CANADIAN BLOOD SERVICES SOCIÉTÉ CANADIENNE DU SANG

SUMMARY notes of the meeting of the National Liaison Committee held at the Ottawa Marriott, Mackenzie Salon, on Monday, September 23, 2002, at 8 a.m. EST.

PRESENT:	Dr. Robin Moore-Orr	Anemia Institute
	Ms. Eleanor Holmgren	Canadian Association of Transplantation
	Dr. Stephen Couban	Canadian Blood & Marrow Transplant Group
	Ms. Kate Gagliardi	Canadian Society for Transfusion Medicine
	Dr. Greg Knoll	Canadian Transplant Society
	Ms. Wendy Chaulk	CLC - St. John's
	Ms. Kathie Leigh	CLC - London
	Ms. Elizabeth Tough	Canadian Immunodeficiencies Patient Organization
	Mr. Howard Leung	Thalassemia Foundation of Canada
	Mr. Jim Rodger	CLC- Winnipeg
	Mr. Shane Wood	CLC - Winnipeg
	Ms. Lorna Stevens	Neutropenia Support Association
	Mr. James Davies	Arthritis Society of Canada
	Ms. Nikki Roy	Physicians and Nurses for Blood Conservation Inc.
	Mr. Francois Perron	Canadian Society of Clinical Perfusion
	Dr. Davy Cheng	Canadian Cardiovascular Society
	Ms. Barbara Johnson	Candlelighters Childhood Cancer Foundation
PRESENTATIONS:	Dr. Heather Hume	Canadian Blood Services
	Mr. Ian Mumford	Canadian Blood Services
OBSERVING:	Ms. Jennifer Spencer	Canadian Blood Services
	Ms. Lorna Tessier	Canadian Blood Services
	Ms. Lisa Bussell	Canadian Blood Services
REGRETS:	Mr. Stuart Edmonds	Canadian Cancer Society
	Mr. Howard Waldner	Canadian Healthcare Association
	Mr. Glen Dietz	CLC- London
	Mr. Morley Reid	CLC- St. John's

FINAL

CO-CHAIRS:	Ms. Adélaïde La Plante	Canadian Blood Services Board of Directors
	Mr. James Kreppner	Canadian Blood Services Board of Directors

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Introduction of participants

The co-chairs welcomed all participants to the meeting. New NLC participants were introduced as well as the new Consumer Representative to the CBS Board of Directors.

Review and adoption of agenda

MOTION: To approve the agenda as presented. Moved and seconded. All in favour.

Review/approval of July 8, 2002 Summary Notes

MOTION: To approve the summary notes with the following changes:

Under the section, Cross-Over of Directed Donations
- an expanded program, would yield a projected additional 300 to 600 red cell units per year
- any expansion to the policy has an impact on resources, computer systems and tracking at the hospital level

Moved and seconded. All in favour.

Business Arising from Summary Notes

Items raised

NLC and CLC evaluation update

An evaluation presentation to the NLC included:
1. Report on results
2. Clarification/validation of responses
3. Preparation of recommendations to Board

The suggestions included:

Structure
1. Topic will determine the amount of discussion time needed
2. Limit/control vocal participants
3. Increase number of meetings
4. Board can request group come together for an issue
5. NLC members should bring emerging issues forward
6. Increase hospital user group representation- people who deliver blood services in hospitals
7. Continue with two representatives from each CLC and draw from end-user groups

Relational
1. Committee members can bring issues forward
2. NLC is recognized by Board – need input from CBS and Board

3. Co-chairs may bring recommendations to the Board and alternately the NLC may bring recommendations to the Board

Development of Evaluation Recommendations for the Board - See presentation to Board

Anti Hep B core (anti-HBc) Antigen Testing

A summary of the previous presentation was provided to the NLC participants. Highlights included:

Options
1. test first donations ± relapsed donors, defer if anti-HBc positive (one time)
2. test all donations, defer if anti-HBc positive (all)
3. test all donations, defer only on second anti-HBc positive donation (repeat)
4. test all donations, defer only if anti-HBc positive and anti-HBs negative (re-entry)

Factors to Consider
1. Decrease in HBV (Hepatitis B) transmission
2. Donor loss
3. Potential effects on manufactured plasma
4. Logistics
5. Cost

Summary
- Small but real risk of TT-HBV could be further decreased with available, affordable technology

EMT Proposal
- Need to find a way to study donors who are deferred. Health Canada needs evidence of safety of these donors
- "repeat" testing option is preferable as it balances safety and donor loss. Héma - Québec is considering this option.

NLC is requested by CBS to make recommendations on the following issues:
- Should anti-core Hep B testing be added
- Should testing phase be one-time or two-time
- What messages should be given to the donor who tests positive on the first test when the unit is not used

Discussions and Recommendations

Issues Raised
- The repeat testing option does not allow for individuals who are naturally immunized. Tests are licensed by Health Canada.
- No individual tests are available. CBS must do testing in a mass capacity

- Mini-pool NAT(nucleic amplification testing) for HPV is less sensitive than current testing
- Single unit NAT may be developed that would address the window period
- U.S will likely keep anti-core testing if single NAT testing occurs
- Recent medical literature examines whether exposure to hepatitis B puts a person in a high risk group
- Health Canada does not allow re-entry into the blood system as a donor
- Upon deferring a donor, communicating with them is paramount
- Should plasma from donors who test positive the first time be used but not red cells and platelets. Canadian fractionator would not use the plasma
- In U.S, another unit is tested 56 days later
- Canada should implement anti-core testing to keep in step with the U.S
- False negative rate is extremely low
- No precedents have been set by CBS where the first test result has been disregarded in favour of the second result
- Rate of false positives quite high with this test (1.3%)
- In the U.S, if second test result is negative, unit is used, if third test result came back positive, unit would not be used
- This type of screening requires an effective communication plan for public education
- Consent for core-antigen testing could be requested in the Record of Donation

Recommendation

NLC participants are in support of anti-core testing but require additional information to provide more definitive recommendations.

Cross-over of Directed Donations

Dr. Heather Hume presented a summary to the NLC on cross-over of directed donations. Presentation highlights included:

- If the directed donation is not compatible or is not used by the intended recipient, the unit could be put into the general inventory
- Cross-over could be difficult with mother to child donations due to the risk of transfusion related to acute lung injury (TRALI). Women must wait six months after giving birth to donate blood with the exception of directed donations of mother to newborn.
- Directed donations are as safe as blood from allogeneic donors. If they weren't as safe they would not be used.
- Crossing over would result 300 - 600 additional units per year
- Donors who are directing their donation should be advised that if they are not compatible, their donation could be used for someone else
- Consent forms will have to explain this thoroughly

Issues Raised

- unused autologous donations are not crossed over due to the difference in criteria
- autologous donations should be handled the same as allogeneic donations

- The importance of responding to the questions on the ROD truthfully must continue to be emphasized. CBS is in the process of changing the donor pamphlets to address this issue
- Due to the relatively small yield, the cost of crossing over donations should be compared to spending resources on recruiting new donors
- Crossing over directed donations is a positive addition to the inventory and helps save lives
- The Board asked that CBS look into the cross-over of directed donations as a way to expand the donor base and ensure maximum utilization of blood products
- No statistical difference in number of TDM between directed donations and allogeneic donations due to the relatively small number of units yielded from directed donations
- Concern regarding peer pressure situations that could create falsification during screening
- Screening process provides for this situation where labels are provided to donors giving them a final confidential opportunity to request that their blood not be used

Group recommendations
1) Expanded policy - see presentation to Board

Issues raised
- Increased hospital workload related to educating donors, screening donors, performing compatibility testing
- Safety issue at hospital resource level, potentially taking technologists away from other responsibilities

2) Cross over of directed donations
- The NLC recommends that with informed consent, CBS could cross over directed donations. Hospital workload and computer systems may not support such activity.

Issues raised
- Safety – increase hospital work-load, greater number of disease markers in first time donors
- Ethics – transparency is satisfied through informed consent prior to the donation NLC would like to provide input on informed consent, marketing, and educational information

West Nile Virus Update

NLC received a presentation on West NileVirus (WNV). Presentation highlights included:

- introduction of the origins of WNV and its spread to North America
- symptoms most severe in those with depressed immune symptoms; most people infected with WNV are asymptomatic

- antibody screening tests are performed**;** if antibodies found, chances most probable that cases become confirmed cases
- when screening donors, emphasis is placed on donors current state of health. If donor is not feeling well post-donation, they are advised to contact CBS

Issues Raised

- Although the risk of contracting WNV through a transfusion is extremely low, the situation needs to be monitored continuously and all messaging needs to be kept in perspective.
- Is it possible that those living in a mosquito dense area could be immune? The immunity levels in humans would depend on the number of birds affected.
- There are many more deaths caused by influenza than by WNV.
- Is WNV detected during fractionation? CBS will look into this.

FOR ACTION BY: CBS

- ❑ NLC to provide input to CBS on informed consent document for crossing over directed donations
- ☐ CBS will provide NLC with information regarding whether West Nile Virus is detected during fractionation.

How can CBS and the NLC support each other?

It was agreed that this item has been dealt with as the committee evolved. The following issues were however raised:

- NLC is pleased with the presentations by CBS but requests information prior to meetings as well as more time for discussion
- Feedback to Board seen as reactive rather than proactive
- CBS has done a good job of identifying topics that it wants feedback on

National Contact Centre (NCC)Update

NLC received an update on NCC that included the following highlights:
Currently there are 14 blood centers. Most telerecruiters work part-time. These centres will soon be merged into one area for national coverage. A new facility has been chosen – measuring 24,000 sq ft – and a new Director has been selected for the NCC. Since the new centre will need to run with one computer system, it will not be ready until CBS finishes the pilot testing of MAK Progesa. This new integrated system will replace 14 separate databases, as per Krever's recommendations. CBS is committed to providing blood donor satisfaction throughout the implementation of the NCC.

Issues Raised

- Concern that personalized donor contact will be lost, especially at the local level. CBS believes this relationship will be enhanced through a customer service relationship software that monitors and tracks relationships with every donor

- The CLCs will be asked to monitor their areas for potential problems
- MAK Progesa will allow for more accurate data storage which will provide better service

Report from the Board of Directors

A brief report on major issues discussed or addressed at the July meeting was made as follows:

The Board is closely monitoring all transformation projects. The Board approved the strategic directions and the approach for the development of the 2003-2004 budget. A high level three-year plan was also approved. It was noted that a new process was approved regarding the development of the corporate three-year plan. The new process allows more time for discussion and better alignment between the strategic plan and the budget plan. It was also noted that the corporate plan is prepared for and submitted to the Members annually.

The Board was informed regarding the development of a new marketing and advertising campaign with a new strategy for radio and television advertising.

The Board is awaiting CBS's performance review that is being carried out on behalf of the provincial and territorial health Ministers.

A list of the five new directors recently appointed to the Board was distributed.

New Business

Launch of new Community Liaison Commitees

New Community Liaison Committees will be launched in Vancouver, Calgary and Halifax, with the first set of meetings taking place in November and December. The criteria for selecting locations include where they will have the biggest impact and how occupied the Centres are with other initiatives. The CLC in Winnipeg will move from an electronic forum to face-to-face forum with its first meeting in November.

Discussion topics for next meeting

Issues likely to be facing CBS in the future are:

- West Nile Virus
- Streamlining the donor process
- Bacterial detection, the safety issue
- Plasma self-sufficiency, ways to increase collection
- Reaction of screening test for vCJD
- How much safety can CBS afford given that risk has already been reduced significantly?

NLC requests guidance on priority areas they are to focus on over the next year.

Discussion summary

- Demand/utilization of blood or safety vs. supply: CBS should collaborate with physicians and nurses regarding education on blood utilization (currently 2/3 of blood used is in the peri-operative care setting). CBS should determine a cost figure for blood to make health care workers aware and accountable for their demands. Héma-Québec has not determined a cost figure.
- Promotion of commitment the blood system
- Autologuous donations have declined due to increased trust in the blood system
- NLC membership should be limited and staggered; each member could serve a maximum of 3 years
- CLC Terms of Reference should reflect that the NLC representative can be changed
- NLC members will take issues back to their own organizations for input unless advised that the matter is confidential
- NLC would like to have input on development of MAK Progesa, NCC, and their impact on hospital inventory management
- NLC wants information on Board's priorities and to continue to be consulted prior to decision making
- Educational information should be based on scientific fact (ie What's Your Type)
- CLCs should be consulted regarding educational programs/information

Four Priority Areas (identified for future discussion)

1) Recruitment and retention
2) Utilization and alternatives
3) Safety of the blood system and perceptions
4) Educating the public/health care professionals

FOR ACTION BY: CBS

- ☐ CBS will provide NLC with the Terms of Reference for the CLCs.
- ☐ NLC participants will provide feedback to CBS on four priority areas.

<u>Emerging Issues</u>

What other deferral policies may be coming up? CBS provided an update on the licensing of NAT testing, which, when licensed, will provide an opportunity to eliminate other testing, such as P24 testing.

The Anemia Institute is hosting a conference on Canada's blood system on November 23 and 24. It will focus on how far the blood system has come, its current state, and future direction.

Whether CBS should address original research on blood alternatives and recombinants was also raised.

Are there any donor screening regulations that can be relaxed? Although donor selection criteria cannot be set aside, CBS is approaching Health Canada to raise the upper age limit. The challenge lies in approaching Health Canada with sufficient data proving that changing the criteria won't put patients at risk.

Adjournment

The meeting was adjourned at 4:00 p.m.