

Newfoundland and Labrador Provincial Blood Coordinating Program

Special Interest Articles:

- Quality System Essentials (QSE)
- WHO Pandemic Planning Phases
- Contingency Planning for the Blood Supply

Individual Highlights:

Pandemic Planning 2

Blood Contingency Planning 2

The Patient's Role In Transfusion Medicine 3

Quality System Essentials 3

Post Transfusion Purpura 4

Case Study # 7 4

Case Study # 6 Interpretation 4

Influenza A H1N1 Virus - Virology

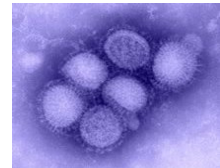
The Influenza A (H1N1) virus is a subtype of influenza virus A. First referred to as "swine flu", the virus was similar to the virus found in pigs. Two proteins on the virus surface are hemagglutinin (H) and neuraminidase (N). An H number and an N number is assigned to the virus strains based on the type of protein the viral strain contains. There are 16 H subtypes and 9 N subtypes found in birds. H1, 2 and 3 and N1 and 2 is found in humans.

This new virus appears to contain genetic material from

4 different flu viruses – 2 human flu viruses, avian virus and swine virus. The structure of the proteins differs from one strain to another due to genetic mutation in the genome of the virus.

The symptoms are similar to those found in seasonal flu. The virus is spread through person-to-person contact, as are other flus. Covering coughs, sneezes and frequent hand washing is the best prevention tool. A vaccine is expected to be available in the fall of 2009. There are two antiviral drugs

considered effective for treating the H1N1 virus – Tamiflu and Relenza. Antivirals reduce the virus' ability to reproduce, but do not provide immunity. There is a risk of resistance to treatment when antivirals are used to treat mild cases. The World Health Organization raised the pandemic alert to level 6 in June.



Pandemic Planning – WHO Phases of Preparedness

The World Health Organization (WHO) monitors disease outbreaks globally through the Global Outbreak Alert & Response network. The WHO published a pandemic guidance document in 1999 and revised its document in 2005. The WHO sets the pandemic alert levels through stakeholder consultation with its global member states. It also has the ability to make recommendations regarding travel, border closures and providing care for the ill.

Canada's government, its provinces and territories have been developing and refining its pandemic plan for several years.

What are the pandemic preparedness and response stages? The WHO identified 6 phases of pandemic preparedness and response.

Phase 1: Circulating influenza virus in animals. No reports of animal viruses infecting humans.

Phase 2: Animal influenza virus infects humans. Potential pandemic threat.

Phase 3: An animal or animal to human influenza virus has caused limited disease in people. Isolated human to human transmission may occur, but is not widespread.

Phase 4: Verified human to animal or human to animal

virus causing widespread or "community-level" outbreaks. Risk of pandemic is much higher.

Phase 5: Human to human spread of the virus is confirmed in at least two countries in one WHO region. Pandemic is likely imminent.

Phase 6: The Pandemic phase. Community outbreaks in at least one country from a second WHO region indicating that a global pandemic is underway.

The Director-General of the WHO decides the elevation of pandemic phases based on reports from countries of the impact of disease.



Who is this professor of Haematology at the University of London, St. Mary's Medical School who wrote the first and best-known textbook about transfusion in clinical medicine, first published in 1951, a classic that is now edited by others, but was so famous that it was, and still is, simply known by his name?

Pandemic Planning – Provincial Measures

In 2007, the Government of Newfoundland and Labrador released a document entitled *"Pandemic Influenza: Planning Guidelines, Roles and Responsibilities for the Health Sector"*. This document provided the health sector at both the provincial and community level with a document that could steer towards an integrated approach to manage the impacts of a pandemic. Regional documents have since been developed that align with the provincial and federal guidelines. The main areas of responsibility include surveillance, antiviral drugs, vaccines, public health measures, health services

that include laboratory services and communications. Since the declaration of pandemic phase 6, surveillance has increased. Cases of H1N1 influenza are reported weekly to both provincial and federal agencies. Stockpiles of antiviral drugs exist. There are plans that address the acquisition, storage and distribution of these drugs. The primary measure for prevention will be vaccination, once a vaccine is available. There will be increased public health awareness campaigns to address personal hygiene (clean, cover, contain), travel, and public gatherings.

Impacts to health services will occur as health care providers become ill as well. The demand for laboratory health services will increase as influenza testing is a central role in surveillance of the pandemic level. National collaboration may be required to support provincial services. Communications is key to ensure the public is informed and educated. Effective communication between the Regional Health Authorities and the Provincial and Federal Governments is key to ensuring the health and safety of all.

For regular updates visit: <http://www.health.gov.nl.ca/health/hsi/default.htm>

Contingency Planning for the Blood Supply

Canadians are very fortunate to have a safe and continuous supply of blood components and blood products. As with all good things, there must be a plan in place to address shortages or impacts, such as a pandemic, on that supply.

Canadian Blood Services (CBS) has developed a draft document to address such shortages. The draft document was distributed to provincial bodies for review and comments. As a result, the Provincial Blood Coordinating Programs or Ministries of Health have begun the process to develop provincial plans.

The NL plan is now in its second draft. The plan is being sent to stakeholders for review and comments. It is expected that the final draft of the plan will be ready

for implementation in late 2009 or early 2010. The plan is modeled using several other plans and provides an effective mechanism and toolkit for Regional Health Authorities (RHAs) to use in the development of their own specific plan. Each plan will role up to the national plan and provide consistent coding, and reporting across all RHAs.

The Plan consists of four reporting phases: Green, Amber, Red and Recovery. The plan is broken out into segments that address identification and communication, assessment and response plan development, communication of response plan, implementation of the response plan and recovery.

The pivotal and key component of the plan hinges on top notch

communication at all levels from Canadian Blood Services – both nationally and locally, the Department of Health and Community Services, Provincial Blood Coordinating Program, Regional Health Authorities, and Hospital Facilities.

One of the key issues in the plan requires ethical support and understanding. Another key element is ensuring that patient advocates can convey to the general public the impacts of a shortage and that appropriate, thought out actions are in the interest of patient safety.

When you or one of your colleagues receives the plan, please take the time to review it carefully and understand your role and responsibility. Together whether in a pandemic event or a shortage due to disaster or other causes, we can provide quality patient care.

"Be a first rate version of yourself, not a second rate version of someone else".

Judy Garland
1922-1969
(to her daughter,
Liza Minelli)



The Patient's Role in Transfusion Medicine

The patient is at the centre of everything we do related to transfusion medicine. We want to ensure the patient is informed, the transfusion experience is uneventful, the benefits outweigh the risks and the right product is transfused for the right reason.

What is the role of the patient? The patient receiving a blood component or blood product should be provided with sufficient information, have time to ask questions if they are unclear about the transfusion as well as address any concerns or fears. Many patients know in very simple terms what blood is, but do not know that there are many components / products, nor do they know what the product is intended to correct.

Informed consent does not mean telling the patient (s) he is going to receive blood and obtaining a signature on a document. The physician is required to explain the types of components/products the patient may need, the frequency of the transfusion, if more than one may be required, and describe the benefits and risks of transfusion. The individual making the decision must have substantial understanding of the choices available without controlling influence.

The patient has the legal right to refuse a transfusion. In this instance, the physician must ensure the patient understands the implications refusal may have on his/her health.

There are occasions when a

substitute decision maker (SDM) is required to assume the legal responsibility for the patient including informed consent or refusal.

Religious beliefs and ethics are also the responsibility of the patient. The patient has a right to uphold their convictions. Patient's rights have been challenged in the law courts in many instances.

The consenting patient once informed of the signs and symptoms of an adverse event should notify the nurse or care provider as soon as possible and if any such signs / symptoms occur.

The CSA Z902-04 Standards require that a patient be informed in writing of a transfusion. The PBCP is currently drafting such a document.

Questions a Patient May Ask?

- Why do I need a transfusion?
- What type of blood components will I receive?
- What is the risk of AIDS or other diseases?
- What are the benefits?
- What will happen if I do not want a transfusion?
- Are there alternatives to transfusion?
- Will I need more than one transfusion?
- Will I have a reaction?
- Do I have the right to refuse a transfusion?

Quality Systems Essentials –12 QSE's of the Quality Manual

A Quality Management System should include all the activities and processes related to quality assurance. Quality systems essentials identify the necessary infrastructure in an organization, irrespective of the goods and services provided. The QSE model adopted by the Clinical and Laboratory and Standards Institute (CLSI), formerly the National Committee for Clinical Laboratory Standards (NCCLS), is based on 12 of the 20-quality system elements in ISO 9001 that include:

1. Organization
2. Personnel
3. Equipment
4. Purchasing & Inventory
5. Process Control

6. Information Management
7. Documents & Records
8. Occurrence Management
9. Assessments
10. Process Improvement
11. Service & Satisfaction
12. Facilities & Safety

There are various styles of quality manuals depending on the standard(s) to which the manual is written against. The detail of the contents may be drilled down to include subsections that ensure each QSE is addressed. QSEs apply to all operations in the path of workflow from pre-analytical to analytical to post-analytical to information management.

An introductory section in the Quality Manual (QM)

provides a brief overview of the QM for your facility and may include the vision, mission and values statements along with a glossary of terms and/or definitions. It should also contain a quality policy statement that defines the direction of the quality management system and the facility's commitment to quality. Leadership must come from the senior management as they promote the quality culture of the laboratory. A Quality Manual is a requirement for accreditation. It is a living document that requires constant revision to remain current with the standards and auditing practice.

Upcoming Events:

- ◆ Transfusion Safety Officers Meeting
Sept. 9, 2009
- ◆ Transfusion Medicine Advisory Group Meeting –
Sept. 11, 2009
- ◆ Adverse Event Day
Nov. 20, 2009



Post-Transfusion Purpura Reaction

This uncommon transfusion reaction occurs mainly in females negative for human platelet specific antigen HPA-1a who have been sensitized during pregnancy with HPA-1a+ children or by previous transfusion with HPA-1a+ blood components. Post-transfusion Purpura (PTP) presents as a sudden and dramatic drop in the platelet count (usually to less than 10,000) five to ten days post transfusion. Other clinical symptoms include purpura, epistaxis, intracranial and/or gastrointestinal bleeding and hematuria. Although most cases are self-limiting and do

not require aggressive treatment, there is an 8% mortality rate due to hemorrhage. In most cases, the platelet specific antibodies are directed against antigens located on the GPIIb-IIIa complex. Anti-HPA-1a may be IgG alone or a combination of IgM and IgG and activates complement.

Several hypotheses have been proposed as to the mechanism for autologous platelet destruction. One suggests that formation and adherence of immune complexes to patient's platelets promote

sequestration. The other theory proposes the development of auto-antibodies during the secondary immune response to the allo-antigen.

First line therapy for PTP is IVIG at a dose of 1g/kg daily for 2 days. Platelet antigen negative blood components should be used for subsequent transfusions.

Neonatal alloimmune thrombocytopenia (NAIT) affects the fetus whose mother has anti-platelet antibodies resulting in severe thrombocytopenia and possible intracranial hemorrhage.

Case Study #7

A 21 day old premature infant with a perforated bowel developed symptoms of an adverse reaction after receiving 31mL of CP2D single donor platelets. The patient was A Positive and had been transfused RBCs, FFP and platelets the previous day without incident. The infant was not pre-medicated nor transfused under anesthesia. Pre-transfusion vitals were: pulse 175 and MBP (mean blood pressure) 42. Post transfusion, the pulse increased to 190 and the MBP decreased to 31. The patient also experienced

tachycardia (heart rate increased to 180s), SOB, flushing and hypoxia – O₂ sats 79% on 60% O₂. The transfusion was stopped, O₂ was increased to 100% and ventilator settings also increased. Although the infant had an element of Respiratory Distress Syndrome (RDS), the post reaction chest x-ray was basically unchanged from the previous day. The patient's symptoms resolved after 1 hour. A Transfusion Medicine specialist recommended testing the donor for WBC antibodies.

Donor testing found weak HLA antibodies present; weak positive results for anti-neutrophil and anti-lymphocyte antibodies. The infant was subsequently transfused RBCs, platelets and albumin without any adverse effects.

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?*

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.

Case Study #6 Interpretation

1. *Hypotensive, probably due to ACE Inhibitors*
2. *Relationship of adverse event to transfusion – Probable*
3. *Severity of the reaction – Grade 2 (severe)*
4. *Outcome – Minor, patient's physician was notified to discontinue ACE Inhibitor prior to any future transfusions.*

Answer from Vol 3, Issue 2

Who was the woman who in 1948 co-founded the California Blood Bank System and initiated its reciprocity plan, whereby blood banks could exchange blood and blood credits with each other?
Bernice Hemphill

Newfoundland and Labrador Provincial Blood Coordinating Program

P.O.Box 8700
St. John's, NL
A1B 4J6

PHONE:
(709) 729-5246
(709) 729-6573

FAX:
(709) 729-4009

E-MAIL:
marilyncollins@gov.nl.ca or
lindaorr@gov.nl.ca

We're on the Web!

See us at:
<http://www.health.gov.nl.ca/health/bloodprogram/index.htm>

