Blood Matters

Provincial Blood Coordinating Office, British Columbia

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Focus on Standards

Aldous Huxley (1894-1963) although he may have not appreciated the conformity that it will create, would have reflected that he could have been describing the blood transfusion community as we enter our ***Brave New World*** of Z902-04. This edition of Blood Matters contains a brilliant précis of this new standard, another of the Krever legacies. This review has been prepared by Pat Letendre with help from colleagues across Canada and is a must read for anyone remotely interested in blood transfusion. In reporting the insights of her associates, Pat takes us through the key areas of change including SOP's, Document Control, Training and Competency Assessment, Error Management and Validation. She describes what she feels will be the impacts on laboratory workers, highlighting current major deficiencies. Z902-04 is also going to have major effects, although most don't yet realize it, on everyone involved in blood transfusion including those of our co-workers who actually hang the products and monitor the patients during transfusion. Who is going to educate and train all these people, and where will the resources for this be found? Pat foresees that the enormity of the changes that Z902-04 portends will mean we may need to operate in groups or clusters of transfusion laboratories in order to fulfill the requirements of the new standard. This is not a process that BC should fear; we have an excellent record in this regard with many examples, over many years, of collaborative and innovative strategies that have improved blood transfusion for all. I believe that the brave new world of Z902-04 is going to provide another opportunity for BC to show innovation, teamwork and leadership which will be a beacon for all.

On a totally separate note we must also highlight the retirement from Vancouver General Hospital of Dr. Growe where he has been blood transfusion service medical director for many years. We are not losing Dr. Growe completely however; Jerry will continue to work as a medical consultant at the CBS (BC & Yukon Centre) and will continue his links with the Hemophilia clinic. We thank Jerry very much for all his contributions to the blood transfusion service within BC and Canada and wish him continuing health and success.

- Dr. Louis Wadsworth, TMAG

CSA Standards Z902-04: Implications and Issues

The much anticipated Canadian Standards Association (CSA) Standards "Blood and blood components" (also known as Z902-04*) have been published and are available for purchase. Many in the transfusion community are wondering what Z902-04 means to them: What do the final Standards say? What impact will the Standards have on the daily operations of transfusion services (TS)? What are TS to do with the Standards right now? Are they regulations like Health Canada GMP are for CBS and Héma-Québec? How and when will they be used in audits for accreditation of TS?

This article will examine the impact of some of the more significant Z902-04 requirements and will attempt to answer these questions. As well, resources to help TS comply with Z902-04 will be featured. Although Z902-04 applies to both blood suppliers and TS, only TS aspects will be discussed. Several individuals contributed their insights to this article and are acknowledged below**.

Impact on Transfusion Services

As a response to the Krever Report* and in anticipation of Z902-04, Canada's blood system has initiated many innovations, e.g., in BC the PBCO* and TraQ program*; in Ontario the TOPS program*, including QUEST programs in Hamilton-Niagara and Ottawa*; in Québec the system of transfusion safety officers, both technologists and nurses, in regional transfusion centers; in Nova

*For links to all cited resources, see:
www.traqprogram.ca/library/BM-July-04.asp

What's Inside?

Scotia, a Provincial Blood Coordinating Program; in New Brunswick, a provincial Quality Assurance Working Group* for transfusion medicine.

The readiness of TS to comply with Z902-04 in Ontario in 2001 was described in *Provincial Survey of the Impact of Standard #Z902 on Transfusion Medicine Laboratories in Ontario Hospitals** ("Ontario TS Survey"). The major deficiencies identified were lack of quality management programs (SOPs, document control, training, competency assessment, and error management); absence of transfusion committees; lack of appropriate equipment; and insufficient staffing. These deficiencies likely still apply to many TS across the country.

Although much progress has been made in recent years, much remains to be done. Two of the biggest impacts of Z902-04 involve quality systems (QS) and out-of-laboratory procedures related to the transfusion of blood. The elements of QS most likely to have a significant influence include requirements for SOPs, document control, training, competency assessment, error management, and validation, as outlined in Z902-04 (Section 4) and paraphrased below. For full details readers are encouraged to purchase Z902-04 from the CSA*.

Quality Systems

1. SOPs. Section 4.2 requires that facilities maintain a manual of current operating procedures (hereafter termed SOPs) that are approved by senior management, reviewed annually, distributed and maintained using a document control system to ensure that all SOPs are current and authorized, and that new procedures and important changes be implemented only after being approved and after training of staff is complete.

Because SOPs are critical for compliance with Z902-04, many TS have chosen to develop SOP manuals as a priority. For example, both the Ottawa SWIM manual* and the Manitoba Transfusion Quality Manual were based extensively on TraQ's Technical Resource Manual* (TRM), and many hospitals in Quebec and elsewhere have used the TRM as a model. The Hamilton Niagara QUEST program* has developed Share Our Strategies (SOS) Manual*, which describes their strategies for developing documentation, document control, and training documentation.

In BC, the TraQ TRM and its Competency Companion* are currently being revised to comply with Z902-04. The revised TRM will have in-text references to specific Z902-04 clauses and also to specific clauses in the new CSTM Standards*, which are expected to be available by Fall 2004. These enhancements will make the revised TRM an invaluable resource for TS as they move towards compliance with Z902-04.

Despite exemplary SOP manuals, SOPs in many regions may not reflect what is actually done. The Ontario TS Survey showed that only 23.2% (25/108) surveyed hospitals had all required Z902 criteria present in their SOP format, and written policies and procedures were frequently lacking with only 8.3% (9/108) hospitals having policies and procedures in place for all laboratory functions assessed in the survey.

Currently, vast differences exist in TS across Canada. Although some regions are well prepared for Z902-04, anecdotally in many locales there has been no annual review and no document control of SOPs, especially when satellite laboratories exist. Although products, labels, how to enter units in the LIS, etc., have changed, facilities have not had the time to keep up with revising the SOPs. Once revised, there may be inadequate resources to maintain them. In the absence of current SOPs, when training new employees, staff are forced to ignore the pieces in the manuals that do not apply. Given these realities, Z902-04's standards for operating procedures (4.2) will have a major impact on Canada's TS.

2. Document control. In any QS, SOPs and document control are integrally linked. Section 4.2.3 requires that facilities establish and maintain a document control procedure that includes specific protocols for revising SOPs; provides for tracking of revisions; describes the means for unique numerical designation and control of versions, and criteria used for a change in version number; includes a distribution list of staff who are to receive copies of new or revised SOPs when a new SOP is implemented. As well facilities must have procedures to remove all copies of superseded SOPs and replace them with current authorized versions; to withdraw obsolete SOPs and notify affected staff in writing; to archive master copies of the current SOPs and superseded or obsolete procedures; to identify, collect, file, store, and maintain any working documents used to prepare SOPs.

TS deficiencies with document control parallel those of SOP development. In the Ontario TS Survey one of the criteria most frequently missing from SOP formats was a unique number identifying documents and their revisions and ~ 40% of hospitals lacked master files for document control of SOPs. To comply with Z902-04, TS will need resources and expertise to develop comprehensive document control systems. See, for example, *Regional Document Control System in a Multi-site Community Hospital Setting** (Hamilton Niagara QUEST).

3. Training and competency assessment. Personnel requirements in Z902-04 (4.3) include training (4.3.2), competency assessment (4.3.3), and records (4.3.4). Facilities must identify training needs and develop training programs, including initial and ongoing training; develop, maintain, and document formal competency assessment programs; assess competency following training and at regular intervals thereafter; assess effectiveness of training programs at least annually; implement SOPs and important changes only after staff training is complete; maintain documentation of qualifications, training, competency assessments, continued competence; and implement remedial measures to correct inadequate performance.

Z902-04 criteria for training and assessment are critical and overwhelming in scope and need for resources. Using existing resources such as the Bloody Easy Online Course* and the TraQ Competency Companion* can help. For example, the Competency Companion is being revised to include expanded checklists and additional quiz questions to highlight new requirements in Z902-04. However the sheer number of staff to be reached in multi-site organizations (where staff continually change) makes training and assessment difficult. Few organizations have adequate numbers of staff and the expertise to design, deliver, maintain and evaluate programs.

4. Error management. Z902-04 (4.6.1.5) requires that an error management system exist that ensures and documents that deviations from SOPs, such as errors and accidents, are identified, investigated, and evaluated, and that corrective action is taken when required. To comply with this clause, TS must develop a documented system that focuses on processes rather than individual performance, that reports errors without fear of blame, uses root

cause analysis to identify actual causes and contributing factors, and promotes a culture of guilt-free questioning and constant learning.

Some TS have developed in-house error management systems. On a national scale, Health Canada's Transfusion Transmitted Injuries (TTI) Section* has piloted several programs, including one to evaluate the Medical Event Reporting System for Transfusion Medicine (MERS-TM*).

5. Validation. Z902-04 (4.6.1.4 and 4.6.2.1) requires that SOPs be validated in a documented process when developed and revised (if changes could be expected to affect the results obtained during the original validation), to include procedures for the identification, documentation, review, and approval of all process changes.

Some TS employ user acceptance to produce better SOPs, however full scale documented validation does not exist in most locales. Indeed, validation is a relatively new concept to TS and is not yet completely understood in the transfusion community, exacerbated because there is no single accepted procedure for conducting validations. Instead regulatory guidance, published literature, and educational tools are consulted, if available. The Alberta College of Physicians and Surgeons offers validation study guidelines*; TraQ's Case A7* discusses validation as applied to blood transport containers.

Procedures Outside the TS Laboratory

Z902-04 encompasses transfusion practices outside the TS laboratory. Such standards merit an article of their own and will be mentioned only briefly here. Clause 4.3.6.2 specifies that training include mechanisms to ensure ongoing training of all staff involved in administering blood components. Clause 4.3.3.1 requires formal competency assessment programs with components such as direct observation, monitoring of reports, written tests, etc. Performing regular audits of clinical staff to assess bedside transfusion practice and knowledge for each individual is huge in scope.

Clause 4.3.6.1 specifies that the TS medical director is responsible for (or shall be consulted in) the development of all policies related to the care and safety of recipients (and donors, if applicable). Transfusion committees with documented terms of reference, composed of key stakeholders who meet at least quarterly, are to play a key role (4.4). Responsibilities include defining transfusion policies, ensuring that transfusion practices are regularly evaluated, developing criteria for assessing ordering practices and blood usage, disseminating information and education, evaluating adverse events, and reviewing alternatives to allogeneic transfusion. While many facilities have transfusion committees, anecdotal evidence suggests that their activity levels vary widely across the country and that achieving active participation by busy professionals is difficult. Education and monitoring mechanisms to promote effective blood utilization alone are significant undertakings, as shown by the utilization management programs* of the BC PBCO.

Section 11.4 requires that there be SOPs for administering blood components and for operating infusion devices and associated equipment; that recipient vital signs be recorded before, during, and after transfusion; that recipients be observed during transfusion and for an appropriate time afterwards for suspected adverse events; that instructions on adverse events be provided to recipients, or to responsible caregivers, when direct medical monitoring is unavailable after transfusion. Blood warmers must be validated and meet applicable national safety standards (11.5.2). Among several standards for perioperative blood collection is the requirement that blood centres or TS be involved in developing the policies and procedures used to manage such programs.

To meet Z902-04 standards, thousands of nurses and physicians, including anesthesiologists, will require training and assessment. Besides the Bloody Easy Online Course*, another resource is the BC PBCO's Clinical Transfusion Resource Manual* (CTRM), which provides guidelines, training, and educational material related to administering blood. The CTRM and its associated Safe Transfusion Practice Video and CD-ROM were specifically designed for clinical practitioners involved in direct patient care.

Implementing many Z902-04 standards will require interdepartmental and inter-facility cooperation. One challenge will be overcoming the layers of management involved in multi-site organizations. Another will be fostering cooperation and eliminating the notion that the TS is policing other departments. Also, largely unknown is what specific role the TS is expected to play in training and assessment of all staff involved in out-of-laboratory transfusion-related practices, including those that have traditionally operated outside the responsibility of the TS, such as perioperative blood collection and the blood salvaging and processing done by perfusionists.

Global Aspects

Several Z902-04 clauses have organization-wide implications. For example, staffing (4.3.1.2) is a deceptively simple standard that, in part, requires sufficient qualified and experienced personnel to perform SOPs based on a facility's size, complexity, and the numbers of blood components that it handles. To meet this standard, organizations will need recognized workload/practice guidelines specifically designed for TS, where much of the work is considered non-workload. Clause 4.3.1.4 specifies that areas of responsibility and lines of authority be identified on an organizational chart; and if the TS medical director is shared between facilities, the chart should include specific information on communication or delegation that ensures that responsibilities are covered. The upcoming massive loss of health professionals to retirement will further complicate these issues, with departments and facilities potentially competing for an increasingly smaller cadre of professionals.

Physical facilities (Section 21) requires that TS be located, designed, constructed, and adapted to suit its operations and permit efficient cleaning and maintenance of premises and equipment; that there is a documented pest control program that ensures chemicals do not contaminate materials or endanger staff health and that is reviewed and updated at least annually; and that facilities be secure against entry of unauthorized personnel.

Potentially, millions of dollars will be needed to meet facility standards. Space is a common problem in TS, especially in community hospitals where often samples are processed, plasma is thawed, and platelets are pooled all in one workstation. Security of the blood supply exists in blood centers but is not widespread in hospital-based TS, except after hours when staff safety is a concern.

Another broad implication is that Z902-04 may serve to decrease the number of facilities involved in transfusion. Many smaller hospitals transfuse and store very little blood and the services of some may need to be centralized in order to meet Z902-04 standards.

Standards vs Regulations vs Accreditation

Confusion surrounds the status of Z902-04 as CSA standards versus Health Canada regulations, and whether they will be used for provincial accreditation of TS.

Standards. Standards are norms of behaviour and best practice. Professional organizations such as the AABB* have Standards that are used for voluntarily accreditation by the AABB. In Canada, CSTM Standards* are used by several provincial Colleges of Physicians and Surgeons or their equivalents as the basis of TS accreditation*. The CSA developed Z902-04 following extensive collaboration with transfusion medicine experts and government stakeholders. The CSA Standards are aimed at maintaining and enhancing the quality and safety of blood collection, processing, and transfusion. CSA Standards are not regulations. However, Health Canada encourages health organizations to follow the practices and procedures in the CSA Standards as they represent the current industry standard for safety.

Regulations. While regulations and standards share many similarities, they differ in one fundamental respect: regulations apply standards through the force of law and provide penalties for non-compliance. Standards, in and of themselves, are never legislative tools. To have the force of law, standards must be incorporated into the regulations. Health Canada is currently developing new regulations specific to blood and blood components intended for transfusion under the Food and Drugs Act.

Health Canada will use CSA Standards as one of several tools employed to develop new federal regulations for blood and blood components. Based on the Standards, a goal of the proposed regulations is to outline clear and intelligible requirements, allowing for timely updating as new technologies/products/issues emerge, and achieving greater harmonization in Canada related to blood collection, handling and post-market surveillance. A review of Z902-04 is currently underway to determine which parts can be referenced in the new regulations. Some sections of the standards fall outside of Health Canada's jurisdiction and will not be referenced in the new regulations. Mechanisms to foster and verify compliance and the extent to which monitoring will be applied are currently being developed and assessed. With the advent of the new Health Canada regulatory framework anticipated within the next two years, a time line for implementing the new regulations and associated compliance monitoring activities will be developed. Stakeholders will have the opportunity to provide input as proposals for a new regulatory framework are refined.

Accreditation. Accreditation of Canada's TS laboratories is mandated by the provinces and is the responsibility of the Colleges of Physicians and Surgeons (CPS) or equivalents*. CPS accredit only laboratories and do not audit key clinical transfusion areas such as patient identification prior to administering blood. Individual accrediting bodies in each province select the particular standards upon which they base audits. Until now, CSTM Standards or AABB Standards or both have been used for accreditation. Provincial accrediting bodies can now choose to use the new CSA Standards as a basis for accreditation.

For example, Québec has mandated that by December 31, 2005 all establishments with a blood bank laboratory be registered with a program of approval of its laboratory by a recognized organization. Facilities with autologous and "walking donor" programs must also be accredited. Accreditation will be based on ISO 15189* and CSA-Z-902, to which *Comité consultatif national de médecine transfusionnelle* (CCNMT) recommendations are added. See *Normes et Pratiques de gestion* (2004-07-07)*. Ontario Laboratory Accreditation (OLA*) also uses ISO 15189 as a basis for accreditation.

Since CSTM Standards* are being revised to comply with the CSA Standards and will be available Fall 2004, they too will be an important option for provinces to consider.

Summary

CSA Standards (Z902-04) are now available and represent current industry standards for safety. These standards will have a huge impact on all segments of our blood system, in which events have moved faster than the system's ability to keep up. Vast differences exist between TS in different regions of the country. Because Z902-04 Standards are not yet regulations, complying with them is currently an option. Moreover, full compliance is beyond the existing resources of most, if not all, Canadian TS. Nonetheless, many regions and TS are now implementing changes designed to meet Z902-04 standards. Even before they become federal regulations, they will likely be used for accreditation in some provinces. In the interim, all TS will strive as best they can to comply with these *de facto* best practice standards for blood safety. Several excellent resources exist to help TS meet this long-range goal.

- Pat Letendre, TraQ Coordinator

** Many thanks to the following for invaluable input:
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Project Updates

Utilization Management

IVIG

The IVIG "Trough Level Monitoring Practices Survey" we sent to hospitals in March revealed some differences in practice. Of the 57 responding hospitals that issue IVIG, 39 (68%) consistently monitor IgG trough levels on IVIG patients, 3 sometimes monitor and 15 do not monitor. According to the IVIG utilization management program guidelines, IgG trough level monitoring is required on all primary and secondary immune deficient patients.

Thirty-three of the hospitals make dose adjustment recommendations to the clinicians and 39 hospitals have an "end date," at which time the trough level should be redone and the clinician consultation revisited. This end date should be one year, providing the patient has a positive clinical outcome and the IgG target level is within or below 6.7 – 7.3 g/L.

Many hospitals appear to be misinformed regarding how often trough levels should be performed. After a dose adjustment, a repeat trough level should be done after steady state is reached (4-5 doses). If the patient's IgG level is within the target range of 6.7-7.3 g/L, the trough level should be done annually. However if the patient suffers from repeated infections, a trough level should be performed so the pathologist and clinician can revisit the dosage. Thank you for completing the survey, which will help us refine the program guidelines and education regarding immune deficiency patients.

The PBCO will be updating the *IVIG Utilization Management Handbook* this fall. If you have suggestions for improving the *Handbook* and/or the IVIG utilization management program, please let us know.

Synagis®

Use of Synagis® grew by 23% in 2003/04, owing primarily to an expansion of the program guidelines to incorporate babies with hemodynamically significant congenital heart disease. According to our end-of-season survey, 146 infants (73%) received all of their approved doses. The RSV Immunoprophylaxis Task Force will meet in September or October to finalize the program parameters for the 2004/05 RSV season.

- Shannon Selin, PBCO

CTR Update

The Central Transfusion Registry (CTR) Upgrade and Validation Project is chugging right along. The new import process will be a welcome change from our old processing method. The job facing the staff over the summer is getting all of the back data from previous workload periods into the new CTR. We are facing approximately 9 months of back data to process. We appreciate everyone sending in their data as usual. Patience is a virtue and we will keep you posted on our forecasted "back in business" date.

Thanks to everyone for returning the HBIG survey. We are looking forward to reviewing the data. It will be a good source of information to make sure all records are being reported appropriately, according to regions, facilities etc. Have a great summer.

- Theresa Witt, PBCO

RBC Working Group has a new name

The former **RBC Working Group** adopted the new name of **Technical Resource Group for Transfusion Medicine (TRG)** at their June meeting to reflect the renewed mandate of the group, which is to be a broader-based advisory body serving as a technical resource to the PBCO. The group also welcomed Pam Quibell from Prince George Regional Hospital as their newest member.

BC Blood Inventory Management Website Update

The BC Blood Inventory Management (BC BIM) website recently went through an interim upgrade in May. The improved website now includes additional security levels and more statistically correct graphs. The following interim modifications have been made:

1) To enhance the security of the website, clearly defined security levels were created with users falling into one of the below categories:

- Regional Administrators - Ability to enter data on behalf of multiple sites in the region.
- Hospital Administrators - Ability to enter data (including data older than two weeks) and edit data, view participant data and make modifications to hospital user access.
- Hospital Users - Access to entering data and viewing participant data.

2) The following changes have been made to the graphs:

- Hospital reports have been changed from a line graph to a bar graph so that the data is presented in a more statistically correct manner. The bar graph delineates between units which expire in less than or equal to ten days and those expiring in greater than ten days. (The Total Participant graphs have remained as line graphs to enable users to view a full month of data.)
- Arrows have been added to allow users to scroll to view previous or next date periods on the graphs.
- CBS inventory data can be viewed in a line or a bar graph.
- Disclaimers have been added to qualify the data being shown.
- Wording has been corrected to ensure terms like "provincial" are not used in the place of "total participant."

The changes to the website may not be as apparent to a front-end user since the back-end of the database has been reviewed and modified as well. Further enhancements will be incorporated in the near future with input from the Technical Resource Group for Transfusion Medicine and the end users.

We would like to thank all the participants for their patience and cooperation during the upgrade. If you have any questions regarding the functionality of the website or if you would like to participate, please do not hesitate to contact the PBCO at 604-806-8840 or click on the "contact us" link at www.bcbim.ca.

- Anita Lam, PBCO

Adverse Event Reporting System

Update on Resources

The Clinical Transfusion Resource Manual (CTRM) was developed in 2001 as a tool for the initial AERS pilot project. The Nursing Resource Group (NRG) is currently revising the CTRM 2002 edition to ensure compliance with the currently published Standards. The 2004 Edition will be compliant with CSA Z902-04 and CSTM Standards and will include several additional resource tools such as a template for preprinted Physician's orders and the

Clinical Competency Assessment Tool. In addition to the manual, the NRG has completed a clinically based template for information related to blood and blood products. This resource will be available to all Transfusion Services to review, approve, implement and update as required if they choose to.

Sites around the province are in various stages of developing or initiating their "triad" and preparing to launch hospital-based education. Those sites that have established programs are reviewing the CSA Standards and assessing their ability to comply with the educational and competency requirements. With another year comes another round of education with updates on TRALI, West Nile Virus, Platelet Bacterial Testing, guidelines etc. A Clinical Resource Guide is being developed to assist in the education process. For further information contact Shelley 604-682-2344 local 63739, or email sfeenstra@providencehealth.bc.ca.

Troubleshooting Product Administration

You are not alone! Let's share our problems related to product administration and learn from them! If you have any issues or challenges in product administration within your facility, please contact Shelley Feenstra RN, Clinical Transfusion Resource Coordinator via email at sfeenstra@providencehealth.bc.ca

AERS Reporting Changes

The PBCO is currently undergoing a consultation process with project stakeholders to look at adopting a nationally standardized reporting form for severe/Health Canada reportable transfusion reactions. This form is longer in length but contains all of the required data elements needed at the national level.

Additional information will be forthcoming with regards to reporting template and mechanism changes as well as some modifications to the project scope and operation. In the meantime, hospitals are asked to please continue reporting as they do normally.

- Shelley Feenstra, PBCO & Aimee Beauchamp, PBCO

CBS Update

Buffy Coat Implementation at Canadian Blood Services

Canadian Blood Services (CBS) will be implementing the 'Buffy Coat' method for the production of platelets from whole blood donations. This method of platelet production has been in widespread use, predominantly in Europe, for over 20 years.

Our current method is known as the 'PRP' or Platelet Rich Plasma method. Whole blood donations are maintained at room temperature and platelets must be processed within eight hours of collection. The whole blood is spun at a low speed (soft spin), and then the PRP is manually extracted through a leukoreduction filter, leaving the red blood cells in the original collection container to undergo further processing (leukoreduction and addition of AS3). The PRP is then spun at high speed (hard spin) to concentrate the platelets, and the platelet poor plasma is extracted into the plasma container.

With the Buffy Coat production method, whole blood donations are rapidly cooled to room temperature on cooling trays, and platelets must be processed within 24 hours of collection. The whole blood is spun at a hard spin, and a semi-automated extractor removes the plasma and red blood cells at the same time, leaving the buffy coat layer in the collection container. The buffy coat contains platelets, white blood cells, and some red blood cells and plasma. The buffy coats from four donations are then sterile-docked together along with plasma from one of the four donors, and pooled together. This pooled buffy coat is then given a soft spin, and the PRP is extracted through a leukoreduction filter to produce a pooled platelet concentrate.

There are many benefits with the Buffy Coat production method:

- a more consistent product, with improved platelet recovery, from whole blood donations,
- the 24 hour production window increases the ability to process platelets from more whole blood donations, improving inventory availability,
- the provision of a pooled, "ready for use" platelet concentrate with a 5-day shelf life. The pooled platelet product is similar in size and volume to an apheresis platelet, and is also more amenable to bacterial detection using the BacT/ALERT system currently being used for apheresis platelets,
- increases the amount of plasma removed from whole blood donations, allowing CBS to send more plasma for fractionation, improving security of supply, and reducing overall cost to the health care system for fractionation products.

The Buffy Coat method is expected to begin in selected pilot sites during the summer of 2005, followed by a staggered implementation across the country throughout 2006.

We want to take this opportunity, early in the planning phase, to notify our hospital customers of the changes expected in the products delivered for transfusion. Following are the key changes that will be seen at the hospital level.

- The change in anticoagulant and red blood cell preservative will change component names and component codes. There will also be the introduction of a new product type: pooled platelets. This may affect hospital laboratory information systems. We will provide a list of changes to component codes, names, and barcode samples as early as possible in the project timelines.
- Change in anticoagulant for all whole blood donations to CPD. For most patients, this will be no significant impact. There will be smaller changes in glucose levels in newborns undergoing massive transfusion with plasma replacement.
- SAG-M will replace AS-3 as the red blood cell preservative solution. For neonates, there are similar safety impacts (ie. No problem with small volume transfusion, for massive transfu-

sion, the theoretical risks are similar for both.) Shelf life for SAG-M red blood cells is 42 days.

- There is the possibility of introduction of DEHP-free PVC storage containers for blood components from whole blood donations. We would like feedback from our customers on the requirements for these products. This would introduce two types of red blood cells in inventory. We may not have a supply of all blood groups at all times. The DEHP-free packs are also more expensive, and have a distinct odour.
- CPD will be the only anticoagulant used for whole blood donations. Therefore, CBS will no longer supply CPDA-1 whole blood for pediatric and autologous use.
- Autologous donations will be processed into SAG-M red blood cells and plasma. Autologous red blood cells will have a 42-day shelf life. Autologous whole blood will not be available. Autologous plasma will be provided only if specifically requested prior to donation. Autologous donations with adjusted anticoagulant will not be available.
- Whole blood derived platelets will be pre-storage pooled. Group matched buffy coats from four donations will be pooled, along with a plasma from one of the four donors, to produce a pooled platelet concentrate. The pooled platelet will have a volume of approximately 300 mls, and a shelf life of 5 days. Platelets from a single unit of whole blood will not be available.
- Prestorage pooling of platelets also permits CBS to perform bacterial testing by culture at the time of production. Buffy coat platelets will be tested on the BacT/ALERT similar to apheresis platelets. Hospitals will not have to do any bacterial testing of platelet products.
- The preferred product for pediatric platelet transfusion will be apheresis platelets to minimize donor exposures. A sterile docking device may be necessary to optimally use platelet products for small recipients, to prevent wastage by allowing repeat/shared usage.
- Plasma products will not be leukoreduced by filtration with the Buffy Coat production method. Note that there is no Health Canada requirement to leukoreduce plasma.
- All transfusable plasma produced from whole blood donations will be Frozen Plasma, frozen within 24 hours of collection, rather than Fresh Frozen Plasma, frozen within 8 hours of collection.
- Cryoprecipitate will also be produced from Frozen Plasma, rather than Fresh Frozen Plasma. This change will be made only if data support the maintenance of appropriate levels of fibrinogen and von Willebrand factor in cryoprecipitate. Cryoprecipitate may be relabelled to reflect its modern clinical use (ie. Not for the treatment of hemophilia, but as a fibrinogen or vWF replacement).
- During the pilot and staggered implementation of the Buffy Coat project throughout 2005 and 2006, there will be mixed inventory of old and new products, up to one year post implementation (for frozen plasma products).

Every effort will be made to keep you informed of the progress of this project. For further information, please contact: Lyle Unrau, Hospital Customer Services Representative at 604-707-3516 or lyle.unrau@bloodservices.ca

Cessation of Routine anti-D Screening at 34 Weeks Gestation

Testing of Rh Negative women for the presence of anti-D at 34 weeks gestation has been a routine practice for many years at Canadian Blood Services (CBS) BC & Yukon Patient Services Prenatal Program.

The rationale for testing at 34 weeks was reviewed recently with both the Head Office of CBS and BC's Transfusion Medicine Advisory Group (TMAG). Taken into consideration were the recommendations of the Society of Obstetricians and Gynaecologists of Canada and the Obstetrical Society of BC. Review of these references indicated that it was not necessary to test women negative for anti-D routinely at this time.

Therefore as of June 1, 2004, CBS, BC&Yukon has eliminated anti-D screening for Rh Negative women at 34 weeks. All other prenatal testing remains the same. Please discontinue forwarding 34 week samples to CBS.

If you have any questions regarding this policy or the supporting references, please contact Dr. Jerry Growe at 604-707-3449.

Note: A reminder that the Patient Services Prenatal Laboratory has a direct telephone line, 604-707-3527, as well as a dedicated fax number, 604-874-6582. If you are phoning in on the toll free number 1-888-332-5663, at the prompt dial 3527.

- Dr. Jerry Growe, CBS

Anti-HBc Testing

The anti-HBc test was previously scheduled for implementation in September 2004. We have delayed it primarily because of the time and attention we have devoted to West Nile Virus testing over the past 18 months. We are currently developing a new timeline for the anti-HBc test's implementation and will announce a new date once the new timeline has been approved by the Board of Directors at the September Board Meeting.

CBS and the PBCO will co-host the 4th annual **Joint Symposium on Blood Transfusion Issues**. The one-day symposium will take place on September 29, 2004 in Richmond, BC. Registration is free and will include lunch, however space is limited so please register early. Tentative topics include: BacT/ALERT System, Quality Manual Development, Update on the Buffy Coat Project and a Status Review of the Emergency Donor Program. Please contact Sabrina Gunkel to register - SGunkel@providencehealth.bc.ca or 604-682-2344 ext. 63469.

Reports

CSTM Joint Conference 2004

The CSTM Joint Conference 2004 was held at Niagara-on-the-Lake, May 13 - 16, 2004. The theme of the Conference was "Embracing the Cascade of Change". The topics presented met the challenges of the theme. The Conference offered the delegates a good mix of presentations on many different levels. There were lectures on current scientific research (the "OME" series of lectures), lectures on everyday issues (neonatal transfusion controversies, inventory management issues, error management systems, training and competency) to topics of general interest (the time line for the 2003 SARS infection threat in the Toronto / Hamilton hospitals).

A highlight of the Conference was a presentation by Dr. Rizoli, a trauma surgeon at Sunnybrook Women's College Health Science Centre. Dr. Rizoli presented a first hand view of issues facing a surgeon attending trauma patients. He spoke of a potential role of recombinant factor VIIa (rFVIIa) in the treatment of uncontrolled bleeding in trauma. The traditional role for the product has been in the treatment of bleeding due to hemophilia. It is a relatively safe, but expensive product, which will cause thrombosis only at the site of injury. Preliminary findings from a multi-national randomized control trial (Canada was a participant) have produced encouraging results. Recombinant factor VIIa could reduce the need for extensive blood transfusions during trauma treatment. The emphasis must be on "preliminary". Dr. Rizoli emphasized this is not a sure thing in the treatment of severely bleeding trauma patients. At this time there is no evidence it stops mortality. The complete results of the clinical trial are pending, and further trials will be necessary. There are other ongoing investigations for the possible use of rFVIIa in other bleeding situations, such as elective prostatectomy.

Congratulations to the organizers, who put together an interesting and varied group of sessions. The setting for the Congress was wonderful. Free time could be spent at Niagara Falls or in the historic town of Niagara-on-the Lake.

The next CSTM Joint Conference will be held in Banff, Alberta in April 2005. The preliminary program has 3 main topics: quality essentials, prevention of adverse events, and blood inventory issues. So mark your calendars, springtime in the Rockies, sounds like a plan.

- Theresa Witt, PBCO

Editor's Note: In the April 2004 edition we incorrectly reported that hospitals in BC with an annual transfusion volume of less than 100 units account for approximately one third of the provincial blood consumption. In actual fact these hospitals represent a very small portion of blood consumption. This statement should have read: *approximately one third of hospitals in BC have an annual transfusion volume of less than 100 units.*

People

In May, the PBCO welcomed two new staff members, **Sabrina Gunkel** and **David Lockstead**. Sabrina is currently providing administrative support to the Nursing Resource Group and assisting with the CTRM revision while David is working on data analysis for a variety of projects. We are fortunate to have two new team members as we gear up for a busy fall!

Donna Fulton, RN from Royal Jubilee Hospital has recently moved to Kelowna. Fortunately, she will continue to be very involved with the PBCO in her role with NRG. A welcome is extended to **Donna Miller** who is now the Transfusion Medicine Nursing Coordinator for South Vancouver Island.

We would like to wish **Dr. Gershon Growe** well in his retirement. Dr. Growe, Division Head of Haematology has retired from Vancouver General Hospital. His colleagues are planning to honour his 35 years of service with a retirement dinner planned for the fall when his new lifestyle schedule permits! Best wishes to you, Dr. Growe!

Canadian Blood Services is very pleased to welcome Dr. Growe as Medical Director for BC/Yukon. Working part time, Dr. Growe will provide medical support and expertise to Patient Services, Transmissible Diseases Notification and various other aspects of the blood program, as well as consultative support to hospitals.

Calendar

September 29, 2004 – PBCO-CBS Symposium on Transfusion Issues. Best Western Richmond Hotel and Convention Centre, Richmond, British Columbia. Registration is free, lunch will be provided. Space is limited. Please contact Sabrina Gunkel at PBCO at 604-806-8840 or SGunkel@providencehealth.bc.ca to register or for more information.

September 30 – October 2, 2004 - BC Society of Laboratory Science (BCSLS) Congress. Best Western Richmond Hotel and Convention Centre, Richmond, British Columbia http://www.bcsls.net/

October 23 – 26, 2004 – American Association of Blood Banks (AABB) Annual Meeting and TXPO 2004. Baltimore Convention Center, Baltimore, Maryland USA www.aabb.org

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