The President's Emergency Plan for AIDS Relief

Report on Blood Safety and HIV/AIDS

June 2006

House Report 109-152, accompanying H.R. 3057, called upon the Office of the United States Global AIDS Coordinator to report as follows:

The Committee asks that the Office of the Global AIDS Coordinator, in coordination with USAID, CDC, and WHO, provide a report to the Committees on Appropriations on the magnitude of the problem posed by unsafe blood supplies, the level of resources required to address the problem, the feasibility of a non-incremental approach, and the cost effectiveness of implementing a Safe Blood Program in reducing rates of infection.

Report to Congress Mandated by House Report 109-152
Accompanying H.R. 3057

Submitted by the Office of the U.S. Global AIDS Coordinator
U.S. Department of State

June 2006

Executive Summary

A focus of the President's Emergency Plan for AIDS Relief (PEPFAR/Emergency Plan) is to build local capacity to provide long-term, sustainable HIV/AIDS prevention, care and treatment programs. Ensuring the availability of safe blood is one component of a multi-prong strategy to prevent HIV transmission. For developing countries, there are significant challenges to developing and maintaining an adequate sustainable supply of safe blood, including lack of basic infrastructures (consistent electricity, refrigeration, physical structures, laboratory equipment, etc.), strong health care systems, no or inadequate policy around blood safety and the clinical use of blood, and inadequate administrative procedures in place to allow for the purchase and management of blood-related commodities. These issues are part of a larger and more complex development challenge, and the Emergency Plan alone cannot address the infrastructure, policy and capacity challenges faced by developing countries.

As unsafe blood continues to account for some infections in the focus countries, PEPFAR is lending support tailored to the needs of each host nation. To reduce the risks of blood transfusions, the Emergency Plan supports national programs to improve the quality of blood supplies through improved policies, establishment of laboratory facilities, commodity procurement, and management. The Emergency Plan also provides technical assistance to aid countries in implementing the foundational components of effective national blood transfusion services. In fiscal year (FY) 2005, the Emergency Plan supported approximately 600 blood safety service outlets or programs in the focus countries.

During the first 2 years of funding, countries spent one-third of the Emergency Plan funds allocated to Ministries of Health and National Blood Transfusion Services (MOH/NBTS) to establish safe blood systems. This is largely due to the infrastructure, human capacity, policy, and economic constraints experienced by the focus countries. These countries cannot effectively spend funding until another layer of infrastructure is in place to allow for sustainable expansion of services. Because countries differ in their absorptive capacity and ability to

establish sustainable safe blood systems, Emergency Plan support is channeled largely to national governmental initiatives to implement and manage distribution and logistics systems on which blood transmission prevention relies. The Emergency Plan also makes significant investments in training of health care workers and managers of blood safety activities. As demonstrated in the table below, only 3 out of 14 focus countries outlayed more than 50% of the funds awarded in the 20-month period from August 1 2004 to September 30 2005. Pipelines remain full with over 60% of funding unused.

Table 1: PEPFAR Central Funding : 14-Month Period Awarded, Outlayed and Pipeline Funding for Blood Safety Activities (funding rounded to the nearest million)

	AWARDED 8/1/04 to 9/30/05 (in millions)	TOTAL OUTLAYS (in millions)	OUTLAY %	FUNDING IN PIPELINE (in millions)
Botswana	$4.2	$0.1	3%	$4.0
Cote D'Ivoire	$5.9	$3.0	52%	$2.8
Ethiopia	$4.2	-	0%	$4.2
Guyana	$2.2	$0.4	19%	$1.8
Haiti	$3.7	$1.3	36%	$2.4
Kenya	$5.9	$1.6	28%	$4.2
Mozambique	$2.6	$0.6	22%	$2.0
Namibia	$1.9	$0.8	41%	$1.1
Nigeria	$2.7	$1.6	61%	$1.0
Rwanda	$4.5	$1.0	23%	$3.4
South Africa	$5.9	-	0%	$5.9
Tanzania	$5.9	$2.0	34%	$3.9
Uganda	$5.9	$2.9	50%	$2.9
Zambia	$5.0	$2.6	52%	$2.4
Total	$60.3	$18.1	40%	$42.1
Technical Assistance Funding	$14.1	$5.3	37%	$8.8
Grand Total	**$74,350,000**	**$23,359,531**	**31%**	**$50,990,469**

In 2002, the World Health Organization (WHO) estimated that 5-10% of HIV infections in Africa were transmitted by unsafe blood transfusion, based on some presumptions regarding prevalence of infections among general population and blood donors, and the

coverage of screening.[1] However, actual data collected from current focus country blood safety programs shows a lower average percentage of HIV infection among blood donors than has been cited. In fact, an average of only 3.19% of donors were HIV positive.

Table 2: Prevalence of HIV in Screened Blood Donors

Country	Prevalence Rate
Botswana	4.00%
Ethiopia	3.40%
Guyana	1.20%
Kenya	1.80%
Mozambique	6.43%
Namibia	0.50%
Nigeria	4.40%
Rwanda	1.10%
South Africa	0.09%
Tanzania	5.70%
Uganda	1.60%
Zambia	8.00%
Average	**3.19%**

*Based on HHS/CDC Data from Country Clinics Continuing Applications submitted 3/06

The Office of the Global AIDS Coordinator (OGAC), in coordination with the Department of Health and Human Services/Center for Disease Control (HHS/CDC), the U.S. Agency for International Development (USAID), and WHO, invited technical consultants with expertise in blood safety to convene in Washington, D.C. on January 25-26 2006. The purposes of the meeting were to: review and discuss the nature and magnitude of the problem posed by unsafe blood in PEPFAR countries; review centrally-funded technical assistance providers' accomplishments, challenges and barriers; and discuss suggestions for improved effectiveness. The white papers prepared for this consultation and the discussion that occurred during the meeting are integrated into the findings of this report.

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[1] WHO, Blood Safety and Clinical Technology Progress 2000-2001, 2002.

Background

In the United States, the blood supply for transfusions is very safe, and the risks from blood-borne pathogens, including HIV, are minimal because of exclusion guidelines and extensive blood testing. The medical transfusion community maintains continuous efforts to collect blood only from the safest donors and to screen all donated blood for HIV and other blood-borne pathogens. The safety of the blood supply in the developing world, however, is markedly different than that in the United States.

Barriers to maintaining an adequate, safe blood supply in developing countries exist on many levels. Infrastructure challenges include problems with the consistent refrigeration and electricity needed to store blood donations. Additionally, consistent funding to purchase blood-banking equipment and test kits is inadequate, especially in countries with extreme poverty, political instability, and armed conflict. In these same countries, salary and training for blood-banking and transfusion personnel is not supported. Many hospitals in the developing world do not have effective or complete screening of blood for HIV, and as a result, the risk of transfusion-transmitted HIV, can be considerable. In countries with a high prevalence of HIV among blood donors, this risk is especially high.

A continuous and adequate supply of low-risk, voluntary, and non-remunerated blood donors is needed for high-quality blood services worldwide. Identifying and targeting low-risk volunteers for blood donations can be difficult in areas with high HIV prevalence, such as many developing countries. Currently, volunteer donors account for less than half of the blood supply in developing countries, and few countries have mobilized efforts to encourage voluntary blood donation. In many countries, there are cultural attitudes that limit acceptance of blood donation activities, and governments and other institutions do little to counteract these attitudes with educational outreach programs. Many countries are currently forced to rely on emergency donations from paid donors or family members; however, blood collected from paid or family donors presents an increased risk of transmitting HIV.

Based on findings that donors not paid for their donations have the lowest risk of transfusion-transmitted viruses, the World Health Assembly (WHA) adopted Resolution WHA 28.72 in 1975, which urged all WHO member states to base national transfusion services on non-remunerated volunteer blood donors.

In Africa, transfusions are most frequently used for pediatric malaria and obstetrical clinical cases. Inappropriate transfusion practice is common in developing countries, and medical guidelines for safe transfusion are frequently not followed. Several studies in African healthcare settings have documented that from 12.9 percent to 47 percent of all pediatric transfusions are unnecessary.[2]

Limited amounts of safe and volunteer-donated blood, poor infrastructure (including a lack of clean water and constant electricity), and healthcare system limitations all call attention to the need for strategies to ensure blood safety.

The President's Emergency Plan for AIDS Relief Strategy for Safe Blood

The Emergency Plan currently supports the Ministries of Health or the government's NBTS in 14 of the 15 focus countries[3] to assist in the development of a well-functioning blood supply system that includes low-risk blood donor selection, blood banking, and blood safety training. It also promotes international blood safety organizations to partner with each of these countries to help in the development of this comprehensive system. The goal of these programs is to increase blood supply through donor recruitment, and to work to ensure its safety through proper screening of donors and donated blood and the development or improvement of a national blood service in each country.

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[2] Jager H, N'Galy B, Perriens J, Nska K, Davachi F, Kabeya CM, et al. Prevention of transfusion-associated HIV transmission in Kinshasa, Zaire. HIV screening is not enough. AIDS 1990;4:571-5747 Lackritz, E.M., Ruebush, T.K., Zucker, J.R., Adungosi, J.E., Were J.B., Campbell C.C. (1993).

[3] Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Zambia; Vietnam is the 15th focus country not included.

Table 3: Total Obligated and Planned PEPFAR Funds for Blood Safety, 2004-2006

	Obligated FY 2004 (millions)	Obligated FY 2005 (millions)	Planned FY 2006 (millions)
Country Managed Funds	$4.2	$3.4	$5.7
Central Funds	$24.3	$50.0	$24.6
Total Funds	$28.5	$53.4	$30.3

The integrated strategy for blood safety adopted by the Emergency Plan and endorsed by focus countries' Ministers of Health includes support for the following:

- Sufficient supply of blood to meet the needs of the country;
- Voluntary non-remunerated blood donation; collection of blood only from the safest possible, regular, unpaid blood donors from low risk populations;
- Universal testing of donated blood; quality-assured screening of all donated blood for HIV; and
- Reduction of unnecessary transfusions; safe and rational blood utilization and the use of alternatives to transfusions whenever possible.

The Emergency Plan supports the efforts of the countries to develop nationally directed regionalized blood systems. The purpose of the nationally-regulated systems approach is to develop a network of centralized and controlled blood centers able to address all the processes of a well-functioning system of blood supply.

Each country addresses six key elements of a safe blood supply:
1) Infrastructure;
2) Donor recruitment and blood collection;
3) Testing;
4) Transfusion practice and blood utilization;
5) Training; and
(6) Monitoring and evaluation.

Baseline assessments were conducted in each of the 14 countries and the assessments found that countries were at various stages of development. During the first year of the program many countries had to concentrate on basic infrastructure and policy development. Such undertakings are time-consuming but essential.

Magnitude of the Problem of Unsafe Blood

Countries in sub-Saharan Africa and other parts of the developing world experience a greater degree of transfusion-associated hepatitis viruses, HIV, malaria and syphilis than industrialized nations. Reasons include high rates of transfusion in some groups of patients (particularly women and children), a higher prevalence of these diseases in the general and blood donor populations, inadequate antibody screening in some countries, and a higher residual risk of contamination in blood supplies despite antibody screening. Blood transfusion is commonly administered in Africa, particularly to young children (age 1 – 3 years) in cases of malaria anemia, and in cases of complications of delivery.

However, several studies have documented that blood transfusions are not the major cause of HIV transmission in most countries. Among young women the risk associated with transfusions appears low compared to the proportions infected by heterosexual transmission. For instance, in Rwanda in the early days of the epidemic (1986 – 1987) when HIV seroprevalence was 29% among antenatal clinic attendants and before major efforts to screen the blood bank were undertaken, the population-attributable risk of HIV infection by blood transfusion was only 9.3% (the relative risk of HIV infection associated with blood transfusion was 1.6, and the proportion of women who ever had a blood transfusion was 6%).[4] Risks associated with blood transfusion were greatly reduced in Africa in the late 1980s, after a major concerted effort supported by the international community. In Kenya, it is estimated that no more than 2% of blood transfusions could transmit

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[4] Allen S, Van de Perre P, Serufilira A, et al. HIV and Malaria in a representative sample of childbearing women in Kigali, Rwanda. *J Infect Dis 1991; 164:67-71*

HIV[5]. Multiplied by the number of women who receive a blood
transfusion (approximately 2%), this would represent only a tiny
fraction of HIV infected adult female adults (roughly 1%). In a highly
infected country such as South Africa, the National Blood Service did
not find any evidence of HIV transmission by blood transfusion among
the 881,673 transfusions provided in 2000.[6]

In many developing countries, substantial problems have been
documented in each of the following components: assuring that a
sufficient amount of blood is collected in the country; implementation
of a system to recruit low risk donors; quality screening of donated
blood; and national policies and oversight to reduce unnecessary
transfusions.

Sufficient supply of blood: The WHO Global Database on Blood
Safety (GDBS) provides information on blood safety and on the nature
and extent of the problems associated with unsafe blood transfusion.
GDBS data for 2001-2002 shows that Africa has access to only 6% of
the global blood supply. Thirty-nine percent of blood is donated in
developing countries where 82% of the world's population lives. An
estimated 14 million blood units are needed in sub-Saharan Africa.
Information provided to the GDBS by Ministries of Health in 39
countries indicates that only 3.6 million units were collected in 2004.
The 15 focus countries of the Emergency Plan have a total population
of nearly 40 million people. The annual whole blood collection in these
countries in 2004 was approximately 2.8 million units as compared to
an estimated requirement of 8.3 million units. Therefore, populations
of these countries generally have limited access to blood and blood
products.

Voluntary, non-remunerated donors: A continuous and adequate
supply of low-risk, voluntary, and non-remunerated blood donors are
needed for high-quality blood services worldwide. Identifying and
targeting low-risk volunteers for blood donations can be difficult in
areas with high HIV prevalence, such as in many developing countries.

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[5] Moore A, Herrera G, Nyamongo J, et al. Estimated risk of HIV transmission by blood transfusion
in Kenya. *Lancet 2001;358:675-660.*
[6] South Africa-NBS web site - www.sanbs.org.za

Many countries currently rely on emergency donations from paid donors or family members; however, blood collected from paid or family donors presents an increased risk for transmitting HIV. Evidence from around the world demonstrates that patients who receive blood from unpaid donors who give blood regularly are at the lowest risk for acquiring HIV and other life threatening infections through transfusion. Based on these findings, the World Health Assembly (WHA) adopted Resolution WHA 28.72 in 1975, which urged all WHO member states to base national transfusion services on non-remunerated volunteer blood donors. Best practice in countries such as South Africa and Zimbabwe have shown that even in countries with high HIV prevalence, a well organized program of voluntary unpaid donations and procedures for assessing the suitability of donors can achieve a low prevalence of infection in the blood donor population.

Of the 15 Emergency Plan focus countries, five countries reported 100% voluntary unpaid blood donation in 2004 while the remainder of the countries continue to rely on replacement family blood donors (with the percentage of voluntary unpaid donation ranging from 5% in Uganda to 95% in Haiti).

Low prevalence of HIV in screened blood demonstrates good donor screening practices. An HIV prevalence in screened blood of 8% was seen only in Zambia; in Botswana, Mozambique, Nigeria, and Tanzania prevalence was between 4 – 8%. The remaining PEPFAR countries had less than 4% HIV prevalence in screened blood. Three of the Emergency Plan focus countries reported significant decreases in HIV prevalence of screened blood after initiation of the Emergency Plan, suggesting improvements in the quality of donor recruitment.

Screening of donated blood: The screening of donated blood coupled with procedures to ensure the collection of blood from suitable voluntary unpaid donors has a major impact on reducing the risk and further transmission of HIV. Thirteen of the Emergency Plan focus countries report 100% screening of blood, with one reporting less than 100%.

Some countries report that blood has not been tested at times due to the lack of availability of reagents and test kits. In sub-Saharan Africa, 33% of the countries report that they do not have an adequate system of stock control in place. Interruptions to general supplies of consumables have been reported by 51% of sub-Saharan African countries. Universal screening of donated blood cannot be achieved without mechanisms to ensure continuity in testing.

Quality control and quality assurance of testing procedures must also be in place to assure that blood is safe. In sub-Saharan African countries, a national external quality assessment program is reported to be in place in only 37% of the countries. Nine of the Emergency Plan focus countries in Africa report a national external quality assessment program.

Reduction of unnecessary transfusions: Despite the inadequate supply of blood in African countries, blood is often prescribed unnecessarily, thus needlessly exposing patients to the risk of transfusion-transmitted infections. Unnecessary transfusions also contribute to an increase in the cost of providing blood which leads to added financial strains on the NBTS that may threaten sustainability. These inappropriate transfusion practices are common in developing countries, and medical guidelines for safe transfusion are frequently not followed. Only 33% of sub-Saharan Africa countries and seven of the African Emergency Plan focus countries report having national guidelines on the clinical use of blood.

A number of studies have attempted to quantify the extent to which unnecessary transfusions are given. Several studies in African healthcare settings have documented that from 12.9% to 47% of all pediatric transfusions are unnecessary[7]. A study in Kenya suggested that nearly half of pediatric transfusions may have been preventable if prescribing practices had been in accordance with standard transfusion guidelines. A study of surgical transfusion in Cameroon indicated that

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[7] Clark KA. Pediatric Transfusion in Developing Countries. In: Hillyer, Strauss and Luban, editor. Handbook of Pediatric Transfusion Medicine. San Diego, CA: Elsevier Academic Press; 2004. p. 149-157.

blood transfusion was unjustified in 81% of cases. Informal data from a research study in Zambia indicate that pediatric blood transfusions have been reduced from 100 per month in the peak season for malaria transmission to a total of 3 transfusions in 2004 through better community malaria control.

In summary, there are significant challenges to developing and maintaining a safe blood supply throughout a large part of the developing world. Currently fewer that 30% of countries worldwide have fully functioning nationwide blood transfusion services. Consequently, many countries do not have a sufficient supply of blood to meet the needs of the country. Blood donors tend to be primarily paid and/or family/replacement donors. Universal testing of donated blood and quality screening of all donated blood is unknown because of the poor quality of data collection and reporting, and unnecessary blood transfusions remain exceptionally common.

Incremental versus Non-incremental Approach

For the purposes of this report, "non-incremental funding" is defined as establishing a blood service in a country over a period of several years using one round of funding while "incremental funding" is the establishment of a transfusion service over a five to ten year period with multiple or successive rounds of funding. Much of the information included in this section was derived from an "Analysis of Establishing Blood Services in Africa based on an Incremental vs. Non-Incremental Approach" authored by Safe Blood International Foundation, AABB, Sanquin, and blood transfusion specialists in Nigeria, Uganda, Malawi, Zimbabwe, and Botswana.

In many sub-Saharan Africa countries, blood services are non-existent, significantly under-resourced or without the infrastructure and capacity to ensure sustainable operations. Blood testing, processing and transfusing procedure are often managed by overworked general laboratory workers in poorly equipped, hospital-based laboratories. It is well established that support for developing blood services must be based on solid infrastructures and trained workers to reduce the risk of disease transmission. Consequently, an **incremental approach** is the

only realistic approach for establishing blood services in developing countries including sub-Saharan Africa. There are substantial reasons for this conclusion.

A first step in developing a NBTS is to secure buy-in from various stakeholders. The government, usually represented by its MOH, is the major stakeholder in the development of a NBTS in any given country. In addition, the country must develop a national policy for blood transfusion and the government must ensure that the appropriate legislation and regulations supporting the policy are put in place. Legislative processes are frequently protracted.

It also takes time to develop an adequate blood service workforce. Administrators of other healthcare services must be informed and support developments in the national blood transfusion service. It is also important to recruit and train medical, laboratory and nursing staff in appropriate use of blood. A quality management system must be developed and implemented.

In addition, the development of acceptable, sustainable infrastructure is time-consuming. A NBTS must have suitable buildings to house a centralized (non-hospital based) blood service. Infrastructure and services such as electricity, water supply and telecommunications vary greatly by country and are often unpredictable but critical for a NBTS. The NBTS must evaluate and purchase equipment to collect, process and test donated blood. And, most modern blood transfusion systems operate under a quality management system, which requires full traceability of all processes and procedures from donor through to use of blood. A quality management system requires some degree of computerization, and the planning and development of appropriate automated systems may take several years.

Country case examples are used in this report to represent a spectrum of experience in establishing blood transfusion services in developing countries The examples have been included to illustrate some of the major issues which must be addressed by countries and which argue that only an incremental approach can build sustainable blood systems in developing countries.

Nigeria – A Case Study

The current President of Nigeria has been extremely supportive of improving the blood supply in his country and he supported the development of a demonstration blood center in Abuja. The blood center was refurbished and equipped using USAID seed funding, and the intention is that this center will become the headquarters of the newly formed National Blood Transfusion service. The demonstration blood center will serve as the first of a network of zonal blood centers located in each of the six geopolitical zones of the country. The zonal blood centers will create a hub to catalyze the development of blood centers in each of the 36 states. Even with this degree of commitment, training to adequately provide staff with the necessary skills to carry out and sustain a good transfusion service, on a national level, will be a profound challenge for many years. At present, blood transfusion is highly fragmented, hospital-based and dependent on family replacement and commercial donors. In Nigeria there is strong leadership to improve the blood supply at the highest level; however, even with ample funding, the development of a national blood transfusion program will require a sustained effort over many years.

Malawi – A Case Study

Even though Malawi is not an Emergency Plan focus country, it was included as one of the case studies because it demonstrates key findings related to the issue of non-incremental versus incremental funding. Malawi has a population of 11.3 million and is one of the world's least developed countries, being the third poorest country in the world. Malawi has an HIV prevalence rate of 14.2% (2003). In February 2000, a Financing Agreement [European Development Fund (EDF8)] was signed between the Commission of the European Communities and the Government of the Republic of Malawi to establish an independent blood transfusion service in Malawi (MBTS). Funding was to run until March 2006 and rest with the MBTS Trust. The overall objective of the project was to reduce the incidence of HIV/AIDS and other diseases transmissible by blood transfusion in the Malawi population and to ensure the appropriate clinical use of blood through the establishment

of a centralized and sustainable blood transfusion service. No organized blood transfusion services were available before that time as all services were hospital-based and totally reliant on relatives and paid blood donors.

Many elements were already in place for the development of this system. A legal framework was established and approved at the ministerial level. A national blood policy and plan existed. The MBTS Trust drafted a constitution for and facilitated the formation of the Blood Donor Association of Malawi (BDAM) to bring together all the disparate blood donor interests under one body. Finance and administration was controlled directly by a finance and administration director responsible to the MBTS Trust. The Government of Malawi was committed to meeting 30% of the running costs by the end of 2005 and to develop a service cost recovery system.

Even though many of the elements were present to establish this system (e.g., adequate funding, government buy-in, national policy), during the first three years of EU funding to Malawi through the EDF there was little progress. The funding agency had not taken into account the lack of local experience or expertise to implement the Plans of Action and only considered employing a full-time experienced Project Manager after three years. One major lesson learned from this experience is that the appointment of experienced senior staff is essential to the success of this type of project, yet such staff are in short supply in many developing countries.

Today Malawi has a revamped blood service, which is now recognized by the WHO as a successful model. This model was built on years of training to create the staff capacity required to sustain the blood service in the long-term.

The development of a Blood Transfusion Service entails a number of processes which underpin sustainability. These steps have to be systematically and successfully taken in order to ensure that the service is supported by adequate infrastructure such as laboratories and reliable power; that staff are recruited, trained and retained; that laboratory equipment and reagents are appropriate, purchased, and supported; and

that processing procedures are properly managed. In addition, substantial time is required to effect legislation or policy supporting the blood service; to establish relationships with each country's Ministry of Health; to develop a financial/management system; and to train an adequate blood service workforce. There is a wide array of challenges to achieving adequate capacity and sustainability to support blood transfusion services in developing countries. Capacity building is a process that requires a period of years which realistically must be approached incrementally.

Level of Resources

Currently, there is little information available on the relative cost and likely impact of blood safety programs in different settings. When estimating the resources needed to scale up blood safety activities, there are two challenges: first, obtaining costs for these strategies from the empirical literature, and second, forecasting the scale-up costs for national programs. Due to low national coverage of many programs, even when cost information is available, it is generally obtained at the individual facility or project level, operating on a small scale (e.g., community or district), and based primarily on urban rather than rural services. Multiple models have been developed to estimate the resources needed to implement an HIV/AIDS intervention. Two models are presented here and used to estimate level of resources needed for establishment and maintenance of blood safety programs in three Emergency Plan countries.

The first method, proposed by WHO, estimates that countries require sufficient number of units of blood to cover 2% of the total country population. The model then applies a cost per unit of blood to estimate the level of resources required to support a blood safety program in that country. When determining the cost per unit of blood, both capital and recurrent costs are considered:
- Recurrent Costs include:
  - Personnel
  - Utilities
  - Insurance
  - Transportation

- Supplies
- Administration

- Capital Costs include:
  - Buildings
  - Vehicles
  - Training
  - Equipment
  - Furniture

The recurrent costs are based on the assumption that basic infrastructure components such as functioning roadways, consistent supply of electricity, and sufficiently trained and available healthcare workers are in place and accessible. There are recurrent and capital costs associated with each of the following blood transfusion activities. The sum of the cost of each of these activities provides a cost per unit of safe blood.
- Recruitment: education, motivation, recruitment and retention of voluntary, non-remunerated blood donors
- Collection: selection and screening of blood donors as well as all activities associated with the actual collection of blood
- Processing: screening collected blood for infectious agents, blood grouping, preparation of blood components and all other activities necessary to ensure the safety of blood and blood products before they leave the processing unit for storage
- Storage and Distribution: all activities related to the storage and transportation of blood and blood products through to their final transfusion, including the maintenance of an efficient blood cold chain

With these four factors in mind, WHO has concluded that the average cost of a unit of safe blood is $40~45 US dollars. For the purposes of the following calculations, $45 US dollars per unit of blood is used in the model:

Table 4: 2006 Estimated Cost for 3 countries Using WHO Resource Costing Model

Country	Total Population	2% of Population	Cost per Unit of Blood*	Resources Required for 2006**
Cote d'Ivoire	16,944,000	338,880	$45	$15,249,600
Kenya	32,982,000	659,640	$45	$29,683,800
Mozambique	19,110,000	382,200	$45	$17,199,000

*Includes capital costs.
**Amount will increase or decrease based on total population.

Utilizing this simple WHO model formula, the cost per infection averted can be extrapolated. Using a prevalence rate of 3% (as stated earlier in this report), 1 in 33 units of blood would be found to be HIV-positive. Testing 33 units of blood at $45 a unit equals $1500 per unit identified. As transmission efficiency is approximately 80%, the approximate cost per infection averted is $2000 per infection (assuming all units of blood are used).

Another method, the Resource Determination Model (RDM), estimates the resources needed to scale up blood safety using the following steps:

1) Establish the size of the populations that are at greatest need and will benefit from a safe blood program;
2) Establish the proportion of the target group that has access to health services;
3) Determine the average requirement of blood for each target group; for example, for children under age five, the average number of blood units per case is .5 unit versus on average a pregnant woman needs 2.5 units;
4) Project growth for the future;
5) Determine per unit cost which varies by country. Variables included in the cost calculation are:
   - Recruitment donor (e.g., communication, vehicles)
   - Collection (materials, blood bags, cold chain)
   - Lab testing
   - Processing
   - Storage and Cold Chain, Distribution

- Quality Assurance, informatics, administration, logistics, incineration, maintenance of buildings and equipment
- Personnel (salaries and training)

All of the expenditures listed above are recurrent costs which continue over the life of the national system. Based on the above model, the recurrent cost of a safe unit of blood in Cote d'Ivoire is approximately $40, and in Mozambique and Kenya it is $30. The recurrent cost does not include the capital expenditures needed for the national blood system, which include funds for lab facilities, lab equipment, vehicles, cold chain equipment, and generators. In the RDM model, capital costs are equally dispersed over the first three years of the project.

Assumptions of the RDM model:

- The requirement of safe blood for the potential target group (with access to health services) as projected with base year (2004) Blood Transfusion Service capacity will remain constant.
- The number of safe blood units provided would increase in 2005 by 30% in Kenya, and by a growth rate in the other three countries in the same ratio to 30% as each county's adjusted growth factor is to Kenya's adjusted growth factor
- The increase in safe blood units in absolute number from year 2004 to 2005 will remain constant for the projected years.
- The recurrent cost of safe unit of blood in Cote d'Ivoire = $40, Kenya = $30 and Mozambique=$30.

Table 5: 2006 Estimated Cost for 3 Countries Using RDM

Country	Total Population	Capital Cost*	Recurrent Cost**	Resources Required for 2006***
Cote d'Ivoire	16,944,000	$1,529,351	$4,628160	$6,157,511
Kenya	32,982,000	$3,000,000	$5760,000	$8,760,000
Mozambique	19,110,000	$1,637,635	$3,159,090	$4,796,725

*capital cost budget at $1 million for a new regional bank with capacity to collect, screen and distribute 20,000 safe blood units

*recurrent cost= number of units required by the country multiplied by the cost per unit of safe blood
***Resources required = Capital cost budget + Recurrent Cost (replacement of capital for existing capacity not included).

The models differ on a number of dimensions but the primary difference between the two models is that the WHO model uses estimates based on the entire country population whereas the RDM model reduces the scenario to only those with access to health care. By design, the RDM model leaves out a large portion of the population in developing countries as access to health care is limited. The second significant difference is the cost per unit of blood. The first model has calculated a universal cost per unit whereas the second model has used anecdotal evidence from the four countries to calculate the recurrent cost per unit of blood and a more complex formula to spread the capital costs.

While it is true that HIV-infected blood carries a high risk of transmitting HIV to the recipients of that blood, this does not necessarily translate into a safe blood program having a major impact on HIV prevention. In fact, the impact and cost-effectiveness of blood safety programs are highly dependent on HIV prevalence in the service area. This is particularly true because the cost of testing a unit of blood is the same regardless of whether the blood proves to be infected. Health benefits are achieved only if the blood product is actually infected and if the potential recipient was HIV-negative. Thus, there is a need to include a diversified portfolio of prevention interventions, because many programs complement each other and target specific, exhaustible populations.

Conclusion

The Emergency Plan invests in the reduction of the transmission of HIV by unsafe blood transfusions using systematic change and technological interventions. In FY 2005, the Emergency Plan provided training on blood safety to 8,000 individuals in the focus countries. Responding to the urgent need to produce an adequate and safe blood supply in developing countries requires a comprehensive and coordinated effort among Ministries of Health, outside donors, and experts in blood transfusion throughout the world. As countries continue to develop

basic infrastructure and strengthening systems that they can maintain over the long-term, safe blood services will begin to expand for national coverage. The large-scale programs implemented as part of the Emergency Plan have begun to address this need with a thorough and comprehensive approach that will produce immediate results, long-term improvement, and the likelihood of sustainability.