



**Expert Consensus Statement on
achieving self-sufficiency in safe blood
and blood products, based on voluntary
non-remunerated blood donation
(VNRBD)***

*WHO Expert Group** on Self-sufficiency in Safe Blood and
Blood Products based on VNRBD*

Correspondence:

Dr Neelam Dhingra, Coordinator, Blood Transfusion Safety, Department of Health Systems Policies and Workforce, World Health Organization, 20 Avenue Appia, 1211 Geneva, Switzerland.

E-mail: dhingran@who.int

Abstract

All countries face challenges in making sufficient supplies of blood and blood products available and sustainable, while also ensuring the quality and safety of these products in the face of known and emerging threats to public health. Since 1975, the World Health Assembly (WHA) has highlighted the global need for blood safety and availability. WHA resolutions 63.12, 58.13 and 28.72, *The Melbourne Declaration on 100% Voluntary Non-Remunerated Donation of Blood and Blood Components* and WHO Global Blood Safety Network recommendations have reaffirmed the achievement of “Self-sufficiency in blood and blood products based on voluntary non-remunerated blood donation (VNRBD)” as the important national policy direction for ensuring a safe, secure and sufficient supply of blood and blood products, including labile blood components and plasma-derived medicinal products. 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.

Introduction

Blood transfusion services play an essential, underpinning role in health systems. Countries throughout the world are facing serious challenges in making sufficient supplies of blood and blood products, including labile blood components and plasma-derived medicinal products, available and sustainable, while also ensuring the quality and safety of these products in the face of known and emerging threats to public health. These challenges include the risk of transfusion-transmitted infections, an inadequate number of blood donors, increasing needs for blood and blood products, inefficient blood supply systems, weak quality systems, and inappropriate and unsafe use of blood and blood products, which lead to chronic blood shortages, inequitable access, unsafe blood products and unsound clinical transfusion practices.

Since 1975, the World Health Assembly (WHA) has highlighted the global need for blood safety and availability through the adoption of several resolutions [1,2], giving greater priority to this issue within the global and national health agendas, and as part of strategies for the achievement of the Millennium Developmental Goals. Key resolutions include: WHA28.72 *Utilization and supply of human blood and blood products* (1975); WHA56.30 *Global health-sector strategy for HIV/AIDS* (2003); WHA58.13 *Blood safety: proposal to establish World Blood Donor Day* (2005); and WHA63.12 *Availability, safety and quality of blood products* (2010). These resolutions have also identified the guiding principles and essential elements for the development of sustainable national blood systems to meet the transfusion needs of all patients.

The WHA resolutions, *The Melbourne Declaration on 100% Voluntary Non-Remunerated Donation of Blood and Blood Components* (June 2009) [3] and the recommendations of the WHO Global Blood Safety Network [4] have reaffirmed the achievement of self-sufficiency in blood and blood products based on voluntary non-remunerated blood donation (VNRBD) as the important national policy direction for ensuring a safe, secure and sufficient supply of blood and blood products.

While some successes have been achieved, self-sufficiency is not yet a reality in many countries or regions. There is an urgent need to establish strategies and mechanisms for achieving self-sufficiency in safe blood and blood products based on VNRBD. Such strategies need to be applied to labile blood components as well as plasma-derived medicinal products.

Expert Consultation on Achieving Self-sufficiency in Safe Blood and Blood Products based on VNRBD

A meeting of experts was convened by WHO on 21–23 September 2011 in Geneva, Switzerland, to develop a consensus statement which would provide guidance on mechanisms for achieving self-sufficiency in safe blood and blood products based on VNRBD. Thirty-seven participants attended the consultation, including experts from 17 developed and developing countries and representatives of inter-governmental organizations: the Council of Europe, the European Commission and the World Health Organization.

The objectives of this consultation were to: discuss the concept and rationale of self-sufficiency and develop a practical definition of self-sufficiency in safe blood and blood products based on VNRBD; share information and country perspectives and experiences regarding self-sufficiency; analyse factors influencing the global implementation of self-sufficiency based on VNRBD including the issues of safety, ethics, security and sustainability of supply, trade and its potential impact on public health, availability and access for patients; and define strategies, mechanisms and options to achieve self-sufficiency.

Experts participating in the WHO Consultation endorsed the following definitions and Consensus Statement.

Definition of self-sufficiency in safe blood and blood products based on voluntary non-remunerated blood donation

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.

Recognizing that six blood products will most likely form the drivers for the number of donations of blood, plasma and cellular blood components needed, these should be given priority in policy and strategy development for achieving self-sufficiency based on VNRBD. These six driver products are: 1) whole blood and red blood cells either recovered from whole blood or by apheresis (WB/RBC); 2) platelets either recovered from whole blood or by apheresis (PLT); 3) plasma for transfusion either recovered from whole blood or sourced by apheresis and prepared by any production method (FFP); 4) plasma-derived clotting factor VIII prepared by any production method (pd-FVIII); 5) polyvalent human (H) immune globulin (IgIV or IgSC); and 6) human albumin solutions for transfusion (Alb).

Definition of voluntary non-remunerated blood donation

Voluntary non-remunerated blood donation (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.

This definition has already been endorsed by the World Health Organization, 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.

Consensus Statement

Rationale

- Blood, plasma and cellular blood components, and other therapeutic substances derived from the human body, should not be considered as mere 'commodities'. Donated blood that is provided voluntarily by healthy and socially committed people is a precious national resource. Governments should be accountable for ensuring a sufficient supply of products from these special resources which are and will remain limited by nature. The availability and safety of the supply, the safety of both donors and recipients and the appropriate use of blood, plasma and cellular blood donations are and must remain a public affair. The donation of whole blood or its components is an ultimate expression of community and citizen participation in the health system, which also requires effective intersectoral collaboration.
- The management of this precious national resource requires a long-term perspective and systematic approach aimed at ensuring the continuity, sustainability and security of the supply of safe blood and blood products. Universal and timely access to safe blood products of assured quality and efficacy and the appropriate use of such products are essential for quality service provision. This requires a strong foundation based on an adequate number of regular, voluntary, non-remunerated blood donors as the most robust and safe blood systems globally are based on VNRBD.
- The need for blood and blood products is growing every year and large numbers of patients who require life-saving support with blood and blood products still do not have access to them. It is therefore essential that all countries have the national capacity to

Achieving self-sufficiency in safe blood and blood products based on VNRBD

collect blood, plasma and cellular components of optimal quality and safety from voluntary, non-remunerated donors in order to meet the national needs for blood components for transfusion and plasma-derived medicinal products. For the supply of plasma-derived medicinal products in particular, in the long term it will not be feasible for a small number of countries to collect sufficient plasma to produce enough plasma-derived medicinal products to meet global needs.

- The HIV epidemic and the outbreak of vCJD have demonstrated that global distributions of plasma-derived medicinal products or intermediates could increase the risk of global spread in the event of a new emerging transfusion-transmissible infection.
- Voluntary non-remunerated blood donation is the cornerstone of a safe and sufficient blood supply and is the first line of defence against the transmission of infectious diseases through transfusion. Informed and regular, voluntary, non-remunerated blood donors from low-risk populations have been demonstrated to be at lower risk of HIV and other transfusion-transmissible infections than paid and family/replacement donors.
- The Oviedo Convention on Human Rights and Biomedicine of 1997 [5] explicitly prohibits any financial gain from the human body and its parts. Prevention of the commercialization of blood donation and exploitation of blood donors are important ethical principles on which a national blood system should be based. The right to equal opportunity in access to blood and blood products of uniform and high quality based on patients' needs is rooted in social justice and the social right to health care.
- Payment for the donation of blood (including donations of plasma and cellular components) not only threatens blood safety, it also erodes community solidarity and social cohesion which, on the contrary, can be enhanced by the act of voluntary non-remunerated donation. By placing an onus on under-privileged populations in need of money, it also compromises the development of a voluntary, non-remunerated blood donor programme. There are concerns that sufficient safe donations and sustainable supply, availability and access to blood and blood products based on VNRBD may be compromised through the presence of parallel systems of paid donation.
- In many countries, systems based on family/replacement donation are currently in use for providing blood for patients. These systems, however, often lead to coercion and place undue burden on patients' families and friends to give blood, also leading to systems of hidden payment. Such systems are unreliable, putting the onus for the provision of blood on the patients' families rather than on the health system. In the long term, family/replacement donation systems will be unable to provide safe, sufficient and sustainable national blood supplies, employing both component preparation and apheresis donations, to ensure equitable access for all patients. Such systems will inevitably act as a barrier to enabling national blood systems to develop appropriately alongside countries' overall health systems.
- Large volumes of plasma recovered from whole blood donations based on VNRBD, mainly in low- and middle-income countries, are currently not used and are discarded because of concerns that quality requirements are not being met for plasma for fractionation for the manufacture of plasma-derived medicinal products.
- The commitment by national governments to self-sufficiency in safe blood and blood

products based on VNRBD, and a coordinated, integrated and collaborative approach to policy development and planning are prerequisites for ensuring the implementation of fully effective national blood systems.

- It is recognized that the implementation of a policy for self-sufficiency in blood and blood products generally follows a stepwise progression in scope, from whole blood transfusions towards blood components for transfusion and further towards plasma fractionation, aligned to the state of development of the national health system. Achieving self-sufficiency in the supply of blood and blood products from VNRBD and ensuring the security of that supply are important national goals and countries may set different timelines in the achievement of these goals, depending on their health system development.

Recommendations to National Health Authorities

Experts participating in the WHO Consultation recommend that national health authorities should:

1. Incorporate the goal of achieving self-sufficiency in safe blood and blood products based on VNRBD into the national health policy, and strengthen the national blood system accordingly, by:
 - clearly positioning self-sufficiency, based on VNRBD, in blood components for transfusion and human plasma-derived medicinal products in the national blood policy and its legislative framework;
 - implementing strategies and mechanisms to achieve self-sufficiency based on VNRBD in blood components for transfusion as well as plasma-derived medicinal products [6];
 - providing appropriate and sufficient financial, technical and human resources.
2. Introduce legislation with specific implementation timelines for the achievement of self-sufficiency based on VNRBD, by:
 - identifying VNRBD as the sole source of blood, plasma and cellular components for the production of the six driver blood products (blood components for transfusion as well as plasma-derived medicinal products) for the treatment of patients;
 - instituting the preferential use of plasma-derived medicinal products sourced from VNRBD, as a transitional measure;
 - prohibiting payment in cash or in kind for the donation of blood, plasma and cellular components, thus ensuring alignment with similar legislations and WHO recommendations on the donation of other substances of human origin such as organs, tissues and cells.
3. Introduce specific measures, consistent with relevant international trade agreements, to protect the health of the public by ensuring the provision of safe and sufficient blood components for transfusion and plasma-derived medicinal products in the national health system through nationally, or where needed, regionally (such as from neighbouring countries) sourced VNRBD.
4. Establish mechanisms of cooperation between countries to secure regional self-sufficiency in blood and blood products based on VNRBD.

Achieving self-sufficiency in safe blood and blood products based on VNRBD

5. Incorporate measures to achieve self-sufficiency based on VNRBD for blood components for transfusion and plasma-derived medicinal products into the regulatory framework, to facilitate:
 - the supply of plasma from VNRBD and plasma-derived medicinal products sourced from VNRBD within regional or other collaborative self-sufficiency arrangements, including contract fractionation;
 - phasing out the use and restricting the imports of blood components for transfusion and plasma-derived medicinal products based on paid donations.
6. Introduce strategies and measures to establish appropriate quality systems and standardized procedures in the national blood system for the collection, testing and preparation, storage, distribution, transportation and use of blood components for transfusion and plasma (either recovered from whole blood or by apheresis).
7. Put in place mechanisms for the fractionation of surplus recovered plasma from VNRBD for national or regional self-sufficiency to avoid the discard of recovered plasma donated by VNRBD. This may require:
 - formal agreements between the blood system and the fractionator(s) to support contract fractionation [7] and/or for the procurement or exchange of plasma and plasma-derived medicinal products, with oversight of the ministry of health or an appropriate authority accountable to the ministry of health; and
 - negotiations with (contract) fractionators to provide an appropriate part of the resources and technological knowledge needed.
8. Establish mechanisms, such as an independent national clinical transfusion expert committee, to:
 - estimate and monitor trends in demand, patient needs and the clinical use of blood components for transfusion and plasma-derived medicinal products;
 - regularly evaluate and report on the level of sufficiency for the driver blood and blood products within the framework of the national health system;
 - advise and recommend on priorities in the national supply of blood components for transfusion and plasma-derived medicinal products.
9. Establish mechanisms to:
 - collect all data on blood and blood product safety and supply (including proprietary information) and annual reports from blood transfusion services and manufacturers of plasma-derived medicinal products on:
 - national distributions (deliveries, sales), imports and exports of the driver blood products and related intermediates, and;
 - contribution of donations derived from VNRBD.
 - monitor these data with a view to regularly evaluating and anonymously reporting on the state of and trends in the national supply of driver blood products (blood components for transfusion and plasma-derived medicinal products).
 - share key blood and blood product safety and supply (anonymized) reports internationally to enable countries to make informed policy decisions for the safety and sufficiency of the supply of blood and blood products.

10. Introduce labelling requirements to distinguish blood components for transfusion and plasma-derived medicinal products of VNRBD origin versus paid donations, consistent with labelling as used by manufacturers globally in other fields practising environmentally and ethically sustainable production methods, to enable informed choices for hospitals, clinicians and patients on the source of blood components for transfusion and plasma-derived medicinal products.
11. Promote VNRBD both for blood components for transfusion and plasma-derived medicinal products as agreed in WHA28.72, 58.13 and 63.12, and to achieve 100% VNRBD by 2020 as guided by the Melbourne Declaration.
12. Warrant that the donation of blood and plasma - in line with other substances of human origin - be only from VNRBD and that the donation of blood, plasma and cellular blood components remains a public affair.

Recommendations to WHO

Experts participating in the WHO Consultation recommend that WHO should:

1. Provide policy guidance and technical support to countries in establishing and implementing nationally coordinated, efficiently-managed and sustainable blood and plasma programmes, and in implementing the above mentioned recommendations, to move towards self-sufficiency in safe blood and blood products based on VNRBD.
2. Support countries to develop and implement strategies and mechanisms to share recovered plasma, intermediates and plasma-derived medicinal products based on VNRBD at regional levels or through other collaborative arrangements in order to make complete use of these donations from voluntary non-remunerated donors and make the products available for patient care.
3. Develop methodologies and models to estimate and predict context-sensitive national clinical and patient requirements for blood components for transfusion and plasma-derived medicinal products, estimate the numbers and types of donations required, and assess progress towards self-sufficiency based on VNRBD.
4. Facilitate international technology transfer to improve self-sufficiency based on VNRBD.
5. Develop a comprehensive report on global blood safety, including the global status of self-sufficiency in safe blood and blood products based on VNRBD.
6. Establish global governance mechanisms to support the implementation of self-sufficiency based on VNRBD by:
 - global monitoring and reporting on self-sufficiency in safe blood and blood products based on VNRBD; and
 - assessing options and the feasibility of global instruments to prevent the commercialization of the donation of blood, plasma and cellular components and for the implementation of strategies and mechanisms to move towards self-sufficiency based on VNRBD.

References

- 1 *World Health Assembly and Executive Board resolutions on blood safety and availability*. Geneva, World Health Organization, 2011
www.who.int/bloodsafety/resolutions/en/index.html
- 2 *Self-sufficiency in blood and blood products based on voluntary non-remunerated blood and plasma donations*. Geneva, World Health Organization, 2011
www.who.int/bloodsafety/transfusion_services/self_sufficiency/en/index.html
- 3 *The Melbourne Declaration on 100% voluntary non-remunerated donation of blood and blood components*. Geneva, World Health Organization, 2009
www.who.int/worldblooddonorday/Melbourne_Declaration_VNRBD_2009.pdf
- 4 WHO Global Blood Safety Network. *Meeting of WHO Collaborating Centres, Expert Panel Members, NGOs in Official Relations and Key Implementing Partners for Blood Safety*. 16 -18 March 2011, Dubai, United Arab Emirates
www.who.int/entity/bloodsafety/collaboration/who_gbsn_2011_03_recommendations.pdf
- 5 Council of Europe. *Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*. CETS No.: 164
conventions.coe.int/Treaty/Commun/ListeTraites.asp?MA=9&CM=7&CL=ENG
- 6 *Towards 100% voluntary blood donation: a global framework for action*. Geneva, World Health Organization/International Federation of Red Cross and Red Crescent Societies, 2010
www.who.int/bloodsafety/publications/9789241599696/en/index.html
- 7 *Information Sheet. Plasma Contract Fractionation Program*. Geneva, World Health Organization, 2006
www.who.int/bloodproducts/publications/en/Information%20Sheet%20PLASMA.pdf

***Voluntary non-remunerated blood donation** also includes the donation of plasma and cellular blood components.

****Members of the WHO Expert Group on Achieving Self-sufficiency in Safe Blood and Blood Products based on VNRBD**

Noryati ABU AMIN, Medical Officer, Blood Transfusion Safety, WHO, Geneva, Switzerland; Duncan ARMSTRONG, Executive Director, Natal Bioproducts Institute, Pinetown, South Africa; Marie-Emmanuelle BEHR-GROSS, Scientific Officer, DBO/Blood Transfusion, European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, Strasbourg, France; Peter BEYER, Senior Advisor, Department of Public Health, Innovation and Intellectual Property, WHO, Geneva, Switzerland; Ubonwon CHAROONRUANGRIT, Deputy Director, National Blood Center, Thai Red Cross Society, Bangkok, Thailand; James CHITSVA, Technical Officer, Blood Transfusion Safety, WHO, Geneva, Switzerland; Jose Ramiro CRUZ, Regional Adviser, Blood Services, WHO Regional Office for the Americas, Pan American Health

Achieving self-sufficiency in safe blood and blood products based on VNRBD

Organization, Washington DC, United States of America; Bernard DAVID, French Blood Establishment, Saint-Denis Cedex, France; Jeroen DE WIT, Vice Chairman Executive Board, Sanquin Blood Supply Foundation, Amsterdam, Netherlands; Neelam DHINGRA, Coordinator, Blood Transfusion Safety, WHO, Geneva, Switzerland; Yvonne FISCHER, Head of Planning and Controlling, Swiss Transfusion SRC, Bern, Switzerland; Peter FLANAGAN, Medical Director, New Zealand Blood Service, Auckland, New Zealand; Dongying GAO, Deputy Director, Beijing Red Cross Blood Center, Beijing, People's Republic of China; Giuliano GRAZZINI, Director, Italian National Blood Centre, Rome, Italy; Ananda GUNASEKERA, Director, National Blood Transfusion Service, Colombo, Sri Lanka; HUI Ping, Director, Macao Blood Transfusion Service, Macao SAR, People's Republic of China; Sandhya KABRA, ADG (Blood Safety & Lab Services), National AIDS Control Organization, Ministry of Health and Family Welfare, New Delhi, India; Che Kit LIN, Chief Executive and Medical Director, Hong Kong Red Cross Blood Transfusion Service, Hong Kong SAR, People's Republic of China; Jun MATSUMOTO, Division of Blood and Blood Products, Ministry of Health, Labour and Welfare, Tokyo, Japan; Bridon M'BAYA, Medical Director, Malawi Blood Transfusion Service, Blantyre, Malawi; Peter MCDONALD, Executive Director, Australian Red Cross Blood Service, Melbourne, Australia; Satoru MIYAKE, Director of Division of Blood and Blood Products, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare, Tokyo, Japan; Faten MOFTAH, Director General, National Blood Transfusion Service, Ministry of Health and Population, Cairo, Egypt; Loyiso MPUNTSHA-MOTAU, Chief Executive Officer, South African National Blood Service, Constantia Kloof, South Africa; David MVERE, Chief Executive Officer, National Blood Service Zimbabwe, Harare, Zimbabwe; Koji NABAE, Infectious Disease Surveillance Center, National Institute of Infectious Diseases, Tokyo, Japan; Shinjiro NOZAKI, External Relations Officer, Global Health Workforce Alliance, WHO, Geneva, Switzerland; Paul ROGERS, Technical Officer, Health Technology and Laboratories, WHO Regional Office for the Western Pacific, Manila, Philippines; Leslie SOBAGA, Programme Assistant, Directorate of International Affairs, French Blood Establishment, Saint-Denis Cedex, France; Anthony STEED, Director, Donor and Clinic Services, Canadian Blood Services, Ottawa, Canada; Dr Jean-Baptiste TAPKO, Regional Adviser, Blood Safety, WHO Regional Office for Africa, Brazzaville, Republic of Congo; Diana Lay Tin TEO, Director, Blood Services Group, Health Sciences Authority, Singapore; Cornelis L. VAN DER POEL, Associates Professor in Epidemiology, Bilthoven, Netherlands; Wim VAN LERBERGHE, Director, Department for Health Systems Policies and Workforce, WHO, Geneva, Switzerland; Silvia VILLANUEVA, Policy Officer, European Commission, Brussels, Belgium; Edward YEE, Director, Donor and Clinic Services, Canadian Blood Services, Vancouver, Canada; YU Junping, Technical Officer, Blood Transfusion Safety, WHO, Geneva, Switzerland.

Note: This Expert Consensus Statement contains the collective views of an international group of experts and participants in the WHO Expert Consultation on Achieving Self-Sufficiency in Safe Blood and Blood Products based on Voluntary Non-Remunerated Blood Donation (VNRBD) September 2011, and the Statement does not necessarily represent the decisions or stated policies of the participating organizations.