Universal Access to Safe Blood Transfusion

Scaling Up the Implementation of the
WHO Strategy for Blood Safety and Availability
for Improving Patient Health and Saving Lives

WHO Global Strategic Plan, 2008–2015

November 2007
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Overview of the WHO Global Strategic Plan, 2008–2015

Strategic direction 1
Building a conducive political, social and economic environment for the effective integration of sustainable national blood programmes in health systems

Goals
- Significant increase in commitment to blood safety and availability in countries and within the international community
- Inclusion of blood safety and availability in national health plans, with sufficient investment from national budgets and developmental partners.

Strategy 1
Demonstrate the need for universal access to safe blood transfusion and provide advocacy on its role in the provision of effective health care and in achieving the health-related Millennium Development Goals.

Strategy 2
Provide up-to-date information and evidence-based strategies on blood safety and availability to governments and stakeholders.

Strategy 3
Seek enhanced government support to establish sustainable national blood programmes for the planning, implementation and monitoring of all activities related to blood transfusion.

Strategy 4
Mobilize support at national, regional and global levels among governments and development partners to invest in, strengthen and sustain national blood programmes.

Strategy 5
Raise public awareness on the need for voluntary blood donation, patients’ rights and informed consent as a foundation for universal access to safe blood transfusion.

Strategic direction 2
Responding to country needs to strengthen national blood programmes and improve clinical transfusion practice

Goal
- Strengthened national capacity for the implementation of effective systems to achieve universal access to safe blood transfusion.

Strategy 6
Develop, update and provide evidence-based WHO strategies, norms, standards, recommendations, guidelines, tools and materials on safe blood transfusion.

**Strategy 7**
Build national and regional capacity through technical support for the planning, organization and management of national blood programmes, including the development of effective financial structures, quality systems, blood donor programmes, testing and processing, storage and distribution, and for best practice in clinical transfusion procedures.

**Strategy 8**
Develop effective mechanisms to assist countries in the selection, procurement and management of equipment, devices and commodities.

**Strategy 9**
Develop effective national, regional and global capacity and mechanisms for human resource development and the education and training of staff working throughout the transfusion chain.

**Strategy 10**
Keep pace with new scientific and technical developments and develop mechanisms to improve access to new and existing technologies in countries.

**Strategic direction 3**
**Building effective collaboration and partnerships for coordinated action**

**Goals**
- Coordination of complementary programmes within healthcare systems at national level
- Active community participation in the promotion and support of voluntary blood donation and the rational use of blood transfusion
- Strengthened sector-wide linkages to promote blood safety and availability
- Strengthened partnerships and networks between technical experts, institutions and developmental agencies.

**Strategy 11**
Promote strengthened collaboration and integration of blood transfusion with complementary health care programmes

**Strategy 12**
Build partnerships with non-health sectors to which blood safety and availability issues are relevant.

**Strategy 13**
Build and strengthen partnerships and networks in transfusion medicine and science at global, regional and country levels for enhanced communication and coordinated action.

**Strategic direction 4**
**Strengthening systems for assessment, surveillance, vigilance and alert, and monitoring and evaluation**
Goals

- Effective systems for data collection and management, risk assessment and management, and surveillance for policy decisions and programme planning
- Monitoring of progress towards universal access to safe blood transfusion.

**Strategy 14**
Support the development of effective national systems for the collection and management of data throughout the transfusion chain.

**Strategy 15**
Build and strengthen global, regional and national surveillance, vigilance and alert systems for blood safety and availability, and adverse transfusion events.

**Strategy 16**
Strengthen global, regional and national monitoring of process and outcome indicators on blood safety and availability and measure progress.
Section 1

Context and Current Situation

1.1 Introduction

Blood transfusion is an essential component of health care which saves millions of lives each year. The need for equitable and timely access to safe blood is universal, but is not available to many patients requiring transfusion as part of their clinical management. Despite advances in medical science, it will be many years before artificial red blood cell substitutes can routinely replace the need for donated human blood. 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 transfusion. Blood safety is integral to the WHO HIV/AIDS plan to accelerate the prevention of HIV infection and to the achievement of the health-related Millennium Development Goals to reduce child mortality, improve maternal health, combat HIV and develop global partnership for development.

Lack of access to safe blood and blood products continues to place an unacceptable burden on health and economic development in many parts of the developing world. Blood transfusion is an essential and life-saving support within the health care system, yet the safety of transfusion is not assured globally, particularly in countries with less developed health care systems. Threats associated with transfusion include:

- Inadequate supplies of blood and blood products to meet the needs of all patients requiring transfusion
- Risk of transmission of infection through unsafe blood and blood products
- Technical and clerical errors in the processing and testing of blood
- Inappropriate use of blood and unnecessary transfusions
- Errors in the administration of blood and blood products.

WHO strategy for blood safety and availability

The World Health Organization (WHO) advocates the following integrated strategy to national health authorities to promote the safety and accessibility of blood and reduce the risks associated with transfusion.

1 Establishment of a well-organized, nationally coordinated blood transfusion service (BTS) that can provide adequate and timely supplies of safe blood to meet the transfusion needs of the patient population.

2 Collection of blood only from voluntary non-remunerated blood donors at low risk of acquiring infections that can be transmitted through unsafe blood and blood products.

3 Quality-assured testing of all donated blood for transfusion-transmissible infections, including HIV, hepatitis B, hepatitis C, syphilis and other infections, where relevant, such as Chagas disease and malaria, and for blood groups and compatibility.

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4 Reduction in unnecessary transfusions through the appropriate clinical use of blood and the safe administration of blood and blood products.

5 Implementation of effective quality systems in all areas, including quality management, development and implementation of quality standards, effective documentation systems, training of all staff and regular quality assessment.

This strategy has been successfully implemented by most developed countries \(^3\) where patients requiring transfusion support anywhere in 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 more than 125 countries, the development of blood transfusion services has been largely restricted to major urban cities and universal access is still not guaranteed for those in most critical need for safe blood for their survival\(^3\). Furthermore, the need for blood continues to grow globally as health systems become more developed, with improved diagnostic and treatment options 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.

### 1.2 The need to scale up action

Every country shares the need to ensure the quality, safety and accessibility of blood transfusion but, in a world of economic challenges and competing needs and priorities for overstretched health care resources, blood safety and availability remain major challenges. The need for safe blood is growing, although the demand for blood and blood products in individual countries to some extent depends on the level of development of the healthcare system. In developed countries, transfusion is most commonly used to support advanced medical and surgical procedures, including trauma, cardiovascular surgery, neurosurgery and transplantation. It is also used in the treatment of conditions such as leukaemia, aplastic anaemia, thalassaemia, sickle cell disease and haemophilia. The demand for blood is increasing, particularly with changing demographics and increasing lifespans, but there is increasing evidence of significant variations between and within countries in blood utilization patterns. Blood is sometimes used unnecessarily, for example, in cardiac surgery, despite the fact that blood shortages are common, with seasonal variations due to increased demand or lower donation rates. More blood donors are needed to replace those that are lost every year due to ill health, retirement, relocation or increasingly stringent donor selection criteria. Unnecessary use of blood places even greater pressure on blood supplies and widens the gap between demand and supply.

In the developing world, where diagnostic and treatment options are generally more limited, many lives that could otherwise have been saved are still being lost because of limited supplies or lack of availability of safe blood, even in some urban healthcare facilities. Few data are available on actual blood requirements in developing countries, but blood shortages have a serious impact on women with complications of pregnancy and childbirth, children with severe life-threatening anaemia and trauma patients.

Despite the proven effectiveness of measures to ensure blood safety, there remains a significant risk of transmission of HIV, hepatitis B and C and other life-threatening blood borne pathogens through the transfusion of unsafe blood and labile blood products. The risks of transmission of infection are generally higher in countries which remain dependent on family/replacement or paid donors, have poor donor selection procedures and where the effectiveness of blood screening is

compromised by a lack of quality systems, inadequate staff training and unreliable or inadequate supplies of quality test kits and reagents. Serious blood shortages and the lack of a reliable donor base also contribute to an increased risk of transmission of HIV and viral hepatitis through transfusion because an inadequate stock of blood forces a reliance on unsafe replacement or paid donors and increased pressure to issue blood without testing. Bacterial contamination during blood collection or processing poses a further risk of infection.

**Women and children: the most vulnerable groups**

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. 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 7300 in rich countries\(^4\). Regional rates mask very large 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\(^5\).

Severe bleeding during delivery or after childbirth is the commonest 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\(^6\). Postpartum bleeding is unpredictable and the quickest of maternal killers – it can kill even a healthy woman within two hours, if unattended. Blood transfusion has been identified as one of the eight life-saving signal functions that should be available in a first referral level healthcare facility providing comprehensive emergency obstetric care\(^7\). Access to safe blood could help to prevent up to one quarter of maternal deaths 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 blood borne infections through unsafe blood is equally preventable. The challenge is therefore not technological, but strategic and organizational.

In the southern African region, one study has shown safe and timely blood transfusion could help to prevent up to 20% of maternal deaths and 15% of child deaths attributable to severe anaemia resulting from malnutrition and malaria, often exacerbated by HIV/AIDS and intestinal worm infestations\(^2\). WHO estimates that as many as 4–5 billion people (66–80% of the world’s population) may be iron deficient; two billion people – over 30% of the world’s population – are anaemic, mainly due to iron deficiency, and in developing countries, frequently exacerbated by malaria and helminthic infections. Around 60% of the cases of clinical malaria and over 80% of the deaths occur in Sub-Saharan Africa. Of the more than one million Africans who die from malaria each year, most are children under five years of age. It has been estimated that severe malarial anaemia causes between 190,000 and 974,000 deaths each year among children under the age of five years. In addition to acute disease episodes and deaths, malaria also contributes significantly to anaemia in children and pregnant women, adverse birth outcomes such as

spontaneous abortion, stillbirth, premature delivery and low birth weight, and overall child mortality.

With high numbers of obstetric complications, malaria, helminthic infections, malnutrition and sickle cell disease, life-threatening anaemia occurs more frequently in Africa than in most parts of the world. African children are particularly vulnerable. It is estimated, for example, that 19–47% of children hospitalized in Africa are transfused during admission. War injuries, interpersonal violence and road traffic accidents were the third, fourth and fifth leading causes of death for young people aged 15–29 years in 2008.

1.3 The global picture

The most recent global data on blood safety and availability in 2004 were reported to the WHO Global Database for Blood Safety by 172 countries, covering 95.1% of the world's population. Data are still being analysed and will be published in 2008. Preliminary findings indicate that while tangible progress has been made since the previous surveys covering the periods 1998-1999 and 2001-2002, much remains to be done.

Blood supply

While the need for blood is universal, the imbalance between developing and developed countries in access to safe blood remains:

- Only 45% of the global blood supply is collected in developing countries, which are home to more than 80% of the world’s population.
- In sub-Saharan Africa, fewer than 3 million units of blood are collected each year for a population of more than 700 million people.
- Out of 80 countries that have donation rates of less than 1% of the population (fewer than 10 donations per thousand people), 79 are in developing regions; it is generally recommended that the equivalent of 1-3% of the population donate blood to meet a country's needs.
- The average number of blood donations per 1,000 population is 11 times higher in high-income countries than in low-income countries.

Type of blood donations

The safest blood is donated by the safest blood donors. The prevalence of HIV, hepatitis viruses and other blood borne infections is 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. The highest prevalence 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.

The 2004 data reveal some tangible improvements since 2001-2002, but family/replacement donors and paid donors still remain a significant source of blood for transfusion in many developing and transitional countries.

- A total of 60 countries reported an increase in the percentage of blood donated by voluntary unpaid blood donors and a further 41 countries maintained the same level; although 37

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countries showed a decline in the percentage of blood donations from unpaid voluntary blood donors.

- In 2002, only 39 countries had achieved 100% unpaid voluntary blood donation, of which five were developing countries. By 2004, this had risen to 50 countries. Out of the 11 new countries that achieved this, three were least developed countries.

- More and more countries are moving towards voluntary blood donation. In 2002, 63 countries were collecting less than 25% of their blood from voluntary unpaid donors; by 2004, this had fallen to 46 countries.

- Particularly striking was the increase from 25% to 47% of the total global donations collected from voluntary non-remunerated blood donors in developing and transitional countries.

- The number of units of blood donated in transitional countries increased from 29 million in 2002 to 36 million in 2004.

- 92% of donations in developed countries are from voluntary unpaid donors as compared to about 67% in developing and transitional countries. This means that family/replacement donors still remain a significant source of blood for transfusion in many countries.

- More than 2.2 million units were still collected from paid blood donors in 2004, a similar level to that in the previous survey in 2001-2002. The majority of these (94%) were collected in transitional countries.

Blood screening

WHO recommends that, at minimum, all blood for transfusion should be screened for HIV, hepatitis B, hepatitis C and syphilis. Complete and accurate data on the testing of donated blood are simply not available in the majority of developing countries, particularly in those where blood services are fragmented, but many do not yet have reliable systems for testing because of staff shortages, poor quality test kits or irregular supplies, and lack of basic laboratory quality systems. The advanced technology used in many developed countries is unable to detect very recent infections and is not affordable or cost-effective in most developing and transitional countries.

- 41 out of 148 countries (28%) that provided data on screening for transfusion-transmissible infections including HIV, hepatitis B and C, and syphilis were not able to screen all donated blood for one or more of these infections.

- However, globally, the number of tests not performed for the markers for all four main infections (HIV, HBV, HCV and syphilis) decreased from 6 million in 2002 to 1.5 million in 2004. The most marked reduction was seen in the African region where the number of tests not performed was reduced from more than 1 million in 2001-02 to 380 000 in 2004.

Blood usage

Data on blood utilization are limited, but studies suggest that transfusions are often given unnecessarily when simpler, less expensive treatments can provide equal or greater benefit. Not only is this wasteful of a scarce resource, it also exposes patients unnecessarily to the risk of serious adverse transfusion reactions or transfusion-transmitted infections.
1.4 Meeting the needs: a global strategic approach to universal access to safe blood transfusion

The objective of the WHO programme on blood safety and availability is a reduction in avoidable morbidity and mortality through improved access to safe blood and blood products and the safe and rational use of blood transfusion, with a particular focus on life-saving emergency transfusions for reducing maternal and child mortality, and on the prevention of HIV/AIDS, hepatitis B and C.

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 earliest resolution (WHA28.72) was adopted in 1975 and urged Member States to promote the development of national blood transfusion services based on voluntary non-remunerated blood donation, enact effective legislation governing the operation of blood programmes and take other actions necessary to protect and promote the health of blood donors and recipients of blood and blood products.

In September 2000, representatives of 189 countries endorsed the United Nations Millennium Declaration9 and resolved, by 2015, to reduce the under-5 mortality rate by two-thirds, to reduce the maternal mortality ratio by three quarters and to halt and begin to reverse the spread of HIV/AIDS, tuberculosis and malaria. They also resolved to develop a global partnership for development and to address the special needs of the least developed countries. Achievement of the health-related Millennium Development Goals will never be possible without universal and equitable access to safe blood transfusion.

In 2004, the UN Millennium Project defined health sector interventions highlighting blood safety as an intervention for combating HIV, to introduce measures to reduce the risk of receiving infected blood through a transfusion, including HIV antibody screening, avoiding unnecessary blood transfusions and excluding high risk blood donors.

In 2005, the Fifty-Eighth World Health Assembly adopted resolution WHA58.13 which urged Member States to strengthen national blood programmes, addressing areas relating to policy formulation, legislation, blood donation, donor selection, testing and processing, and the clinical use of blood and blood products. It also requested WHO to work with concerned organizations to provide support to Member States in strengthening their capacity to ensure that all blood collected and transfused is safe.

In 2007, more than 30 years after the first World Health Assembly resolution (WHA28.72) addressed the issue of blood safety, equitable access to safe blood and blood products and the rational and safe use of blood transfusion still remain major challenges throughout the world. 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, many countries are making slow progress towards their implementation. Today, at the midway point in the UN Millennium Project, the world is a long way from achieving universal access to safe blood transfusion. This 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.

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Recognizing the need for concerted action if universal access to safe blood transfusion is to be achieved by 2015, this document sets out a unifying vision and strategies for 2008-2015 which are intended to form a framework for the WHO Blood Transfusion Safety Programme at global, regional and country levels and stimulate collective action and renewed commitment by governments and partners in blood safety and availability. It offers a broad strategic framework rather than a detailed strategic plan.
Section 2

Guiding principles

The following guiding principles provide the basis for the WHO global strategic approach to achieving universal access to safe blood transfusion.

Ethics

Universal principles and ethical norms are observed in the field of transfusion medicine, in relation both to blood donors and the recipients of transfusion. The WHO Constitution\(^{10}\) and the International Society of Blood Transfusion's Code of Ethics for Blood Donation and Transfusion\(^{11}\) provide a framework for ethical policy making and programme delivery.

Equity

All patients – without distinction of race, religion, political belief, economic and social status, geographical situation or clinical condition – have a right to equitable access to safe blood transfusion, when needed.

Volunteerism

The donation of whole blood and blood components, including haematopoietic stem cells, is based on voluntary, altruistic, non-remunerated donation. The law prevents the commercialization of blood transfusion and the exploitation of blood donors. No coercion or pressure to donate blood is brought to bear on the family or friends of patients or other potential donors.

Assurance of high quality services and products

All blood and blood products made available for transfusion meet basic, essential standards of quality and safety, and blood donor and transfusion services are provided according to evidence-based best practices.

Integrated approach

Blood transfusion is an integral component of health care delivery systems. Comprehensive public health and primary health care services are made available to prevent the need for transfusion, where possible.

Ownership

Goals, objectives and strategic approaches are commonly agreed upon and pursued by governments and their partners, and are supported by the international community through coordinated actions and activities determined by national plans.


Transparency, responsibility and accountability
The provision of an adequate supply of safe blood and blood products depends on the efficient, cost-effective organization and management of sustainable blood transfusion services which optimize the use of resources and maintain uniform standards of quality.

Sustainability
National governments and partners work collectively towards the sustainability, financial and technical self-reliance of national blood programmes, through human resource development and continuing incremental infrastructure building.

Policies and strategic approaches based on evidence and best practices
Policies, strategic approaches and practice by national governments and partners are informed by research findings, needs assessments, cost-benefit and cost-effectiveness analyses, surveillance, monitoring and evaluation, and by the sharing of lessons learned and other available evidence-based norms, standards and strategies.

Partnership
In an increasingly mobile, interconnected and interdependent world, action to combat known and emerging threats to blood safety depends on effective collaboration, communication and coordination between stakeholders throughout the world.
Section 3

Vision, goals and targets

3.1 Our vision

Our vision – a world in which there is universal access to safe blood transfusion

The ultimate goal is that blood transfusion contributes to saving lives and improving health and that no patient should die because blood or blood products are not available when required for survival or improved health and no patient should acquire an infection or develop a serious reaction through the transfusion of blood.

3.2 Our mission

The mission of WHO is to provide an enhanced level of country support for the development of effective systems, fully integrated into the health care system, to:

- Prevent the need for transfusion through effective prevention programmes for conditions that might otherwise result in the need for transfusion
- Reduce blood loss through good surgical, anaesthetic and medical techniques and the use of simple alternatives to transfusion, wherever possible
- Ensure access to a sufficient supply of safe and quality blood and labile blood products for transfusion
- Reduce unnecessary transfusions through careful assessment of the need for transfusion and prescribing it only when required to treat conditions associated with serious morbidity or mortality that cannot be prevented or managed effectively by other means
- Establish systems for safe clinical transfusion practice at the patient's bedside.

3.3 Specific goals

The WHO Blood Safety programme seeks to work with countries and partners to strengthen their capacity to ensure universal access to safe, quality blood and blood products, and their safe and appropriate use, ensuring minimal risks to the health and safety of blood donors, staff and the community and maximum benefit to the recipients of blood transfusion. This can best be achieved through sustainable national blood programmes, including well-organized national blood transfusion services and hospital blood banks, and effective mechanisms for liaison between blood transfusion services and clinical services at policy and operational levels.

Particular emphasis will be placed on countries with limited access to safe blood at national, regional or district level and with high maternal, perinatal and child mortality rates in order to contribute to the achievement of the health-related Millennium Development Goals to reduce child mortality and improve maternal health. Priority will also be given to the prevention of the transmission of HIV, hepatitis B, hepatitis C and other life-threatening blood borne pathogens, particularly in countries with weak or fragmented blood transfusion services and/or a high prevalence of infection.
Targets and milestones
Between 2008 and 2015, WHO will work with countries and partners to achieve the following targets and milestones.

Implementation of national blood policies/plans for blood safety and availability
In 2004, 37 countries globally had already implemented national blood policies/plans for blood safety and availability: Between 2008 and 2015, WHO will work with countries and partners in achieving the following targets and milestones:

- By 2009, 45 countries, will have implemented a national blood policy/plan for blood safety and availability
- By 2012, 81 countries, will have implemented a national blood policy/plan for blood safety and availability
- By 2015, 109 countries, will have implemented a national blood policy/plan for blood safety and availability

Legislative framework in countries for national blood programme
In 2004, 82 countries globally had developed a legislative framework for the oversight of the national blood programme. Between 2008 and 2015, WHO will work with countries and partners in achieving the following targets and milestones.

- By 2009, 92 countries, will have developed a legislative framework for the national blood programme
- By 2012, 100 countries, will have developed a legislative framework for the national blood programme
- By 2015, 110 countries, will have developed a legislative framework for the national blood programme

100% voluntary non-remunerated donation of whole blood and labile blood products
In 2004, 51 countries globally had achieved 100% voluntary non-remunerated donation of whole blood and labile blood products. Between 2008 and 2015, WHO will work with countries and partners in achieving the following targets and milestones.

- By 2009, 60 countries, will have achieved 100% voluntary non-remunerated donation of whole blood and labile blood products
- By 2012, 70 countries, will have achieved 100% voluntary non-remunerated donation of whole blood and labile blood products
- By 2015, 80 countries, will have achieved 100% voluntary non-remunerated donation of whole blood and labile blood products

100% quality-assured testing of donated blood for HIV, hepatitis B, hepatitis C and syphilis
In 2004, 43 countries globally had achieved 100% quality-assured testing of donated blood. Between 2008 and 2015, WHO will work with countries and partners in achieving the following targets and milestones.

- By 2009, 60 countries, will have achieved 100% quality-assured testing of donated blood
- By 2012, 75 countries, will have achieved 100% quality-assured testing of donated blood
- By 2015, 100 countries, will have achieved 100% quality-assured testing of donated blood

Haemovigilance systems for improved blood safety
In 2004, 42 countries globally had established haemovigilance systems for improved blood safety. Between 2008 and 2015, WHO will work with countries and partners in achieving the following targets and milestones.

- By 2009, 50 countries will have established haemovigilance systems for improved blood safety
- By 2012, 60 countries will have established haemovigilance systems for improved blood safety
- By 2015, 80 countries will have established haemovigilance systems for improved blood safety

National guidelines on the clinical use of blood
In 2004, 73 countries globally had national guidelines on clinical use of blood. Between 2008 and 2015, WHO will work with countries and partners in achieving the following targets and milestones.

- By 2009, 85 countries will have national guidelines on the clinical use of blood
- By 2012, 100 countries will have national guidelines on the clinical use of blood
- By 2015, 115 countries will have national guidelines on the clinical use of blood

75% of hospitals with transfusion committees
In 2004, 21 countries globally had 75% of hospitals with transfusion committees. Between 2008 and 2015, WHO will work with countries and partners in achieving the following targets and milestones.

- By 2009, 30 countries will have 75% of hospitals with transfusion committees
- By 2012, 45 countries will have 75% of hospitals with transfusion committees
- By 2015, 60 countries will have 75% of hospitals with transfusion committees
Section 4

Realizing the goals

The key objective of this strategic plan is to provide a framework within which the WHO Blood Safety programme, through its global, regional and country offices, will work with Member States to realize the goal of universal access to safe blood transfusion and ensure the safe and rational use of blood transfusion for patient care. This plan will help to shape advocacy, policy guidance and technical support to countries in strategic and systematic ways to improve the safety, quality, availability and accessibility of the transfusion of blood and labile blood products.

The strategic plan sets out four strategic directions with 16 component strategies to reach the target of universal access to safe blood transfusion, fully integrated into healthcare delivery systems.

Strategic direction 1: Building a conducive political, social and economic environment for the improved integration of blood transfusion services into health systems

Advocacy and communication must be strengthened in order to ensure that policy-makers, health planners, healthcare personnel and the public understand the vital role of safe blood transfusion in healthcare delivery. This direction focuses on advocating that blood safety and availability should be regarded as a priority at national, regional and global levels since blood transfusion is a cross-cutting intervention that underpins key healthcare services. The WHO Blood Safety programme will also work with countries and developmental partners to mobilize resources for the strengthening of national blood programmes.

Goals

- Significant increase in commitment to blood safety and availability in countries and within the international community
- Inclusion of blood safety and availability in national health plans, with sufficient investment from national budgets and developmental partners.

Strategy 1

Demonstrate the need for universal access to safe blood transfusion and provide advocacy on its role in the provision of effective health care and in achieving the health-related Millennium Development Goals

The onset of the HIV/AIDS pandemic in 1981 brought blood safety into the global limelight, but more than 30 years after the first World Health Assembly resolution (WHA28.72) addressed the issue of blood safety, equitable access to safe blood and blood products and the rational and safe use of blood transfusion still remain major challenges throughout the world. In a world of competing health care priorities, the WHO Blood Safety programme will strive to keep blood safety and availability on the national and international health agendas.
WHO has initiated a programme of high-level advocacy in respect to safe blood transfusion with national governments, ministries of health, education and finance and gaining formal commitment through the World Health Assembly, WHO Regional Committees and in-country visits.

**Activities**
- Build national, regional and global capacity for advocacy on the need for the availability of safe blood in health system development
- WHO global conference on safe blood transfusion with focal points from all Member States
- Global consultations with Member States and experts in transfusion medicine to assess progress, review strategies and identify priorities for future action
- Technical cooperation missions by WHO staff and consultants and the permanent presence of the World Health Representative in each WHO country office
- Facilitate visits by high level delegations to priority countries to drive reforms.

**Strategy 2**

**Provide up-to-date information and evidence-based strategies to governments and stakeholders to improve blood safety and availability**

Evidence-based information on the effectiveness of different strategies and on emerging threats to blood safety and availability is an essential tool for advocacy. Information technology, including the internet and other electronic media, has significantly improved access to all types of information.

**Activities**
- Identify gaps in knowledge and research priorities in the developing world to shape the research and development agenda
- Promote, support and conduct operational research
- Provide data from global, regional and national sources (Global Database on Blood Safety, regional databases, national data systems) to advise on evidence-based, cost-effective blood safety strategies
- Utilize international forums to share information and experience
- Develop information and advocacy materials
- Utilize the WHO blood safety website (www.who.int/bloodsafety) for the wider dissemination of guidelines, tools and materials.

**Strategy 3**

**Seek enhanced government support for the establishment of national blood programmes for the planning, implementation and monitoring of all activities related to blood transfusion**

Efforts to ensure universal access to safe blood transfusion will require the political and financial commitment of all stakeholders. The Blood Safety programme will provide policy guidance and technical support in response to identified needs in ways that catalyse change, stimulate cooperation and action and help to build sustainable national capacity in blood transfusion.

**Activities**
- Reports to the World Health Assembly
- Advocacy to senior officials in ministries of health and other policy-makers
- Inter-regional, regional and sub-regional meetings or workshops for national blood programme managers and directors of national blood transfusion services
- Policy guidance for the development of national blood policies and strategic plans
- Technical support in the development of national legislation and regulatory mechanisms for blood transfusion services
- Organized study tours for sharing experiences.

**Strategy 4**

**Mobilize support at national, regional and global levels among governments and developmental partners to invest in, strengthen and sustain national blood programmes**

Sustainability is a key issue for every national blood programme. Increased investment by national governments and donors will be crucial if the goal of universal access is to be achieved. The sharing of information and expertise between countries, coupled with effective advocacy, will be necessary to identify the most cost-effective approaches and achieve increased commitment.

**Activities**

- Build national, regional and global capacity for resource mobilization
- Develop resource mobilization strategies for the effective support of Member States
- Identify key developmental and donor agencies
- Provide technical briefings to external partners, donor countries and agencies and the media
- Prepare project proposals for resource mobilization from donor countries, foundations and other international funding agencies. Facilitate bilateral and multilateral funding for dedicated resources for country support
- Develop twinning relationships with key interested organizations and share resources.

**Strategy 5**

**Raise public awareness of the need for voluntary blood donation, patients’ rights and informed consent as a foundation for universal access to safe blood transfusion.**

Safe, voluntary non-remunerated blood donors who donate blood regularly are the foundation of a safe and adequate blood supply. In developing countries, a substantial increase in voluntary blood donation is essential to ensure the safety and sufficiency of blood supplies. The developed world faces a constant need to recruit new donors to replace those who are lost through ill-health, age, relocation or deferral because of increasingly stringent donor selection criteria.

**Activities**

- Strengthen the capacity within WHO to provide guidance and technical support to Member States on all aspects of voluntary blood donor programmes, including quality systems to promote optimal donor care
- Provide training and technical support for the strengthening of national blood donor programmes
- Facilitate enhanced donor support at national, regional and global levels for blood donor programmes and campaigns
- Build partnerships with international agencies and nongovernmental organizations to support national and community-based activities and campaigns
- Provide advocacy and policy guidance to Member States on the role of legislation in progressing the cause of 100 per cent voluntary blood donation
- Provide tools and technical support in the development of systems for assessing donor suitability, including national donor selection criteria, prevention of iron storage depletion and monitoring of adverse events and reactions
- Strengthen and expand World Blood Donor Day campaigns as a platform for increasing awareness of the requirement for voluntary blood donation in making safe blood transfusion available
- Designate a special envoy for voluntary blood donation to analyse obstacles at country level and propose solutions, based on WHO recommendations and evidence of best practice.
- Promote and support the establishment of national Club 25/Pledge 5 programmes for young blood donors
- Designate youth ambassadors to promote voluntary blood donation, Club 25 and World Blood Donor Day
- Provide evidence-based information and guidance on different systems for blood and plasma donation as a basis for policy and decision-making.

**Strategic direction 2: Responding to country needs to strengthen national blood programmes and improve clinical transfusion practice**

This direction includes providing technical support to countries to build capacity for the implementation of cost-effective, evidence-based strategies for blood safety and availability. This will include reviewing challenges in achieving universal access to safe blood transfusion and developing effective country strategies and innovative approaches to support healthcare needs.

**Goal**

- Strengthened national capacity for the implementation of strategic approaches and the development of effective systems to achieve universal access to safe blood transfusion.

**Strategy 6**

**Develop, update and provide evidence-based WHO strategies, norms, standards, recommendations, guidelines, tools and materials on safe blood transfusion**

The WHO Blood Safety programme has already developed a number of policy, programme development and technical guidelines, tools and materials. Other relevant norms and tools are in the process of development and more may be needed as knowledge and evidence becomes available and gaps are revealed during the process of implementation.

**Activities**

- Identify priority areas for further policy guidance and technical support
- Develop evidence-based strategies, norms, standards, recommendations, guidelines, tools and training materials to support Member States
- Facilitate and support countries in the adaptation, dissemination and use of these guidelines, tools and materials
Promote and monitor the use of WHO strategies, norms, standards, recommendations, guidelines, tools and training materials

Evaluate, update and modify guidelines, tools and materials, as required.

**Strategy 7**

Build national and regional capacity through technical support for the planning, organization and management of national blood programmes, including the development of effective financial structures, quality systems, blood donor programmes, testing and processing, storage and distribution, and for best practice in clinical transfusion procedures

WHO will build regional and national capacity by providing technical support and training of staff involved in the transfusion process. This will assist countries to adapt and utilize evidence-based guidelines to develop policies and strategic approaches to improve health system quality and accountability, as well as mobilize resources and monitor and evaluate implementation.

Priority will be given to supporting countries in the areas of:

- Identifying needs and responding to priorities in strengthening national blood programmes, legislative and regulatory frameworks, blood supply structures and vigilance systems
- Organization and management of blood transfusion services to meet estimated blood requirements
- Achieving 100% voluntary non-remunerated blood donation
- Providing high quality care in donor selection, donor counselling, blood collection and donor care
- Ensuring 100% quality-assured testing of donated blood for transfusion-transmissible infections, blood group serology and compatibility testing
- Maintaining optimal conditions in storage and transportation
- Optimizing blood usage for patient health and safety
- Developing quality systems in the transfusion chain, including quality standards, training, documentation systems, traceability and quality assessment.

**Activities**

- Provide training and technical support at regional and national levels to build capacity in countries
- Strengthen collaboration with WHO Collaborating Centres and other regional and national centres of excellence in the provision of technical support and follow-up
- In-country visits by WHO staff and consultants
- Promote strengthened interfaces between blood providers, users and regulators.
- Facilitate and provide technical support for the establishment of regional and national External Quality Assessment (EQA) schemes
- Promote twinning and exchange programmes between blood transfusion services for capacity building and technical support

These strategic approaches include local level education, community action, partnerships, institutional strengthening and advocacy.
Strategy 8
Develop effective mechanisms for the selection, procurement and management of equipment, devices and commodities

Suitable equipment and high quality blood collection bags, test kits, reagents and consumables are fundamental to blood collection, testing and processing, storage and transportation, compatibility testing and blood administration. High costs, poor quality and irregular supplies are major constraints on blood safety. WHO will work with countries to resolve procurement and supply problems that affect the smooth operation, safety and reliability of services in blood transfusion services, hospital blood banks and clinical areas.

Activities
- Provide technical guidance and support for the establishment of national policies and systems for the selection, acquisition and management of equipment, devices and consumables
- Advocate and provide guidelines and technical support for the development of effective procurement and supply chain systems for essential equipment and consumables for blood transfusion services, hospital blood banks and clinical transfusion services
- Expand the WHO prequalification (pre-market evaluation) programme and bulk procurement scheme for HIV, hepatitis B and hepatitis C test kits to include blood collection bags, test kits and reagents for blood group serology and compatibility testing
- Evaluate new equipment, technology and assay systems.

Strategy 9
Develop effective national, regional and global capacity and mechanisms for human resource development and the education and training of staff working throughout the transfusion chain

The quality and safety of blood transfusion are dependent on a stable, well-trained, motivated workforce with opportunities for career progression and continuing professional development, including leadership and management skills. WHO will strengthen capacity in education and training through the development of training strategies and materials, training of trainers and the sharing of information and expertise in education and training.

Activities
- Provide advocacy and technical support to ministries of health, education and other relevant authorities for the establishment of recognized qualifications and career paths in transfusion medicine and science, and related disciplines
- Maintain an international database of education and training institutions and experts in blood transfusion
- Develop practical guidelines on the development of national education and training programmes in blood transfusion, including training needs assessment, criteria for the designation of training institutions and validation of training courses, evaluation of training activities, and case studies of successful programmes
- Provide advocacy and technical support to ministries of health, education and other relevant authorities, professional bodies, universities, schools of medicine, nursing, midwifery and medical laboratory technology for the establishment of undergraduate and postgraduate programmes in transfusion medicine and science
- Advocate to national education and health authorities and provide technical support for the incorporation of transfusion medicine and science in existing undergraduate and
postgraduate curricula in schools of medicine, nursing, midwifery and medical laboratory technology and in practical internships

- Collaborate with scientific, medical, nursing and technical institutions, and professional bodies in the development of continuing education programmes
- Develop a management skills training programme to support senior personnel in establishing efficient, sustainable blood transfusion services
- Develop training tools and materials for all categories of staff involved in the transfusion process
- Identify and train core groups of global and regional facilitators
- Conduct regional, sub-regional and national training courses for cascade training
- Provide materials and technical support for the establishment of distance learning and e-learning programmes in transfusion medicine and science and related fields
- Develop tools for the follow-up, monitoring and evaluation of the impact of WHO training programmes.

**Strategy 10**

**Keep pace with new scientific, technical and medical developments and develop mechanisms to improve access to new and existing technologies and procedures in countries**

The science and technology used in the provision of safe blood and blood products and their safe administration to patients are constantly changing in the face of new scientific and technical developments and new threats to blood safety. WHO will identify and facilitate improved access to technologies as part of its Global Initiative on Health Technologies.

**Activities**

- Identify gaps in knowledge and research priorities in the developing world
- Promote operational research in technological development
- Identify, evaluate and facilitate improved access to new strategies, tools and technologies for blood safety
- Pilot testing of new strategies, tools and technologies
- Provide information, guidance and tools to assist countries in the identification of priority technology needs and the assessment, selection, procurement, management and use of new technologies
- Promote and support technology transfer across countries
- Promote partnerships between health-care providers, industry, patients’ associations and professional, scientific and technical organizations in the development and dissemination of affordable new technologies to enhance blood safety.

**Strategic direction 3: Building effective collaboration and partnerships for coordinated action**

This direction focuses on synergizing the efforts of the global community in strengthening blood transfusion and blood donation programmes at national, state/regional/provincial, district and
peripheral levels. This will involve closer linkages and collaboration with other WHO programmes for which blood safety and availability are particularly important, including HIV/AIDS, Making Pregnancy Safer, Reproductive Health and Research, Child and Adolescent Health and Development, Emergency Trauma Care, Malaria, Nutrition, Health Promotion, Health Action in Crises and Patient Safety as well as other cross-cutting departments, including Health Systems Strengthening, Information, Evidence and Research, and Policy and Safety of Medicines. Closer collaboration will also be established with developmental partners, including UNICEF, UNFPA, International Labour Organization, UNESCO, UNHCR, International Organization for Migration, the World Bank and regional development banks, professional societies, nongovernmental organizations and the private sector.

The blood safety programmes will continue to engage with key actors on matters critical to better health and build partnerships where sustained joint action is required. It will seek to maximize utilization of scarce resources and minimize duplication of efforts.

Goals

- Coordination of complementary programmes within healthcare systems at national level
- Community participation by nongovernmental organizations, civil society and the private sector in the promotion and support of effective blood donor education, recruitment and retention programmes
- Strengthened linkages with non-health sectors to which blood safety and availability issues are relevant.
- Strengthened partnerships and networks between technical experts, institutions and developmental agencies.

Strategy 11

Promote strengthened collaboration and integration of blood transfusion with complementary health care programmes

Blood transfusion is an integral part of the health care system and underpins a wide range of health care programmes. These include maternal and child health, HIV/AIDS prevention and management, surgery and emergency trauma care, nutrition, the management of malaria and severe anaemia, and haematological and other tissue malignancies. Any developments in a health care system, such as new prevention, diagnostic or treatment options and new medical and surgical procedures should always be planned with due recognition for any additional requirements for blood and labile blood products to support these programmes.

Activities

- Harness the strengths of other programmes and partnerships by extending linkages with departments within WHO and other global initiatives, including the World Alliance for Patient Safety, UNAIDS, the Global Fund to fight AIDS, Tuberculosis and Malaria, the Partnership for Maternal, Newborn and Child Health and the International Health Partnership
- Establish a Global Initiative for Safe Blood for Safe Motherhood to promote and support the availability of safe blood transfusion in all health care facilities providing comprehensive emergency obstetric care
- Support the establishment of national mechanisms for coordination and collaboration between blood transfusion services and complementary health programmes to achieve the health-related Millennium Development Goals.
Strategy 12
Build partnerships with non-health sectors to which blood safety and availability issues are relevant

- Involve non-health sectors, such as education, defence, youth, culture, sports, labour, tourism, commerce and trade, and build linkages with global and regional events
- Build coalitions at global, regional and national levels to strengthen blood donor education, recruitment and retention programmes and the rational use of blood transfusion.

Strategy 13
Build and strengthen partnerships and networks in transfusion medicine and science at global, regional and country levels for enhanced communication and coordinated action

Developmental partners, including the World Bank and regional development banks, bilateral donors, nongovernmental organizations, professional bodies, academic institutions, civil society and the private sector, play an important role in the strengthening of blood transfusion services and the provision of safe and adequate blood supplies throughout the world. The Blood Safety Programme will collaborate with its partners at global, regional and national levels to maximize the utilization of scarce resources and minimize duplication of efforts.

Activities

- Broaden the stakeholder base in blood safety and availability and identify new opportunities and mechanisms for collaboration
- Update, maintain and expand the WHO Expert Advisory Panel on Transfusion Medicine for advice in specific technical fields related to the transfusion of blood and blood products
- Expand and strengthen global, regional and national collaborative networks and partnerships, including the Global Collaboration for Blood Safety, to promote the harmonization of international and national efforts for country support and maximize their effectiveness
- Provide assistance to countries through systematic needs assessments and data collection to match needs for financial and technical support with the mandates and flexibilities of donor organizations
- Work with developmental and funding partners and countries to promote the coordination of activities to optimize the use of donor funds
- Promote and support bilateral and multilateral partnership agreements with international and national agencies, organizations and institutions for country support
- Identify, designate and work with additional centres of excellences as WHO Collaborating Centres to enhance the effectiveness of regional networks
- Target support to existing societies and networks in transfusion medicine/science and related fields, facilitate their establishment where none yet exist and promote communication and collaboration between them
- Identify key voluntary organizations for partnership, designate nongovernmental organizations in official relations with WHO and develop joint action plans for activities at global, regional and country level
- Update and expand a database of international experts in all aspects of blood transfusion.
Strategic direction 4: Strengthening systems for assessment, surveillance, vigilance and alert, and monitoring and evaluation

This direction covers the building of national assessment and monitoring systems as part of the national blood transfusion service. This would require data to be collected using standardized tools from blood centres, hospital blood banks and hospitals practising transfusion at provincial/regional and district levels to ensure national coverage, quality data and monitoring of progress to identify and implement timely and appropriate actions. Ultimately, the data from national systems will be used to inform global monitoring of progress and the evaluation of achievements.

Goals

- Strengthening and expanding systems for data collection and management, risk assessment and management, and surveillance for policy decisions and programme planning
- Monitoring progress towards universal access to safe blood transfusion.

Strategy 14
Support the development of effective national systems for the collection and management of data throughout the transfusion chain

Efficient national data collection and information management systems form the basis for policy and decision making, for the monitoring and evaluation of blood transfusion services and to ensure the traceability of all donated blood. However, information reported to WHO global and regional databases on blood safety indicates that many countries do not yet have the capacity to collect comprehensive national data. The Blood Safety programme will work with other WHO departments to build national capacity for the collection, management and sharing of information and its use for assessing trends and comparing performance.

Activities

- Provide tools and technical support for the establishment of efficient national data collection and information management systems for situation and gap analysis, estimating blood requirements, planning a sustainable blood supply, assessing trends and progress and measuring the impact through monitoring indicators
- Convene consultative meetings to advocate to countries for the establishment of national databases of all BTS and hospital blood banks and effective BTS data management systems
- Provide technical guidance on the mapping of blood centres, blood banks and hospitals in which transfusion is performed, using Geographic information systems (GIS), in order to assess the geographical distribution of blood transfusion services in relation to the health care system
- Technical support by WHO staff and consultants through training, on-site visits and exchange programmes for:
  - Development of protocols and procedures for data management
  - Mechanisms for data collection on BTS and the use of blood
  - Pilot testing, review and modification of data collection systems
  - Analysis, interpretation and use of data
  - Data storage and retrieval
- Development of a good manual (paper) system and/or assessment of the feasibility, including the support needed from the country’s infrastructure, and impact of computerization of BTS
- Evaluation, validation, development and training for computerization of BTS.

**Strategy 15**

**Build and strengthen global, regional and national surveillance, vigilance and alert systems for blood safety and availability, and adverse transfusion events**

In an increasingly interdependent world, surveillance, vigilance and alert systems for blood safety and availability are required at global, regional and national levels. WHO will collaborate with partners at all levels to build systems and human capacity for surveillance and for the collection, compilation, analysis, interpretation, sharing and use of data.

**Activities**

- Promote and provide technical support for the development of global, regional and national surveillance, vigilance and alert systems for blood safety
- Development of taxonomy
- Strengthen risk assessment, communication and management through the promotion and support for the development of networks for sharing information, evidence and research on emerging threats to the safety of the blood supply and providing technical guidance.

**Strategy 16**

**Strengthen the global, regional and national monitoring of process and outcome indicators on blood safety and availability and measure progress**

Monitoring and evaluation is an integral part of WHO’s blood safety activities, both in assessing the implementation of its own programmes and in supporting countries to establish effective systems for monitoring and evaluation at national level. Countries, international agencies and other organizations routinely collect and publish data on progress, but better coordination is required. The Blood Safety Programme will collaborate with other partners in the development and harmonization of indicators, sharing data and measuring progress in improving blood safety and availability at national, regional and global levels and report to Member States and the international community.

**Activities**

- Update and maintain global and regional indicators on blood safety and strengthen systems for national monitoring and evaluation
- Improve the coverage and reliability of data from the WHO Global Database on Blood Safety and regional databases
- Identify priority areas and countries requiring technical support in strengthening national systems for monitoring and evaluation
- Advise on evidence-based, cost-effective strategies for blood safety and availability, based on information obtained from indicators.