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Transfusion Clinique et Biologique 20 (2013) 148–152

Séance plénière

# International challenges of self-sufficiency in blood products

*Enjeux internationaux de l'autosuffisance en produits sanguins*

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Available online 2 May 2013

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## Abstract

To face known and emerging threats to public health, all countries have to overcome the challenges of providing sufficient supplies of blood and blood products of the highest quality and safety. Unfortunately, self-sufficiency is not yet a reality in many countries. In 2011, experts from WHO addressed the urgent need to establish strategies and mechanisms for achieving this goal. A summary of these recommendations is further discussed.

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*Keywords:* Blood supply; Plasma; Safety; Voluntary non-remunerated blood donation

## Résumé

Pour faire face aux menaces connues et émergentes de santé publique, tous les pays doivent maîtriser les enjeux d'approvisionnement de sang et de produits sanguins au plus haut niveau possible de qualité et de sécurité. Malheureusement, l'autosuffisance n'est pas encore une réalité dans de nombreux pays. En 2011, des experts de l'OMS ont rappelé le besoin urgent de mettre en place des stratégies et des mécanismes permettant d'atteindre ce but. Un résumé de ces recommandations sera discuté.

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*Mots clés :* Approvisionnement en sang ; Plasma ; Sécurité ; Don volontaire non rémunéré

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## 1. Introduction

Blood transfusion services play a central, underpinning role in health systems by providing safe and adequate supplies of blood and blood products for patients requiring transfusion (blood products are defined as any therapeutic substances derived from human blood, including whole blood, labile blood components and blood- or plasma-derived medicinal products [PDMPs]). Availability and safety of blood and blood products remains a major concern in many countries around the world and countries are facing unique challenges in ensuring self-sufficiency in safe blood and blood products based on voluntary non-remunerated blood donations (VNRBD)<sup>1</sup> [1].

Only 62 countries (32%) of 193 WHO Member States report collecting 100% or more than 99% of their blood supplies for whole blood from VNRBD [2]. Typically these are countries in the higher-income group; where health care systems are more developed and where VNRBD is associated with sufficient supply and a stable blood donor base. On the other end of the scale, there are many countries in the world where the supply of blood and blood products is insufficient, and where a stable donor base is more difficult to achieve. Typically these are countries in the low- and medium-income group, where supply is met partly with VNRBD as well as with replacement donors and paid donors. Clearly the demand for blood and blood products depends on state of development of the local health care system, but in countries where less than 1% of the general population donates (77 Member States), supply is clearly insufficient to meet the needs of patients.

Voluntary non-remunerated blood donors are the cornerstone of a safe and sufficient blood supply and are the first line of defense against the transmission of infection through

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<sup>1</sup> Voluntary non-remunerated blood donation also includes the donation of plasma and cellular blood components.

transfusion. Regular VNRBD from low-risk populations have repeatedly been demonstrated to have low rates of markers of HIV and other transfusion-transmissible infections (TTIs) than paid or replacement donors. This has particular significance for countries with high burdens of TTIs. The importance of VNRBD has been reaffirmed by several World Health Assembly resolutions and declarations (including WHA28.72, WHA58.13 and WHA63.12) [3].

## 2. Self-sufficiency in safe blood and blood products based on VNRBD

The issue of self-sufficiency in blood and blood products generated much interests and discussion among the Member States during the 126th WHO Executive Board (resolution EB126.R14) and the 63rd World Health Assembly adopted the resolution WHA 63.12 on the ‘Availability, safety and quality of blood products’. The WHA resolutions, The Melbourne Declaration on 100% Voluntary Non-Remunerated Donation of Blood and Blood Components (June 2009) [4] and the recommendations of the WHO Global Blood Safety Network [5,6] have reaffirmed the achievement of self-sufficiency in blood and blood products based on VNRBD and the security of that supply as the important national policy direction for ensuring a safe, secure and sufficient supply of blood and blood products.

WHA 63.12, thereby, urges the WHO Member States “to take all the necessary steps to establish, implement and support nationally-coordinated, efficiently-managed and sustainable blood and plasma programmes according to availability of resources, with the aim of achieving self-sufficiency”.

Despite some successes, self-sufficiency is not yet a reality in many countries. A consultation of experts, convened by the World Health Organization (WHO) in September 2011 in Geneva, Switzerland, addressed the urgent need to establish strategies and mechanisms for achieving self-sufficiency. Information on the current situation, and country perspectives and experiences were shared. Factors influencing the global implementation of self-sufficiency, including safety, ethics, security and sustainability of supply, trade and its potential impact on public health, availability and access for patients, were analysed to define strategies and mechanisms and provide practical guidance on achieving self-sufficiency. Experts developed a consensus statement outlining the rationale and definition of self-sufficiency in safe blood and blood products based on VNRBD and made recommendations to national health authorities and WHO [7].

## 3. Expert Consensus Statement on achieving self-sufficiency in safe blood and blood products, based on voluntary non-remunerated blood donation (VNRBD) [7]

Experts Consensus Statement also defines that self-sufficiency in safe blood and blood products based on VNRBD means that the national needs of patients for safe blood and

blood products, as assessed within the framework of the national health system, are met in a timely manner, that patients have equitable access to transfusion services and blood products, and that these products are obtained from VNRBD of national and, where needed, of regional origin, such as from neighbouring countries.

The Statement also recognizes that six blood products will most likely form the drivers for the number of donations of blood, plasma and cellular blood components needed and these should be given priority in policy and strategy development for achieving self-sufficiency based on VNRBD. These six driver products are:

- whole blood and red blood cells either recovered from whole blood or by apheresis (WB/RBC);
- platelets either recovered from whole blood or by apheresis (PLT);
- plasma for transfusion either recovered from whole blood or sourced by apheresis and prepared by any production method (FFP);
- plasma-derived clotting factor VIII prepared by any production method (pd-FVIII);
- polyvalent human (H) immune globulin (IgIV or IgSC);
- human albumin solutions for transfusion (Alb).

VNRBD means that a person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary non-remunerated donation.

Definition of VNRBD has already been endorsed by the WHO, the International Society of Blood Transfusion, the Council of Europe, the International Federation of Red Cross and Red Crescent Societies and the International Federation of Blood Donor Associations.

In 1972, Titmuss [8] stated his warning: “If blood is considered in theory, in law, and is treated in practice as a trading commodity then ultimately human hearts, kidneys, eyes and other organs of the body may also come to be treated as commodities to be bought and sold in the marketplace”. It remains customary for countries to supply their own needs of whole blood (WB) and blood components (BC), usually by VNRBD. However, for PDMPs, many countries rely on importing the finished products. These often originate from plasma obtained from donors paid by the fractionation companies, sometimes mixed with plasma from VNRBD. This challenges the warning of Titmuss [8]. Reliance on imported products from paid donors also is at variance with resolutions, statements and recommendations from the WHO, the International Red Cross, the Council of Europe and the International Society of Blood Transfusion [7,9–11].

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