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About CBBS →

How to Join

e-Network Forum →

Fast Breaking News →

Contacts →

CBBS Meetings →

Education Fund

Corporate Support →

Jobs & Sale Listings →

Useful Links →

Site Help/Info →

Member Area Login

HOME

Reconstituting blood for exchange transfusion in neonates

A transfusion medicine physician in Southern California wishes to initiate a discussion about an issue that comes up about once a year at his 350-bed facility, which is part of an eleven-hospital HMO system. The issue, which involves reconstituting blood for exchange transfusion in neonates, arises with nearly similar frequency at most of the other institutions in their HMO system. According to the inquiring colleague, the nurses and physicians on the hospital floor wish to have the "blood" (for example, group O Rh negative red cells and group AB plasma) reconstituted by the blood bank laboratory and then dispensed for exchange transfusion. The blood bank technologists do not feel that they do this mixing procedure often enough to be comfortable doing it, and they want the reconstitution of the blood products to be performed on the floors, claiming the blood product is less likely to expire if the units are first entered at the bedside. There are also issues of labeling the new blood product, if it is created in the blood bank.

The inquiring physician adds that their regional transfusion committee is investigating this issue, and any input from the e-Network Forum regarding how other facilities handle reconstituting blood for neonatal exchange transfusion would be appreciated. In particular:

- Is the reconstitution procedure usually performed in a blood bank or on the ward?
- What procedure is followed?
- Do facilities attempt to provide a specific final hematocrit for the product, and if so, what formulas are used?
- Finally, what do transfusion services see as pros and cons of the way their institution handles this issue?

The following responses have been received.

1. **A colleague in Massachusetts** reports that at her institution about 10,000 babies per year are delivered. Despite the large number of babies in their NICU, the number of babies requiring neonatal exchange transfusions is small, so that there is no constant experience with preparation of reconstituted whole blood. However, because their blood bank is so much more familiar with manipulating blood products than any other area of their institution, they feel that it is **better for the Transfusion Service to prepare this product**. She comments that the best solution is to have an extremely well-written **procedure**, but interestingly, their SOP is in transition right now. Several times a year they practice using expired units of red cells and FFP. They made up the name of the product "Whole Blood, Reconstituted". They have a custom label that states the volumes and ABO/Rh types of the components that were added. They have yet to find rules about this so they are doing what they think is the best approach for them locally.
2. **A blood bank and Bone Marrow Transplant Laboratory Manager at an institution in North Carolina** comments that there is (in her opinion) an excellent formula in the **10th ed. of the AABB Technical Manual**, pp.398-99. Although her staff does not perform the procedure of reconstituting whole blood for neonatal transfusion very often, when they do, the AABB Technical Manual formula has been incorporated into the procedure, with mixing and labeling instructions that any technologist can follow.

ADDENDA Sept. 22, 2003

3. **A colleague in Iowa** reports that exchange transfusions are performed at her institution only a few times a year. A very detailed procedure, step by step, and easily followed procedure is imperative. They reconstitute whole blood in their **laboratory** using a selection of RBCs and FFP

that is appropriate for the neonate, and they adjust the hematocrit using the formula in the Technical Manual 10th Edition.

4. **A colleague in Northern California** reports that their blood center provides reconstituted whole blood for their client hospitals. In this colleague's opinion, the manipulation of this type of product is best done in the **laboratory or the Blood Bank**, and not at the bedside. They request that the ordering physician indicate a **target hematocrit and volume** for the unit and they perform the reconstitution procedure.

ADDENDA Sept. 24, 2003

5. **A colleague who is very familiar with federal regulations** is of the opinion that if RBCs and FFP are reconstituted into whole blood, the institution performing this procedure should **consider the following**:

- There should be detailed SOP's to address **requirements for a physician to request the product**
- There should be step-by-step instructions for the **manufacturing process**
- There should be **instructions regarding** expiration dating, product sampling, product testing, acceptable storage, transporting requirements, guidance when to use mini-satellite bags or syringes, and what information is required to be documented and where to document it
- Physicians should be advised that if they order the reconstituted product to have a very **specific hematocrit**, that it may be extremely difficult for the blood bank to meet such specifications. An acceptable range would be preferred
- A reference should be made to the **Circular of Information**
- **Labeling requirements** should be defined

The above list is not an all inclusive.

ADDENDA Sept. 25, 2003

6. **A colleague in Southern California** reports that at her hospital the **laboratory** reconstitutes RBCs and FFP into whole blood for selected neonatal transfusion therapy. Her hospital agrees that the laboratory is the most appropriate place for this manufacturing step to take place. The **physician's order includes a target hematocrit** and they have written into their procedure to test the final product and accept a tolerance of +/- 5% of that value. Their physicians seem to be happy with this. The responding colleague would also like to share that an FDA investigator, after reviewing their detailed procedure stated that they also need to write a "Circular of Information" for this product, since they were creating a "new" product that was not covered by the uniform "Circular". They ended up **writing a very brief Addendum to the "Circular"** that included a product Description and Indications for the unique product and then referenced the uniform "Circular" for General Information, Actions, Contraindications, Storage, Side-effects, and Hazards. That was 4 years ago and they have had no comments from an FDA investigator regarding reconstituted whole blood since that time.

ADDENDA Nov. 7, 2003

7. **A physician in India** who is chief of the transfusion service at a 650-bed hospital reports that at his institution "Reconstitution of blood" is a part of their blood processing (Manufacturing of Blood/Blood components/Blood products) and they **do not allow this activity to be done by the ward staff**. The responding physician's hospital has a very active neonatal intensive care unit and they do reconstitute blood for exchange transfusion in a significant number of cases. In their hands, this a very simple procedure that can be accomplished by adding the required quantity of plasma after thawing, into the the bag containing red cells. Normally, they prefer to add a standard unit of plasma (volume 180-220 ml) to one unit of red cells (200-250 ml). The resultant solution after reconstitution is thus similar to whole blood and suitable for exchange transfusion. However, the desired hematocrit can be achieved by varying the amount of plasma added.

ADDENDA Nov. 10, 2003

8. **The colleague from Massachusetts who submitted reply #1 (above)** is pleased to share their **updated SOP** on Preparation of Whole Blood Reconstituted, which has been edited and finalized (*PDF*).

9. **A colleague from Spain** reports that in his opinion, he agrees that the best place to prepare the component is the blood bank laboratory, and that one should take into account the following (his opinion paraphrased is shown below):

- The desired hematocrit is a critical issue, since the neonate hematocrit is physiologically higher than the adult. If you use an adult hematocrit (about 35-40%) for a baby with 55%, you can cause hemodilution. In the actual clinical case, the neonate could have low or high hematocrits, and the reconstituted blood should help the baby reach a desired level.
- If you want to minimize donor exposure, maybe it is not necessary to use whole blood. The hematocrit of red blood cells in additive solution (i.e. Adsol, SAG-mannitol) is usually within the clinically desired range. In this way, you should only use plasma if the baby shows additional coagulopathy (this is standard practice in the British Health Service). The case for washing red cells could arise from mannitol-containing solutions if the baby is not stable. Sometimes the pediatrician feels safer without mannitol.

AND, he adds, "DON'T FORGET TO IRRADIATE"

ADDENDA April 5, 2008

10. **A Technical Specialist in a large healthcare organization** points out that there are serious issues with **ISBT-compliant labeling of reconstituted Whole Blood**. She reports that their software package does not allow them to pool products in a way that protects ABO/Rh restrictions, and their blood supplier will not provide the product (similarly, due to labeling issues). She also points out that the **FDA considers mixing blood products to be a modification which requires registration** (quoted below). She asks "Does anyone have a protocol they could share for performing **neonatal exchange with the RBC and Plasma products hung separately?**"

The AABB website includes a [transcript of the 2007 AABB Ask the FDA session](#), which includes the statement "if you are irradiating or washing red cells or you are mixing red cells and FFP for exchange transfusions, you do have to register with the FDA."

Editor's note: It sounds as if some transfusion services are experiencing unintended consequences of ISBT-128 implementation. **How is your facility handling neonatal exchange transfusions?**

ADDENDA April 15, 2008

11. **The medical director of a transfusion service in Houston** reports that at her institution when a unit of FFP is combined with a unit of RBC to reconstitute whole blood for exchange transfusion, the **product numbers** for the RBC's and FFP are **entered into the computer** and a **new number is generated for the final product**. In that way the original numbers are there for back tracking.

Please submit comments to the [e-Network Forum](#).

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