“Identifying the Risks of Blood Transfusion”

Blood Matters

October 29, 2010

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PROMOTING EXCELLENCE IN TRANSFUSION MEDICINE
Conflict of Interest

This presenter does not have any involvement with industry that may be perceived as potentially influencing the presentation of the educational material contained within.
Learning Objectives…

- Identify common signs and symptoms of adverse transfusion reactions and the appropriate actions to follow
- Review of Nova Scotia adverse transfusion reaction data
- Understand the investigation and reporting process in the event of an adverse transfusion reaction

MAXIMIZE PATIENT SAFETY!!
The Krever Report…

- On Nov. 25, 1997, Justice Horace Krever released his landmark report on how Canada's blood system managed the threat of HIV and hepatitis C transmission from blood transfusions.
- The tainted blood tragedy, as it came to be called, was arguably the largest public health catastrophe in this country's history.
- About 1000 individuals who received blood transfusions between the late-1970s and 1980s were infected with HIV, and another 30,000 were infected with hepatitis C.
Importance of Surveillance

- Justice Krever emphasized in his report, the importance of surveillance and tracking of blood.
- He referred to the concept of vein-to-vein management of blood.
In response to the Krever report, the federal government launched a series of initiatives to improve the safety of Canada’s blood system. TTISS is a national surveillance system for the monitoring of adverse transfusion reactions, providing data for managing the risk of transfusion in Canada. Nova Scotia was one of the first provinces in Canada to participate in the initial pilot project.
TTISS in Canada

Percentage of transfusions captured by TTISS

Note: Population estimates (in thousands) from Statistics Canada, as of July 1, 2007.

NSPBCP would like to acknowledge the Public Health Agency of Canada for their continuing support and for providing information for the above slide.
**Adverse Event…**

**Adverse event:**
- An undesirable and unintended occurrence during or after the administration of whole blood or blood components, whether or not considered to be related to the administration of the whole blood or blood components.

- The following are considered to be adverse events: Accident, Error, and/or an Adverse Reaction

**Serious Adverse Event**

**is an Adverse event that:**
- Requires hospital stay or extends hospital stay directly attributable to the event.

- Results in persistent or significant disability or incapacity.

- Necessitates medical or surgical intervention to preclude permanent damage or impairment of a body function.

- Is life threatening.

- May result in death.
Types of Adverse Transfusion Reactions

- Febrile Non-Hemolytic
- Minor Allergic
- Anaphylactic
- Bacterial Contamination
- TACO
- TRALI
- Hypotensive
- Acute/Delayed Hemolytic
- Other/Delayed reactions
Febrile Non-Hemolytic Reaction

- Incidence:
  - 1 in 200 (Platelet transfusion)
  - 1 in 500 (RBC transfusion)
- Pt may experience one or more of the following:
  - Fever (≥ 38°C and a change of ≥ 1°C)
  - Chills
  - Sensation of cold
  - Rigors
- Symptoms may be accompanied by headache and nausea
- Occurs during transfusion or within 4 hours of its completion without any other cause such as hemolytic transfusion reaction, bacterial contamination or underlying condition
- If mild fever, transfusion may be resumed cautiously ONLY as directed by physician

Canadian Blood Services: Clinical Guide to Transfusion, July 2006
ALLERGIC REACTION

MINOR
Skin reaction (hives or rash)

SEVERE ALLERGIC
Minor reaction + Airway compromise

ANAPHYLACTIC
Minor+Severe+Shock
Minor Allergic

Incidence:
- 1 in 100

Etiology:
- Antibody to donor plasma proteins

Signs & symptoms:
- Pruritis, rash, urticaria, flushing
- Rash over less than or equal to ¼ of the body and no other symptoms

Treatment:
- Antihistamines
- If minor allergic reaction, transfusion may be resumed cautiously ONLY as directed by physician

Canadian Blood Services: Clinical Guide to Transfusion, July 2006
Anaphylactic

Incidence:
- Rare

Etiology:
- Antibody to donor plasma proteins

Signs & symptoms:
- Rash/Hives over greater than \(\frac{1}{4}\) of the body
- Dyspnea, cough, wheezing, respiratory distress, hypotension, laryngeal/pharyngeal edema, bronchospasm

Treatment:
- Epinephrine
- Antihistamines

Canadian Blood Services: Clinical Guide to Transfusion, July 2006
Bacterial Contamination

- Fever: $\geq 38^\circ$ and $\geq 1^\circ$ from pre-transfusion value AND
  rigors, hypotension, shock, tachycardia, dyspnea, or nausea and vomiting
- OR: Fever $\geq 1^\circ$ from pre-transfusion AND Temp $>39^\circ$
  with absence of other symptoms
- OR: Fever not responding to antipyretics
- OR: High suspicion of sepsis even in absence of fever
Bacterial Contamination

Incidence:
- 1 in 1,000 in platelets
- 1 in 50,000 in red cell components

Etiology: Bacteria possibly originating from:
- Donor with an undiagnosed bacterial infection
- Proliferation during storage
- Donor venipuncture site contamination

Treatment:
- Treatment of Shock, renal failure
- Antibiotics
- Blood Cultures from the patient AND the product

Notify Blood Transfusion Services (BTS) immediately if bacterial contamination is highly suspected. BTS will notify the Blood Supplier as components from the involved donation may also be contaminated.
Transfusion Associated Circulatory Overload (TACO)

Incidence:
- 1 in 700

Etiology:
- Fluid volume overload

Signs & symptoms:
- Dyspnea, orthopnea, cyanosis, hypertension, congestive heart failure within 6 hours of completion of transfusion

Treatment:
- Elevate head of bed
- Oxygen & diuretics may be ordered

PREVENTION is Key!!! Increased risk to the elderly, infants, cardiac, pulmonary, renal failure patients

Canadian Blood Services: Clinical Guide to Transfusion, July 2006
Transfusion Related Acute Lung Injury (TRALI)

(No evidence of ALI prior to transfusion)

**TRALI**
- New ALI is present
  - Acute onset
  - Hypoxemia
  - Lung infiltrates
  - No evidence of CO
- Occurs during or within 6hrs post transfusion
- No other risk factors for ALI

**Possible TRALI**
- Signs and Symptoms of TRALI plus have one or more risk factors for ALI
- Direct Lung Injury
  - aspiration, pneumonia
- Indirect Lung Injury
  - sepsis, shock, trauma
TRALI

Incidence:
• 1 in 5,000 (RBCs); 1 in 1,200-5,000 (Plasma/Platelets)

Etiology:
• Transfused antibodies to HLA or white cell antigens which may react with recipient leukocytes.

Treatment:
• Oxygen therapy
• Ventilation assistance
• ICU support
• Blood pressure support

Signs & symptoms:
• Shortness of breath, hypoxemia, chills, fever, cyanosis & hypotension
• X-ray findings consistent with pulmonary infiltrates but no evidence of cardiac failure
• Acute onset of symptoms

Canadian Blood Services: Clinical Guide to Transfusion, July 2006
Hypotensive Reactions

- Hypotensive: a drop in Systolic BP greater than or equal to 30mmHg and Systolic BP below 80mm Hg
- Signs of Shock
- Incidence: Unknown

**Note: In Pediatric patients look for any significant change in BP**
Hemolytic Reactions

Acute
- Reaction occurs within 24 hrs but most severe usually occur within first 15 minutes of transfusion

Delayed
- Symptoms occur more than 24hrs and up to one month after transfusion.
Acute Hemolytic Reaction

Signs & Symptoms:
- Acute onset usually within 15 minutes of the start of transfusion
- Fever, chills
- Hemoglobinuria, renal failure
- Hypotension, DIC, oliguria
- Oozing from IV site, back pain, pain along infusion vein

Etiology:
Can be caused by the administration of incompatible blood!!
Red blood cells are destroyed/damaged (Hemolysis)

Treatment:
- Aimed primarily at prevention of renal failure

Incidence:
- 1 in 40,000
Medical errors do happen...

"The day you were born was a medical error!"
Causes??

- Cross match error
- Wrong identification of blood specimen
- Blood collected from wrong patient
- Wrong blood in tube
- Blood administered to wrong patient
- Patient Misidentification
Results of Misidentification

“Incorrect blood component transfused”

- Considered a serious transfusion error
- May result in an Acute Hemolytic Transfusion Reaction (AHTR)
- AHTR most frequent severe reaction and is the leading cause of death associated with transfusion
- 80% of AHTR related deaths occur as a result of ABO incompatibility due to an error
- These errors are often associated with incorrect patient identification, sample errors and administration errors

Ensuring positive patient identification, and strict adherence to blood administration policies, promotes prevention and maximizes patient safety

Transfusion Error Prevention

The bedside check is a vital step in preventing transfusion error

If you are not sure – **DO NOT** give blood until the patient has an accurate ID armband on their person.
If you have any doubts, **DO NOT** give the blood.
Delayed Transfusion Reactions
Symptoms may occur DURING or FOLLOWING A TRANSFUSION
Delayed Transfusion Reactions

**Delayed hemolytic reaction:** Fatigue, jaundice, pain, fever, urine color change greater than 24 hrs and up to 1 month post transfusion.

**PTP (Post Transfusion Purpura):** sudden and severe platelet drop to <10,000/L, 5-12 days after a transfusion.

**TA-GVHD (Graft vs. Host):** Rare and very severe reaction characterized by fever, skin rash (starting on palms, soles of feet and ear lobes), elevated liver enzymes/bilirubin, and diarrhea 1-6 weeks post transfusion. Preventative with irradiated products to immunocompromised recipients.
Infectious complications

HIV: 1 in 7.8 million
HCV: 1 in 2.3 million
HBV: 1 in 153,000
HTLV: 1 in 4.3 million*
vCJD: Very rare
Syphilis, Lyme disease: Extremely rare
WNV: rare
Chagas, Babesiosis: Rare

*This number represents potentially infectious units being released into inventory. The risk to recipients would be much lower due to universal leukoreduction.
Nova Scotia Data...
## Components distributed in Nova Scotia in 2009

<table>
<thead>
<tr>
<th>Blood Components</th>
<th>Number of units distributed</th>
<th>N</th>
<th>Percent per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Blood Cells</td>
<td></td>
<td>30763</td>
<td>68.29</td>
</tr>
<tr>
<td>Fresh Plasma</td>
<td></td>
<td>1597</td>
<td>3.55</td>
</tr>
<tr>
<td>Apheresed Fresh Frozen Plasma</td>
<td></td>
<td>4285</td>
<td>9.51</td>
</tr>
<tr>
<td>Platelets</td>
<td></td>
<td>2914</td>
<td>6.47</td>
</tr>
<tr>
<td>Apheresed Platelets</td>
<td></td>
<td>1204</td>
<td>2.67</td>
</tr>
<tr>
<td>Cyro Super &amp; Cyro Prec</td>
<td></td>
<td>4284</td>
<td>9.51</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>45047</td>
<td>100</td>
</tr>
</tbody>
</table>

*Disclaimer: Transfused data not available at this time. Based on CBS distribution data to obtain a view of incidence rates in Nova Scotia*
Incidence Rates for 2009 in Nova Scotia for blood components*

<table>
<thead>
<tr>
<th>ATEs</th>
<th>Incident Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delayed Hemolytic Reaction</td>
<td>1 : 45047</td>
</tr>
<tr>
<td>Febrile Non-Hemolytic Reaction</td>
<td>1 : 469</td>
</tr>
<tr>
<td>Hypotensive Reaction</td>
<td>1 : 6435</td>
</tr>
<tr>
<td>Minor Allergic Reaction</td>
<td>1 : 653</td>
</tr>
<tr>
<td>Possible TRALI / TRALI</td>
<td>1 : 45047</td>
</tr>
<tr>
<td>Severe Anaphylactic/Anaphylactoid</td>
<td>1 : 15016</td>
</tr>
<tr>
<td>TACO</td>
<td>1 : 7508</td>
</tr>
</tbody>
</table>

*Disclaimer: Transfused data not available at this time. Based on CBS distribution data to obtain a view of incidence rates in Nova Scotia.
Overall Picture of Transfusion Reactions 2008, 2009, and 1st 2 quarters 2010*

*TTISS data based on calendar year
### Transfusion Reactions 2008, 2009, and 1st 2 quarters 2010* for blood components

<table>
<thead>
<tr>
<th>Type of Transfusion Reaction</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Hemolytic Reaction</td>
<td>Less than 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delayed Hemolytic Reaction</td>
<td>Less than 5</td>
<td>Less than 5</td>
<td></td>
</tr>
<tr>
<td>Delayed Serological Transfusion Reaction (new alloantibodies)</td>
<td>16</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Febrile Non-Hemolytic Reaction</td>
<td>126</td>
<td>96</td>
<td>59</td>
</tr>
<tr>
<td>Hypotensive Reaction</td>
<td>Less than 5</td>
<td>7</td>
<td>Less than 5</td>
</tr>
<tr>
<td>Minor Allergic Reaction</td>
<td>60</td>
<td>69</td>
<td>35</td>
</tr>
<tr>
<td>Severe Anaphylactic/Anaphylactoid</td>
<td>Less than 5</td>
<td>Less than 5</td>
<td>Less than 5</td>
</tr>
<tr>
<td>TACO</td>
<td>17</td>
<td>6</td>
<td>Less than 5</td>
</tr>
<tr>
<td>TAD</td>
<td>Less than 5</td>
<td>Less than 5</td>
<td>Less than 5</td>
</tr>
<tr>
<td>TRALI</td>
<td>Less than 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Possible TRALI</td>
<td>Less than 5</td>
<td>Less than 5</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>Less than 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Transfusion Reaction</td>
<td>Less than 5</td>
<td>Less than 5</td>
<td>Less than 5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>237</strong></td>
<td><strong>196</strong></td>
<td><strong>112</strong></td>
</tr>
</tbody>
</table>

*TTS data based on calendar year. Reactions are listed as “Less than 5” if there were less than 5 of the related reaction reported within the calendar year. The arrow ↑ indicates the number of reactions is increased from the previous year, while the arrow ↓ indicates the number of reactions is decreased from the previous year. If there is no arrow present this indicates that the number of reactions is unchanged from the previous year.
### Transfusion Reactions 2008, 2009, and 1st 2 quarters 2010* for blood products

<table>
<thead>
<tr>
<th>Type of Transfusion Reaction</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Hemolytic Reaction</td>
<td></td>
<td></td>
<td>Less than 5</td>
</tr>
<tr>
<td>Delayed Hemolytic Reaction</td>
<td>Less than 5</td>
<td>Less than 5 ↓</td>
<td>Less than 5 ↓</td>
</tr>
<tr>
<td>Delayed Serological Transfusion Reaction (new alloantibodies)</td>
<td>Less than 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Febrile Non-Hemolytic Reaction</td>
<td>Less than 5</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Hypotensive Reaction</td>
<td>Less than 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IVIg Headache</td>
<td>Less than 5</td>
<td>Less than 5</td>
<td>Less than 5</td>
</tr>
<tr>
<td>Minor Allergic Reaction</td>
<td>7</td>
<td>Less than 5</td>
<td>Less than 5 ↓</td>
</tr>
<tr>
<td>TACO</td>
<td></td>
<td></td>
<td>Less than 5</td>
</tr>
<tr>
<td>TAD</td>
<td></td>
<td></td>
<td>Less than 5</td>
</tr>
<tr>
<td>Unknown</td>
<td>Less than 5</td>
<td>Less than 5</td>
<td></td>
</tr>
<tr>
<td>Other Transfusion Reaction</td>
<td>Less than 5</td>
<td>Less than 5 ↓</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>22</td>
<td>18</td>
<td>7</td>
</tr>
</tbody>
</table>

*TTISS data based on calendar year. Reactions are listed as “Less than 5” if there were less than 5 of the related reaction reported within the calendar year. The arrow ↑ indicates the number of reactions is increased from the previous year, while the arrow ↓ indicates the number of reactions is decreased from the previous year. If there is no arrow present this indicates that the number of reactions is unchanged from the previous year.
Serious Transfusion Reactions

Number of Cases

Year

2008

2009

2010
Severity from 2008 to 2010 (Q1+Q2)
Safe Transfusion Practices

- Prior to administration…refer to facility Policy and Procedure
- Review consent policy for blood transfusion
- Patient education resources available to support informed consent
- Observation and monitoring of patient for signs of adverse transfusion reactions
Immediate action in the event of a transfusion reaction:

**STOP** the Transfusion!!
# Investigation of Adverse Reactions

## Investigation of Adverse Transfusion Reactions

<table>
<thead>
<tr>
<th>Suspected Reaction</th>
<th>Signs and Symptoms</th>
<th>Testing Requirements</th>
<th>Laboratory Tier Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor Allergic</td>
<td>Rash/hives over 1/4 of body with no other symptoms</td>
<td>None</td>
<td>Tier One Testing</td>
</tr>
<tr>
<td>Does Not Meet TTESS Definition of a Reaction</td>
<td>Temperature rises 2°C and 28°C with no other signs or symptoms and reaction starts from 13 minutes into transfusion</td>
<td>Tier Testing</td>
<td>Tier One Testing</td>
</tr>
<tr>
<td>Febrile Non-Hemolytic Reaction (FNH)</td>
<td>Temperature rise 2°C and 28°C with no other signs or symptoms</td>
<td>Tier Testing</td>
<td>Tier One Testing</td>
</tr>
<tr>
<td>FNIIR</td>
<td>Temperature rise 2°C and 28°C with no other signs or symptoms</td>
<td>Tier Testing</td>
<td>Tier One Testing</td>
</tr>
<tr>
<td>Acute Hemolytic Reactions</td>
<td>Temperature rise 2°C and 28°C</td>
<td>Tier Testing</td>
<td>Tier One Testing</td>
</tr>
<tr>
<td>Bacterial Contamination</td>
<td>Temperature rise &gt;29°C and 28°C in the absence of other signs or symptoms</td>
<td>Tier Testing</td>
<td>Tier One Testing</td>
</tr>
<tr>
<td>Acute Hemolytic Febrile Headache Other</td>
<td>Any one or more of the following:</td>
<td>Tier Testing</td>
<td>Tier One Testing</td>
</tr>
<tr>
<td>Hypotensive Reaction</td>
<td>Drop in systolic BP greater than 50 mmHg</td>
<td>Tier Testing</td>
<td>Tier One Testing</td>
</tr>
<tr>
<td><strong>Thrombolytic therapy</strong> (TPS)</td>
<td>Shortness of breath, dyspnea, cyanosis, hypotension, respiratory distress</td>
<td>Tier Testing</td>
<td>Tier One Testing</td>
</tr>
<tr>
<td>Transfusion Associated Circulatory Overload (TACO)</td>
<td>Acute onset of respiratory distress, during or within 6 hours of completion of transfusion</td>
<td>Tier Testing</td>
<td>Tier One Testing</td>
</tr>
<tr>
<td>Transfusion Associated Dyspnea (TAD)</td>
<td>Acute onset of respiratory distress, during or within 6 hours of completion of transfusion</td>
<td>Tier Testing</td>
<td>Tier One Testing</td>
</tr>
<tr>
<td>TRALI (Transfusion Related Acute Lung Injury)</td>
<td>Acute onset of respiratory distress, during or within 6 hours of completion of transfusion</td>
<td>Tier Testing</td>
<td>Tier One Testing</td>
</tr>
<tr>
<td>TRALI (Transfusion Related Acute Lung Injury)</td>
<td>Acute onset of respiratory distress, during or within 6 hours of completion of transfusion</td>
<td>Tier Testing</td>
<td>Tier One Testing</td>
</tr>
</tbody>
</table>

**Tier One Testing**
- Clotting check for procedurally identified errors
- Visual check of post-transfusion plasma for hemolysis
- Perform ABO/Rh on post-transfusion sample and compare to pre-transfusion sample ABO/Rh
- Direct Antihemolysin Test (DAT) on post-transfusion sample

**Reports**
- If Tier One testing is negative, generate a preliminary report supporting ongoing transfusion.
- If Tier One testing is positive, investigation must be complete prior to any further transfusion. Further release can only occur with the approval of the patient's attending physician.

**Tier Two Testing**
- Repeat pre-transfusion sample ABO/Rh
- Perform ABO/Rh and DAT on the unit in question
- Repeat Antibody Screen on pre-transfusion samples
- Perform antihemolysin encephalomyelitis on the pre and post blood specimens with theunit
- Perform urine dipstick for hemoglobin

**Tier Three Testing**
- Antibody Investigation (phenotype unit & pre-transfusion sample)
- Elastase (pre and post samples)
- Antibody Investigation on donor units
- Investigate transfusion technique and blood component storage conditions

**Samples Required for Tier One Adverse Reaction Investigation**
- 1 tube

**RTS** may request additional samples

**Key**
- > Greater than or equal to
- < Less than or equal to
- ≥ Complete Blood Count
- LDH Lactate Dehydrogenase
- CBC Canadian Blood Services
- BTPS Blood Transfusion Services

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Consider signs and symptoms and investigation required for other suspected delayed transfusion reactions

NSP/ECIP October 7, 2016
Overview of BTS Reporting

Serious Event? YES
Report to CBS IMMEDIATELY by phone:
#1-902-474-8300
AND
Fax: Product unit numbers/lot numbers using the Canadian Transfusion Adverse Event Report Form to:
CBS: 1-902-474-8277
And
NSPBCP: 1-902-473-2589
Serious Event? Yes

CBS forwards adverse reactions to Biologics and Genetics Therapies Directorate (BGTD) or manufacturer as indicated

NSPBCP forwards non-nominal data to the Public Health Agency of Canada and Canada Vigilance Program as indicated
Serious Event? No

Complete Canadian Transfusion Adverse Event Reporting form and forward at the end of month to NSPBCP

NSPBCP forwards completed Canadian Transfusion Adverse Event Reporting forms to CBS as indicated

NSPBCP forwards non-nominal data to the Public Health Agency of Canada and Canada Vigilance Program, as indicated
Communication is Key!!

...AND THAT IS WHY WE LIFT ON THREE...

COMMUNICATION
“The most important thing in Communication is to hear what isn’t being said”

(Peter Drucker, 1909-2005)
Together we can work together…

to maximize patient safety!!
Nova Scotia Provincial Blood Coordinating Program

The Department of Health continuously strives to make sure that Nova Scotians receive safe, quality health care and health-care services. There are many programs and projects that specifically address safeguarding our health care system. The Provincial Blood Coordinating Program is one of them.

The Provincial Blood Coordinating Program was created in January 2003 and provides the leadership to collaborate with health care providers across the province and Canadian Blood Services to maximize the safe and appropriate management of blood and related products received by Nova Scotians.

Blood Matters, Educational Event October 29, 2010

Questions???