Concerning Hansen E, Altmeyen J: Proposal for Internal Quality Management in Intra- and Postoperative Blood Salvage. *Infus Ther Transfus Med* 2002;29:147–150

We concur with Hansen and Altmeyen that the recommended red blood cell recovery (>80%) and plasma wash out rate (>90%) are appropriate tools for determining the product quality of perioperatively salvaged washed products. However, because different cell salvage technology may produce washed products with very different hematocrits, using free hemoglobin (fHb) concentration as a measure of quality may be misleading. We believe that calculating fHb dose, using the formula $\text{fHb (mg)} = \text{fHb concentration (mg/dl)} \times \text{plasma volume (dl)}$, would take into account hematocrit differences between products and be more useful.

An example would be if product 1 has a volume of 500 ml, with a hematocrit and a fHb concentration of 200 mg/dl. The fHb dose would be $200 \text{ mg/dl} \times 2.5 \text{ dl}$, or 500 mg. If product 2 was the same as product 1, but with 75% hematocrit, the fHb dose would be $200 \text{ mg/dl} \times 1.25 \text{ dl}$, or 250 mg. Even though both products have the same fHb concentration because of hematocrit differences, product 1 would contain twice the total fHb as product 1. The use of fHb dose indicates the amount of fHb that the patient is actually receiving and is extremely helpful if a site needs to compare products produced from different technologies.

In trying to determine what fHb dose would be acceptable, we suggest looking at whole blood collections as a guide. In whole blood collection, hemolysis less than or equal to 1% at 42 days of storage has been an acceptable standard in the USA. In a 500 ml unit collected from a donor with a 38% hematocrit the fHb concentration is 199 mg/dl. The fHb dose in this unit of whole blood would be 625 mg. From long-standing clinical practice, this level of fHb does not seem to have clinical significance as there is no limit to the number of units of 42-day-old blood that a patient may receive.

Using the 'whole blood guideline', it is suggested that a fHb dose of 625 mg would be an appropriate standard to use to determine acceptability of salvaged washed red blood cells.

C. Martin, M. Popovsky, Braintree, MA

Reply of the Author

Setting an absolute value of fHb, either concentration or total amount, for quality control in intraoperative blood salvage is of only limited usefulness because:

- The amount or concentration of fHb that is toxic is not known.
- fHb is not the only or the most harmful contamination in wound blood. At best, it can be used as a marker for (red blood cell) cytolysis. However, activation of coagulation, fibrinolysis, complement and kinins as well as activation of platelets and cells of the immune system and release of mediators may have occurred in wound blood without extensive hemolysis. For most of these bioactive substances the limit of toxicity is also unknown.
- If there is any parameter showing a quantitative correlation to complications, it would be the total amount of fHb resulting from the number of units transfused. As most of the complications of the retransfusion of unwashed wound blood and also the life-threatening complications described in case reports show no dose dependency, we rather have to consider a nonlinear correlation. This corresponds to the cascade systems of activation in which potentiation is characteristic.
- We therefore prefer to use plasma wash-out as the relevant parameter for quality control. The reduction of any soluble contaminant by 90 or 95% is considered safe. With fHb in wound blood rarely exceeding 2 g/dl, this results in a value below 200 mg/dl which corresponds well with the 1.0% hemolysis (or 0.8% in Germany) accepted for banked blood. Like the latter value represents a parameter of the process (storage) rather than a toxic limit, the process of cell washing is better described by the rate of plasma wash-out.
- Even for the determination of plasma wash-out, we do not prefer fHb but total protein since fHb is a mixed parameter affected by both wash-out and hemolysis during the procedure.

The statement of Martin and Popovsky suggests an advantage of producing red blood cells with higher hematocrit which (above hematocrit 50%) has not been demonstrated. In contrast, in ongoing studies on the effects of the cell washing parameter on product quality we find higher hematocrits unfavorable, at least in discontinuous systems.

E. Hansen, Regensburg

Zu Hasskarl H: Transfusionsgesetz vom 1. Juli 1998 (BGBl. I, S. 1752): Bestellung eines nicht institutsangehörigen Transfusionsverantwortlichen – gutachterliche Stellungnahme. Infus Ther Transfus Med 2002;29:331–337

Die klinische Information Von H. Hasskarl fokussiert sich auf die Bestellung des *Transfusionsverantwortlichen* und beschreibt auch in zwei Absätzen die Funktion und Sachkenntnisvoraussetzung des *Transfusionsbeauftragten*. Für die Qualifikation als *Transfusionsbeauftragter* wird unter Hinweis auf die Richtlinien zur Gewinnung von Blut und Blutbestandteilen und zur Anwendung von Blutprodukten (Hämotherapie) auf die Facharztanerkennung für Transfusionsmedizin sowie auf das Vorliegen der Zusatzbezeichnung «Bluttransfusionswesen» in Kombination mit einer anderen Facharztanerkennung hingewiesen. Zudem wird auf das Weiterbestehen der Qualifikationsvoraussetzung für die Kollegen, die diese Tätigkeit als *Transfusionsbeauftragter* bei Inkrafttreten der Richt-

linien auf der Grundlage der Richtlinien aus dem Jahr 1996 innehatten, verwiesen. Leider fehlen die Voraussetzungen für die ausschließliche Anwendung von Plasmaderivaten (8 h theoretische Fortbildung einer Landesärztekammer) sowie insbesondere die Facharztanerkennung mit 16-stündiger theoretischer Fortbildung einer Landesärztekammer [1]. Insbesondere letzte Gruppe stellt das Gros der *Transfusionsbeauftragten* dar, die in den klinischen Abteilungen den ordnungsgemäßen Umgang mit Blutprodukten regeln.

Abschließend sei darauf hingewiesen, dass bei einem im Sommer 2002 eingereichten Manuskript auch die aktuelle Währung in Euro in § 4 des Entwurfs für den freien Mitarbeitervertrag über die Bestellung als Transfusionsverantwortlicher verwandt werden sollte.

R. Moog, Essen

Literatur

- 1 Richtlinien zur Gewinnung von Blut und Blutbestandteilen und zur Anwendung von Blutprodukten (Hämotherapie). Neubearbeitete Fassung 2000. Köln, Deutscher Ärzteverlag, 2000.