

Statement by

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Making Safe Blood Available in Africa

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Mr Chairman and members of the Subcommittee, on behalf of the World Health Organization (WHO), I thank you for the opportunity to brief the Committee on the needs and strategies for making safe blood available in Africa. The two crucial issues related to blood transfusion in the developing world, particularly Africa, are *blood shortages* and *unsafe blood*, which all too frequently lead to serious health consequences such as death from postpartum hemorrhage or the transmission of life-threatening infections such as HIV and hepatitis. These deaths and serious side-effects are preventable through actions to improve blood safety and availability.

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 dating from 1975. WHO strongly advocates the implementation of its global strategy for blood safety and provides ongoing policy guidance and technical support to Member States on its implementation. The US Government has made a major contribution to the realization of this goal, especially through the President's Emergency Plan for HIV/AIDS Relief under which WHO is proud to be providing technical assistance in the strengthening of blood transfusion services in Ethiopia, Haiti and Namibia, three of the PEPFAR-focus countries.

WHO also convenes and provides the secretariat for a unique forum, the Global Collaboration for Blood Safety, which is a network of about 60 internationally recognized organizations, institutions, associations, agencies and experts from developing and developed countries for sharing expertise, identifying problems, seeking solutions and working towards the common goal of global blood safety and availability. This goal has never been more important than in the era of HIV/AIDS.

Unsafe blood transfusions and HIV/AIDS in Africa

Globally, AIDS has been responsible for more than 25 million deaths since 1981; an estimated 40.3 million people are currently living with HIV. Sub-Saharan Africa, with just over 10% of the world's population, is home to more than 60% of all people living with HIV – 25.8 million in 2005. With an estimated 3.2 million new infections in sub-Saharan Africa in 2005 (65% of all new infections globally), prevention is the mainstay of controlling the pandemic.

Unsafe blood transfusions have contributed to the enormous burden of HIV infections in sub-Saharan Africa and still continue to add to this burden. The risk of HIV infection through unsafe blood and blood products is exceptionally high (95–100%) compared to other common routes of HIV exposure: for example, 11–32% for mother-to-child transmission and 0.1%–10% for sexual contact. Sub-Saharan Africa has a particularly high level of transfusion-associated HIV compared with other regions due to a higher risk of infected blood being transfused. This results from a combination of factors: high rates of transfusion in some groups of patients (particularly women and children), a higher incidence and prevalence of HIV infection, dependence on unsafe blood donors and inadequate testing of blood for HIV in some countries. Women and children account for a disproportionate number of HIV infections through unsafe blood because they are the main groups of patients receiving blood transfusion.

The safety and availability of blood transfusion is particularly under threat among refugee populations and in emergency situations where health systems have collapsed or have been

weakened as a result of armed conflict, displacement of populations, natural disasters and other complex emergencies. In these extreme circumstances, making safe blood available to all patients needing transfusion is currently impossible.

Blood shortages in Africa

Blood donation rates in Africa are generally very low (about 5 per 1000 population) compared with developed countries (for example, 47 per 1000 population in the United States). In its most recent global survey¹ on blood safety and availability, WHO collected data from 40 of the 48 countries in sub-Saharan Africa. These data indicate that 35 (87.5%) countries collect less than half of the blood needed to meet the transfusion requirements of their populations. In 2004, only about 2.8 million units of blood were collected for a population of around 720 million people (11% of the world's population).

Severe anemia occurs more frequently in Africa than in most other parts of the world. This results from the high number of patients with pregnancy-related complications, malaria, worm infestations, malnutrition and sickle cell disease. Blood transfusion is frequently central to the management of life-threatening anemia, but blood shortages are experienced throughout Africa. These have a particular impact on women and children. Globally, more than half a million women die each year as a result of complications of pregnancy and childbirth². Of the 20 countries with the highest maternal death rates, 19 are in sub-Saharan Africa where the risk of maternal death is 1 in 16, compared with 1 in 2800 in rich countries. The most common cause of maternal death is severe bleeding, which can kill even a healthy woman within two hours, if unattended; in Africa, severe bleeding during delivery or after childbirth contributes to up to 44% of maternal deaths³. Many of these deaths could be prevented through access to safe blood.

Children are also particularly vulnerable to shortages of blood in Africa because of their high requirement for transfusion arising from severe life-threatening anemia caused by malaria or malnutrition. *Falciparum* malaria causes more than 1 million deaths each year worldwide⁴. It also contributes indirectly to many additional deaths, mainly in young children, through synergy with other infections and illnesses. Around 60% of the cases of clinical malaria and over 80% of malarial deaths occur in sub-Saharan Africa where 9 out of 10 malarial deaths occur in children under five years of age. Studies report that up to 50% of transfusions given to children are related to malaria-induced anemia.

Paradoxically, despite a severely inadequate supply of blood in African countries, blood is often transfused unnecessarily. This needlessly exposes patients to the risk of HIV, hepatitis and other serious side-effects. This poor quality clinical care also reduces the availability of blood for patients for whom transfusion is essential and is a waste of scarce resources.

¹ WHO Global Database on Blood Safety, 2004. Geneva, World Health Organization, 2006.

² The World Health Report, 2005. Make every mother and child count. Geneva, World Health Organization, 2005.

³ WHO analysis of causes of maternal death: a systematic review. *Lancet*, 367, April 1, 2006: 1066–1074.

⁴ World Malaria Report. Geneva, UNICEF/World Health Organization, 2005.

Unsafe blood in Africa

Serious blood shortages also contribute to an increased risk of HIV and hepatitis because an inadequate stock of blood forces a reliance on unsafe family or paid donors and increased pressure to issue blood without testing. In 2004, about 1.2 million units of blood were collected from family or paid donors who are considered at high risk for transmitting HIV, hepatitis B or hepatitis C. Only 12 sub-Saharan countries⁵ have achieved 100 per cent voluntary unpaid blood donation, which is the cornerstone of a safe blood supply.

Every African country has a policy to test donated blood for HIV; most also aim to test blood for hepatitis B and syphilis and, increasingly, for hepatitis C. Data from 30 African countries indicate that, in 2004, transfusion-transmissible infections were detected in 183,000 units of blood (9.8%) which were subsequently discarded. Countries with a predominance of family or paid donors had higher rates of infected blood units than countries with voluntary unpaid blood donors.

In countries where blood collection and testing systems are fragmented and hospital-based, complete and accurate data on testing are simply not available. This indicates that some countries are unable to fully implement their national policies on testing and that universal testing cannot be assured. The risk of disease transmission through unsafe blood is further increased when poor quality test kits are used or blood has to be issued without testing due to interrupted or unreliable supplies of test kits. The risk is compounded by poor testing procedures resulting from shortages of trained staff and a lack of quality systems. Thirty-three (83%) of the 40 sub-Saharan African countries which provided data to WHO reported that they do not have fully operational quality systems in the blood transfusion service, including HIV testing. Around 2.7 million units of blood were collected in these 40 countries in 2004; 88.5% of these were not tested for HIV in a quality-assured manner.

Strategy for blood safety and availability in Africa

The good news is that 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. Blood safety is therefore one of the most cost-effective strategies for reducing the burden of HIV infection in Africa. The strategy advocated by WHO to achieve effective, cost-efficient and safe national blood supply systems^{6,7} has been endorsed by all governments through successive World Health Assembly resolutions and has also been adopted by the PEPFAR initiative. It has three main components:

- **Voluntary unpaid blood donation:** the first line of defense is the donation of blood only by regular, voluntary unpaid blood donors from low-risk populations, who are the safest possible blood donors, and a careful assessment of their suitability to donate blood.
- **Universal testing of donated blood:** the second line of defense is the screening of all donated blood in accordance with quality requirements for, at minimum, HIV, hepatitis B, hepatitis C and syphilis.

⁵ Botswana, Burundi, Central African Republic, Côte d'Ivoire, Malawi, Namibia, Rwanda, Senegal, South Africa, Swaziland, Togo and Zimbabwe.

⁶ World Health Assembly Resolution WHA58.13: Proposal to establish World Blood Donor Day.

⁷ Blood Safety: Strategy for the African Region. Brazzaville, WHO Regional Office for Africa. 2002.

- **Reducing unnecessary transfusions:** the third line of defense is the appropriate use of transfusion only when medically indicated for patient survival and wellbeing, minimizing the loss of blood during surgery, and the use of suitable alternative treatment.

The successful implementation of this strategy is dependent on the national coordination of services, clear roles and responsibilities between different national stakeholders, a suitable infrastructure and proper organization and management. Uniform standards of performance and economies of scale can be achieved only where the key functions of the blood service are centralized or regionalized in main centers. Also required are quality systems covering all activities related to blood transfusion and an adequate number of trained staff.

The impact of blood safety measures is demonstrated by the virtual elimination of transfusion-transmitted infections in the United States (estimated risk of HIV infection of 1 in 1,800,000 per blood unit⁸). Importantly, improved blood donor selection techniques contributed to a dramatic reduction in the risk of transmission of infection, even before specific laboratory screening tests were available.

The implementation of this strategy for blood safety, through the development of efficient systems, has also resulted in improved access to safe blood in developing countries in all regions of the world, including some countries in sub-Saharan Africa. In Malawi, for example, following the establishment of the National Blood Transfusion Service in 2003, a 60% decrease in mortality among seriously ill children and a 50% decrease in mortality in pregnant women with severe blood loss was recorded in patients admitted to the Queen Elizabeth Hospital in Blantyre. These reductions were directly attributable to the availability of safe blood. In addition, South Africa has demonstrated how, in a country with an HIV prevalence of 21.5% in the general population, it has been possible to reduce the HIV prevalence to 0.46% among first-time blood donors and to 0.03% among regular blood donors.

It can be cautiously estimated that nearly 500,000 HIV infections through blood transfusion are already being averted each year in sub-Saharan Africa through the adoption of simple blood safety measures in voluntary blood donation, blood donor selection and quality-assured testing of donated blood.

Advanced technologies such as nucleic acid testing and pathogen inactivation have been introduced in the US and other developed countries to reduce the risk of disease transmission. In developing countries, priority has to be given to the implementation of more basic, proven strategies for blood safety before incorporating sophisticated new technologies for blood testing and processing which are not cost-effective or feasible in the absence of a nationally-coordinated, sustainable and effective blood transfusion service. Significant efforts are also being put into the development of blood substitutes, but their widescale use cannot be anticipated for another decade or two, even in developed countries. Artificial blood will certainly not be widely available in developing countries within the foreseeable future.

⁸ Transfusion medicine: looking to the future. Goodnough L, Shander A, Brecher M. *Lancet*, January 11 2003; 361: 161–169.

The way forward

The experience of working in PEPFAR focus countries has demonstrated that the major challenges in improving the safety and availability of national blood supplies in Africa are institutional as well as technical. Key issues that have had to be addressed include the fragmentation of blood transfusion services, poor institutional coordination and a lack of clarity of roles and responsibilities among various stakeholders, including ministries of health. In addition, there are acute shortages of trained and dedicated manpower to support safe national blood programs. The lack of sufficient trained staff is consistently cited as one of the main constraints faced by fragmented blood transfusion services in many sub-Saharan countries.

The main factors facilitating positive change in national blood transfusion systems have been the availability of funds; the development of trust and good working relations between ministries of health, other national stakeholders and technical assistance agencies; and enhanced levels of commitment and support from governments, demonstrated by the adoption of national blood policies and long-term strategic plans, paving the way for sustainable blood transfusion services.

This experience indicates that the following key interventions will be needed to strengthen systems for blood safety and availability throughout sub-Saharan Africa:

- **Policy and program development:** nationwide situation analysis of existing blood services and assessment of current and future needs, development of national blood policy and strategic plan, establishment of legislative framework and regulatory mechanism, national coordination of blood transfusion services and establishment of systems for financial sustainability.
- **Infrastructure development:** to ensure adequate and suitable facilities for blood collection, testing, processing, storage and distribution.
- **National data collection and information management system:** to ensure the traceability of donors, donated blood and transfusion recipients.
- **Strengthening of blood donor programs:** to increase the total number of donations by voluntary blood donors, reduce family and paid donation and implement strict criteria for assessing the suitability of donors.
- **Testing and processing:** centralized/regionalized testing of all donated blood in accordance with quality standards.
- **Quality systems:** in blood transfusion services and at the clinical interface.
- **Training:** of all staff in blood transfusion services and hospital staff involved in the clinical transfusion process.
- **Blood utilization:** prescribing of blood in accordance with national transfusion guidelines and the safe clinical transfusion procedures.
- **Monitoring and evaluation:** of all activities related to blood transfusion to assess progress, monitor trends and impact, and replan, as necessary.

Priorities

First, global advocacy and coordinated efforts by governments, donor agencies, technical agencies and other stakeholders are urgently needed in Africa. Progress depends on raising the need for safe

blood on health and development agendas, and mobilizing increased political commitment and funding among African countries.

Second, increased support is required for building institutional and technical capacity as well as the strengthening of national blood transfusion services within health care systems. This requires increased staffing, specific measures to retain staff once recruited and a huge increase in training.

Third, close collaboration is required between national blood programs and other programs at national level, including national AIDS control programs, maternal and child health, malaria and anemia management. A commitment is needed by national health authorities, health care providers and clinicians to the prevention, early diagnosis and treatment of conditions that could otherwise lead to the need for transfusion by strengthening public health and primary health care programs.

Fourth, the resources available for blood safety and availability should be increased and sustained at country level. A systematic approach is required to assess the level of resources needed, based on the clinical requirements for blood and blood products, the current capacity of blood transfusion services to meet these needs and the level of access of the population to health care services. With the strengthening of health care systems and improvements in diagnostic and treatment options, there will be increased clinical demands for blood and blood products. Measures to reduce transfusion-associated HIV infection must therefore address future requirements as well as current needs.

Fifth, resources will need to be allocated specifically for international technical assistance in the strengthening of national blood transfusion services.

Sixth, investment is also needed for research and development to enable developing countries to identify and implement innovative methodologies and appropriate technologies for blood safety.

Conclusion

It is clear that least developed countries and transitional countries in Africa will need long-term technical and financial support to develop sustainable systems which can meet the transfusion needs of their patient populations. The development and implementation of a road map for blood safety throughout Africa can ultimately result in a safe, high quality blood supply for all patients requiring blood transfusion and the elimination of unsafe transfusion as a route of HIV transmission.

In conclusion, Africa is in desperate need of a significant scaling-up of efforts to make safe blood available to all patients, whose survival and wellbeing depends on this treatment intervention. It is technically feasible, lacking only the political commitment and the financial resources. Considering the high effectiveness of HIV prevention through safe blood, there should be zero tolerance of any transmission of HIV and other infections within the health care system.

WHO appreciates the opportunity to brief the Committee on this important issue. I thank you for your attention.