Update on New York Requirements

Jeanne V. Linden, MD, MPH, Director, Blood & Tissue Resources, Wadsworth Center, New York State Department of Health

Amendments to the blood bank regulations, 10 NYCRR Subpart 58-2, were approved by the New York State Council on Human Blood and Transfusion Services in late November, 2014. They had been distributed for public comment twice and all comments were considered. The amendments will go into effect 60 days after a Notice of Adoption is published in the New York State Register. It is anticipated that they will go into effect sometime this fall. A copy of the revised Subpart 58-2, incorporating the revisions into the unchanged sections, will be distributed to facilities holding a blood services permit.

Many revisions will merely clarify wording or numbering. These include types of blood collection sites, donors aged 76 years or older, description of “reinfusion procedures” and some records. Errors and accidents detected prior to distribution need not be reported to the Department, but the facility must evaluate the event.

With respect to transfusion committees, the requirement for attendance by 50% or more members is eliminated and membership is slightly modified. There is clarification that the committee may review a representative sample of transfusions and that review must include all categories of components (e.g. RBCs, FFP, PF24) and all transfusion locations (e.g. outpatient transfusion area). It must include blood issued to a Limited Transfusion Service or, now, Ambulance Transfusion Service, and intraoperative and post-operative blood recovery.
Update on New York Requirements, con’t.

Some sections increase flexibility or are less restrictive. These include:

• Acute respiratory disease evaluation is eliminated
• Timing of Confidential Unit Exclusion is not specified
• Pre-collection donor infectious disease testing permitted if short shelf life (e.g. granulocytes)
• Labeling anti-HBc-positive autogeneic units is not required
• ID labeling not required if confirmatory testing is negative
• Deglycerolized RBCs have a 14-day outdate if closed system
• Provides for electronic staff identification
• Transfusion service director to set policy re: issuance > 1 unit at a time
• Frozen plasma to have 7-year outdate stored at ≤65 C
• For donor re-entry, the Director may designate another physician
• Pheresis donor H/H minimum 12.5/38, as FDA approved
• Autogeneic pheresis H/H minimum 11.0/33, as FDA approved

Some sections are revised to include federal requirements. New York is CLIA exempt, but requirements must equal or exceed those of CMS and FDA in pertinent areas. These include:

• Facilities must report events to FDA, if required
• Reporting is to be prompt
• Visual inspection prior to issuance is required
• Retain records for 10 years
• Blood administration SOPs must be designed to prevent transfusion reactions

Collection of lymphocytes from HPC donors is no longer subject to blood bank regulations. They are not subject to HPC regulations in Subpart 58-5 either. They will not be addressed in any regulations. However, the vast majority of, if not all, sites performing such collections must be licensed as a blood bank or HPC bank for other services, and will thus be subject to regulatory oversight, including inspection.

There are a few new requirements, which the Council believes reflect the standard of practice. These include:

• Alarm function checks must be documented
• Must label when refreezing thawed frozen RBCs
• Protect component thawed in waterbath (by positioning or overwrap)
• Tubes for transfusion-related testing to be labeled at collection
• QC records to be retained 5 years
• Donor HIV and HCV nucleic acid testing (NAT) required
• Cryoprecipitate for Factor VIII replacement to be transfused within 6 hours
• If renumber units, must record both unit IDs
• Crossmatch is required following emergency release

Dear BBANYS members,

It is my honor and pleasure to serve as your President for the next two years. The year has gotten off to a great start. The Annual Meeting in June was extremely successful in all aspects and I would once again like to thank all of the committee members for their extraordinary efforts:

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The board’s goals for this year are to further expand membership by targeting members new to the field and by expanding our offerings. You will hear news of these endeavors throughout the year as we begin to highlight our committee accomplishments beginning with the next newsletter. Please consider joining our committees to help make a difference in our organization and in our field. We welcome your participation.

I look forward to an exciting two years as we keep up with the ever-changing fields of Transfusion Medicine and Cellular Therapy.

Sincerely,

Melissa Cushing, MD
President, BBANYS
An entirely new section provides for “Ambulance Transfusion Services (ATS).” These are ambulance services that will be approved by the Department to continue transfusions initiated in a hospital and initiate additional units during inter-facility transport to a facility with a higher level of care or specialized services. Blood will not be carried to the field. Such care will be provided only by Advanced Life Support-certified Emergency Medical Technicians (EMT), such as paramedics, after additional training.

Some key elements include (BB = blood bank):
- Blood may be issued for transfusion in a ground or air ambulance
- The ATS must have an agreement with each transferring hospital
- Form for Blood Transfusion Transfer Orders: Continue and/or initiate new units
- Vital signs must include temperature; ambulances must carry a validated thermometer (not in place now)
- The EMT is to participate in 2-person ID at transferring hospital (Site 1)
- If blood is not already hanging, a validated cooler is needed for transport
- Standardized Blood Transfusion Record form
- EMT protocol specifies criteria for action and consulting with medical control
- Ambulance must carry needed supplies
- Site 1 BB needs a process for issuing blood to an ATS
- Site 1 BB needs validated coolers and SOP
- Records will be electronic, but Site 1 may not receive Blood Transfusion Record back
- Receiving hospital (Site 2) BB needs to establish a process and SOPs, including determining disposition of units issued (by Site 1) but not transfused

Some issues include:
- Process is new, much of it out of BB control
- Many new players, with limited experience in this area
- Only Site 1 has pre-transfusion specimen and patient history
- EMT will not draw any blood specimens; may transport Site 1 specimen if packed with blood
- Site 2 will need to draw post-tx specimens
- BBs will need to collaborate on work-up of any possible transfusion reaction
- Transfusion Committee review

Below are clarifications of some FAQs.

Testing “waived” by CMS and FDA:
- Unlicensed personnel (trained) may perform
- SOPs, recordkeeping requirements apply
- Fixed sites must register Limited Service Laboratory (can be part of a NYS-permitted laboratory or blood bank)
- Mobile sites are under parent laboratory or blood bank

Off-permit vs. on-permit testing:
- Quality control, validation, training
- Pre-apheresis platelet count to set instrument
- Pre-apheresis ABO screen (to determine type of collection)

Research, if results not reported to clinician for possible use in patient care
- Performed on each donation
- The basis for donor qualification decision
- Is the test of record, in LIS/records
- Research testing, if results are reported to clinician for possible use in patient care

Limited Transfusion Service (same owner-operator or separate):
- No lab permit at remote site
- No overnight storage
- BB issues blood, performs all testing, and maintains usual records
- Oversight/review under permitted BB’s Transfusion Committee
- LTS must have a director, but no Certificate of Qualification is required
- LTS must have adequate SOPs for functions, including identification process, recordkeeping, and completion of transfusion record

Transfusion – Storage Only permit:
- Blood inventory can be maintained, including overnight storage, for use by any patient
- Transfusion Service holding full Transfusion permit performs all testing, including transfusion reaction work-ups
- Review by Transfusion Service Transfusion Committee
- Transfusion – SO BB issues blood to the clinical service for a particular patient
- Director must hold CQ; may be same person as the Transfusion Service director
- The remote site has a laboratory permit in other categories

Tissue Bank License vs. Laboratory Permit:
Tissue Bank License:
- Tissue bank is processing tissue (in an sterile or aseptic fashion) to be administered to a patient
- Staff are qualified for functions, as determined by the director

Laboratory permit:
- Laboratory tests a sample not to be administered (e.g. cell counts, infectious disease testing of tissue products)
- Testing staff must hold Clinical Laboratory Technologist or Technician license, as required
- Licensure in “Stem Cell Process” pertains to such testing, but no such licenses have been issued or applied for
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The hemoglobinopathies, such as beta-thalassemia and sickle cell anemia (SCA), are characterized by mutations of the beta-globin gene resulting in either decreased or functionally abnormal hemoglobin (Hb) production. As bone marrow transplant is the only curative option for these patients, there is a strong need for new therapeutic approaches. Both beta-thalassemia and SCA represent ideal targets for gene therapy since introduction of a normal beta-globin gene can ameliorate the phenotype, as we and others have shown previously. Overcoming the developmental silencing of the fetal gamma-globin gene represents an additional approach for the treatment of hemoglobinopathies. We directly compared a recently established approach to activate the gamma-globin gene using forced chromatin looping with pharmacologic approaches to raise gamma-globin expression.

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The beta-type globin genes are activated through dynamic interactions with the distal locus control region. This region physically contacts the developmental stage appropriate globin gene via chromatin looping, a process partially dependent on the protein Ldb1. We have shown that tethering Ldb1 to the human gamma-globin promoter with a custom designed zinc finger protein (ZF-Ldb1) can redirect loop formation from the beta- to gamma-promoter and potently reactivate gamma-globin gene expression in adult human erythroid cells (Deng et al., Cell, 2012 and 2014).

We also tested this recently established approach in comparison to pharmacological induction of fetal hemoglobin (HbF) in cells with abnormal beta-globin function, as in Sickle Cell Anemia (SCA).

We isolated hematopoietic stem cells from blood of 11 SCA patients. These cells were expanded and differentiated into mature erythroid cells in vitro, and treated with a lentivirus expressing the ZF-Ldb1 transgene. Specimens were also treated with hydroxyurea, the only FDA-approved HbF inducer used in SCA patients, or with the experimental inducers decitabine, tranylcypromine, pomalidomide and butyrate.

ZF-Ldb1 increased HbF synthesis in SCA erythroid cells up to 86% and, concurrently, reduced sickle Hb (HbS) below 15%, showing a balanced synthesis between alpha and beta-like globins, and consistent with additional studies with healthy erythroid cells. In addition, the induction of HbF in cells treated with ZF-Ldb1 was roughly three times higher (at a dose of ~ one transgene copy per cell) than that observed using decitabine and pomalidomide (0.5 μM and 10μM respectively). Tranylcypromine had an intermediate effect (1.5 μM). Hydroxyurea and butyrate showed the lowest HbF increase (both 100μM). Importantly, ZF-Ldb1 expressing cells did not show significant changes in viability as observed in pomalidomide-treated cells.

For future studies, we plan to introduce with the same lentivirus the therapeutic effects of the beta-globin transgene and the ZF-Ldb1 fusion cassette. The advantage of using this approach is that it combines the expression of higher amount of functional hemoglobins with the simultaneous reduction of toxic hemoglobin, like the sickle one, in patients with hemoglobinopathies.

Blood Product Support of Massive Transfusion Protocols

Beth Hartwell, MD, MT(ASCP)SBB, Medical Director, Gulf Coast Regional Blood Center, Houston, TX

Up until the 1960’s and early 1970’s, Whole Blood was the component of choice for transfusion. Then component therapy came into existence and the mantra was to only transfuse those blood components a patient needed. Nowadays, when we discuss massive transfusion protocols (MTPs), we may find ourselves essentially “recombining” blood components in an effort to transfuse an end product much like Whole Blood! The results of the PROPPR (Pragmatic Randomized Optimal Plasma and Platelet Ratios) clinical trial were recently published and showed that both the 1:1:1 and 1:1:2 ratios of plasma:platelets:RBCs were safe and not associated with increased complications. In other words, the days of transfusing 8 to 10 units of RBCs before transfusing any plasma or platelets are slowly fading as more aggressive resuscitation protocols are being put into place for massive hemorrhage.

Developing and following massive transfusion protocols can be challenging for blood centers and transfusion services. Plasma is being transfused to trauma victims earlier in the resuscitation process, resulting in an increased need for the immediate provision of universally compatible O Negative RBCs and AB plasma. The limited supply of both of these products requires the blood banking community to consider other options. Recent studies have shown that the emergency transfusion of O Positive versus O Negative RBCs is associated with a much lower rate of alloimmunization (11%-22%) in trauma patients than originally thought. In addition, the use of “low titer” (anti-B titer <50-100) group A plasma has become a reasonable alternative to the limited supply of AB
Blood Product Support, con’t.

plasma. Group A plasma would be expected to be compatible with approximately 85% of all individuals requiring plasma transfusion prior to determination of a blood type. Other blood products such as liquid plasma and low-titer (anti-A, anti-B titers <100) group O Whole Blood are being used in selected trauma centers. Freeze-dried lyophilized plasma is already used in Europe for trauma victims. In addition, massive transfusion protocols are now becoming massive hemorrhage protocols as the need for emergency transfusion also finds its way into more than the trauma patient population. As blood bankers and transfusionists, it is becoming more and more important to keep abreast of the trauma literature in order to make appropriate decisions about which blood products may be requested and why.

Plasma, Platelet & RBC Products: What’s the Difference and What to Use?

Beth H. Shaz, MD, Chief Medical Officer
New York Blood Center, New York, NY

Transfusion management continues to improve through new products, better inventory management and more appropriate blood utilization. The estimated total red cell transfusion cost is over $1000 due to direct costs (unit acquisition, supplies, testing, and staff), indirect costs (overhead, nursing, and benefits) and adverse events. New products have less adverse events (pathogen inactivation, and platelet additive solution) and better inventory management (freeze dried plasma and group A plasma) and, thus, should decrease the cost of transfusion. When a patient on warfarin has a life threatening bleed, warfarin reversal can be accomplished more quickly and effectively by giving prothrombin complex concentrates, which have smaller volumes and are immediately available, compared to plasma. Blood product support of massive hemorrhage due to trauma now calls for early plasma and platelet transfusion. Trauma centers are supplying early plasma through the use of liquid plasma, lyophilized plasma (non-US), thawed plasma (group AB or group A) and factor concentrates (non-US). Patients with sickle cell disease have superior transfusion outcomes with the use of antigen negative units matched to their genotype. Lastly Babesia mitigation strategies emerging include antigen/antibody negative units, units from non-endemic areas, and pathogen inactivated units with S-303 plus glutathione or riboflavin plus ultraviolet light. In conclusion, a variety of products are available to improve patient outcome.

Vector-borne Infections We Should Be Thinking About

Louis M. Katz MD, Chief Medical Officer
America’s Blood Centers, 725 15th St. NW, Washington, DC

The general topic of vector-borne infection was introduced with a discussion of their scope worldwide, factors associated with their occurrence and emergence and what features may raise questions about the risk from of transfusions from infected donors.

West Nile virus (WNV), dengue and chikungunya were examples used to outline the factors the blood community must consider when deciding whether and how to respond to emerging infectious agents that are demonstrable or theoretical threats to transfusion recipients. WNV contrasts with the latter two agents in that the threat from WNV was quickly apparent in 2002 when transfusion transmissions were first observed. This compares to the paucity of dengue and absence of chikungunya transmissions by blood and components despite millions of infections worldwide. Reasons for these disparities were considered. They include inadequate surveillance, the challenge of recognizing isolated transfusion transmissions in the face of explosive vector-borne epidemics, the fact that “asymptomatic” donors might, in fact, have mild illnesses that keep them out of donor centers and the consideration that parenteral inoculation may entail a different pathogenesis than vector-borne resulting in milder disease. Potential interventions for mitigation of the risks from these pathogens range from deferrals for travelers to epidemic areas, to donor queries with deferrals, active donor follow up, and/product quarantines when these viruses are locally transmitted, as have been dengue and chikungunya in recent years.

Transfusion-transmitted babesiosis (TTB) is of particular interest to members of BBANYS. The epidemiology of TTB was described for context, most particularly by citing data that show its risk in high endemity areas of the Northeast US is at least an order of magnitude higher than that which we tolerate for classic transfusion-transmitted infections like HIV, HCV and HBV. Data from prospective studies of donor screening assays in development were shared. Several health economic analyses of potential regional screening strategies were compared in order to highlight the impact of the extent of screening, even in “high risk” areas on the cost effectiveness of donor testing.

Appropriate decisions about mitigation of the risks discussed should be made within an evidence-based framework that promotes broad stakeholder engagement (e.g. the blood community, the regulator, payers, clinicians and transfusion service physicians, hospital administrators, patient groups). An example is that produced by the Alliance of Blood Operators, available at https://www.allianceofbloodoperators.org/abo-resources/risk-based-decision-making/rbdm-framework.aspx.
Your BBANYS Education Committee is focused on providing a variety of educational opportunities throughout the year. We strive to offer education on a range of topics and settings to provide the greatest range of applicability and accessibility. Toward that end, we are continuing and expanding our educational offerings.

We have expanded the webinar schedule to four webinars each fall and four each spring. These webinars continue to increase in popularity, with an average attendance of 66 participants for the Spring 2015 webinar series. Be sure to check out the schedule of webinars on the BBANYS website. We are also recording webinars to allow for viewing (or re-viewing) after the initial broadcast.

The Annual Fall Half-day Seminar returns Friday, November 6, to Syracuse with speakers discussing electronic cross-matching, the Rhesus system, and platelet-additive solution platelets. We are actively seeking other members who are interested in organizing additional half-day seminars around the state.

The 2016 BBANYS Annual Meeting will be coming to Albany June 9-10. We will be returning to the Radisson Hotel at 205 Wolf Road (previously a Holiday Inn) for a day and a half of education, networking, and fun. Keep an eye on the BBANYS website for registration and housing information.

In addition to these activities, we are looking for any input from our members for other educational opportunities that we can offer. Please feel to contact the members of the Education Committee or Education Chair, Terri Bostock, with any comments or suggestions. If you would like to join our committee, suggest a location for an onsite seminar in your area, or suggest an interesting topic or a great speaker for a webinar, please email Terri at tbostock@ormc.org. We want our members to feel included and empowered to be a part of BBANYS.

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Manager, Transfusion Services
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Antibody Reagents for Anti-D & Variable Reactivity
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