

**Keywords:** American Red Cross; civilian; deferral rate; onor; military; support; US Army Blood Services Program; volunteers  
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## Session 3: Logistics of Blood Supply

### Blood Supply in Slovenia

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Every year, 95,000 units of blood are collected in Slovenia (4.7% of the population of 2 million). All of the blood collected is processed in red blood cell concentrate and plasma. Some 30% of platelets are produced from random donors. All of the donations are tested for hepatitis B (HB), hepatitis C (HC), HIV, and syphilis. We use NAT testing for HC.

We have contract fractionation and a national self-sufficiency program. We use three units of factor VIII per inhabitant and 290 kg of albumin per million inhabitants. We have a unique quality assurance system and a unique information system supported by computers. We regularly supply 23 hospitals, and have an average stock of red blood cells for 14 to 21 days. We also have extra stock of albumin and blood bags for extraordinary circumstances.

**Keywords:** albumin; blood; factor VIII; plasma; platelets; processing; quality assurance; red blood cells; Slovenia; transfusion  
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### Clinical Perspective of Frozen Blood

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During the past 50 years, many different protocols were developed to freeze blood components. In this session, the experience of the Dutch Military Blood Bank (MBB) with several freezing protocols will be summarized, the modern production techniques using GLP, GMP, and GDP will be shown, and the resulting clinical application in theatre will be discussed.

With the current protocols (designed by Dr. C.R. Valeri) used by the MBB, frozen red cells can be stored for at least 10 years, frozen platelets for two years, and FFP for seven years at  $-80^{\circ}\text{C}$ . These products can be transported at  $-80^{\circ}\text{C}$  over five days, which should be enough for worldwide distribution. After thawing and resuspension in FFP ( $\pm 30$  min), the platelets are ready for transfusion. After thawing of the red cells ( $\pm 30$  min), the cryoprotectant glycerol has to be removed using a cell-washer ( $\pm 60$  min) prior to transfusion. By using a sterile cellwasher, it now is possible to store the thawed washed red cells for an additional two weeks at  $4^{\circ}\text{C}$  before transfusion.

Different methods of freezing red cells were compared. The 40% glycerol/ $-80^{\circ}\text{C}$  protocol not only was the most practical way to freeze red cells, but also the protocol that yields the most stable red cells after thawing and washing. This protocol now is FDA approved. In 1999 Dr. Valeri

and collaborators showed that their freezing protocol did not deteriorate, but instead, improved the hemostatic properties of platelets both in vitro and in vivo. Although this method is not yet FDA approved, the need for platelets in the military setting, the impossibility to quickly send fresh platelets on demand and the danger of having to use fresh whole blood without complete repeated testing of the donor, in 2002, the MBB decided to supply the MTF with units of frozen platelets.

Thus, the MBB provides  $-80^{\circ}\text{C}$  frozen red blood cells, platelet, and plasma to containerized frozen blood banks of role 2+ and role 3 MTF. Without re-supply, one frozen blood bank is able to provide enough blood products for two operating rooms non-stop for 48 hours. Several patients have been treated successfully with the frozen products, and to date, no patients have shown adverse effects from the transfusions.

**Conclusion:** Freezing blood components is a safe, effective, and easy way to provide blood products to remote areas. Thanks to the frozen blood module, the military now can be provided with leukodepleted, fully tested, blood products at the time when they need it.

**Keywords:** blood bank; blood products; freezing; military; plasma; platelets; protocols; red blood cells; safety; supplies; transfusions  
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### Vaccinia Immunoglobulin (VIG) Production in Israel

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In response to a possible threat of smallpox as a biological weapon, 21,000 previously immunized healthcare workers and "first responders" were vaccinated in Israel, between August 2002-April 2003. Preparation of vaccinia immunoglobulin (VIG) was essential for treatment of serious, post-vaccination adverse events, in case of mass immunization.

The Magen David Adom (MDA) National Blood Services conducted blood and plasma collections sufficient to reach 2,500 liters of plasma. The VIG production process was granted to a local manufacturer (Omrix Biopharmaceuticals Ltd.), operating in an MDA fractionation plant. This manufacturer developed a quantitative ELISA assay, enabling in-process monitoring of anti-vaccinia antibodies in the product. Seven senior phlebotomists were trained intensively in apheresis procedures and joined the regular team of four technicians, thus quadrupling the unit performance. An additional six portable machines were purchased (MCS+, Hemonetics) to double the existing apheresis equipment. Mobile drives were conducted at workplaces to improve donor accessibility, and minimize time lost from work.

A surprisingly poor response to the donation appeal was noted. Only 37% (5,059/13,500 who had a successful vaccine "take") donated a total of 6,050 units (61% "jumbo" plasma units and 22% whole blood). This unsatisfactory reaction resulted from misinformation regarding plasmapheresis procedures, time lost from work, and the lowered alertness after the war in Iraq. Subsequently, 134 of the regular volunteer apheresis donors requested to be vaccinated.

The 100 who had a successful “take”(75%) donated 215 units (82% plasma and 22% blood).

A detailed informative campaign must be conducted among healthcare personnel. Volunteer qualified blood and plasma donors should be considered as a reliable alternative for special campaigns.

**Keywords:** adverse events; antibodies; immunizations, mass; immunoglobulin: plasma; plasmapheresis; production; smallpox; vaccination; volunteers

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### Five Decades of Voluntary Blood-Donation Service

*Srečko Zajc*

Secretary General of Slovenian Red Cross

This year, we celebrate five decades of voluntary blood-donation service on the territory of Republic of Slovenia. Actually, this long tradition has its roots in the Partisans’ improvisations during the Second World War. During the period of transition, many of the traditional issues were under question, e.g, where to go and how to find the proper answers on a new challenges? Even during such a turbulent time, everyone involved in the blood-donation process was responsible enough so that today, the Republic of Slovenia is self-sufficient with an adequate and safe supply of blood and its products.

Nowadays, we are faced with reorganization of the transfusion system so that the Slovenian Red Cross, as a major motivator and organizer of volunteers, must work more closely with experts to find a “new” volunteer. Such a volunteer probably works in an office, he (mostly not she) is well-educated, is able to use a personal computer (PC), and can be accessed using a mobile telephone. But, he has no time and is master of his free time. How can this new type of volunteer be motivated?

Another difficult task is to be prepared for all kinds of disaster, and to respond immediately to every request for an extra quantity of a fresh and necessary blood. It means more work not only for volunteers in the branches of Slovenian Red Cross, but also more well-coordinated work between medicals, Red Cross professionals, volunteers, and the Government including their plans and expenses.

**Keywords:** blood; blood products; coordination; donation; motivation; Red Cross; Slovenia; supplies; transfusion; volunteers

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### Hemopure® (HBOC-201) Compared With Blood (PRBC) for Two-Unit Infusion in Orthopedic Surgery Following Trauma

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**Introduction:** Approximately 250,000 trauma patients require blood (PRBC) transfusions in the U.S. each year; 50,000 receive two units of PRBC or less.<sup>1</sup> It was hypothesized that such two-unit PRBC exposure could safely be avoided by the alternative use of a hemoglobin-based O<sub>2</sub> carrier (HBOC).

**Methods:** The physiological changes and adverse events (AEs) within 24 hours of a two-unit HBOC infusion of Hemopure (n = 34) were compared with two units of

PRBC (n = 28) in 62 patients who had sustained blunt trauma and who underwent orthopedic surgery.

**Results:** 14/28 (50%) PRBC and 25/34 (74%) HBOC-201 patients had mean values of 1.04 (CL = 0.54–1.53) and 1.44 (CL = 0.96–1.92) AEs as defined by the U.S. Food and Drug Administration (FDA), respectively. Five HBOC-201 and four PRBC patients had cardiovascular AEs; seven HBOC-201 and four PRBC patients had gastrointestinal AEs; and three HBOC-201 and one PRBC patient had pyrexia. Other AEs were numerically and systematically no different. Serious AEs with HBOC-201 included one vascular (HTN) and one respiratory failure. Mean and 95% confidence limits (CL) of serial hemoglobin concentrations [Hb] and systolic blood pressures (SBP) are shown in Table.

	Total Hb g/dl <sup>1,2</sup>	
	HBOC-201	PRBC
Baseline	8.8 8.4-9.2	8.5 8.1-8.9
Post 2 unit <sup>1</sup>	8.7 8.1-9.2	10.3 9.7-10.9
24 hrs	8.5 7.6-9.3	10.0 8.5-11.5

	Plasma Hb g/dl <sup>1</sup>	
	HBOC-201	PRBC
Baseline	0.04 0.0-0.1	0.01 0.0-0.01
Post 2 unit <sup>1</sup>	1.5 1.3-1.8	0.0 0.0-0.01
24 hrs	1.4 0.4-2.3	0.01 0.0-0.02

	Met Hb <sup>3</sup>	
	HBOC-201	PRBC
Baseline	0.9 0.6-1.1	0.9 0.6-1.3
Post 2 unit <sup>1</sup>	2.6 1.8-3.4	1.0 0.7-1.3
24 hrs	3.9 3.0-4.7	0.6 0.2-1.0

	Systolic BP(SBP)mmHg	
	HBOC-201	PRBC
Baseline	125 (117-134)	118 (110-126)
Post 2 unit <sup>1</sup>	135 126-143)	129 (121-137)
24 hrs	146 (135-158)	128 (116-140)

<sup>1</sup> = 27/34 OX and 24/28 PRBC Samples

<sup>2</sup> = 32/34 OX 28/28 PRBC data

<sup>3</sup> = not all patients sampled

**Discussion:** Pyrexia, mild HTN, and gastrointestinal symptoms following HBOC are well recognized.<sup>2</sup> A two-unit HBOC-201 infusion (60 g/dL Hb) would be expected to elevate plasma Hb by approximately 1.5–1.7 g/dL. The low plasma Hb in these blunt trauma patients may reflect either the oncotic effects or pharmacokinetics of HBOC-201 or an interstitial leakage of plasma Hb. Use of HBOC-201 could save 100,000 PRBC and avoid blood exposure by 20–25% or more nationwide.

**Conclusion:** Infusion of two units of HBOC-201 has the advantage of similar overall AEs to the infusion of PRBC and of avoiding allogenic blood exposure. And the use of