DIS-17

GLOBAL DATABASE ON BLOOD SAFETY

Summary Report

1998–1999



World Health Organization
Blood Transfusion Safety
Department of Blood Safety and Clinical Technology
20 Avenue Appia, 1211 Geneva 27, Switzerland
Tel: +41 22 791 4385 Fax: +41 22 791 4836
http://www.who.int/HTP/BCT/BTS
E-mail: bloodsafety@who.int

Background

Millions of lives are saved each year through blood transfusions. In most developing countries, however, people still die due to an inadequate supply of blood and blood products. This has a particular impact on women (as a consequence of pregnancy-related complications), children (malnutrition, malaria and severe life-threatening anaemia), trauma victims and, especially, the poor and disadvantaged. It is estimated that up to 150 000 pregnancy-related deaths each year could be avoided with adequate transfusion therapy.

The emergence of HIV in the 1980s highlighted the importance of ensuring the safety, as well as the adequacy, of national blood supplies. In many countries, even where blood is available, many recipients remain at risk of transfusion-transmissible infections (TTIs) as a result of poor blood donor recruitment and selection practices and the use of untested units of blood.

WHO strategy for blood safety

The World Health Organization (WHO) has identified blood safety as a health issue requiring high priority and launched the Global Collaboration for Blood Safety (GCBS) as a worldwide effort to improve blood safety by building on knowledge, utilizing existing expertise, promoting dialogue and suggesting realistic, effective and practical mechanisms.

WHO has developed the following strategy for global blood safety, which is described more fully in the WHO *Aide-Mémoire: Blood Safety.*

Organization and management

The establishment of well-organized, nationally-coordinated blood transfusion services with quality systems in all areas.

Blood donors

The collection of blood only from voluntary non-remunerated donors from low-risk populations.

Blood screening

The screening of all donated blood for transfusion-transmissible infections, including HIV, hepatitis viruses and syphilis; blood grouping; compatibility testing; blood processing.

The clinical use of blood

A reduction in unnecessary transfusions through the appropriate clinical use of blood.

WHO Global Database on Blood Safety

Following the launch of the Global Collaboration for Blood Safety, it became apparent that baseline information was required about blood transfusion services in Member States to identify the exact nature of problems and develop appropriate strategies.

The WHO Global Database on Blood Safety (GDBS) was therefore established to obtain data on blood transfusion services in all Member States of the World Health Organization, with the following objectives:

- To assess the global situation on blood safety
- To obtain best available information on blood transfusion services in each Member State
- To identify problems and needs in order to provide appropriate technical support
- To identify countries for priority assistance
- To monitor progress and trends in blood safety.

A questionnaire, based on the *Aide-Mémoire*, was developed in 1997 as a tool for the standardized collection of data from Member States and was sent to national heath authorities for completion. The status of blood transfusion services in selected countries was also assessed during field visits by WHO consultants, whose observations assisted in the analysis of the data.

Data analysis

Data was obtained from 175 of the 191 Member States and was analysed on a regional and global basis. Since significant differences were revealed between some countries in the same regions, a common factor was sought to enable meaningful analysis. The Human Development Index (HDI), devised by the United Nations Development Programme *(Human Development Report,* UNDP, 1999), satisfied this requirement.

The Human Development Index classifies countries as having a low, medium or high HDI, based on the following criteria:

- Life expectancy
- Educational attainment
- Adjusted income.

In the majority of developing countries (low and medium HDI), there is little systematic collection of data at national level due to a lack of coordination of blood transfusion services. The data obtained from these countries was therefore limited to information from the main centres, usually based in cities.

Key observations

Global blood supply

Globally, more than 75 million units of blood are donated each year. Although the majority of the world's population live in low or medium HDI countries, around 60% of the global blood supply is donated in countries with a high HDI, as shown in Table 1.

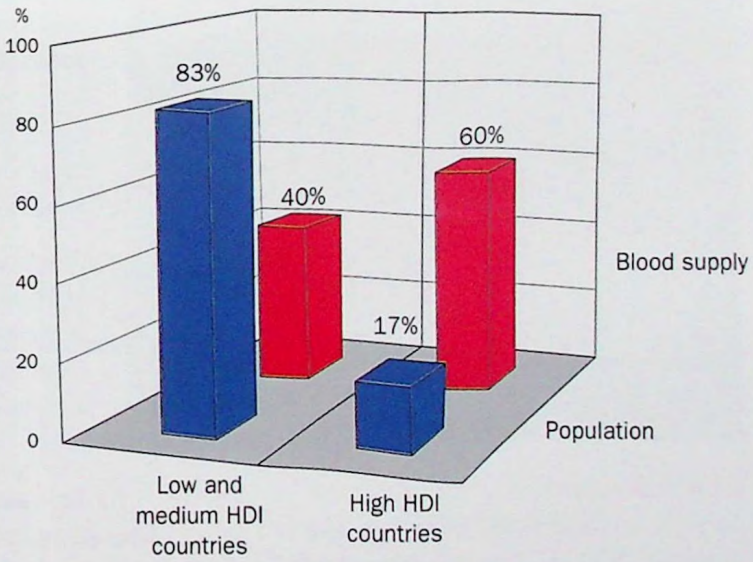
Table 1: Global annual blood donations, analysed according to HDI criteria, 1998–1999

	Low HDI countries (n=41)		Medium HDI countries (n=89)		High HDI countries (n=45)	
Blood supply, in millions of units and by percentage	1.3m	1.7%	28.9m	38.5%	44.9m	59.8%
Estimated blood donation rates per 1000 population	Average Range	2 0.3–5.3	Average Range	10 1.7–50.3	Average Range	40 10.4–74.0

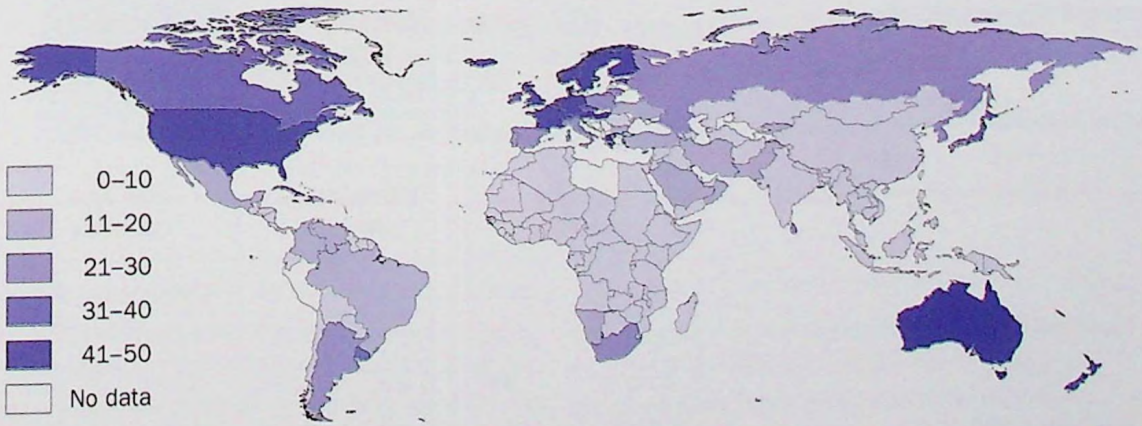
Analysis of the blood supply in relation to the population reveals that 83% of the world's population has access to only 40% of the global blood supply (Figure 1).

The blood donation rate per 1000 population is almost 20 times higher in developed countries (high HDI) than in countries with a low HDI (Map 1).

Figure 1: Global population and global blood supply, 1998–1999



Map 1: Number of whole blood donations per 1000 population, 1998–1999



Organization and management

The safety and adequacy of the blood supply is dependent on the commitment of each national health authority to the establishment of a well-organized, nationally-coordinated blood programme. This requires official recognition of a specific organization with sole responsibility for blood transfusion services, an adequate budget and a national blood policy and plan, supported by a legislative and regulatory framework that governs all activities.

GDBS data indicates marked differences globally in the formulation and implementation of national blood policies. In the developed world (high HDI), 94% of countries with strong government commitment and support reported the implementation of a national blood policy and plan. In comparison, national policies have been implemented in only 59% of low and medium HDI countries, particularly those with hospital-based services. Only 20% of countries reported that all aspects of a well-organized BTS were in place.

A key indicator of a well-organized and coordinated national blood programme is a successful programme for the recruitment and retention of voluntary non-remunerated blood donors. Using this indicator, a marked difference is evident between countries with a nationally-coordinated blood transfusion service and those without, regardless of HDI classification.



Blood donors

In 1975, the World Health Assembly passed Resolution WHA 28.72 urging all Member States to promote the development of national blood transfusion services based on voluntary non-remunerated blood donation.

Regular, voluntary non-remunerated donors from low-risk populations are the safest blood donors. A number of studies have shown that family/replacement and paid donors have a higher incidence and prevalence of transfusion-transmissible infections than voluntary non-remunerated donors.

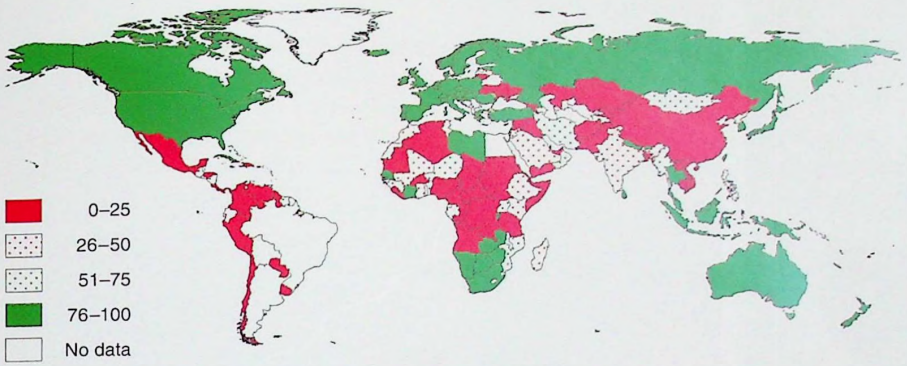
Unfortunately, the World Health Assembly Resolution has not been translated into reality in many low and medium HDI countries since it was adopted more than 25 years ago, as indicated by Table 2 and Map 2.

In low and medium HDI countries less than 40% of blood donations were from voluntary non-remunerated blood donors. In contrast, 98% of donations in high HDI countries were from voluntary non-remunerated blood donors.

Table 2: Estimated number (in millions) and percentage of donations, by type of donation, 1998–1999

	Low HDI countries		Medium HDI countries		High HDI countries	
Voluntary non-remunerated donations	0.4m	31%	11.6m	40%	43.9m	98%
Family/replacement donations	0.8m	61%	11.7m	41%	1.0m	2%
Paid donations	0.1m	8%	5.6m	19%	0.03m	n/a
Total donations	**1.3m**	**100%**	**28.9m**	**100%**	**44.93m**	**100%**

Map 2: Percentage of voluntary, non-remunerated blood donations, 1998–1999

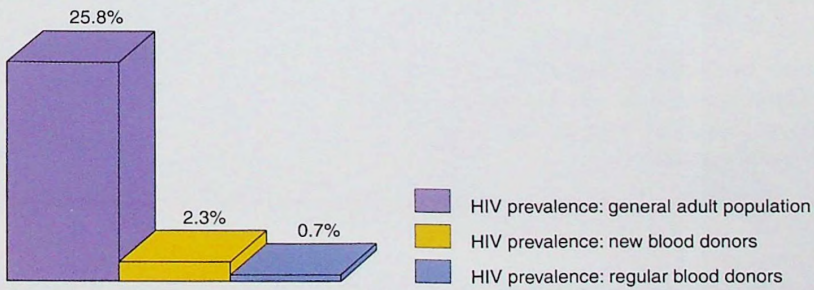


The analysis clearly illustrates that the lack of a well-organized blood donor programme based on voluntary non-remunerated blood donation leads to dependence on family/replacement blood donors. This paves the way for a 'hidden' paid and unsafe donation system since families may pay others to donate.

Globally, there were about 6 million donations from paid donors and 13.5 million from family/replacement donors. Up to 60–70% of donations in the developing world were given by family/replacement or paid donors, often in countries where the seroprevalence of HIV and other infectious agents, such as hepatitis B and hepatitis C, is relatively high.

Best practice has shown that, even in high prevalence areas for infections such as HIV, a well-organized programme of voluntary non-remunerated blood donation and effective donor selection procedures can achieve a low prevalence of infectious disease markers in the blood donor population. This is clearly demonstrated by model blood transfusion services such as those in Zimbabwe (Figure 2) and South Africa.

Figure 2: HIV prevalence in blood donors compared with the general adult population in Zimbabwe, 1998–1999



Blood screening

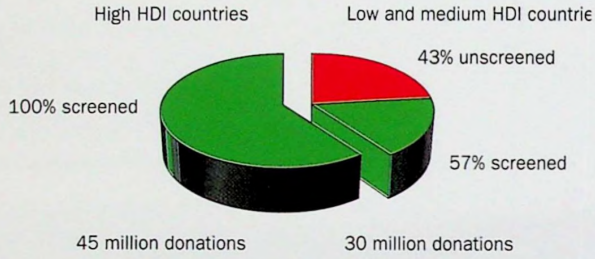
The WHO strategy for blood safety recommends that all donated blood should be tested for HIV, hepatitis B and syphilis. Where feasible and appropriate, all donated blood should also be screened for hepatitis C, malaria and Chagas disease. Screening for transfusion-transmissible infections, coupled with appropriate donor selection, has a major impact on reducing the risk and further spread of these infections.

GDBS data indicates that more than 40% of donated blood was not screened for TTIs in low and medium HDI countries. This means that around 80% of the world's population had access to only 20% of the global supply of safe, screened blood.

Millions of patients who are transfused with untested blood are therefore at risk of transfusion-transmissible infections.

Up to 13 million units of the global blood supply were not screened for all relevant transfusion-transmissible infections, mainly in low or medium HDI countries

Figure 3: Screening of the global blood supply, 1998–1999



The most common causes of poor blood screening programmes include irregular supplies of high quality reagents and test kits, inadequately trained and skilled staff, and an absence of quality assurance programmes and screening strategies for transfusion-transmissible infections.

Analysis of the data regarding ABO and RhD grouping and compatibility testing indicates that more than 70% of countries perform these tests. However, there is no information on the level of standardization of these test procedures.

ABO incompatibility remains one of the major causes of transfusion-associated mortality, often resulting from inappropriate testing and a lack of standard operating procedures.

Analysis of other key elements in the immuno-haematology laboratory reveals a general lack of traceability because of inadequate documentation of patients requiring transfusion and failure to preserve patients' blood samples.

This highlights the need for the implementation of:

- Appropriate testing of all donated blood for relevant transfusion-transmissible infections and blood group serology
- Good laboratory practice
- Adequate procedures for the identification of blood donors, blood units, blood samples and the recipients of blood and blood products.

The clinical use of blood

Transfusion should be prescribed only to treat conditions that might result in mortality or significant morbidity and that cannot be prevented or managed effectively by other means. The effective clinical use of blood and blood products therefore requires a reduction in unnecessary transfusions and the use of intravenous replacement fluids and other simple alternatives to transfusion, wherever possible.

A number of studies in both the developed and developing world have reported considerable variations in prescribing practice, often with a high number of unnecessary transfusions.

The inappropriate use of blood and blood products, coupled with the transfusion of unscreened or improperly screened units, particularly in countries with poor blood programmes, increases the risk of TTIs to recipients. It also widens the gap between supply and demand and contributes to shortages of blood and blood products for patients requiring transfusion.

National policies and guidelines are required to encourage the appropriate clinical use of blood, together with systems for the monitoring and evaluation of clinical transfusion practice. GDBS data indicates that the majority (>60%) of low and medium HDI countries do not have national policies and guidelines on clinical blood usage.

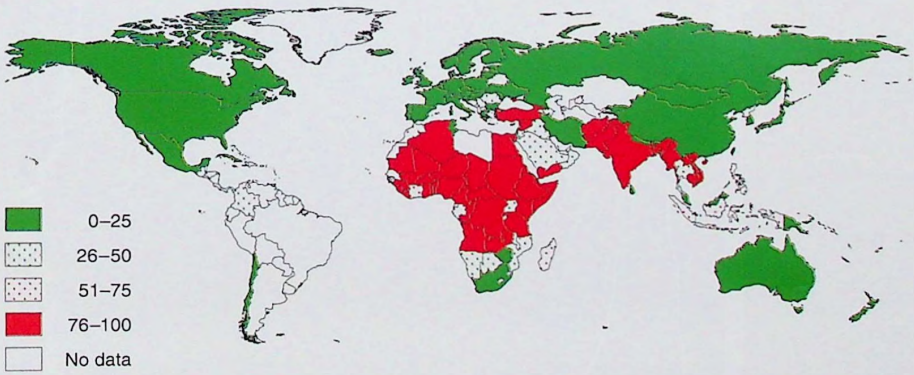
The appropriate use of blood and blood products is also dependent on consistent, adequate supplies of plasma substitutes, including crystalloid and colloid solutions. While more than 70% of countries report that plasma substitutes are available, field observations in many low and medium HDI countries suggest that these are often not readily accessible to patients when needed.

Effective clinical transfusion practice requires that whole blood is separated into its various components so that the right component is available for the right patient. The availability and use of blood components is limited in many low and medium HDI countries, as shown in Map 3, often as a result of a lack of organization, a poor infrastructure and a low level of awareness about the appropriate clinical use of blood.

GDBS data indicates that the use of whole blood is ten times higher in low and medium HDI countries than in the developed world, resulting in inadequate provision of life-saving support for patients requiring specialized treatment with blood component therapy.



Map 3: Percentage of blood transfused as whole blood, 1998–1999



Training

Blood transfusion services require a comprehensive, multi-disciplinary approach to training for all personnel, including donor recruitment and blood collection staff, laboratory staff, medical officers and quality managers. Training is also required for clinicians who prescribe transfusion.

Inadequate training jeopardizes the safety of blood and blood products and adversely affects the quality of care for patients requiring transfusion.

Analysis of GDBS data suggests that the facilities and infrastructure required for appropriate training are not

available universally, despite a recognition of training needs in both the developed and developing world. Globally, 72% of countries cannot meet identified training needs and many workers remain unfamiliar with quality concepts and the application of quality management tools that can improve efficiency without extra effort or resources.

A new initiative by WHO

Recognizing the need for capacity-building, WHO initiated the Quality Management Project (QMP) for Blood Transfusion Services in 2000.

This global project aims to improve blood safety through regional training programmes in quality management, the establishment of Regional External Quality Assessment Schemes and the creation of Regional Quality Networks.

Conclusions

The data generated from the GDBS has been invaluable in assisting countries to prioritize their needs in strengthening their blood safety programmes. It has also been an important tool for major programme initiatives by the WHO Blood Transfusion Safety Team, including the GCBS and the Quality Management Project, and will assist in monitoring progress, setting priorities and allow for re-planning of activities to achieve global blood safety. The data has also been used extensively in the preparation of WHO guidelines, recommendations, learning materials and other documents.

The Global Database on Blood Safety is a dynamic, ongoing project. WHO has recently modified the GDBS questionnaire to widen its scope and it is being distributed to national health authorities for data collection for the period 2000–2001.

Acknowledgements

WHO wishes to thank the Ministry of Health and Welfare, Government of Japan, for its continued support to the GDBS project.

The invaluable effort of all WHO regional and country offices, national health authorities, directors of blood transfusion services and national blood programme managers is also fully acknowledged.

Copyright © World Health Organization, 2001

This document is issued by WHO for general distribution.

This document is not a formal publication of the World Health Organization (WHO), and all rights are reserved by the Organization. Subject to due acknowledgement to WHO, the document may, however, be freely reviewed, abstracted, reproduced or translated, in part or in whole, but not for sale or for use in conjunction with commercial purposes.

This report is the result of contributions made by various national health authorities and experts in the field of blood transfusion safety. The data and information contained herein are being provided as is and WHO makes no representations or warranties, either express or implied, as to their accuracy, completeness or fitness for a particular purpose. Similarly, WHO does not provide any representations or warranties in regard of non-infringement of third party proprietary rights. Thus, WHO does not accept any responsibility or liability in regard of the reliance on, or use of, such data and information. The views expressed in this report do not necessarily reflect the views, decisions or stated policy of WHO.

The designations employed and the presentation of the material in this report do not imply the expression of any opinion whatsoever on the part of the Secretariat of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate borderlines for which there may not yet be full agreement.