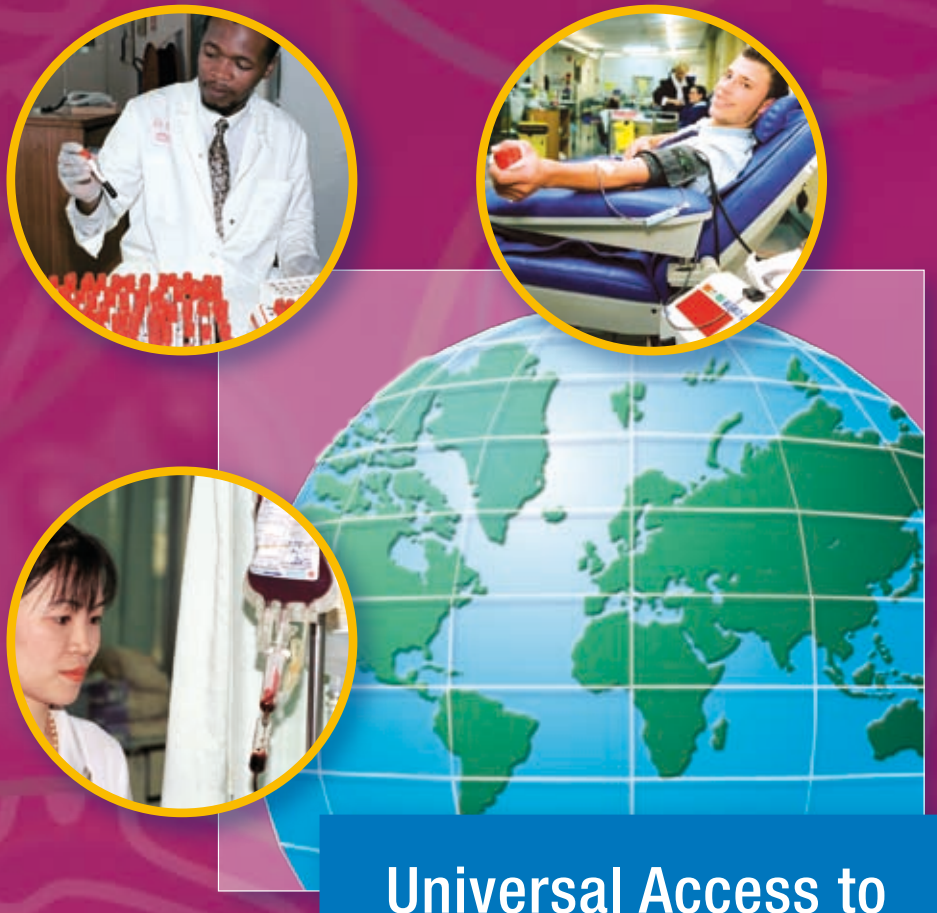
World Health Organization



Universal Access to Safe Blood Transfusion

World Health Organization

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World Health Organization
Department of Essential Health Technologies
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Contents

Executive Summary

Each year, more than 100 million people sustain injuries and more than five million die from violence and injury. Road traffic accidents are the second leading cause of all deaths and the primary reason for serious injury in people aged 5 to 29 years.[1] More than 536 000 women die each year during pregnancy or childbirth, 99% of them in developing countries.[2] Haemorrhage is the principal cause of maternal deaths worldwide, accounting for up to 44% of maternal deaths in some areas of sub-Saharan Africa.[3] Up to 20% of maternal mortality and 15% of child deaths have been attributed to severe anaemia due to malaria in the Southern African Region.[4] Timely access to safe blood transfusion is a life-saving measure in many of these clinical conditions and can also prevent serious illness in these patients.

More than 30 years after the first World Heath Assembly resolution (WHA28.72) addressed the issue of blood safety, equitable access to safe blood and blood products and their safe and rational use still remain major concerns throughout the world. To address the challenge of inadequate access to safe blood transfusion, the Blood Transfusion Safety team at WHO headquarters organized a 'Global Consultation on Universal Access to Safe Blood Transfusion' on 9–11 June 2007 in Ottawa, Canada. This consultation was organized with the objectives to review the current challenges to global blood safety and availability and to analyse the strategies for ensuring universal access to safe blood transfusion. The strategies outlined in this document also provide a direction for the development of the WHO Global Strategic Plan for Universal Access to Safe Blood Transfusion 2008–2015.

The consultation assessed the nature and magnitude of current problems and reviewed progress relating to global blood safety and availability, access to safe blood and blood products and their rational use, with particular focus on developing countries. Country experiences and innovative approaches to the implementation of the WHO strategy for blood safety and availability were reviewed. The consultation identified ways to integrate blood transfusion into healthcare systems as a cross-cutting service that underpins the achievement of the health-related Millennium Development Goals (MDGs).

Known and emerging threats to blood safety and the impact of measures to contain them on the adequacy and accessibility of national blood supplies were also reviewed. Opportunities for using wider global health initiatives to promote blood safety and availability were explored. The consultation participants shared their experiences in order to refine evidence-based strategies for blood safety. They also defined new approaches to developing effective, sustainable national blood programmes and promoting safe clinical transfusion practice for patients' health and safety.

Recommendations were made to WHO and other key stakeholders to strengthen the implementation of key strategies for ensuring access to a safe and sufficient blood supply, to achieve 100% voluntary blood donation and to ensure 100% quality-assured testing of donated blood. These also include recommendations for optimizing blood usage for patient health, developing quality systems in the transfusion chain, strengthening the workforce, keeping pace with new developments and building effective partnerships.

1. *Injury. A leading cause of the global burden of disease, 2000.* Geneva, World Health Organization, 2002.
2. *Maternal mortality in 2005. Estimates developed by WHO, UNICEF, UNFPA and the World Bank.* Geneva, World Health Organization, 2007.
3. WHO analysis of causes of maternal death: a systematic review. *Lancet,* 2006, 367:1066–1074.
4. *Africa Malaria Report, 2003.* Geneva, World Health Organization/UNICEF, 2003.

A Safe Blood Saves Lives

Blood transfusion is an essential component of health care which saves millions of lives each year. Every second, someone in the world needs blood for surgery, trauma, severe anaemia or complications of pregnancy. Despite ongoing efforts, it will still be many years before artificial substitutes can routinely replace the need for donated human blood.

Even though blood is universally required for the management of patients suffering from cancer and blood diseases such as aplastic anaemia, thalassaemia, sickle cell disease, haemophilia and leukaemia, the pattern of blood usage differs markedly across the globe. In developed countries, transfusion is most commonly used to support advanced medical and surgical procedures, including trauma, cardiovascular surgery, neurosurgery and transplantation. In countries where diagnostic and treatment options are limited, a much greater proportion of blood is used to treat women with obstetric emergencies and children suffering from severe anaemia, often resulting from malaria and malnutrition.

Whatever the degree of development of the health care system, transfusion is the only option for survival for many patients. Every country needs to meet its requirements for blood and blood products and ensure that blood supplies are free from HIV, hepatitis viruses and other life-threatening infections that can be transmitted through unsafe blood. Blood safety is integral to the WHO HIV/AIDS plan to scale up efforts to prevent HIV infection and for the achievement of the health-related Millennium Development Goals on reducing child mortality, improving maternal health and combating HIV/AIDS.[5]

Blood transfusion is a unique technology that blends science with altruism. Though its collection, processing and use are technical, its availability depends entirely on the extraordinary generosity of the blood donor who donates this most precious of gifts – the gift of life. Safe transfusion not only requires the application of science and technology to blood processing and testing, but also social mobilization to promote voluntary blood donation by sufficient numbers of people who are healthy and are at low risk of infections that can be transmitted to the recipients of their blood.

B Universal Access to Safe Blood Transfusion

While the need for blood is universal, millions of patients requiring transfusion do not have timely access to safe blood and there is a major imbalance between developing and industrialized countries in access to safe blood. Of the estimated 80 million units of blood donated annually worldwide, less than 45% is collected in developing countries, home to 80% of the world's population.

The average number of blood donations per 1,000 population is 10 times higher in high-income countries than in low-income countries. It is generally recommended that the equivalent of 1–3% of the population should donate blood to meet a country's needs.

5. *UN Millennium Development Goals.* http://mdgs.un.org/unsd/mdg; http://www.who.int/mdg/goals/en/index.html

Of the 73 countries that had donation rates of less than 1% of the population (fewer than 10 donations per thousand people) in 2006, 70 are developing countries. Data from sub-Saharan Africa show that fewer than 3 million units of blood were collected in 2006 for a population of nearly 600 million people.[6] The inequity in the availability of blood is also manifested within countries, with some major urban areas having access to the majority of blood available.

The prevalence of HIV, hepatitis viruses and other blood-borne infections has been reported to be lowest among voluntary unpaid blood donors who give blood purely for altruistic reasons. Higher infection rates are found among family or family replacement donors who give blood only when it is required by a member of the patient's family or community. Worldwide, the highest rate of infection is found among donors who give blood for money or other form of payment. Adequate stocks of safe blood can only be assured by regular donation by voluntary unpaid blood donors. By 2006, only a total of 54 countries reported having achieved 100% unpaid voluntary blood donation.

Even where sufficient blood is available, many recipients are exposed to avoidable, life-threatening risks through the transfusion of unsafe blood. Data in 2006 from 132 countries reveals that 31 (23.5%) countries have less than 100% screening for at least one of the four infection markers for HIV, HBV, HCV and syphilis with many countries unable to provide complete information regarding screening for infection. Even when blood is tested, often the testing is either incomplete or has inadequate quality assurance. Serious blood shortages and the lack of a reliable donor base also contribute to an increased risk of transfusion-transmitted HIV and viral hepatitis. An inadequate stock of blood forces a reliance on unsafe replacement or paid donors and also increases the risk of the issue of blood without adequate testing. Bacterial contamination during blood collection or processing poses a further risk of infection.

In many countries, the risk of transmission of infections through transfusion is further compounded by an insufficient infrastructure and systems for ensuring a safe blood supply. These include a shortage of trained staff, irregular supplies of test kits or use of poor quality test kits and the lack of a reliable supply system and appropriate cold chain facilities. Furthermore, safety measures can also be disrupted by a fragmented blood supply system, with varying technical standards and no central supervision.

Paradoxically, despite a markedly inadequate blood supply in many countries, transfusions are sometimes given unnecessarily when the availability and use of simpler, less expensive treatments would provide equal or greater benefit. Not only does this expose patients needlessly to the risk of potentially fatal transfusion reactions, it also widens the gap between supply and demand and contributes to shortages of blood and blood products for patients who really need them.

Evidence-based strategies for blood safety and availability have been successfully implemented by most developed nations where patients requiring transfusion support in any part of the country usually have timely access to safe blood. In contrast, despite tangible progress, many developing and transitional countries are unable to meet their national requirements for blood and blood products at all times. In many countries, the development of blood transfusion services has been largely restricted to major cities and universal access is still not guaranteed for those in most critical need for safe blood for their survival. Furthermore, the need for blood continues to grow globally as health systems become more developed, with improved diagnostic and treatment options

6. WHO Blood Safety Indicators 2006, preliminary analysis.

and increasingly sophisticated medical and surgical procedures requiring blood transfusion. These factors are compounded by population growth and changing demographics, with ageing populations requiring more medical care.

Today, more than 30 years after the first World Heath Assembly resolution (WHA28.72) addressed the issue of blood safety, and at the midway point in the UN Millennium Project, equitable access to safe blood and blood products and the rational and safe use of blood transfusion still remain major challenges throughout the world. Unless urgent scaled-up action to achieve universal access is taken globally, it will have a direct impact on the achievement of the health-related Millennium Development Goals and the provision of effective support to health care systems in a range of clinical disciplines that are dependent on the availability of a safe and sufficient blood supply.

C WHO Blood Transfusion Safety Programme

With the goal of ensuring universal access to safe blood, WHO has been at the forefront of the movement to improve blood safety as mandated by successive World Health Assembly resolutions.

The global need for blood safety and availability has been highlighted in the following WHA and Executive Board (EB) resolutions and regional resolutions that provide specific direction on strategies and activities within individual regions:

1975: WHA Resolution WHA28.72: Utilization and Supply of Human Blood and Blood Products

1987: EB Resolution EB79.R1: Blood and Blood Products

1995: WHA Resolution WHA48.27: Paris AIDS Summit

1999: DC-PAHO/AMRO Resolution CD41.R15: Strengthening Blood Banks in the Region of the Americas

2000: WHA Resolution WHA53.14: HIV/AIDS: Confronting the Epidemic

2001: RC-AFRO Resolution AFR/RC51/R2: Blood Safety Strategy for the African Region

2002: WHA Resolution WHA55.18: Quality of Care: Patient Safety

2003: WHA Resolution WHA56.30: Global Health Sector Strategy for HIV/AIDS

2005: WHA Resolution WHA58.13: Blood Safety: Proposal to Establish World Blood Donor Day

2007: WHA Resolution WHA60.24: Health Promotion in a Globalized World

2007: WHA Resolution WHA60.29: Health Technologies

The WHO Blood Transfusion Safety Programme at WHO-HQ, Geneva, evolved from the WHO Global Programme on AIDS and the Global Blood Safety Initiative of the late 1980s. In 2000, Safe Blood was declared an organization-wide priority and Blood Safety was designated the theme of World Health Day 2000. This was co-sponsored by the International Federation of Red Cross and Red Crescent Societies and was celebrated by ministries of health, blood transfusion services, blood donor organizations, nongovernmental organizations, professional bodies and community organizations throughout the world.

The WHO strategy for blood safety and availability, endorsed by the World Health Assembly, addresses five key areas:

- The establishment of well-organized, nationally-coordinated blood transfusion services to ensure the timely availability of safe blood and blood products for all patients requiring transfusion
- The collection of blood from voluntary non-remunerated blood donors from low-risk populations
- Quality-assured testing for transfusion-transmissible infections, blood grouping and compatibility testing
- The safe and appropriate use of blood and a reduction in unnecessary transfusions
- Quality systems covering the entire transfusion process, from donor recruitment to the follow-up of the recipients of transfusion.

WHO has supported a large number of countries in developing their national blood services through its Blood Transfusion Safety programme, the sole UN programme to provide policy guidance and technical assistance on working towards equitable access to safe blood and blood products and their safe and rational use.

The objectives of the WHO Blood Transfusion Safety programme are to:

- Support Member States in developing and/or strengthening efficient and sustainable national blood programmes with appropriate government commitment, support and regulatory mechanisms, integrated within national health care systems
- Develop norms, standards, best practice guidelines, tools and materials on various steps of the blood transfusion process to ensure blood safety
- Promote the harmonization of national and international efforts to ensure sufficient safe blood products through bilateral and multilateral collaboration and also through global partnerships such as the Global Collaboration for Blood Safety
- Build capacity in countries through structured training activities for the establishment of cost-effective sustainable nationally coordinated blood services, financial management systems, data and quality management systems, voluntary unpaid blood donation, testing of blood, blood cold chain, haemovigilance, education and training programmes in blood transfusion, and the clinical use of blood in medicine, obstetrics, paediatrics, surgery and anaesthesiology, trauma and burns
- Work with partners to observe and promote World Blood Donor Day
- Provide scientific and evidence-based guidance and support on risk assessment
- Collect, analyse and disseminate reliable information on blood safety and availability through the WHO Global Database on Blood Safety and Blood Safety Indicators
- Promote research and development in the provision and appropriate use of safe blood and blood products.

D Global Initiative on Safe Blood for Safe Motherhood

Globally, more than half a million women die each year during pregnancy, childbirth or in the postpartum period – 99% of them in the developing world. About 25% of those deaths are caused by severe bleeding during childbirth, making this the most common cause of maternal mortality.

Of the 20 countries with the highest maternal mortality ratios, 19 are in sub-Saharan Africa where the lifetime risk of maternal death is 1 in 16, compared with 1 in 2 800 in rich countries.[2] Regional rates, however, mask very wide disparities between countries. Regions with low overall mortality rates, such as the European region, contain countries with high rates. Within one single country there can be striking differences between subgroups of the population. Rural populations suffer higher mortality than urban dwellers, rates can vary widely by ethnicity or wealth status and remote areas bear a heavy burden of deaths.[7]

Severe bleeding during delivery or after childbirth is the most common cause of maternal mortality and contributes to around 34% of maternal deaths in Africa, 31% in Asia and 21% in Latin America and the Caribbean.[3] Postpartum bleeding is unpredictable and the quickest of maternal killers – it can kill even a healthy woman within two hours, if unattended. Access to a safe and sufficient blood supply could help to prevent the deaths of a significant number of mothers and their newborn children each year.

In developing countries, pregnant women are particularly vulnerable to blood shortages and account for a disproportionate number of HIV, hepatitis B and hepatitis C infections through unsafe blood because they are one of the main groups of patients requiring blood transfusion. However, the transmission of HIV through unsafe blood transfusion is preventable – and is, in fact, the only approach to HIV prevention that is almost 100% effective. The transmission of hepatitis and other bloodborne infections through unsafe blood is equally preventable.

Key life-saving intervention

Blood transfusion has been identified as one of the eight key life-saving interventions that should be available in first-referral level healthcare facilities providing emergency obstetric care.[8] Timely, appropriate and safe blood transfusion during and after labour and delivery can make the difference between life and death for many women and their newborns.

On the occasion of World Blood Donor Day 14 June 2007, with the theme of 'Safe Blood for Safe Motherhood', WHO launched a new initiative to improve the availability and use of safe blood to save the lives of women during and after childbirth. The initiative is the beginning of a broader blood safety agenda redefined during the Global Consultation on Universal Access to Safe Blood Transfusion, held in Ottawa, Canada, and aims to work towards universal access to safe blood transfusion in support of the Millennium Development Goals.

7. *The World Health Report, 2005. Make every mother and child count.* Geneva, World Health Organization, 2005.
8. *Guidelines for monitoring the availability and use of obstetric services.* UNICEF/WHO/UNFPA. New York, NY, UNICEF, 1997.

The objectives of the Global Initiative on Safe Blood for Safe Motherhood are to:

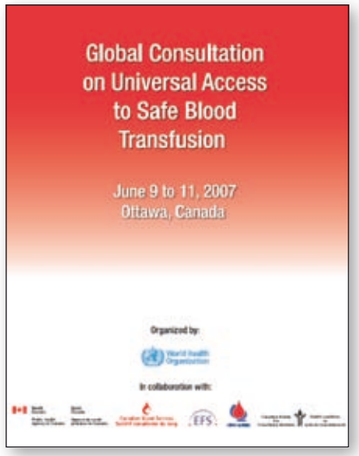
- Provide technical support in the areas of voluntary blood donation, safe blood collection, quality-assured testing and best clinical practices to strengthen the capacity of blood banks and district hospitals to provide adequate supplies of safe blood.
- Improve access to safe blood to manage pregnancy-related complications as part of a comprehensive approach to maternal care. This includes good antenatal care, prevention and timely treatment of anaemia, assessment of the need for transfusion and safe blood transfusion given only when really required.
- Train clinicians, nurses, technicians and other key health personnel at peripheral and district level facilities through its regional networks across the world.

The WHO Blood Transfusion Safety programme is committed to universal access to safe blood transfusion and supporting the global community, in particular the developing world, to ensure that safe blood is available for all patients needing transfusion in a timely manner, thus contributing to patients' health, safety and survival.

E Report of the Global Consultation on Universal Access to Safe Blood Transfusion, 9–11 June 2007, Ottawa, Canada

1 Introduction

To address the challenge of inadequate access to safe blood transfusion in developing countries, the Blood Transfusion Safety team at WHO headquarters organized a 'Global Consultation on Universal Access to Safe Blood Transfusion' on 9–11 June 2007 in Ottawa, Canada. The consultation was organized in collaboration with Health Canada, the Public Health Agency of Canada, Canadian Blood Services, Héma-Québec, the Canadian Society for Transfusion Medicine and Établissement Français du Sang. The consultation was timed to precede a global event marking World Blood Donor Day on 14 June 2007 that was hosted by Canada.



The consultation was attended by about 100 participants. They included members of the WHO Expert Advisory Panel on Transfusion Medicine, international experts and representatives of WHO Collaborating Centres, national blood transfusion services, international organizations and developmental partners.

The onset of the HIV/AIDS pandemic in the 1980s brought blood safety into the global limelight. In developed countries, the lessons learned from the legal, financial and public health consequence of the HIV/AIDS crisis have led to the effective implementation of blood safety policies with a 'zero-tolerance' approach to maintaining the safety of national blood supplies. In developing countries, however, transfusion transmissible infections (TTIs) are still a cause of grave concern. Many countries still rely on unsafe family/replacement or paid donors and are unable to consistently screen all the donated blood for TTIs in a quality-assured manner.

Evidence-based strategies for blood safety and availability have been successfully implemented in most developed countries and some transitional and developing nations. However, despite the proven effectiveness of these strategies, their implementation is progressing slowly in many countries.

Today, at the midway point in the UN Millennium Project and the MDGs, internationally agreed-upon goals to be met by 2015, the world is still a long way from achieving universal access to safe blood transfusion. This will have a direct impact on the achievement of the health-related MDGs to reduce child mortality, improve maternal health and combat HIV/AIDS.

This report analyses the current situation of global blood safety and availability, identifies the major challenges to be addressed, reiterates the urgency of addressing these problems in developing countries, and outlines the necessary steps to improve access to safe blood transfusion, particularly in developing nations. The implementation of the strategies and recommendations contained in this report will lead to significant improvements in universal access to safe blood transfusion globally. The strategies and recommendations outlined in this report also provide a direction to the development of the WHO Global Strategic Plan on Universal Access to Safe Blood Transfusion, 2008–2015.

2 Keynote Address: Investing in Maternal and Child Health — Achieving the Millennium Development Goals

Presenter: Ms Daisy Mafubelu, Assistant Director-General, Family and Community Health, WHO-HQ

Ms Mafubelu critically analysed the progress on the two United Nations' Millennium Development Goals specifically relating to maternal and child health. She highlighted that no clear progress has been made towards MDG 4: Reducing the under-five child mortality by two-thirds between 1990 and 2015. She reiterated that, alarmingly, almost 90% of newborn deaths still occur in sub-Saharan Africa and Asia. Similarly, no progress has been reported for MDG 5: Improving maternal health by reducing the maternal mortality ratio by three-quarters between 1990 and 2015. Deaths resulting from complications of pregnancy and childbirth are still extremely high in sub-Saharan Africa, with one death every minute.

Assistance with delivery by skilled attendants was identified as a key component in reducing

3 Challenges in Achieving Universal Access to Safe Blood Transfusion

3.1 A global perspective on transfusion safety

Presenter: Dr Neelam Dhingra, Coordinator, Blood Transfusion Safety, WHO-HQ

Dr Dhingra reviewed the current status of the global blood safety situation and identified trends and current challenges in ensuring universal access to safe blood.

The presentation covered the main aspects related to the need for access to a safe blood supply, including a global overview of the blood supply and safety situation, and key milestones and achievements of the WHO Blood Transfusion Safety programme. Dr Dhingra emphasized that maternal mortality could be significantly reduced if safe blood was available in all healthcare facilities providing comprehensive emergency obstetric care. Key facts and figures on maternal mortality, severe malaria, anaemia and trauma were presented.

The main challenges identified were organizational ones, such as fragmentation and low efficiency of blood services' operations, lack of tangible political commitment and support, and poor institutional coordination. Difficulties in ensuring the sustainability of blood services were elaborated upon. These could be due to inadequate financial resources or trained human resources, inadequate integration of blood transfusion services in health care systems and problems of geographically isolated communities of small populations.

Blood shortages, low donation rates and high discard rates were seen as impediments in making safe blood available to all patients in all situations in a timely manner. It was mentioned that considerable reliance on family/replacement and paid donations in many countries, high prevalence of transfusion-transmissible infections in some regions and a shrinking base of safe voluntary blood donors also contributes to unsafe blood transfusions. A total of 79 countries with donation rates of <1% (< 10 donations/1000 population) in 2004 were identified as priority countries requiring urgent attention and support. The safety of the blood supply is considered important for patients' health, for public trust in the blood transfusion service and for the avoidance of legal and financial penalties.

Dr Dhingra highlighted the major challenges to universal access to safe blood transfusion, which include a weak donor interface and clinical interface with blood services, poor quality systems and traceability of blood between donor and patients, unsafe clinical transfusion practices and unnecessary use, and significant variations in blood prescribing patterns.