

HEALTH CANADA/SANTÉ CANADA
Health Products & Food Branch
Direction Générale Des Produits De Santé et Des
Aliments



WEST NILE VIRUS
REGULATORY CONSULTATIVE WORKSHOP /
ATELIER CONSULTATIF RÉGLEMENTAIRE
SUR LE VIRUS DU NIL OCCIDENTAL

WEST NILE VIRUS
SAFETY & REGULATORY OVERVIEW
CANADA

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Health Canada
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West Nile Virus- Background

- WNV is a mosquito-borne flavivirus with a natural reservoir in different species of birds
- Most people infected with WNV develop no symptoms or only minor disease with fever, headaches, skin rash and body aches and sometimes swollen lymph nodes
- less than 1% develop serious health effects associated with neurological disease (encephalitis or meningitis)
- There is no specific treatment or vaccination and most of infected individuals recover
- WNV infection exhibits a brief period of viremia prior to the onset of symptoms



West Nile Virus- Transmission Through Transfusion & Transplantation: What do we know?

- In Sept 2002 U.S. Centers for Disease Control and Prevention (CDC) confirmed that 4 individuals who received organs during transplantation from a single organ donor were infected with WNV.
- WNV infection was confirmed by NA testing of serum from the organ donor: 3 organ recipients developed encephalitis with 1 death.
- Organ donor infected with WNV by mosquito exposure or through transfusion (63 units of blood transfused)
- Other subsequent confirmed reports of transmission of WNV through blood transfusion



West Nile Virus- Transmission through Blood

- Clear evidence of transmission through blood
- Higher risk of infection through mosquito bites than by Blood Transfusion
- WNV can survive in RBC units for at least 26 days, some data that other blood components may also harbour the virus. 44 days in FFP; platelets- 5 days. More studies are needed.
- In U.S., 14 cases of transmission of WNV through transfusion
- In Canada, 2 possible cases of transmission of WNV through transfusion



West Nile Virus- Paths to Human Infection

- Blood Transfusion
- Organ transplantation
- Mosquito bites
- Intrauterine infection
- Occupational exposure-percutaneous transmission
- possibly breast milk



West Nile Virus: Managing Risks

General Measures for WNV infection

- Co-operative action by all stakeholders, multi-jurisdictional co-operation
- Active Surveillance System to detect WNV activity
- Education & Prevention: Reduce Exposure
- Communication re: exposure risks
- Vector abatement and control measures



West Nile Virus: Managing Risks-Blood

- Blood donor screening tests or pathogen inactivation for WNV would provide effective risk management strategies
- Contingency planning for options in the event that tests or pathogen inactivation for WNV may not be available
- For test development
 - Industry to move early WNV tests in an expedited fashion through development pipeline to a validated test to screen blood donors
 - Blood operators to have in place processes to adapt new technology in a timely manner
 - Health Canada to have in place flexible regulatory regime to review data for approval of tests



West Nile Virus- Risk Management Options-Blood

- Pre-donation screening-rigorous assessment
- Post Donation action on probable cases
- Post Donation action on confirmed cases



West Nile Virus- Risk Management Options-Blood

- Retrieve blood components collected during mosquito season-replace with "out of season" components; stockpiling of latter
- Obtain blood from low risk areas for "high risk" patients
- Consideration of introduction of pathogen inactivation technologies
- Testing of donated blood for WNV



West Nile Virus- Options to Reduce Transfusion Risk-Status

Option:

- Retrieve blood components collected during mosquito season-replace with "out of season" components

Comment:

Both CBS and HQ have recalled frozen components and begun to replenish inventory. Inventories of frozen components could be built up for use during mosquito season.



West Nile Virus- Options to Reduce Transfusion Risk-Status

Option:

- Obtain blood from low risk areas for susceptible patients

Comment:

Surveillance data is essential to developing a geographic risk assessment on which to base decision making. Animal, mosquito and human data are highly informative.

Needs to be considered further by all stakeholders.



West Nile Virus- Options to Reduce Transfusion Risk-Status

Option:

- Consideration of introduction of pathogen inactivation technologies

Comment:

Technology is new. Only one approved methodology in Canada which would require major changes to blood operations to implement across Canada. Needs to be further considered with stakeholders.



West Nile Virus- Options to Reduce Transfusion Risk-Status

Option:

- Testing of donated blood for WNV

Comment:

A highly favoured option. However, there is currently no WNV donor screening test.

- Health Canada would expedite review and give highest priority to operational implementation of an investigational test. Health Canada is working with Industry, blood operators to test feasibility of implementing tests in 2003



West Nile Virus- Options to Reduce Transfusion Risk-Status

Option:

- Selective Testing of donated blood for WNV

Comment:

Instead of testing all blood, only components destined for high risk patients would be tested. As part of contingency planning, this option has been discussed with both CBS and HQ.



West Nile Virus- Test Development: *Challenges*

- WNV serological based screening tests for donor screening are not ideal
- Even when using NA based tests, titres of virus may be low and this complicates testing of more dilute minipools
- Several unknowns e.g. period of viremia, infectious dose, prevalence in donors, transfusion transmission incidence rate etc.
- Need to develop reference standards, reagents and test panels



West Nile Virus- Test Development: *Challenges*

- While recognizing that a Nucleic Acid based test for WNV donor screening is a preferred option:
 - Moving a research or clinical diagnostic test to a full fledged donor screening test, including regulatory approval and implementation in a manufacturing environment, is generally a very lengthy process (several years).
 - Reducing this timeframe will represent a considerable challenge for all stakeholders



West Nile Virus- Testing in Canada: *Status*

- Health Canada has been in contact with Industry to discuss the status of their WNV testing programs and to discuss regulatory options for bringing these tests to market in Canada.
- Health Canada has met with CBS and HQ to discuss interest and feasibility of moving existing research and diagnostics WNV tests to within blood operators manufacturing environment.
 - This is one of several options to be considered as part of contingency planning in case no test is available



West Nile Virus- Health Canada Actions to Date

- Managing WNV Risk is a high priority for Health Canada
- Formed internal working group on WNV.
- WNV Issues raised, options discussed with EAC-BR
- Reviewed options and issued requirements to operators indicating:
 - no additional tests or donor screening questions are required at this time
 - for confirmed cases, products are to be withdrawn and donor deferred
 - for probable cases, products are to be quarantined and donors deferred
 - no requirement for retrieval of plasma once pooled for fractionation



West Nile Virus- Health Canada Actions to Date

- Active surveillance system for WNV has been established across Canada
- Working with Provincial and Territorial Health Authorities, procedures have been established for recording and transmitting case data from physicians/hospitals to provincial labs to CBS and HQ
- Health Canada is working with all jurisdictions in testing of WNV in Canada



Summary

- Health Canada is moving forward with various options to address WNV risk
- Development of tests for WNV are being closely followed and Health Canada will analyze data and prepare recommendations for test implementation once a test is available



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Summary

- Health Canada will continue to evaluate the potential impact of WNV risks in the area of transfusion and transplantation and will take steps to ensure that adequate measures are in place to protect the public



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