood products may still be in inventory in the Transfusion Medicine Laboratory. Other times, the patient may have been transfused the blood components already. Health Canada provides regulations that direct the handling of recalls.

In 2012, the National Advisory Committee on Blood and Blood Products (NAC) in collaboration with CBS developed recommendations to guide hospital transfusion services with regard to notification of patients who have received blood components or blood products associated with a recall. In the event of a recall, the National Recipient Advisory Committee (NRAC) may be convened if the recall is unusual or of a large scale. NRAC will make a recommendation to CBS. CBS will communicate that recommendation to hospital customers.

It is important to note that recalls associated with a donor testing positive for transmissible diseases is addressed through CBS lookback procedures.

The question that arises frequently is whether all patients who receive blood components should be informed that the blood component received was associated with a recall, even though the cause for the recall may not impact the quality of patient care or place the patient at risk.

The physician should consider the recipient’s clinical status and the recommendations as described by the NAC and the Provincial Blood Coordinating Program’s Policies when considering informing the patient.

In certain instances, the physician may consider notifying next of kin or the substitute decision maker. The development of policies associated with patient notification should include representatives from ethics, legal counsel and risk management departments.

It is important each regional health authority clearly describes the process and that it aligns with provincial policy.

CPSI recommends that through ongoing education, open and effective communication, and simulation, healthcare providers will be better equipped to support the safety culture.

In addition to informing the patient, other supports should be in place that respect the patient, including supporting the patient clinically, emotionally and psychologically, and practically.

Patient safety continues to be focus of our daily lives as we strive to ensure the practice of Transfusion Medicine is safe for all Canadians.

Effective in 2014, Bloody Good News will be published twice yearly, in April and October.

We will continue to provide this educational forum for Transfusion Medicine professionals.

Hemovigilance: Transfusion Medicine Risk Management

The first reported transfusion related adverse event occurred in the seventeenth century in France. At that time, live calf or lamb blood was successfully 'directly' transfused to human recipients. Xenoantibodies, those produced in one species in response to an antigen from a different species, developed in recipients causing significant, and at times, severe hemolysis. One recipient died, resulting in the charge of murder being laid on the physicians responsible for the transfusion activities. The physicians were found 'not guilty,' but the verdict proclaimed that further blood transfusion experimentation would require prior authorization from the Faculty of Medicine at the famous Paris University, the Sorbonne.

Hemovigilance, according to the International Society for Blood Transfusion (ISBT), is a set of surveillance procedures covering the whole transfusion chain from collection of blood and its components to follow-up of transfusion recipients. The intent of hemovigilance activities is to collect and assess information on unexpected or undesirable effects resulting from therapeutic use of blood and to prevent occurrence or recurrence.

Hemovigilance initiatives by safety leaders such as the centers for Disease Control and the National Health Care Safety Network emerged in 2006 and 2009 respectively, focusing on documentation and traceability through the transfusion chain. Three surveillance procedures, on which data is collected are:
1. notification (to the recipient of receipt of blood component or product);
2. traceability (of the component or product back to the blood supplier and donor if a transmissible infection is suspected); and
3. prevention of adverse events. All health care professionals and support workers involved in the transfusion chain, for example, physicians, nurses, laboratory technologists, and porters, play a role in safe transfusion practice.

In Canada, hemovigilance initiatives were initiated by Justice Krever 's report tabled in the House of Commons in 1997, in which he emphasized the importance of surveillance and tracking of blood, blood components or plasma derived blood products. In response, the Government of Canada launched the Transfusion Transmitted Injury Surveillance System or TTISS for reporting adverse transfusion reactions. Health care facilities providing transfusion services collect and report data on locally experienced transfusion related adverse events. This information is, in turn shared with the Public Health Agency of Canada, whose mandate is to provide a national surveillance and monitoring system for reporting of adverse transfusion events.

Hemovigilance initiatives such as TTISS have improved the collection of information on transfusion related adverse events. Nationally, the data produced from adverse transfusion event reporting is used to manage and reduce transfusion associated risk. Globally, the data has provided countries with the opportunity to compare adverse event experiences. The scientific knowledge that is gained from data sharing informs clinical practice, resulting in better recognition, prevention, and treatment of transfusion related complications, and therefore, safer patient care.

TACO - Transfusion Associated Circulatory Overload

TACO, what is it? No, it's not the convenient and tasty Mexican food! TACO, or transfusion associated circulatory overload is an adverse transfusion event that occurs during or following the administration of blood components due to excessive transfused volume or excessive infusion rate. TACO is common and preventable. Clinically, TACO presents similar to congestive heart failure; the recipient experiences dyspnea, orthopnea, cyanosis, tachycardia, hypertension, elevated jugular venous pressure, pedal edema and headache.

According the Centers for Disease Control and the AABB, formerly known as the American Association of Blood Banks, TACO is defined as: acute respiratory distress, a positive fluid balance, radiologic evidence of pulmonary edema, elevated central venous pressure, and clinical evidence of left heart failure. The United Kingdom's Serious Hazards of Transfusion (SHOT) organization also includes hypertension and tachycardia as diagnostic criteria.

The finding of elevated brain natriuretic peptide (BNP) may also be helpful in making the diagnosis. Brain natriuretic peptide is secreted by the ventricles of the heart in response to high filling pressures, which can result from transfusion of excessive volume. The test currently is not performed in NL hospitals. To diagnose TACO, the clinician must consider clinical presentation and pre-existing risk factors when determining whether circulatory overload symptoms are attributable to transfusion.

Those at greatest risk for TACO are individuals who have pre-existing cardiac disease, such as valvular disease, or recipients who receive multiple component

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Transfusion Triggers cont'd / TACO cont'd...

Guidelines have been published and it is acknowledged that transfusions are not beneficial when a patient's hemoglobin concentration is above 100g/l and may be beneficial when the hemoglobin falls between 60-70g/l. Assigning a distinct hemoglobin level for a transfusion trigger still remains contestable.

units, especially when administered over a short period of time. If signs and symptoms of TACO appear, the transfusionist should interrupt the transfusion or reduce the rate significantly if time permits, that is, if the unit has not been removed from temperature controlled storage for greater than four hours. In some transfusion centres, 'split units' are transfused. To split units, the component unit is divided into two smaller units under aseptic technique, to allow the transfusion of a smaller volume of blood over the maximal 'out of temperature controlled storage' time frame. The recipient will still receive the full volume; however, it will be infused over twice as long, one 'split' unit followed by a second 'split' unit. Oxygen therapy (with physician order) may be required to treat associated dyspnea. The patient should be positioned in an upright position to maximize lung expansion. The most effective treatment with which significant improvement is achieved is with diuretic treatment. Clinicians may opt to attempt to pre-empt TACO by pre-medicating with diuretics prior to start of transfusion. TACO causes significant morbidity, especially in at-risk transfusion recipients, so heath care professionals and transfusionists, spread the word! Be aware of the recipient's co-morbidities, if any, complete a thorough pre-transfusion clinical assessment, including vital signs, and closely monitor for signs of volume overload during the transfusion. Efforts should be directed toward prevention of this very serious adverse transfusion event.

Case Study #19

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An eighteen year old male chemo recipient admitted under the services of Hematology, was transfused one unit of group specific O positive red blood cells.

The recipient received transfusions within the previous three months. No pre-transfusion medications were administered.

Two hours following initiation of the transfusion, the recipient complained of headache and his temperature increased from 37.4 to 39ºC. No other clinical symptoms were documented.

The transfusion was discontinued with 300 mLs infused.

Antipyretics and antibiotics were administered. Product and recipient cultures were negative. Chest x-ray was negative.

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 #18 Interpretation

1. *Type of Reaction – TACO Transfusion Associated Circulatory Overload*
2. *Relationship of adverse event to transfusion – Possible*
3. *Severity of the reaction – Grade 1*
4. *Outcome – Minor-no sequelae*

See TACO article Pages 3 and 4 of this issue for more information.

Learn from yesterday,

Live for today,

Hope for tomorrow.

The important thing is not to stop questioning.

Albert Einstein

(1879-1955)

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For reference documents including policies visit:
http://www.health.gov.nl.ca/health/bloodservices/index.html

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