

MAKING SAFE BLOOD AVAILABLE IN AFRICA

HEARING AND BRIEFING
BEFORE THE
SUBCOMMITTEE ON AFRICA, GLOBAL HUMAN
RIGHTS AND INTERNATIONAL OPERATIONS
OF THE
COMMITTEE ON
INTERNATIONAL RELATIONS
HOUSE OF REPRESENTATIVES
ONE HUNDRED NINTH CONGRESS

SECOND SESSION

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MAKING SAFE BLOOD AVAILABLE IN AFRICA

TUESDAY, JUNE 27, 2006

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON AFRICA, GLOBAL HUMAN RIGHTS
AND INTERNATIONAL OPERATIONS,
COMMITTEE ON INTERNATIONAL RELATIONS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 3 o'clock p.m. in room 2172, Rayburn House Office Building, Hon. Christopher Smith (Chairman of the Subcommittee) presiding.

Mr. SMITH. The Subcommittee will come to order. Good afternoon everyone, and welcome to the Subcommittee on Africa, Global Human Rights and International Operations, and I do apologize to our witnesses for the hour delay. We did, as you know, have a markup on an important resolution dealing with India, which, because of several amendments that were considered, carried into the early afternoon. Again, I apologize for that delay.

It is my pleasure to convene this hearing of the Subcommittee. Today the Subcommittee is examining the important issue of the availability of safe blood within the medical systems of sub-Saharan Africa. I want to thank Chakah Fattah for originally suggesting that the Subcommittee convene this hearing. He brought to the Subcommittee a great deal, a wealth of information that all of us on the Committee found to be very, very useful, informative, provocative and more importantly demanding of our action. So I want to thank him for his leadership both on the Appropriations Committee in the Congress and for helping this Subcommittee as well.

From my extensive travels to Africa, which have included visits to HIV/AIDS clinics and other healthcare facilities, I too have long been concerned about global health issues including HIV/AIDS, malaria and maternal health. It is disturbing, to say the least, to visit a district hospital in remote areas of Africa that only have one or two pints of blood in their refrigerators and to see rooms filled with expectant mothers and emaciated children experiencing an emergency.

One also has to experience a long drive on the narrow, sub-Saharan two-lane highways to appreciate the significant danger of serious road accidents and resulting need for blood to save the injured. One dodges past overloaded trucks broken down in the middle of the road and passes within feet of adults and children walking on the road's edge intermingled with goats and other livestock.

The increased dangers and health crises in Africa call for increased means to address them, including adequate and safe sup-

plies of blood. A medical benefit related to safe blood that I have long promoted is the use of umbilical cord blood stem cells. On December 20, 2005, the Stem Cell Therapeutic and Research Act of 2005—which I sponsored and my good friend and colleague was one of the principle cosponsors—that legislation provides \$265 million for life-saving stem cell therapy, cord blood and bone marrow transplant, and it was signed into law by the President.

Today in America, umbilical cord blood stem cells and adult stem cells are curing people of a myriad of terrible conditions and diseases. One of my greatest hopes is that these current day miracles will become common medical practice and available to tens of thousands of patients, including, one day, to the peoples of sub-Saharan Africa.

This hope is inspired by people who have overcome incredible odds, thanks to cord blood stem cell transplants, like Keone Penn. He was born with severe sickle cell anemia, which afflicts more than 70,000 Americans, about one out of every 500 in America, and a disproportionate number of others. It is also a serious problem in Africa. According to a WHO report on sickle cell anemia, in 2005 over 200,000 infants are born each year with sickle cell disease on the subcontinent of Africa.

After years of suffering when no other treatments worked, Keone Penn's doctors decided as a measure of last resort to perform a transplant with cord blood from an unrelated donor. This was the first time such a transplant had been tried for sickle cell disease, and it proved successful. One year after the transplant, Keone's doctors pronounced him cured.

Cord blood stem cells hold enormous promise, and have already been used to treat thousands of patients of more than 67 diseases. This potential should not be limited to the developing world but also for those in Africa and in other parts of the world where it has great utility.

Again, I want to thank my good friend and colleague, Congressman Chakah Fattah, who knows of my interest and the interest of other Members of this Committee in Africa and health issues. I know that he shares my related interest in cord blood, and he helped to move the legislation, particularly when it was bottlenecked over on the Senate side.

Therefore, again, I am happy to take his suggestion of having this hearing to propel the Subcommittee into this debate. We have not done all that much in the past on the availability of blood in Africa. I can assure you, my friend and colleague, that we will now really focus on this.

In its recent report for 2007, it bears noting, the House Appropriations Committee expressed its concern about the existence of unsafe blood as a source of HIV infection in the developing world. The report notes that contaminated blood is of particular concern for women who require a blood transfusion to address complications from pregnancy and childbirth and for children whose lives are threatened by anemia.

Based on these concerns, the Committee requested that the Office of the U.S. Global AIDS Coordinator together with the Agency for International Development, the Department of Health and Human Services and other relevant parties develop a comprehen-

sive multi-year strategy for the PEPFAR focus countries. The strategy should aim to achieve a sufficient supply of blood for each country's needs, the recruitment of voluntary non-remunerated blood donors, universal testing of donated blood for infectious diseases and the reduction of unnecessary transfusions.

A separate strategy is requested for non-focus countries that would provide for the standardized operation and control of blood collection, adequate training, documentation and assessment measures.

This hearing provides the opportunity to examine the extent of the current need in sub-Saharan Africa for an adequate supply of safe blood. We look forward to hearing from our distinguished witnesses about the challenges as well as the opportunities that this region faces in providing this essential medical service.

We also hope to learn about what we need to do to overcome the difficulties and the best means to accomplish our common goal: A safe and adequate supply of blood to meet the needs of the people of Africa.

I would like to yield to my friend and colleague, Mr. Payne, for his opening comments.

[The prepared statement of Mr. Smith follows:]

PREPARED STATEMENT OF THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HUMAN RIGHTS AND INTERNATIONAL OPERATIONS

It is my pleasure to convene this hearing of the Subcommittee on Africa, Global Human Rights and International Operations. Today, the Subcommittee is examining the important issue of the availability of safe blood within the medical systems of sub-Saharan Africa.

My extensive travels to Africa have included visits to HIV/AIDS clinics and other health care facilities, and I have long been concerned about global health issues including HIV/AIDS, malaria, and maternal health. It is disturbing, to say the least, to visit district hospitals in remote areas of Africa that have only one or two pints of blood in their refrigerators and to see rooms filled with expectant mothers and emaciated children experiencing an emergency. One also has to experience a long drive on the narrow, sub-Saharan two-lane highways to appreciate the significant danger of serious road accidents and the resulting need for blood to save the injured. One dodges past overloaded trucks broken down in the middle of the road and passes within feet of adults and children walking on the road's edge, intermingled with goats and other livestock. The increased dangers and health crises in Africa call for increased means to address them, including adequate and safe supplies of blood.

A medical benefit related to safe blood that I have long promoted is umbilical cord-blood stem cells. On December 20, 2005, the Stem Cell Therapeutic and Research Act of 2005, which I sponsored, was signed into law. This law provides \$265 million for life saving stem cell therapy, cord blood and bone marrow transplant. Today, in America, umbilical cord-blood stem cells and adult stem cells are curing people of a myriad of terrible conditions and diseases.

One of my greatest hopes is that these current-day miracles will become common medical practice and available to tens of thousands of patients, including one day to the peoples of sub-Saharan Africa. This hope is inspired by people who have overcome incredible odds thanks to cord-blood stem cells transplants, like Keone Penn who was born with severe sickle cell anemia. Sickle cell anemia afflicts more than 70,000 Americans and a disproportionate number of African-Americans. It is also a serious problem in Africa. According to a WHO report on sickle cell anemia, in 2005 over 200,000 infants are born each year with sickle cell disease in Africa.

After years of suffering, when no other treatments worked, Keone's doctors decided as a measure of last resort to perform a transplant with cord blood from an unrelated donor. This was the first time such a transplant had been tried for sickle cell disease, and it proved successful. One year after the transplant, Keone's doctors pronounced him cured.

Cord blood stem cells hold enormous promise, and have already been used to treat thousands of patients of more than 67 diseases. This potential should not be limited to the developed world, but should also be explored for the benefit of the peoples in Africa and around the world.

My good friend and colleague Congressman Chakah Fattah knows of my interest in health issues in Africa, and shares my related interest in cord blood stem cell research and medical treatments. Therefore, I was happy to take up his suggestion that the sub-committee conduct this hearing on the availability of safe blood transfusions in Africa.

In its recent report for FY 2007, the House Appropriations Committee expressed its continued concern about the existence of unsafe blood as a source of HIV infection in the developing world. The report notes that contaminated blood is of particular concern for women who require a blood transfusion to address complications from pregnancy and childbirth and for children whose lives are threatened by anemia.

Based on these concerns, the Committee requested that the Office of the Global AIDS Coordinator, together with the Agency for International Development, the Department of Health and Human Services and other relevant parties, develop a comprehensive multi-year strategy for the PEPFAR focus countries. The strategy should aim at achieving a sufficient supply of blood for each country's needs, the recruitment of voluntary, non-remunerated blood donors, universal testing of donated blood for infectious diseases, and the reduction of unnecessary transfusions. A separate strategy is requested for non-focus countries that would provide for the standardized operation and control of blood collection, adequate training, documentation and assessment measures.

This hearing is providing the opportunity to examine the extent of the current need in sub-Saharan Africa for an adequate and safe supply of blood. We look forward to hearing from our distinguished witnesses about the challenges as well as the opportunities that this region faces in providing this essential medical service. We also hope to learn about what we need to do to overcome the difficulties and the best means to accomplish our common goal: a safe and adequate supply of blood to meet the needs of the people of Africa.

Mr. PAYNE. Thank you very much, Mr. Chairman. I do not think there is anything more important than what our hearing is on today, making safe blood available in Africa. I commend you for calling this important hearing and of course to acknowledge my good friend and colleague, the Honorable Chakah Fattah, who early on a year or 2 ago talked about his idea of making safe blood available in Africa. I commend him for steadfastness.

There are many, many programs that are important and necessary and needed. However, the appropriators have a very difficult time venturing into new programs. It is with a great deal of persistence that we could see a new program come in that we are talking about. I would like to actually commend you for your persistence and concern.

As we will be hearing from our witnesses, there is a need for our immediate assistance concerning the urgent problem of blood storage and unsafe blood particularly in Africa. Unsafe blood only contributes to the enormous burden of HIV and AIDS. The risks of HIV infections through unsafe blood and blood products is exceptionally high, 95 to 100 percent compared to other routes of HIV exposure such as mother to child which is 11 to 32 percent and for other sexual contacts.

In an era where HIV and AIDS has and still is devastating and killing millions, the importance of making safe blood available in Africa is very, very crucial. The problem of blood storage is another issue especially because the primary people affected are women and children. We must not ignore that we face many challenges such as limited resources and inadequate infrastructures that will greatly slow efforts.

However, we must still take immediate steps to prevent further crises, and strive for improved health conditions. For example, organizations such as the World Health Organization along with others have advocated a strategy to achieve effective, cost efficient and safe national blood supply systems with the aim of increasing voluntary blood donations, screening blood for infections and prioritizing blood transfusions.

I would like to hear about U.S. support for these efforts and innovative strategies that the international community can collaborate on. I hope that we can work together to strengthen the system for blood safety and availability. I was very pleased at the announcement yesterday where the Buffet and the Gates group would be coming together, and this may be that, an area where we could even make an inquiry into that new expanded foundation to even assist in some of the Federal dollars that we are looking at putting into this.

I certainly would like to thank all of our witnesses for their efforts and progress in ensuring universal access to safe blood, and look forward to hearing the testimony of our witnesses. Thank you.

Mr. SMITH. Thank you very much, Mr. Payne. Mr. Tancredo? If not, then I would like to welcome the Honorable Chakah Fattah, an experienced lawmaker serving in his sixth term in the U.S. House. He represents the Second Congressional District of Pennsylvania, which includes parts of Philadelphia and Cheltenham Township. Congressman Fattah has been a leader and a strong and powerful advocate on the issue of safe blood for Africa for a number of years in his position on the House Appropriations Committee. Congressman, the floor is yours.

STATEMENT OF THE HONORABLE CHAKAH FATTAH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF PENNSYLVANIA

Mr. FATTAH. Thank you, Mr. Chairman. Let me first of all commend you in your leadership on this Subcommittee and the Ranking Member for your interest in this matter, and for convening this hearing today on a subject that I think has gotten far too little attention, and also it is exceptionally unique in our chamber that you would have a collaboration between appropriators and authorizers on a matter.

I want to indicate my appreciation for your willingness to hear from an appropriator on a policy matter but this is something of extreme importance. I have had long conversations with you and the Ranking Member, and I want to thank you.

Before I get into the substance of my abbreviated remarks I want to also add into the record letters from the Secretary General of the UN in support of this initiative, and also the Ambassador for the European Union, and also from Prime Minister Tony Blair, all indicating in sum and substance the same points that you made which is that this issue has gotten far too little attention.

There have been billions assembled to combat the problem of AIDS, particularly in sub-Saharan Africa. We have had a long debate between abstinence and condoms and the whole focus on the ABC approach but too little attention has been focused on this particular problem.

We have in these 45 countries something less than 10 percent of the world's population but 60 percent of the cases of people living with HIV and some 15,000 people dying everyday. It is clear that a significant number of people have gotten through blood transfusions diseases that are transmitted through the blood supply including HIV, and the World Health Organization in an executive summary of a report that I will also provide for the Committee's records, says that, 'Unsafe blood transfusions have significantly contributed to the burden of new HIV infections in Africa. The risk of transfusion associated transmissions of HIV infection is exceptionally high, 95 to 100 percent, compared to other routes of HIV exposure.'

Now, in our own country we recall not too long ago when we had problems in our blood supply, and we had to create new routines for testing blood and making sure that the blood supply was safe in terms of for transfusion purposes from HIV, and we accomplished that in the early 1980s. We actually know how to do this. It is not something that we have not accomplished. We know how to do it. We know how to train others to do it, and it is something that we could accomplish and save many, many lives in sub-Saharan Africa.

This is a problem in other parts of the world also, in developing countries, and it is critically important I think that we focus some of our efforts in areas where we can demonstrate a result, and we know for certain that just because a child has malaria does not mean they have to have a death sentence through a blood transfusion that gives them a disease that will be fatal like HIV. There would also be the benefits of being able to screen for other diseases that would be transmitted through the blood supply.

I come today first of all to say that we have asked for a study and a review of this matter. You are going to hear from officials with a variety of agencies, the Global AIDS Coordinating Office, the CDC, the World Health Organization and others about their review of this matter but clearly it is an area where we can have an impact. We are today having an impact in terms of some of the pediatric cases through efforts through USAID and through entities here in America and around the world working on this problem.

I believe that we can have a major impact on this if we would make it a major part of our policy focus in terms of the HIV epidemic in Africa, that we can save many, many lives and the cost benefit ratio compared to other dollars spent I think would bear out well. I also think that there are plenty of others who want to be helpful, and I met with the Ambassador from the European Union, and they provide substantial aid sub-Saharan Africa.

They indicate in the communications that I am putting in the record that they would like to see this as a major part of their thrust. I think there are partnerships that can be developed.

I have also met with officials from the Gates Foundation because you do point out correctly that there are a number of entities, including some Mr. Chairman that you have mentioned associated with the Catholic Charities Organization that is doing work there and others that we could involve in a way to substantially respond to this problem.

I appreciate the fact that you are holding this hearing, and resting on our decisionmaking we could impact perhaps millions of lives that otherwise would be lost to a disease that we do not have a cure for, we do not have a vaccine for but we could make certain that when people have a blood transfusion that they in fact do not have to be infected with this disease. That is one route that we can cut off. We know how to do it, and the resources are available to do it.

It is just a matter of us coming together, and we have found a bipartisan support for this on the Appropriations Committee, Chairman Jerry Lewis, and the Chairman of my Subcommittee on Foreign Operations, Chairman Kolbe, and others are quite supportive of this effort, and we would like to find a way after this hearing for us to go down this road together and make a dynamic difference in terms of the chances of people, particularly women and children—19 of the 20 countries in this world in which women die through post pregnancy hemorrhages and in need of safe transfusions are in sub-Saharan Africa.

We can make a difference. This is I think a signal that we can work together and find concrete routes to solve some of the more intractable problems that we face in this world. It is not just Warren Buffet and Bill Gates who have gotten together but if appropriators and authorizers can find a way to join hands on this I think we can make a significant difference. I thank you, Mr. Chairman, and I thank the Committee. I also thank the Ranking Member.

[The prepared statement of Mr. Fattah follows:]

PREPARED STATEMENT OF THE HONORABLE CHAKAH FATTAH, A REPRESENTATIVE IN
CONGRESS FROM THE STATE OF PENNSYLVANIA

Thank you, Chairman Smith, Ranking Member Payne, and distinguished members of this committee. I appreciate the opportunity to appear before you today, and would like to thank this committee, particularly the Chairman and the Ranking Member, for your continued interest in matters of social justice and human rights.

Mr. Chairman, much of the current discussion pertaining to the fight against global HIV/AIDS involves advocating for the implementation of one of three possible options. One possible option is to demand increased funding to the United States' contribution to the Global Fund, which was established to provide funding to mostly developing countries to combat HIV/AIDS, tuberculosis, malaria, and other infectious diseases. Another frequently advocated option is to place continued pressure on pharmaceutical manufactures to provide low cost antiretroviral drugs to developing countries. Antiretroviral medicines prevent HIV from replicating and causing further damage to a compromised immune system, but many of these drugs require funds that are far beyond the means of most people residing in developing countries. The third option involves either the aggressive promotion of abstinence from all sexual activity, or encouraging the use of condoms to drastically reduce the possibility of transmission of HIV/AIDS due to unprotected sex.

Mr. Chairman, I suggest to you a different focus that does not involve battling over the relative size of the U.S. contribution to internationally funded programs as compared to other donor nations, evoking the invariably passionate debate on the merits of whether abstinence is an effective strategy, or weighing the morality of potentially promoting sexual promiscuity of providing condoms to adults and sexually active children. Rather, more must be done to ensure the availability of a safe, clean, blood supply in Sub-Saharan Africa and other parts of the developing world, where preventable contamination from numerous infectious diseases such as HIV, hepatitis B, and hepatitis C occurs at unacceptable levels.

The transmission of infectious diseases such as HIV due to an unsafe blood supply is *completely preventable*. Ensuring a clean blood supply is the only HIV/AIDS preventative measure that is virtually 100 percent effective. In the United States, for example, the blood supply has never been safer than it is today. Techniques for screening and testing blood donors have dramatically reduced the risk of transfusion transmitted viral infection. The risk of infection from HIV or AIDS from contami-

nated blood has decreased from as high as 1 in 100 units in some U.S. cities in the early 1980s to currently 1 in 1 billion units. The safety and integrity of the blood supply is maintained in the U.S. by mandating all collected and donated blood must comply with the Food and Drug Administration's (FDA) blood safety regulations, which consist of five layers of overlapping safeguards. The regulations address:

- *Donor Screening*: Potential donors are screened by questioning them about their health, medical history, and risk factors for infectious diseases. Individuals whose blood may pose a health hazard are deferred
- *Deferral Registries*: Independent blood centers maintain a list, or registry, of all deferred donors and check all potential donors against that list. The American Red Cross has established a national registry that covers all its regional blood centers. Donors who are deferred on a temporary basis may resume donating once the deferral period has ended and provided the reason for the deferral no longer exists.
- *Blood Testing*: Donated blood is tested for infectious disease, including HIV, HBV, and HCV. Positive tests are discarded and the donors are deferred.
- *Blood Quarantining*: Blood donations are quarantined until they have been tested and the donation records verified.
- *Correcting System Deficiencies*: Blood centers must investigate any breaches of these safeguards and correct deficiencies that are identified by themselves or during FDA inspections.

With HIV-positive rates approaching or exceeding 20 percent in Sub-Saharan Africa, blood transfusions account for an ever-growing percentage of new HIV/AIDS cases. Of the estimated 6 million blood transfusions performed each year in sub-Saharan Africa, as many as half are improperly or untested for infectious diseases. Less than half of all African countries have adopted standard national blood transfusion policies that would limit HIV infections. More disturbingly, less than one-third of all African countries have some type of policy that attempts to limit HIV infection through blood transfusion.

The global AIDS pandemic is well documented. Sub-Saharan Africa has just over 10 percent of the world's population, but is home to more than 60 percent of all people living with HIV, which is approximately 25.8 million. In 2005, an estimated 3.2 million people in the region became newly infected, while 2.4 million adults and children died of AIDS. Worldwide, there will be an estimated 45 million new cases of infections due to HIV/AIDS by 2010 if efforts to fight the pandemic are not aggressively increased.

The World Health Organization (WHO) estimates that approximately 120 countries lack proper blood supplies and offer inadequate screening. Out of the total population of HIV/AIDS infected persons, the WHO estimates that up to 10 percent of infections are from corrupted blood supplies and tainted blood transfusions. As I previously noted, these infections are *100 percent preventable*. Understand, over 300,000 people in Sub-Saharan Africa alone would be saved from enduring unbearable hardship and pain due to HIV/AIDS each year.

There are many moving examples of personal tragedy throughout the world due to blood transfusions from unsafe blood supplies. Five years ago, a gentleman by the name of Raj Shekhar received a blood transfusion after an accident at a time when blood harvesting programs in India had few safeguards. Nearly a year later, he tested positive for HIV after being hospitalized for severe chest pain. Instead of being admitted to the operating room, his doctor refused to perform the necessary surgery due to fears of infection. Soon after learning Raj was infected with HIV, his wife left him.

In a similar instance, the wife of a couple living in the Philippines in a squatter camp near Manila's financial district required a blood transfusion due to a serious illness. Hospital officials gave the wife six units of blood, some of which were infected by HIV. Before her own contraction of the disease, she believed the virus to be a disease that afflicted homosexual men. Fearing her husband's reaction, she chose not to tell him of her infection. The wife and her husband continued to engage in unprotected sex despite the wife's knowledge she would probably infect her husband with HIV. The wife later became pregnant and gave birth to a baby girl. Though the couple's daughter did not contract the disease, both parents developed the AIDS virus to their exposure to HIV.

Assuring the existence of a safe and clean blood supply is the most cost effective and commonsensical approach to reducing the number of newly reported HIV cases each year. Recognizing more needs to be done to ensure the safety of the blood supply in Africa, last year I successfully appealed to my colleagues on the Foreign Operations Subcommittee on Appropriations to direct the Centers for Disease Control,

the Office of the Global AIDS Coordinator, USAID, and the World Health Organization (WHO) to jointly issue a report detailing the severity of the impact contaminated blood has on the global fight against HIV/AIDS, as well as providing specific policy recommendations for immediate implementation. To ensure the safety of each blood unit, the following key activities were identified: (1) establishment of systems for the supply of test kits and reagents for blood screening and good laboratory practice; (2) recruitment of safe blood donors; (3) implementation of quality systems in blood transfusion services, and; (4) safe and appropriate use of blood to reduce unnecessary transfusions.

Acknowledging the importance of the need to provide safe blood, the Foreign Operations Subcommittee on Appropriations has recently indicated in the Foreign Operations Committee Report for Fiscal Year 2007 that:

The Committee remains concerned about the problem of unsafe or contaminated blood as a source of HIV infection in the developing world. According to the March 2006 Report on Blood Safety, submitted by the Office of the Global AIDS Coordinator, "substantial problems have been documented" across all components of safe blood programs in developing countries. Many hospitals in the developing world do not have effective or complete screening of blood, and as a result, there can be a risk of transfusion-transmitted infectious diseases. The prevalence of contaminated blood acutely impacts women requiring blood transfusions due to complications from pregnancy and childbirth, as well as children with life-threatening illnesses such as anemia.

Worldwide the major risk is hepatitis followed by HIV, malaria and syphilis. The Committee recognizes that there are a wide array of challenges in order to achieve adequate capacity and sustainability to support blood transfusion services in developing countries, including adequate infrastructure (such as reliable electricity for refrigeration), staff recruitment and training, laboratory equipment, effective legislation/policy, and financial/management systems to support blood services.

The Committee understands that the Emergency Plan currently supports the Ministries of Health or the government's National Blood Transfusion Service (NBTS) in fourteen of the fifteen focus countries for the purpose of developing nationally directed regionalized blood systems. The Committee strongly supports these activities and the Emergency Plan's goal of establishing high-quality, sustainable blood transfusion-safety programs in each country. The Committee notes that the bill includes an over 40 percent increase in bilateral funding for focus countries and urges the Coordinator to increase significantly funding for safe blood programs over fiscal year 2006 levels.

The Committee also recognizes that capacity building and infrastructure development are processes that require a period of years which realistically must be approached incrementally. In the Committee's view, to achieve success in advancing blood safety requires a comprehensive and coordinated strategy among Ministries of Health, local communities, donors, and experts in blood transfusion.

Therefore, the Committee requests that the Office of the United States Global AIDS Coordinator, working in coordination with other health sectors in USAID and HHS, and in consultation with WHO, other blood safety experts, and private foundations active in global health, develop and submit to the Committee a comprehensive, integrated multi-year strategic plan for PEPFAR focus countries to achieve the following:

- (1) A sufficient supply of safe blood to meet the needs of the country;*
- (2) A continuous and adequate supply of voluntary non-remunerated blood donation from the safest possible donors from low risk populations;*
- (3) The universal testing of donated blood, including quality assured screening of all donated blood for infectious diseases; and*
- (4) The reduction of unnecessary transfusions; safe and rational blood utilization, and the use of alternatives to transfusions whenever possible.*

The pace and resource requirements of the plan should consider the other medical (e.g. mother-to-child transmission and safe medical injections) and non-medical prevention activities in PEPFAR countries and the impact of the strategic plan on maintaining a diversified prevention portfolio. The Committee further requests the Office of the Global AIDS Coordinator, working in coordination with the aforementioned agencies and non-governmental organizations, develop and submit to the Committee a comprehensive implementation strategy for non-focus countries that achieves standardized operation and controls of blood collection, adequate training, documentation, and assessment measures. The strategic plans for both focus and non-focus countries shall be submitted to the Committee no later than 180 days of enactment. Finally, the plan also should examine ex-

penditure rates and factor them into the recommendations in order to ensure the timely obligation and expenditure of funds.

Through the relentless efforts of myself and my staff, I continue to garner enthusiastic support for my call to ensure the availability of a safe and clean blood supply in Africa from numerous countries, international governmental organizations, and non-governmental organizations. Many of these NGOs provide the tactical support necessary for carrying out aid programs and will be an integral part of ensuring Africa's safe blood supply. Africare, U.S. Doctors for Africa, the Global AIDS Interfaith Alliance and the Global Impact Foundation have all enthusiastically endorsed my program. Julius Coles, the President of Africare, has acknowledged that this program is a "necessary component of HIV/AIDS prevention that has gotten too little attention up to now." The support I have received from various NGOs reinforces my conviction that the problem of contaminated blood in Africa is one that we must rectify as quickly as possible.

I am also heartened by the enthusiastic international support for my call for a clean blood supply. English Prime Minister Tony Blair indicates safe blood is an integral part of the development of a health care infrastructure within African nations. Similarly, the Head of the European Union Delegation in Washington, DC, Mr. John Bruton, believes that my fight to secure a safe blood supply will have a lasting effect on the impact of infectious disease in Africa, indicated that, "Blood safety should be an integral part of any national strategy for HIV/AIDS prevention, as well as a standard component of national health policies." Lastly, Secretary General Kofi Annan has also endorsed my efforts, stating that my Safe Blood Initiative "will play an invaluable role in benefiting the lives of millions of Africans." I am humbled by the international support of my initiative, and I look forward to working with these countries and agencies as we work to help improve the lives of Africans now and in the future.

A problem of such magnitude demands an unequivocal commitment from Congress to combat all aspects of the HIV/AIDS scourge. I believe with the leadership of the distinguished Chairman and the Ranking Member, substantive measures can be implemented to ensure significant improvements to blood and transfusion services that will result in a clean and reliable blood supply in Africa. I thank the distinguished members of this committee, and I will gladly answer any questions.

Mr. SMITH. Thank you very much, my friend. First of all, I have read the report that was submitted pursuant to your request, and I think it is a very good report in many ways. It does point out that the integrated strategy for blood safety adopted by the Emergency Plan and endorsed by focus countries includes a sufficient supply of blood, voluntary non-remunerated blood donation, universal testing and I think we all will agree, especially in light of the number you pointed out from the report by the WHO. If some contamination is in the blood, the recipient is going to get it. With 95 to 100 percent probability, if it is in the blood you are going to get infected, and I think that point—as opposed to sexual transfer or some other means, while a baby is being born or whatever—no other means of transmission comes close.

The WHO report did say that 5 to 10 percent of new HIV infections are transmitted through unsafe blood amounting to between 160,000 and 320,000 new infections per year as a result of unsafe blood in sub-Saharan Africa. I will be asking our other witnesses if they agree with that number but that is a staggering number of, again, preventable diseases.

I think you make another good point that other diseases, as well, are transmitted through the blood or contaminated blood: Hepatitis B and C, syphilis, malaria, and West Nile virus to name a few. As the blood is cleaned, certainly there are other positive outcomes from other diseases not contracted, as well.

Your testimony was very comprehensive, so I thank you for that. I basically have one question. Do you think we are spending enough? The Administration, I believe, went from \$25 million to

\$50 million to \$32 million. Their argument, I think, is that there is money in the pipeline, an enormous amount of it, and it is building up an infrastructure and trying to encourage countries to develop that infrastructure. Are we spending that money fast enough in your view? Is there sufficient funding available?

Mr. FATTAH. I would say a couple of things, Mr. Chairman. One is I think there is a tremendous amount of effort being extended but I think that there is too much passivity in terms of the urgency. That is that if you have 15,000 people dying each day in sub-Saharan Africa, and we have billions sitting in a global AIDS fund, if we have billions in the Millennium Challenge Account. There are reasons why we have not spent down large amounts of these dollars but this particular issue has not really been at the forefront.

I question and there is a record of Ambassador Tobias before he took his new position in his old position as focus in terms of the Global AIDS Coordinator, and this really was not at the front and center of their work. I just want to see us move this further.

I was in Nigeria and spoke to the health minister there. It was indicated to me that over 22 percent at that time of the new HIV cases were related to blood transfusions, and some of what is being said once you pull back the envelope is not as accurate as we might want it to be. That is that countries report that they have been 100 percent testing but there is no one that is actually knowledgeable about this that believes that there is actually 100 percent testing of the blood before it is being made available for transfusions. I would invite you to question other witnesses on that.

Secondly, they have a waiver for testing in most of these countries when they say that it is a family contribution, and they produce someone in which many experts believe are remunerated individuals and who then say that they are a family member and provide the blood, and therefore they move around the testing requirement. When I began this effort a year and a half ago, I called up into my office experts from CRS, who know as much as we can know about Africa. I asked them one simple question. These are our own experts here in the Congress. I asked, if I were traveling in Africa and I needed to get a blood transfusion, what country would I want to be in at the time that I needed that transfusion? The CRS experts that work for the Congress said that there would be no place that they would think that I would want to get a blood transfusion. In fact, there would be other circumstances that would be provided for me because there really was not a safe system to control and make sure that the blood supply is free of diseases in much of the continent.

We spend about \$357 per unit of blood in the United States to make sure that if we get a transfusion it is safe. Less than a dollar and a half is being spent in sub-Saharan Africa in any system at all to deal with the availability of safe blood.

Mr. SMITH. You make a good point about whether or not we are getting accurate information. I noted again in the UA Working Group documents they claim, based on their statistics, that 10 percent of the total are from paid donors, 32 percent from family replacement donors, and voluntary unpaid donors make up 57 per-

cent, which sounds pretty positive unless it is inaccurate. I think your point was well taken. Mr. Payne.

Mr. PAYNE. Once again as I have indicated, Congressman Fattah, I commend you for spearheading this initiative in the Appropriations Committee. We certainly, as an authorizing Committee, here will attempt certainly to work closely with you to move this forward. I wonder if in your research has the question about needles come up? The fact that healthcare providers in many instances are themselves being infected by their work around the blood, and in particular needles and sometimes being pricked themselves by mistake? In your talk about clean blood, has there been any conversation regarding needles in general?

Mr. FATTAH. One of the things that I think you are going to hear from future witnesses today is that there is a tremendous need for training and for a laboratory environment in which we can avoid some of that. One of your colleagues, Steve Rothman, there is an expert in New Jersey, a doctor who specializes in helping train doctors in what are called bloodless surgeries but really is a way to limit the need for large amounts of transfusions.

There are a range of ways that we can go about this issue but clearly—and I said this to the Chairman—that if we are going to clean up the blood supply it will require some effort. It will require the ability to store blood, to recruit voluntary healthy donors, to test blood, to train African doctors and healthcare professionals.

The African Union has now set up an entity to focus in on—and you and I have discussed that—the healthcare infrastructure. Clearly some part of the challenges on the continent relate to the whole issue of health and the infrastructure not just on this question but on many questions related to the healthcare infrastructure is weak up to an including creating electricity to rural villages and other places so that you can have an ability to store blood and blood products safely.

Mr. PAYNE. I certainly appreciate and there is no question that the healthcare system is weak in many of the developing countries. As a matter of fact, that was one of the questions that President Toleman Becky in South Africa was talking about when he was sort of misunderstood to some degree on his question about HIV and AIDS being just equal to other diseases. I think he was really trying to make the point that unless you get a healthcare system that can provide safe health in general that you are bound to fail. I think you certainly reiterate the fact that we really have to work on a system to assist developing countries to have a sustainable energy, have various equipment, refrigeration, things that they need in order to try to get the job done.

Once again, let me commend you for this. With that, Mr. Chairman, I will yield back the balance of my time.

Mr. SMITH. Ms. Lee.

Ms. LEE. Thank you, Mr. Chairman. Let me also thank you for this hearing, and thank you for your leadership. I also visited Nigeria several years ago and met with the ministry of health, the President and others—I believe it was Mr. Gadenson when he was our Ranking Member—and learned of this very critical need and aspect of the whole HIV/AIDS pandemic.

For the life of me, I still cannot figure out why understanding that a large percentage of HIV and AIDS transmission are related to unsafe blood transfusions, here in America we have been able to solve that crisis, that problem. Why in the world—and this is one thing that I tried to figure out when we were there—on a country-by-country basis as we look at PEPFAR and the Global Fund and all of these initiatives that this is not a specific requirement, and that we do not find?

Certainly here in the United States we have the Red Cross. We have other partners who could take a country, go over to that country, set up shop and help them within a year's time develop the infrastructure and develop what is needed to be able to begin to turn this around.

You know I cannot figure out why that has not happened or why it is not happening now. I wondered if you had any insights since you have been working so hard on this, Mr. Fattah, and your leadership has been so vital in bringing this to this point? No one has been able to answer that question.

Mr. FATTAH. I think that there is a tendency when you look at the question of the HIV epidemic on the continent and in sub-Saharan Africa to think that it is just so enormous that almost nothing can be done. Then we have through President Bush's leadership created a multibillion dollars initiative that will be scaled up to \$15 billion over a few short years in the global AIDS fund are focused at HIV, malaria and TB.

Now, we have children—it is estimated by one of the State Department vendors that provide safe blood for Americans if they are in need of a transfusion anywhere in Africa—that there are at least 2 million of these 25 million victims of HIV are children who have gotten malaria through mosquito bites and which could have been prevented or could have been treated in other ways but at some point absent that treatment those children are in need of blood transfusions. So you solve one problem by giving almost a death sentence to a young person through an unsafe contaminated blood transfusion.

I think the point that I would make is I think there is obvious benefits in the ABC approach, and I think there are good hearted people working on this. This is an area in which this is an absolute way to prevent transmission through this method, and that is through investing in a safe blood supply and all of the elements that would be needed to do that. That is that you would need laboratories and training and electricity and so on to get this done.

If you think about what we can do when we are compelled to do it, I mean we can transport anything almost anywhere in the world. We just funded a new blood bank in Nigeria through USAID but we could literally put hundreds of new blood banks in sub-Saharan Africa if we decided that we wanted to do it, and we could do it not in 5 year's time. We could literally do it in less than 1 year because we as a nation and especially if we unite with other partners, if we decided that the lives that could be saved were worth saving then we could kind of have a different sense of urgency about this challenge.

Ms. LEE. Mr. Chairman, I think that is the point. This is so clear, and I guess I am asking you from your perspective why have

we not made this a priority, understanding that the Global Fund is there to fund initiatives to prevent and treat HIV and AIDS. We have PEPFAR. We have USAID. We have several initiatives, and we should be going to the world community to say we can reduce the incidence of transmission if in fact we have safe blood supply. It just seems like a no-brainer to me. We have done it here in America. Other countries have done it. Why can we not do it on the continent of Africa?

Mr. FATTAH. I think where we are now is that we have arrived at a consensus that we are going to do it. I have talked to officials in the Bush Administration. We got this study that you are going to hear about, and we have new language in the Foreign Ops bill this year to move this matter forward. I think that the attention that the International Affairs Committee has now brought to this matter and the dialogue that will follow me, will be immensely helpful in having all of the various entities that are involved understand that the Congress in a bipartisan way wants to see some progress made on this matter, and wants to see it as a very high priority.

Ms. LEE. Thank you, Mr. Chairman. This is very important this development in this hearing today because many of us have tried to figure out how to move this forward, and thank you again for your leadership.

Mr. SMITH. Thank you. Let me just conclude with a question and something to take back—something I will be asking of our other witnesses, as well. In the report, Mr. Fattah, which you asked to be produced, there was a discussion on incremental versus non-incremental approaches, and the conclusion is that only the incremental approach is realistic for establishing blood services in developing countries, including in sub-Saharan Africa, and then they give their reasons for that conclusion.

I wonder if there can be accelerated incremental approach, given the fact that so many people are dead or dying. One of our witnesses later on, Dr. Jerry Holmberg, will point out that an estimated 14 million blood units are needed. He cites in 2004 that only 3.6 million units were collected.

The issue, I think, is two-fold. It is one of safe blood, so you do not get infected when you get a transfusion, and the other issue is having capacity, because all these others folks who will get sick and are in need of a transfer of blood who will not get it. You and I have both talked about how we have been to hospitals, particularly in the rural setting, where you open up a refrigerator and there is one pint of blood just sitting there, and you wonder how long it has been sitting there. That is a very discouraging thing to see.

If you wanted to comment on that issue.

Mr. FATTAH. Fortunately, I was a student at one point in my life at the Kennedy School, and they had a whole theory on this whole question of nonincremental versus incremental policy initiatives, and we have seen them and various renditions of them in which the urgency and which we want to accomplish something dictates what we do and how fast we try to do it.

There are several pieces to this obviously. If we want to create a system of voluntary donations in a cultural environment in which

donating blood has not been yet seen as something that people generally do, then that is a matter of public education but we do not have to wait 3 years to design a public education campaign and encourage healthy people in Africa to give blood. We could even have people in other parts of the world donate blood.

You could have African-Americans encouraged here to give blood that can go. I mean we can deal with this in a much more urgent way than I think that the study lays out. Again, I think that even though there are some very good and helpful points that are made, I think that part of the discussion is about how many lives can be saved? If it is just 10 percent of 25 million, and what does that mean yearly and how many lives, and therefore how much resources?

I think that the point that you will see in both Kofi Annan's comment here where he says that the HIV/AIDS pandemic poses an unprecedented threat to human security and development in the continent. The epidemic demands an exceptional response, and that this initiative on safe blood will play an invaluable role in benefiting lives of millions of Africans.

You see the European Union which says that they provide a substantial share of the worldwide package of aid that goes to sub-Saharan Africa. Their Ambassador said they are willing to make this their number one priority. If we would I think find ways to partner with others and if we could have help, since we are politicians, designing a program that actually could work I think we could get at this a little bit sooner but I do think we have to give weight to their viewpoints but I do think that they should be questioned on it because we should have a sense of urgency when we have a chance to save lives.

Mr. SMITH. Chakah, thank you so much for your tremendous leadership and for helping us today to better understand this issue.

Mr. FATTAH. Thank you, Mr. Chairman. Let me thank your staff for all of their assistance and thank my staff for their work on this matter. Thank you.

Mr. SMITH. Thank you. I would like to now invite to the witness table our second panel, beginning with Dr. Caroline Ryan who since October 2004 has been detailed to the Office of the U.S. Global AIDS Coordinator where she serves as senior technical advisor for the prevention and technical team lead. Previously, Dr. Ryan served as the Associate Director for International Activities in the Division of STD Prevention, and subsequently served as chief of the Prevention Branch in CDC's Global AIDS Program.

We will then hear from Dr. Robert E. Ferris. Dr. Ferris has served since 2005 as medical transmission manager at the Office of HIV/AIDS at USAID, Division of Technical Leadership and Research. Dr. Ferris completed his residency in 2003 at Internal Medicine/Pediatrics Program at Saint Vincent's Hospital in New York, New York.

We will then hear from Dr. Jerry Holmberg, who has served since 2003 as Senior Advisor for Blood Policy in the Office of Public Health and Science at the U.S. Department of Health and Human Services. Between 1980 and 2000, Dr. Holmberg served in the U.S. Navy, achieving the rank of Commander. During that period, he

held various positions directing blood banks, blood donor centers and frozen blood bank deposits.

Dr. Ryan, if you could begin with your testimony.

STATEMENT OF CAROLINE RYAN, M.D., SR. TECHNICAL ADVISOR, DEPUTY DIRECTORY FOR PROGRAM SERVICES, OFFICE OF THE GLOBAL AIDS COORDINATOR, U.S. DEPARTMENT OF STATE

Dr. RYAN. Mr. Chairman and Members of the Subcommittee, thank you for this opportunity to discuss President Bush's Emergency Plan for AIDS Relief and the successes and challenges of providing safe blood in the developing world, primarily sub-Saharan Africa. This testimony will be a summary of my written remarks.

We greatly appreciate the partnership between PEPFAR and the International Relations Committee, especially the Subcommittee on Africa, and we would like to thank all the Members of the Subcommittee for your commitment to the U.S. leadership in the fight against this tragic pandemic.

The President and the Congress made a strategic decision to direct the activities of the Emergency Plan to focus on the prevention, care and treatment of HIV and AIDS. A focus of the Emergency Plan is to build local capacity, to provide long-term, sustainable programs in the countries with which we partner. Ensuring the availability of safe blood is one component of a multi prong HIV prevention strategy that includes prevention of sexual transmission, prevention of mother to child transmission and prevention of medical transmission.

For the developing countries in which the Emergency Plan works, there are significant challenges to developing and maintaining an adequate, sustainable supply of safe blood. These include a lack of strong healthcare systems, a lack of or inadequate policy around blood safety and clinical use of blood, a lack of basic infrastructure such as consistent electricity for refrigeration and a lack of available and sufficiently trained health personnel.

These conditions are pervasive in sub-Saharan Africa and are part of a larger and more complex development challenge. The Emergency Plan with its clear mandate to prevention, treatment and care for those infected with and affected by HIV/AIDS cannot alone address the infrastructure, policy and capacity challenges faced by developing countries.

At the request of Representative Fattah and the House Appropriations Subcommittee for Foreign Operations, the Office of the Global AIDS Coordinator has prepared a report on blood safety as a component of the HIV/AIDS prevention strategy. Together with our colleagues from the Department of Health and Human Services, the U.S. Agency for International Development and the World Health Organization, we invited a group of technical consultants with expertise in blood safety to discuss the magnitude of the problem posed by unsafe blood products, the level of resources required to address the problem, the feasibility of a nonincremental approach to expanding transfusion services and the cost effectiveness of implementing a safe blood program in reducing rates of infection.

The group's consensus was presented in the report findings provided to this Committee. Let me first discuss the HIV transmission risk from unsafe blood and program components needed to assure its safety. Actual data from PEPFAR focus countries blood programs show an average of 3.2 percent of donors are HIV positive. Several studies have documented that blood transfusions are not the major cause of HIV transmission in most countries, especially those with generalized epidemics where most new infections are a result of heterosexual contact.

There are challenges to providing safe blood at a national level, and these include assuring that a sufficient amount of blood is collected in the country, assuring the implementation of a system to recruit low risk donors, assuring that quality screening of donated blood is occurring and assuring that national policies and oversights to reduce unnecessary transfusions are in place. Without these components in place, there is a higher risk of transfusion transmitted diseases, and these include viral hepatitis, malaria in addition to HIV and AIDS.

To reduce HIV and AIDS transmission risks prevented by blood transfusions, the Emergency Plan supports national programs to improve the quality of blood supplies through improved policies, the establishment of laboratory facilities and commodity procurement and healthcare worker training and management. The Emergency Plan in the focus countries supports national blood transfusion services, and provides technical assistance to them by partnering them with international blood safety organizations.

The goal of the technical assistance is to increase blood supply through donor recruitment, to ensure blood safety through proper screening of donors and donated blood and to support the development of an improved national blood service in each country.

I would like to discuss the issues on focus countries. In 2004, PEPFAR partners obligated a total of \$24.4 million in funds to blood safety activities in the focus countries. In 2005, that amount was increased to \$50 million. For fiscal year 2006, the current planned amount for blood safety activities is \$32.3 million.

During the first 2 years of the program, countries only spent one-third of the Emergency Plan funds allocated to ministries of health and national blood transfusion services. At the end of fiscal year 2005, approximately \$50 million was still in the pipeline and available in addition to the \$32 million in funding plan for fiscal year 2006.

This is largely due to the infrastructure, human capacity and policy constraints. These countries cannot effectively spend funding until another layer of infrastructure is in place to allow for sustainable expansion of services. Additionally, most blood safety related activities supported by the Emergency Plan are implemented through partnerships with focus country government organizations such as ministries of health. These structures are traditionally slower to act in applying interventions at the national level.

Assuming that those funds currently in the pipeline are appropriately out laid, the planned funding for blood activities in fiscal year 2007 will increase. The current funding level for blood safety activities does strike a reasonable balance between the absorptive capacity of the host country to develop national blood services and

the continuation of a comprehensive and effective prevention program that focuses prevention efforts where new infections are occurring.

The Emergency Plan must continue to be strategic in choosing where each prevention dollar is spent in support of this full portfolio of prevention interventions. Blood safety activities continue to be supported as a necessary element of this portfolio. At current levels we feel this both meets the capacity needs of the focus countries and fits a comprehensive and cost effective prevention strategy consistent with the epidemiology of where new infections are occurring.

Mr. Chairman, the Emergency Plan is experiencing success in supporting HIV strategies in our host nations. Providing safe blood in Africa is a broad issue addressing the risks from all transfusion transmissible diseases including HIV/AIDS, hepatitis and malaria. We at the Office of the Global AIDS Coordinator will continue to work with our colleagues at the Department of Health and Human Services and USAID to support the ongoing blood safety programs as part of the Emergency Plans efforts to focus on HIV and AIDS.

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

The results of this strategy are already visible. The Emergency Plan supports approximately 600 blood safety service outlets or programs in the focus countries, and South Africa and Botswana now have safe blood supplies at the national level. In Kenya, there are 150,000 more units of safe blood up from 40,000 in 2004.

This Subcommittee can be proud that through the President's Emergency Plan the American people are partners with families, communities and nations that are reclaiming their future. Thank you for the opportunity to speak with you today, and I would be happy to address your questions.

[The prepared statement of Dr. Ryan follows:]

PREPARED STATEMENT OF CAROLINE RYAN, M.D., SR. TECHNICAL ADVISOR, DEPUTY DIRECTORY FOR PROGRAM SERVICES, OFFICE OF THE GLOBAL AIDS COORDINATOR, U.S. DEPARTMENT OF STATE

Mr. Chairman and Members of the Subcommittee:

Thank you for this opportunity to discuss President Bush's Emergency Plan for AIDS Relief (PEPFAR/Emergency Plan) and the successes and challenges of providing safe blood in the developing world, primarily Sub-Saharan Africa.

We have greatly appreciated the partnership between PEPFAR and the International Relations Committee, especially the Subcommittee on Africa. We would like to thank all the members of the Subcommittee, and your commitment to the U.S. leadership in the fight against this tragic pandemic.

The President and the Congress made a strategic decision to direct the activities of the Emergency Plan for global HIV/AIDS, and particularly on interventions designed for its prevention, care, and treatment. Of course, HIV/AIDS in the developing world is closely related to numerous other issues: economic development, food security, conflict, gender issues, and many more.

A focus of the Emergency Plan is to build local capacity to provide long-term, sustainable HIV/AIDS prevention, care and treatment programs in the countries with which we partner. Ensuring the availability of safe blood is one component of a multi-prong strategy to prevent HIV transmission. And the results of this strategy

are already visible: South Africa and Botswana now have safe or nearly safe blood supplies available at the national levels. In Kenya, there are 150,000 more units of safe blood, up from 40,000 in 2004.

For the developing countries in which the Emergency Plan works, there are significant challenges to developing and maintaining an adequate sustainable supply of safe blood. These include:

- A lack of basic infrastructure which includes such things as consistent electricity, refrigeration, physical structures, laboratory equipment;
- Inadequate administrative procedures in place to allow for the purchase and management of blood-related commodities;
- A lack of or inadequate policy around blood safety and the clinical use of blood;
- And, A lack of strong health care systems.

These issues are pervasive in Sub-Saharan Africa, and remain part of a larger and more complex development challenge. The Emergency Plan, with its clear mandate to the prevention, treatment, and care for those infected with and affected by HIV/AIDS, cannot alone address the infrastructure, policy and capacity challenges faced by developing countries.

At the request of Representative Fattah and the House Appropriations Sub-Committee for Foreign Operations, the Office of the Global AIDS Coordinator has prepared a report on blood safety as a component of the HIV/AIDS prevention strategy. Together with our colleagues from the Center for Disease Control (HHS/CDC), the U.S. Agency for International Development (USAID), and the World Health Organization (WHO), we invited a group of technical consultants with expertise in blood safety to discuss 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. The group's consensus was presented in the report findings provided to this committee.

Let me first discuss the HIV transmission risk from unsafe blood in the Emergency Plan focus countries. Actual data collected from PEPFAR focus country blood safety programs show an average of 3.19% of donors were HIV positive. Several studies have documented that blood transfusions are not the major cause of HIV transmission in most countries. Among young women, for instance, the risk associated with transfusions appears low compared to the proportions infected by heterosexual transmission. This data reflects the prevalence of HIV/AIDS only.

Even though transmission risk of HIV/AIDS through blood transfusions may be low, we have documented challenges in each of the following components of providing safe blood at the national level:

- Assuring that a sufficient amount of blood is collected in the country;
- Assuring the implementation of a system to recruit low risk donors;
- Assuring that quality screening of donated blood is occurring;
- And assuring that national policies and oversight to reduce unnecessary transfusions are in place.

These issues contribute to the higher risk of transfusion-transmitted diseases, including viral hepatitis and malaria, in addition to HIV/AIDS, in Africa.

To reduce the HIV/AIDS transmission risks presented by blood transfusions, the Emergency Plan supports

- National programs to improve the quality of blood supplies through improved policies;
- The establishment of laboratory facilities and commodity procurement;
- Healthcare worker training and management.

The Emergency Plan also provides technical assistance to aid countries in implementing the foundational components of effective national blood transfusion services.

PEPFAR promotes international blood safety organizations to partner with each of the focus countries to help in the development of a comprehensive system that includes low-risk blood donor selection, blood banking, and blood safety training. The goal of these programs is to increase blood supply through donor recruitment. The programs also work to ensure blood safety through proper screening of donors and donated blood. They support the development or improvement of a national blood service in each country.

In fiscal year 2005, the Emergency Plan supported approximately 600 blood safety service outlets or programs in the focus countries. In 2004, PEPFAR partners obligated a total of \$24.4 million in funds to blood safety activities in the focus countries. In 2005, that amount increased to \$50 million. For fiscal year 2006, the current planned amount for blood safety activities is \$32.3 million.

During the first 20 months of funding, countries spent only one-third of the Emergency Plan funds allocated to Ministries of Health and National Blood Transfusion Services (MOH/NBTS) to establish safe blood systems. Two-thirds of funding remains in the pipeline. At the end of fiscal year 2005, approximately \$50 million was still in the pipeline and available, in addition to the \$32 million in funding planned for FY 2006. 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. Additionally, most blood safety-related activities supported by the Emergency Plan are implemented through partnerships with focus country government organizations such as the MOH. These structures are traditionally slower to act in applying interventions at the national level and often create an excess in available unused funding. Assuming that those funds currently in the pipeline are appropriately outlaid, the planned funding for blood safety activities will increase proportionately in FY 07.

Now I would like to briefly discuss a baseline for assuming the cost effectiveness of safe blood as a means to avert HIV-transmission. Utilizing the simple WHO resource model of a cost of \$45 to produce a unit of safe blood, the cost per HIV-infection averted can be extrapolated. Using a HIV prevalence rate of 3%, Testing 33 units of blood at \$45 a unit equals \$1500 per unit identified. As the potential for contracting HIV from tainted blood is 80%, the approximate cost per infection averted is \$2000 per infection (assuming all units of blood are used). I would point out that the WHO resource model assumes that basic infrastructure components such as functioning roadways, consistent supply of electricity, and sufficiently trained and available healthcare workers are in place and accessible. As I have mentioned, we know this is not the case, and that these development issues still pose a significant challenge in the countries the Emergency Plan supports. In reality, the cost per infection averted would be much more than \$2000 when including the infrastructure costs necessary.

The current levels of funding for blood safety activities strike a reasonable balance between the absorptive capacity of host countries to develop national blood services, and the continuation of a comprehensive and effective prevention program. The Emergency Plan must continue to be strategic in choosing where each prevention dollar is spent in support of this full portfolio of interventions. Blood safety activities continue to be supported as a necessary element of this portfolio. At current levels, we feel this both meets the capacity needs of the focus countries, and fits a comprehensive and cost effective prevention strategy.

Mr. Chairman, the Emergency Plan is experiencing success in supporting the HIV/AIDS strategies of our host nations. Providing safe blood in Africa is a broad issue, addressing the risk from all transfusion-transmissible diseases, including HIV/AIDS, hepatitis, and malaria. We at the Office of the Global AIDS Coordinator will continue to work with our colleagues at the Department of Health and Human Services to support the ongoing blood safety programs as part of the Emergency Plan efforts focusing on HIV/AIDS.

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. This Subcommittee can be proud that through the President's Emergency Plan, the American people are partners with families, communities, and nations that are reclaiming their future.

Thank you for the opportunity to speak with you today, and I would be happy to now address your questions.

Mr. SMITH. Doctor, thank you very much. Dr. Ferris.

**STATEMENT OF ROBERT E. FERRIS, M.D., MEDICAL OFFICER,
BUREAU FOR GLOBAL HEALTH, U.S. AGENCY FOR INTER-
NATIONAL DEVELOPMENT**

Dr. FERRIS. Mr. Chairman, Members of the Subcommittee, good afternoon and thank you for the opportunity to testify on the im-

portant topic of safe blood in Africa. The U.S. Agency for International Development works with its partners to improve blood transfusion practices, obstetrical delivery practices and health systems to create a safer blood supply.

USAID and other U.S. Government partners recognize that safe blood saves lives. The medical knowledge and technical expertise exists. Implementing and sustaining safe blood supply systems in developing countries is the challenge today.

Women and children are likely to be the greatest beneficiaries of safe blood supply in Africa. Women often require blood during a life threatening complication of childbirth. Children often require blood when their own blood levels are dangerously low from diseases such as malaria. During these not uncommon medical emergencies, access to safe blood is lifesaving.

Blood and blood products are not risk free. HIV, hepatitis B, hepatitis C and malaria are just a few of the harmful factors transmissible during blood transfusions. Up to 5 percent of HIV infections in the developing world are estimated to result from transfusion of contaminated blood.

USAID has directly worked to create a safer blood supply in several countries, including Nigeria and Egypt. Through the Safe Blood for Africa project, funded under the President's Emergency Plan for AIDS Relief, USAID, with other Safe Blood for Africa partners, is developing a blood collection and distribution center in Abuja, Nigeria, where blood services historically have been understaffed and underfunded. USAID efforts in this initiative have contributed to the long range goal of sustaining a national blood policy and establishing a Nigerian national blood transfusion service. Through the help of Safe Blood for Africa, 18 national blood transfusion services are now working to safeguard blood supply in developing countries.

In Egypt, USAID worked with public and private partners to enhance the blood banking enterprise. This project has developed a framework to increase voluntary blood donations. The project includes recordkeeping and data management systems to enable the retention of safe blood donors, a course in basic principles of safe blood collection and universal precaution guidelines, policies and procedures.

USAID has had a long history of strengthening health systems and improving the quality and safety of healthcare in developing countries. USAID's health programs in Africa have improved the safety of medical practices through technological innovations in clinical training, through improved governance, policy guidance, strengthened management and logistic systems, better health financing and improvements in service quality.

USAID helps ensure proper blood safety procedures that can reduce the risk of HIV transmission from transfusions and contaminated needles. We do this by supporting education and behavior change among providers and patients, effective supply use by providers, improve distribution systems, improved supply forecasting ability and enhanced waste management practices.

USAID also helps to reduce the need for blood transfusions through better medical management and prevention of transfusion-causing conditions in our child survival, infectious disease and ma-

ternal health programs. While most of these programs are currently funded from our non-HIV/AIDS child survival budget, they make substantial contributions to preventing HIV in medical settings.

Two notable examples are the promotion of safe obstetrical delivery practices and combatting malaria. USAID promotes safe obstetrical delivery and care in its safe motherhood programs. For example, postpartum hemorrhage is a serious complication of childbirth that often requires blood transfusion. Our programs aim to reduce the need for transfusion by developing programs to prevent postpartum hemorrhage as well as protocols to manage hemorrhage appropriately when it occurs.

Also, USAID funded the Program for Appropriate Technology and Health to test the feasibility of putting the drug oxytocin in Uniject prefilled, auto-disable injection devices. Oxytocin is a medication that effectively reduces bleeding following childbirth. The use of the Uniject device to deliver Oxytocin would make this life-saving intervention even safer for patients and providers while decreasing the potential need for blood transfusion.

The USAID-funded maternal and neonatal health program works in 10 countries in Africa on infection prevention practices, for safe motherhood and newborn health. These programs work at the national level on policies and standards which are then reflected in the curricula for preservice and inservice training of healthcare workers, preparation of training sites, the development of job aids and supportive supervision systems.

We emphasize several key infection prevention behaviors: Injection safety, universal precautions, avoiding unnecessary medical procedures, proper sterilization of instruments, proper disposal of hazardous waste as well as newborn umbilical cord care.

USAID is also a partner with the White Ribbon Alliance, an international coalition that increases public awareness about the need to make pregnancy and childbirth safe for all women and newborns. Optimizing a pregnant woman's health is likely to prevent the need for some transfusions and reduce the strain on an already stretched supply of safe blood.

Severe anemia from malaria is also a frequent cause for blood transfusion in Africa especially for young children. USAID has been committed to saving lives from malaria since the 1950s. USAID works closely with national governments to build their capacity to prevent and treat this disease. USAID also advances the discovery and development of new anti-malarial drugs and malaria vaccines.

In addition to its ongoing malaria programs, USAID also manages programs through the President's Malaria Initiative, a \$1.2 billion, 5-year initiative to control malaria in Africa. PMI is a collaborative U.S. Government effort led by USAID in conjunction with the Department of Health and Human Services, the Department of State, the White House and others. The goal of the initiative is to reduce malaria deaths by half in 15 target countries by reaching 85 percent of the most vulnerable groups, children under 5 years of age and pregnant women with proven and effective malaria prevention and control measures.

Clearly in reducing malaria by improved treatment and prevention of malarial infections fewer transfusions will be required to save those severely infected.

Mr. Chairman and Committee Members, directly strengthening blood supply systems ultimately can make safe blood available throughout Africa. In the meantime, efforts that strengthen overall health systems and prevent medical emergencies like postpartum hemorrhage and severe anemia from malaria are critical to reduce the burden on currently fragile blood supply systems.

I would like to assure the Committee that USAID, in partnership with HHS and the President's Emergency Plan for AIDS Relief, will continue to work to strengthen systems to improve the delivery of safe blood in Africa. Thank you again for inviting me to speak on this important topic, and I am happy to take your questions.

[The prepared statement of Dr. Ferris follows:]

PREPARED STATEMENT OF ROBERT E. FERRIS, M.D., MEDICAL OFFICER, BUREAU FOR GLOBAL HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

Mr. Chairman and Members of the Subcommittee:

Good morning and thank you for the opportunity to testify on the important topic of safe blood in Africa. The U.S. Agency for International Development (USAID) works with its partners to improve blood transfusion practices, obstetrical delivery practices and health systems to create a safer blood supply.

USAID and other U.S. Government partners recognize that safe blood saves lives. The medical knowledge and technical expertise exists. Implementing and sustaining safe blood supply systems in developing countries is the challenge today.

Women and children are likely to be the greatest beneficiaries of a safe blood supply in Africa. Women often require blood during a life threatening complication of childbirth. Children often require blood when their own blood levels are dangerously low from diseases such as malaria. During these not uncommon medical emergencies, access to a safe blood supply can be life saving.

Blood and blood products are not risk-free. Human immunodeficiency virus (HIV), hepatitis B, hepatitis C, and malaria are some of the harmful factors transmissible during blood transfusions. Up to five percent of HIV infections in the developing world are estimated to result from transfusion of contaminated blood.

USAID has directly worked to create a safer blood supply in several countries including Nigeria and Egypt. Through the Safe Blood for Africa project, USAID with the ExxonMobil Foundation, the Bill & Melinda Gates Foundation, Merck Pharmaceuticals, the Centers for Disease Control and Prevention (CDC) and Becton Dickson is developing a blood collection and distribution center in Abuja, Nigeria to prevent HIV transmission through blood transfusion. In Abuja, blood services historically had been understaffed and under funded. USAID's efforts in this initiative have contributed to the long range goal of sustaining a National Blood Policy and establishing a Nigerian National Blood Transfusion Service. Through Safe Blood for Africa, 18 national blood transfusion services are now safeguarding the blood supply.

In Egypt, USAID worked with public and private partners to enhance the blood banking enterprise. This project has developed a framework to increase voluntary blood donations. The project includes record-keeping and data-management systems to enable retention of safe donors; a course in basic principles of safe blood collection; and universal-precaution guidelines, policies, and procedures.

HEALTH SYSTEMS

USAID has a long history of strengthening health systems and improving the quality and safety of health care in developing countries. USAID's health programs in Africa have improved the safety of medical practices through technological innovations and clinical training and through improved governance, policy guidance, strengthened management, information and logistics systems; better health financing and improvements in service quality.

USAID helps ensure proper blood safety procedures that can reduce the risk of HIV transmission from transfusions and contaminated needles. We do this by supporting education and behavior change among providers and patients, effective supply chain management, effective supply use by providers, improved distribution sys-

tems, improved supply forecasting ability, and enhanced waste management practices.

USAID also helps to reduce the need for blood transfusions through better medical management and prevention of transfusion-causing conditions in our child survival, infectious disease and maternal health programs. While most of these programs are currently funded from our non-HIV/AIDS child survival budget, they make substantial contributions to preventing HIV in medical settings. Two notable examples are the promotion of safe obstetrical delivery practices and combating malaria.

SAFE OBSTETRICAL DELIVERY PRACTICES

USAID promotes safe obstetrical delivery and care in its safe motherhood programs. For example, postpartum hemorrhage is a serious complication of childbirth that often requires blood transfusions. Our programs aim to reduce the need for transfusions by developing programs to prevent postpartum hemorrhage as well as protocols to manage hemorrhage appropriately when it occurs.

Also, USAID funded the Program for Appropriate Technology in Health to test the feasibility of putting the drug oxytocin in Uniject pre-filled, auto-disable injection devices. Oxytocin is a medication that effectively reduces bleeding following birth, the biggest cause of maternal deaths. The use of the Uniject device to deliver oxytocin would make this life-saving intervention even safer for patients and providers while decreasing the potential need for blood transfusion.

The USAID-funded Maternal and Neonatal Health Program works in 10 countries in Africa on infection prevention practices for safe motherhood and newborn health. These programs work at the national level on policies and standards which are then reflected in curricula for pre-service and in-service training of health care workers, preparation of training sites, the development of job aids and supportive supervision systems. In addition, we emphasize several key infection prevention behaviors: injection safety, universal precautions, hand-washing, avoiding of unnecessary medical procedures, proper sterilization of instruments, proper disposal of hazardous waste, and newborn umbilical cord care.

USAID is also a partner in the White Ribbon Alliance, an international coalition that increases public awareness about the need to make pregnancy and childbirth safe for all women and newborns. The Alliance disseminates technical information on safe delivery practices, mobilizes communities, and calls attention to the needs of HIV positive mothers.

MALARIA

USAID has been committed to saving lives from malaria since the 1950s. The Agency works closely with national governments to build their capacity to prevent and treat the disease. USAID also invests in the discovery and development of new antimalarial drugs and malaria vaccines.

In addition to its ongoing malaria programs, the Agency also manages programs through the President's Malaria Initiative (PMI), a \$1.2 billion, five-year initiative to control malaria in Africa announced by President Bush in June 2005. PMI is a collaborative U.S. Government effort led by USAID, in conjunction with the Department of Health and Human Services (Centers for Disease Control and Prevention), the Department of State, the White House, and others.

The goal of the Initiative is to reduce malaria deaths by half in 15 target countries in Africa by reaching 85 percent of the most vulnerable groups—children under 5 years of age and pregnant women—with proven and effective malaria prevention and treatment control measures. PMI supports control measures including insecticide-treated bed nets, spraying with insecticides in communities, lifesaving antimalarial drugs, and treatment to prevent women from getting malaria. Clearly, in reducing the toll of malaria by improved treatment and prevention of malarial infections, fewer transfusions will be required to save those severely infected.

CONCLUSION

Directly strengthening blood supply systems ultimately can make safe blood available throughout Africa. In the meantime, efforts that strengthen overall health systems and prevent medical emergencies like postpartum hemorrhage and severe anemia from malaria are critical to reduce the burden on currently fragile blood supply systems.

I would like to assure the Committee that USAID, in partnership with HHS and the President's Emergency Plan for AIDS Relief, will continue to work to strengthen systems to improve the delivery of safe blood in Africa. Thank you again for inviting me to speak on this important topic and I am happy to take your questions.

Mr. SMITH. Thank you so very much. And now, Dr. Holmberg.

**STATEMENT OF JERRY A. HOLMBERG, PH.D., SENIOR ADVISOR
FOR BLOOD POLICY, OFFICE OF PUBLIC HEALTH AND
SCIENCE, U.S. DEPARTMENT OF HEALTH AND HUMAN SER-
VICES**

Mr. HOLMBERG. Good afternoon, Mr. Chairman. I am Dr. Jerry Holmberg, Senior Advisor for Blood Policy and the Executive Secretary to the Advisory Committee on Blood Safety and Availability for the Department of Health and Human Services. Sitting behind me today is my colleague from the Center for Disease Control and Prevention, Dr. Matthew Kuehnert. I have asked Dr. Kuehnert to be present at the hearing to collaborate with me on some of the questions you may ask.

In the healthcare setting, HIV, the hepatitis viruses, hepatitis B and C and the parasites that cause malaria are easily transmitted through exposure to blood caused by unsafe injections, poor infection control practices and contaminated blood yet at present fewer than 30 percent of countries worldwide have fully functional national blood services.

The problem is especially acute in Africa where an estimated 14 million blood units are needed while only 3.6 million units were collected for distribution in 39 countries in 2004. Screening in general remains a challenge in many resource constrained countries. One-third of the 90 million units of blood transfused worldwide in 2000 were not screened for one of the three most serious transfusion transmitted viruses, that being HIV, hepatitis B virus and hepatitis C virus.

In 2005, AIDS killed 3 million people, with 80 percent of these deaths in sub-Saharan Africa. In addition, there were almost 5 million new HIV infections worldwide, more than 11,000 new infections each day. Around the world the vast majority of these infections are sexually transmitted. Intravenous drug use and perinatal transmission also accounts for significant numbers of infections.

Although blood transfusion accounts for a minority of new infections in countries with generalized epidemics where most infections are the result of heterosexual contact, contaminated blood remains the most efficient method for transmitting HIV from one person to another. Transfusions are estimated as the cause of 5 percent of HIV infections in developing countries.

Much of the worldwide viral hepatitis burden, which includes acute infections, chronic hepatitis, cirrhosis and liver cancer, is due to hepatitis B virus. Hepatitis B virus kills about 620,000 persons worldwide annually. Approximately 350 million persons, 5 percent of the world population, live with chronic hepatitis B virus infection, with the highest rates of transmission and chronic infection primarily in parts of Africa and Asia.

Young children who become infected with hepatitis B virus are more likely to develop chronic infection. The risk of death from hepatitis B virus related liver cancer or cirrhosis is approximately 25 percent for persons who become chronically infected during childhood.

While less common than hepatitis B virus as the cause of acute hepatitis, hepatitis C is estimated to have infected about 170 mil-

lion people, some 3 percent of the world's population, 130 million of whom are chronic carriers. Disease prevalence is high in many countries in Africa, Latin America, Central and Southeastern Asia. In these countries, prevalence rates range from 5 to 10 percent.

Malaria causes 300 to 500 million acute illnesses annually, and kills as many as 1 million people, mostly children under the age of five. Almost half the world's population lives in areas where malaria is endemic. In Africa alone, malaria is responsible for an estimated 25 to 35 percent of all outpatient visits and 20 to 45 percent of all hospital admissions.

Although malaria can be transmitted by blood, mosquitos are the primary vector of infection. However, blood transfusions play a critical role in sustaining the lives of children suffering from malaria induced anemia. In severe cases these children require blood transfusions to survive, the transfusions that are frequently unavailable due to a lack of blood.

HHS supports the development of a long-term, sustainable blood safety program in Africa and Asia through the Emergency Plan and other initiatives. The creation of a blood safety program requires that attention be paid to issues of sustainability. Strategies must ensure that each new service is supported by adequate infrastructure such as laboratories and reliable power, the staff is recruited, trained and retained, the laboratory equipment and reagents are appropriate and available, and that processing procedures are properly managed.

It is important to ensure that the blood safety strategies are not only comprehensive but integrated in or linked into other U.S. Government funded public health activities in a country. HHS works with its U.S. Government partners and with other international health organizations to ensure the programs funded through various mechanisms like the Emergency Plan, the Global Fund or private foundations do not duplicate efforts.

HHS and its agencies look forward to continuing its collaboration with U.S. and international partners to incrementally strengthen the current blood safety program as part of a diverse portfolio of global disease prevention strategies. Thank you for the opportunity to testify. I am happy to answer any questions.

[The prepared statement of Mr. Holmberg follows:]

PREPARED STATEMENT OF JERRY A. HOLMBERG, PH.D., SENIOR ADVISOR FOR BLOOD POLICY, OFFICE OF PUBLIC HEALTH AND SCIENCE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good morning, I am Dr. Jerry Holmberg, Senior Advisor for Blood Policy and Executive Secretary of the Advisory Committee on Blood Safety and Availability within the Office of Public Health and Science of the Department of Health and Human Services (HHS). I am pleased to be here today to discuss blood safety and transfusion-transmitted diseases, including HIV/AIDS, viral hepatitis, and malaria in Africa. I have over 35 years of experience, primarily in clinical laboratory science, and have been involved in the blood community since the early 1970s, and I take blood safety and the availability of blood products seriously.

Sitting behind me today is my colleague from the Centers for Disease Control and Prevention (CDC), Dr. Matthew Kuehnert. Dr. Kuehnert is the Assistant Director for Blood Safety, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention in Atlanta. I have asked Dr. Kuehnert to be present at this hearing to collaborate with me on questions you may ask.

Please permit me to state that in my official capacity, I participate internationally with the Global Collaboration for Blood Safety (GCBS). Recognition of the need for

a GCBS was first endorsed by 41 countries represented during the Paris AIDS Summit in 1994 and adopted by the Forty-Eighth World Health Assembly (WHA) as WHA resolution 48.27 (1995), by all 191 World Health Organization (WHO) Member States in order to prioritize the need for global collaboration to improve blood safety. WHO is a participant of GCBS and also provides its secretariat.

The GCBS participants agree to collaborate in facilitating progress in the following areas:

- international consensus on essential principles of global blood safety;
- encouraging the recognition and establishment of national blood programs;
- identifying priorities for the prevention of transfusion-related disease;
- implementation of appropriate and recognized transfusion practices, which ensure donor and recipient safety and are free from discrimination;
- effective recruitment of safe donors through the use of appropriate selection criteria;
- assuring quality and safety in the preparation of blood and blood products;
- safe international practices for the collection, storage, and transport of plasma and the preparation and distribution of its derivatives;
- the bi-directional traceability of blood products between donor and recipient whether in-country or across national borders; and
- promote evidence-based use of blood and blood products
- the exchange and use of information by encouraging data collection, management and dissemination.

The GCBS represents some of shared concerns that the Committee has in regards to improving blood safety and the medical infrastructure in Africa.

In my remarks today, I will be addressing the overall burden of disease of HIV/AIDS, viral hepatitis, and malaria in sub-Saharan Africa, and the role that unsafe blood transfusions play in the transmission of these diseases. I also will discuss the barriers and challenges related to implementing a long-term, sustainable blood safety program in the developing world, and will conclude by discussing some of the Department's efforts to improve blood safety and address the burden of disease in sub-Saharan Africa.

HIV, VIRAL HEPATITIS, AND MALARIA IN SUB-SAHARAN AFRICA

In the health care setting, HIV, the hepatitis viruses (hepatitis B virus (HBV) and hepatitis C virus (HCV)), and the parasites that cause malaria are easily transmitted through exposures to blood caused by unsafe injections, poor infection control practices, and contaminated blood. Yet, at present fewer than 30% of countries worldwide have fully functioning national blood transfusion services. The problem is especially acute in Africa, where an estimated 14 million blood units are needed, while only 3.6 million units were collected for distribution in 39 countries in 2004.¹ Improving access to safe blood in the developing world is a daunting challenge requiring development of sustainable infrastructure which is complex and resource- and time-intensive. I will address the barriers faced by many countries and the Department's response to them later in my testimony.

HIV/AIDS

Since 1981, AIDS has killed more than 25 million people, making it one of the most devastating epidemics in history. In 2005, AIDS killed three million people, with 80% of these deaths in sub-Saharan Africa. In addition, there were almost 5 million new HIV infections worldwide—more than 11,000 new infections every day—bringing the number of people living with HIV to more than 40 million (UNAIDS, 2005). Around the world, the vast majority of these infections are sexually transmitted. Intravenous drug use and perinatal transmission also account for significant numbers of infections. The cost in human lives lost is staggering. And there are important subsequent costs that accompany each new infection and each death. Persistent stigma and discrimination in much of the developing world mean infected people remain at risk of losing jobs, friends, and family support. AIDS has torn apart families, orphaned children, and put new stresses on developing economies. For example, countries with an HIV prevalence of 15%, as is the case in a

¹Global Database on Blood Safety, World Health Organization

number of sub-Saharan African countries, are estimated to lose 1% Gross Domestic Product (GDP) every year².

Although blood transfusions account for a minority of new infections in countries with generalized epidemics (where most new infections are the result of heterosexual contact), contaminated blood remains the most efficient method of transmitting HIV from one person to another. According to WHO, transfusions are estimated as the cause of 5% of HIV infections in developing countries.³ I must say that the prevalence may be higher since reporting, documentation, and investigation into causes of the HIV infection may be non-existent in these developing countries. Factors that contribute to transfusion-related transmission in sub-Saharan Africa and other parts of the developing world include: high rates of transfusion in some groups of patients (particularly women and children); a higher prevalence of HIV in the general and blood donor populations; inadequate HIV antibody screening in some countries; and a high residual risk of contamination in blood supplies despite antibody screenings.

Viral Hepatitis

Much of the worldwide viral hepatitis burden, which includes acute infections, chronic hepatitis, cirrhosis and liver cancer, is due to HBV. HBV kills about 620,000 persons worldwide annually. Approximately 350 million persons—5% of the world's population—live with chronic HBV infection, with the highest rates of transmission and chronic infection primarily in parts of Africa and Asia.

In sub-Saharan Africa, most of Asia, and the Pacific, most people become infected with HBV during childhood, and 8% to 10% of the general population is chronically infected. Young children who become infected with HBV are more likely to develop chronic infection. The risk of death from HBV-related liver cancer or cirrhosis is approximately 25% for persons who become chronically infected during childhood.

While less common than HBV as a cause of acute hepatitis, HCV is estimated to have infected about 170 million people, some 3% of the world's population, 130 million of whom are chronic carriers, according to WHO. Disease prevalence is high in many countries in Africa, Latin America and Central and South-Eastern Asia. In these countries, prevalence rates range from 5% to 10% (WHO).

Screening in general remains a challenge in many resource constrained countries. According to WHO estimates based on country reports, one-third of the 90 million units of blood transfused worldwide in 2000 were not screened for one of the three most serious transfusion transmitted viruses, HIV, HBV and HCV.⁴ This gap in screening directly contributed to 78,000 HBV infections and more than half a million HCV infections.

In sub-Saharan Africa in 2000, more than 70% of blood donations were screened for HBV, but only about 10% were screened for HCV. The total number of infections attributed to unsafe blood donations was 30,000 for HBV and 52,000 for HCV, leading to 80 deaths from HBV infection and 440 deaths from HCV.

Although the overall proportion of new infections attributed to transfusion-transmitted HIV and viral hepatitis may be relatively low, because blood safety interventions are likely to be effective once they are implemented, they can be a potentially attractive preventive strategy. This, however, strongly depends on available resources and infrastructure for the interventions to be feasible.

Malaria

Malaria causes 300–500 million acute illnesses annually and kills as many as 1 million people, mostly children under five years of age, according to WHO. Almost half of the world's population lives in areas where malaria is endemic. In Africa alone, malaria is responsible for an estimated 25% to 35% of all outpatient visits and 20% to 45% of all hospital admissions. The economic impact associated with lost work days due to malaria has been estimated to reduce the GDP of heavily burdened countries by between 1% and 4%. The cost of these losses may be as high as US\$12 billion per year.

In the case of malaria, mosquitoes, not blood transfusions, are the primary vector of infection. However, blood transfusions play a critical role in sustaining the lives of children suffering from malaria-induced anemia. Anemic children lack sufficient red blood cells to carry oxygen to their organs. In severe cases, these children re-

²Pavon B (2004). AIDS Slashes Life Expectancy in 23 African Countries. UN Chronicle Online Edition, Issue 3.

³WHO. Blood Safety and Clinical Technology Progress 2000–2001, 2002.

⁴Rapita, E. Dhingra N, Hutin Y, and Lloyd D. 11th International Symposium on Viral Hepatitis and Liver Disease. Sydney, Australia, 2003.

quire blood transfusion to survive—transfusions that are frequently unavailable due to a lack of blood.

Screening donors for malaria has not been a priority activity in the African context because:

- the overwhelming source of exposure to malaria in Africa is from infected mosquitoes rather than transfused blood;
- screening tests are not sufficiently sensitive to effectively identify and defer donors to prevent them from transmitting infection; and
- many children receiving blood transfusions in this setting are already being treated for malaria as the underlying cause of their severe anemia.
- in many countries where malaria has high prevalence, standard protocol is to treat all transfusion recipients for malaria.

Additionally, because of high rates of malaria among potential donors, screening would further diminish an already inadequate blood supply.

ISSUES RELATED TO BLOOD SAFETY IN DEVELOPING COUNTRIES

In the United States, the blood supply is considered very safe. The risks of infection with known blood-borne pathogens are low because of extensive donor exclusion guidelines, including laboratory screening. The medical transfusion community maintains continuously improved efforts to collect blood only from the safest donors and to screen all donated blood for 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. In many sub-Saharan Africa countries, blood services are either non-existent or significantly under-resourced or lacking the infrastructure and capacity to ensure sustainable operations. Infrastructure challenges include problems with electricity to ensure the consistent refrigeration needed to store donated blood. Additionally, funding is frequently inadequate to purchase blood-banking equipment and test kits, especially in countries faced with extreme poverty, political instability, and armed conflict. Also, in these same countries, salaries and training for blood-banking and transfusion personnel may not be supported by the national budget.⁵ This is particularly true in countries lacking policies and legislation for blood safety. In addition, many hospitals do not have effective laboratories to ensure the complete screening of blood. In countries with a high prevalence of HIV, HBV, and HCV among blood donors, this risk is especially high. Consequently, an incremental and time-phased approach that establishes the political, medical, and logistical frameworks for transfusion services is recommended.

Regular, unpaid voluntary blood donors are needed for high-quality blood services worldwide—but identifying and targeting low-risk volunteers for blood donations can be difficult in areas with high disease prevalence. Currently, volunteer donors provide less than half of the blood supply in developing countries, and few countries have mobilized efforts to encourage unpaid, voluntary blood donation. In many countries where cultural attitudes may limit the acceptance of blood donation activities, governments and other institutions are beginning to counteract these attitudes with educational outreach programs.

Still, many countries are forced to rely on emergency blood donations from paid donors or family members. These so-called “replacement” donors carry an increased risk of transmitting disease. Based on findings that unpaid donors have the lowest risk of transfusion-transmitted viruses, the WHA adopted Resolution WHA 28.72 in 1975 and WHA 58.13 in 2005, which urged all WHO member states to base national transfusion services on non-remunerated volunteer blood donors.

Limited amounts of safe and volunteer-donated blood, poor infrastructure (including a lack of clean water and constant electricity), and structural limitations in the healthcare system all contribute to the need for an integrated health and development strategy to ensure blood safety. Achieving a high quality, sustainable public health response will require implementing and strengthening multiple systems, including clinical quality assurance systems; health care infrastructure; human resource development; and procurement and logistics systems.

⁵ 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.

CURRENT HHS/CDC ACTIVITIES RELEVANT TO BLOOD SAFETY AND PREVENTION

There are a group of activities at HHS/CDC that impact the safety of blood in Africa. I want to highlight a few of these, including three of the most relevant programs.

As part of the President's Emergency Plan for AIDS Relief (Emergency Plan), HHS/CDC actively supports the development of integrated strategies for blood safety in 14 of the 15 focus countries,⁶ 12 of which are in sub-Saharan Africa. HHS/CDC's Emergency Plan-funded initiative pairs the National Blood Transfusion Services with one of five non-governmental organizations⁷ that are recognized leaders in blood safety. This approach allows local blood services to obtain world class expertise and provides their personnel to the latest training. At the same time, it ensures that ideas, policies, and strategies are developed at the local level, with national staff serving in key leadership roles. This approach has four elements:

1. Enhancing local laboratories' capacity to test all donated blood for transfusion transmitted infections, with an emphasis on quality-assured screening of all donated blood for HIV.
2. Promoting voluntary non-remunerated blood donations—the collection of blood from, regular, unpaid blood donors from low risk populations.
3. Providing training and education for local medical personnel to reduce the number of unnecessary transfusions, promote safe and rational blood utilization, and increase the use of alternatives to transfusions.
4. Identifying the amount of blood needed each year to ensure a sufficient supply in each country.

HHS/CDC's experience in 14 countries has demonstrated that most countries cannot effectively utilize large increases in financial resources for blood safety, and that moderate increases which enable incremental scale-up are most appropriate.

HHS/CDC also provides subject matter expertise in the prevention of hepatitis B and C infection to community organizations, government agencies, and blood banks responsible for blood safety. It also develops evaluation panels for use internationally to determine the performance of test kits manufactured in other countries for laboratory screening of blood donations for HBV and HCV infections. Additionally, HHS/CDC provides financial support and technical assistance to the WHO for blood safety and the prevention of HBV and HCV transmission in health care settings.

HHS/CDC is also involved in malaria prevention activities through the Presidential Malaria Initiative (PMI). The PMI is focused on expanding access to proven intervention methods like insecticide-treated bednets and indoor residual spraying, as well as scaling up access to effective care and treatment, especially for children and pregnant women.

These efforts help prevent cases and decrease the need for transfusions related to malarial anemia. As such, HHS/CDC is currently focused on making progress in reducing the enormous background rate of infection. Once this is achieved, blood safety activities as they relate to malaria could become more feasible and cost effective.

The National Heart, Lung, and Blood Institute (NHLBI) at HHS's National Institutes of Health supports epidemiological studies at international demonstration sites addressing important blood safety and availability issues to ensure a safe and adequate blood supply. NHLBI is in the process of expanding the study to several sites in developing countries, where researchers will investigate critical scientific issues related to transfusion-transmitted HIV and other established and emerging transfusion-transmitted agents.

NEXT STEPS

To summarize, for persons with HIV, viral hepatitis, or malaria in Africa, transfusion-associated transmissions represent a small proportion of the total number of new infections each year, but the number of these transmissions is substantial nonetheless, and efforts to address these causes are an important component of a comprehensive prevention strategy. The creation of a blood safety program requires that attention be paid to issues of sustainability. Strategies must ensure that each new

⁶Botswana, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia. Vietnam was recently added as the 15th country.

⁷American Association of Blood Banks (AABB), Safe Blood for Africa Foundation, Sanquin Consulting Services, Social and Scientific Systems, Inc. (SSSI), and World Health Organization (WHO/PAHO).

service is supported by adequate infrastructure such as laboratories and reliable power; that staff is recruited, trained, and retained; that laboratory equipment and reagents are appropriate and available; and that processing procedures are properly managed.

These are huge challenges. Yet despite these barriers, US Government support for blood safety programs is worthwhile for three reasons:

- First, proven interventions are available to dramatically reduce or virtually eliminate transfusion-related transmission of these infections.
- Secondly, blood safety programs protect vulnerable populations. Persons in need of transfusion cannot take personal action to reduce their risk.
- Third, blood safety programs build public health capacity by raising standards of care and building technical capacity among laboratory workers, nurses, and physicians. In addition, education, risk assessment, and laboratory screening can be used to support prevention interventions to other at-risk populations and the general public.

CDC has had a leadership role in global blood safety since the early years of the AIDS epidemic, with extensive expertise in epidemiology, laboratory development and management, and scientific and technical training. CDC also has experience in developing and implementing infectious disease control programs domestically and internationally. In addition, CDC has conducted landmark epidemiologic investigations in a number of settings to establish the risk for transfusion-associated infections; CDC scientists have devised and assessed new tests to protect the blood supply and have developed panels of specimens for blood banks to evaluate the quality of their screening of blood donations.

HHS supports the development of long-term, sustainable blood safety programs in Africa and Asia through the Emergency Plan and other initiatives. HHS and its agencies, such as CDC and the Food and Drug Administration, also have long standing relationships with WHO and other international organizations committed to blood safety.

Responding to the need to produce an adequate and safe blood supply in developing countries requires a comprehensive and coordinated effort among Ministries of Health and experts in blood transfusion throughout the world. Efforts 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.

It is important to ensure that blood safety strategies are not only comprehensive, but integrated in or linked to other US Government-funded public health activities in a country. HHS works with its US Government partners and with other international health organizations to ensure that programs funded through various mechanisms, like the Emergency Plan, the Global Fund or private foundations, do not duplicate efforts. HHS/CDC country offices are actively engaged in seeking ways to partner with these external donors and designing projects to complement each organization's inherent strengths.

HHS and its agencies looks forward to continuing its collaborations with U.S. and international partners to incrementally strengthen the current blood safety program as part of a diverse portfolio of global disease prevention strategies.

Thank for you the opportunity to testify today. I am happy to answer any questions you may have.

Mr. SMITH. Dr. Holmberg, thank you very much for your work and for your testimony today. Let me ask a few opening questions. In OGAC's report on blood safety and HIV/AIDS, your agency indicates that significant—and this is to Dr. Ryan—significant amounts of money have been awarded to focus countries for blood safety activities but these funds have not yet been expended.

I looked at the table from August 2004 to 2005 and noted that some of the countries—for example, Nigeria has spent 61 percent of the \$2.7 million that was given. Ethiopia spent zero. Cote d'Ivoire spent 52 percent. Uganda is at 50 percent. I think some of the reasons are obvious: Infrastructure, a lack of trained individuals to implement the program.

I wonder if you might expound for a moment on the kind of resistance or the kind of cooperation you are, or were receiving in the

field because obviously it is a two way street. There has to be that earnest desire to do this on the part of the countries where there is such an acute need.

I would note that going back to 2001 the World Health Assembly Regional Committee for Africa established those goals, what hopefully were doable and will be doable goals by the year 2012, and it looks like we are not going to reach those unless there is some additional hurry-up offense. What can be done? The money is there. It is in a pot, presumably. It has been awarded, and it is not being spent. What could we do to help move that along?

Dr. RYAN. Thank you very much, Mr. Chairman. I think the fact that we did a pipeline analysis assisted us in trying to identify where were the blocks in expenditure, and as a result of that identifying where there were difficulties in expending the funding we were able to accelerate the amount of technical assistance from the collaborating TA provider as well as making sure that the Centers for Disease Control who manages this grant was aggressively monitoring both the expenditures at the national transfusion center level and also by the TA provider.

I think the answer is one, identify the problem and figure out where the blocks are, and two, bring in the technical assistance to help them figure out how to problem solve around those blockages.

Mr. SMITH. Can I ask you, is there a sense of urgency on the part of the parliamentarians, the prime minister, the President, and the ministers of health to get at this? It seems to me that if you have got blood right, you are a long way in ensuring a healthier population.

Dr. RYAN. I think there is a lot of urgency, and certainly that urgency is tempered a little bit by what are the conflicting urgencies that they deal with. When we look at the national AIDS control programs, they definitely want to have safe blood but they are also having to look at how do they prevent 90 percent of the other infections that are occurring.

There are also the issues of how do they deal with the infrastructure challenges. Certainly there is an urgency but they are constantly faced with several conflicting urgencies at the same time.

Mr. SMITH. Could you just, any one of our panelists, speak to how well or poorly the UN Global Fund is focusing on this particular issue of safe blood? Mention was made, and I listened, as I am sure many others did, to the press conference yesterday when Bill and Melinda Gates accepted that very sizable contribution of about \$30 billion, and I noted that I think it was Melinda who said that this will go not toward new initiatives but expanding and building more capacity to existing ones.

I know that the Gates Foundation has been very helpful in the area of safe blood. I am wondering if we will be making an overture to them to expand that effort in Africa.

Dr. RYAN. I will take a stab at it. I think that one of the things we have done in the Emergency Plan is try to create successful models, and we have seen that in treatment. We have seen that in care. We have seen that in other prevention modalities, and what we hope to do is by providing successful models of scaling up safe blood programs that then the Global Fund can come in and either

continue sustainable support of those models or implement those models in other countries.

Mr. SMITH. The Global Fund? Anybody want to comment on that? Have they made this a priority?

Dr. RYAN. I think that in some countries. I cannot tell you which countries but I know that as part of a comprehensive prevention portfolio the Global Fund I would assume would be addressing some of those issues on blood safety.

Mr. SMITH. If you could, you and perhaps our panel of three witnesses, could you get back to us with some of the information about what the Global Fund is doing? Because it would be very helpful to know. Let me ask just a couple of final questions on the issue of blood testing supply kits. The two countries, the Democratic Republic of Congo and Kenya, reported using blood without testing for transfusion-transmitted infections due to the non availability of kits.

We hear that there have been disruptions in the supply. They would love to do it but the kits are not available. How much priority do we give to ensuring that a blood testing kit is readily available for testing?

Mr. HOLMBERG. Sir, are you talking about available to countries in Africa?

Mr. SMITH. Yes, the countries in Africa.

Mr. HOLMBERG. I cannot answer that question directly as far as the release of products from the United States over to Africa but I would like to make a statement that this is really part of the infrastructure that I think Dr. Ryan is talking about is really to try to have a sustainable model where we really work the systems out so that the supplies can get into the countries so that there will not be a disruption of services.

Mr. SMITH. Are we working that problem, in your opinion, sufficient to meet the need?

Dr. FERRIS. I think it is not. I think commodities in general are very difficult to get into certain regions, and there is a lot of work with supply chain management and improving those logistic systems throughout Africa.

Mr. SMITH. Very briefly, I have a question on the voluntary blood donation rate per country from non-remunerated blood donors. The WHO report suggests wildly high numbers of countries that have achieved 100 percent. Does that comport with our experience as well? At least 12 countries are at 100 percent, three at 95 and then it drops down to the worst, which is more attaining at 1 percent. What has been our experience? As Chakah Fattah indicated earlier, there could be a concern here that we are not getting true voluntary donors who are not being paid.

Dr. RYAN. The WHO report—and I am assuming that is from the 2004 blood safety data management report—that is based on a passive reporting system. Any type of passive reporting system you know does have its flaws. That is why we have aggressively put in monitoring and evaluation components into the PEPFAR countries so that we can have our own database that we look at to make sure that we follow that prospectively so we can get what we hope will either be substantial data that will confirm the 2004 report or give us better insight into what is really happening.

Mr. SMITH. WHO suggested in one of their reports that the cost of a unit of blood—and this was not just in Africa, but also other countries—was \$55. Do we have a sense as to what it costs to ensure that a pint of blood is indeed clean in Africa? Is there a number?

Dr. RYAN. We have made some rough calculations. We consider that if there is a 3 percent transfusion HIV prevalence rate then you would have to test one in 33 units to find the unit that is positive. At \$45 that would give us a rate of about \$1,800 per transfusion infection averted. That is not looking into what are the infrastructure costs, the electricity, the roads, et cetera. What we have to consider is how does that relate to what other prevention modalities there are.

For example, prevention of mother to child transmission which accounts for in the focus countries we figure 14 to 20 percent, that costs us including the cost for infrastructure, we estimate that cost to be anywhere from \$1,000 to \$1,800. In terms of cost infection averted, the expenditure for PMTCT included the infrastructure costs is less effective and it has a greater proportion of infections are due to maternal to child transmission.

Mr. SMITH. Finally, Dr. Holmberg, you mentioned 14 million blood units are missing or short in Africa. Obviously, reducing unnecessary transfusions would be one way of mitigating that. Even though you want to build up supply, stopping those that are not necessary would be an important goal. How much progress are the African nations making on trying to stop those unnecessary transfusions? Finally, if one of you might answer this: WHO says 5 to 10 percent of the HIV infections are attributable to bad blood. The number you gave was 3.2 percent. Is that because of better calculations or is it that the programs are beginning to work?

Dr. FERRIS. Regarding other means for reducing unnecessary transfusions, a lot of the focus there is on training physicians, other clinicians, and other healthcare workers on the proper indications and timing to transfuse a patient. It is difficult. Protocols are being developed and are already out there, and clinicians often have to compare the protocol to what they are seeing in front of them in terms of the patient's conditions but those protocols are out there, and are being developed. With other preventative measures, hopefully we can reduce the need for blood transfusions.

Mr. SMITH. Mr. Payne.

Mr. PAYNE. Thank you very much. As it is indicated, we see that there is a logjam in getting the funds down to the root and out. I wonder in the PEPFAR program has there been very much set aside for medical training? Any one of you could answer. Any way to increase the medical infrastructure at the grassroots level?

Dr. RYAN. All of those are very important parts of the strategy, and in each country we try to deal with all of them concurrently so that we can accelerate the process. What we see for example in Kenya is a very interesting thing where the first thing they wanted to do was make sure that there was universal testing of blood, and the second thing to do was to set up in hospitals transfusion committees so that you could train the hospitals and the doctor in those hospitals to say what is appropriate transfusion, and then monitor how well that is working, and a hospital will not be accred-

ited unless 80 percent of its transfusions are appropriate and the doctors have been trained.

So, it is a gradual process but I think that they all occur concurrently, and depending on the needs at different stages.

Mr. PAYNE. Have there been any new tests created for screening blood or is there any basic improvements in that technique?

Mr. HOLMBERG. Specifically for HIV?

Mr. PAYNE. Just in general. Just the screening process of blood. Someone said that CDC has created new tests for screening donated blood, and I was wondering how effective these tests have been in protecting the blood supply, and to what extent are the tests being administered.

Mr. HOLMBERG. As far as HIV and hepatitis C virus here in the United States and in most countries in Europe, there has been a migration to an advanced nucleic acid testing which has reduced the risk down to about one in 2 million for transmission of HIV or hepatitis C. I think what is being seen in the African countries is that the various equipment that is needed to do some of the comprehensive tests requires some of the older technology, and some of these countries are not ready to migrate to the more advanced technology because it does require more equipment and also highly trained individuals.

Mr. PAYNE. Just aside from HIV, with malaria is malaria still a bigger killer than HIV and AIDS?

Dr. RYAN. From transfusion or in general?

Mr. PAYNE. Just in general.

Dr. RYAN. I guess it would depend on sub-Saharan Africa.

Mr. PAYNE. Yes, that is what I am speaking about.

Dr. RYAN. I actually do not know how many deaths there are due to malaria.

Mr. PAYNE. There has been little attention given to malaria over the years. I think that perhaps it has been because where malaria exists poor people live, and in a lot of instances it is not an incentive for pharmaceutical corporations to invest in those areas because the question comes up who is going to pay for it? As we know, the cost of providing an effective drug, according to the drug companies, there are so many failures until you get one, and therefore it seems that although we are dealing with safe blood and HIV, there has not been the attention given to malaria over the years.

I do know that now there seems to be some move toward nets and some of the other programs. Even with the President's initiative it is HIV/AIDS, malaria and tuberculosis and so malaria has kicked in over the past few years but it has been an area that seemed to have been neglected. I just wonder if any of you have any comment on that and then I will end my questioning because we are under time constraint.

Mr. HOLMBERG. Yes, sir. If I can just respond back as far as the prevalence in healthy donors. Once again we have very sketchy data as far as malaria primarily because the testing for malaria is not that refined. Most of the studies that have been done and reported are based on a blood smear in which you actually have to see one of the parasites and the various forms of the parasite but in Benin, the rate is 33.5 percent in their donor population. In Ni-

geria, there has been reports anywhere from 4 percent all the way up to 40 percent.

It depends on the geographic locations, and what you are hitting upon right now as far as even the attention primarily is because we have not been able to have sophisticated testing to be able to detect the malaria, and also various attempts that have happened over the years such as vaccinations has been not as successful as we had hoped they would be. I remember I think yesterday even with the Gates Foundation was talking about pursuing some of the activities with malaria. I heard that on the press release.

That is a real area of concern and study because we have not been able to produce a vaccine to the malarias because there are four different types of malarias that undergo different structures in their development.

Mr. PAYNE. Thank you very much. I will yield.

Mr. SMITH. Ms. McCollum.

Ms. MCCOLLUM. Thank you. I want to thank the Congressman from Pennsylvania for his work on this area because I did get to see, when I was in Tanzania CDC clinic in a hospital, and where there were, as Chairman Smith pointed out, very few units of blood available. I do not even know if the refrigerator was quite working at the right temperature but the awareness was being created and opportunities were hopeful.

They also had a clinic where they had a group of I would call them junior high, high school students volunteering to give blood much like you would see at our high schools, and a couple of things were happening at the same time. They were talking about HIV/AIDS prevention. They were being role modeled as leaders in their community.

I went in and talked to all of them about what a great gift of life that they were giving but that is only going to work in a very few hospitals in the cities but the work needs to start somewhere, and it does need to move forward. My understanding in Africa for the most part they do not even test for malaria because just about everybody in Africa has malaria.

In the maternal child health clinics I was out in, I ran into a couple of places where some doctors, clinicians and nurses had great microscopes to look at blood but they did not have a generator operating to plug in the electric microscope to look at it. Here is where I would like to go kind of with my questioning. PEPFAR was supposed to be all new money, and it was not.

I know that I could get all the numbers from my office but we did not bring them over with me. Maternal child health to the best of the ability of people who are on the Appropriations Committee money has been juggled around. It has been shifted out of one area into another area. PEPFAR seems like I hear there is a little bit of a shift. PEPFAR was first going to kind of have all these free-standing independent this is the PEPFAR clinic and they only do HIV AIDS there.

My understanding now is PEPFAR has come to the conclusion that everything needs to be more integrated because of the limited number of health facilities and the limited number of people available to provide assistance in those health facilities because of the brain drain and other things going on. Can you tell me what part

of the PEPFAR budget is going toward blood versus what part is going toward for example abstinence? The CDC funds that are in here, is that also coming out of PEPFAR or is that funded separate?

Dr. RYAN. The funding is PEPFAR funding to CDC for CDC to be the implementor of the safe blood programs through what is called a track one central. There is also some USAID money that is PEPFAR money but it is coming at the program level from USAID. You are correct in saying that the PEPFAR model is one of integration because what we are really focused on is sustainability, and we work very closely under the three ones, the UNAIDS three ones to make sure that the programs that we put in place are under the country's policies and operations so that they go on to be sustainable over time.

That is a really important piece of the blood safety program too, and it accounts for some of the delay perhaps in funding is that where we are using national transfusion services because most countries rely on their government to supply safe blood, and after PEPFAR or whatever we need to make sure that those governments are empowered to continue supplying safe blood. That has been a very important part of the program.

Ms. MCCOLLUM. Mr. Chair, if I may. Dr. Ryan, you are saying all of the PEPFAR programs are fully integrated? If I go into a PEPFAR area where the President's initiative has been set up and there is HIV, tuberculosis clinic nearby it is all under one roof now? We are not taking healthcare workers from one area to go to another?

Dr. RYAN. No. What I am saying is that we work under the auspices of the national AIDS control program. So the strategies that we have put in place and the programs that we have put in place are in full coordination with the national government. So that government essentially would try to coordinate under their policies and their framework how the PEPFAR programs would be implemented.

Mr. SMITH. I deeply regret that we have four votes on the Floor. I have a number of questions I would like to submit for the record. I will leave as soon as you are done answering. The hearing will be in recess and then we will convene with panel three. On that whole issue of incremental approach, could you elaborate on that for the Committee? I read the report, and it does make a case, but as I said to Chakah Fattah earlier, there is incremental and there is enhanced incremental. It depends on how fast. You cannot build infrastructure in a day but you can build it faster if there is a will.

I say this with a clear understanding of your points about money in the pipeline, and the graph certainly makes a compelling case that the money is there just waiting to be utilized, and hopefully utilized effectively. But if you could speak to that I will look at it as soon as we get back on the record and then we stand in recess.

Dr. RYAN. The question is is it better to supply money for multiple years over time versus one large amount of money. Because of the absorptive capacity and some of the issues that I already raised, in order to get full blood safety program because of the manpower issues, the infrastructure issues, we felt that it was better and the examples of both Nigeria and Malawi I think provide

very good examples of how sustained funding over time led to a much more successful, sustainable program than just one large bolus of funding.

Staff. Thank you. We will now adjourn until the Chairman returns. Thank you.

[Recess.]

Mr. SMITH. The Subcommittee will resume its hearing. I would like to invite to the witness table our third panel, beginning first with Karen Shoos Lipton, who has served as the Chief Executive Officer for AABB since October 1994. Prior to joining AABB, Ms. Lipton was with the American Red Cross for 10 years. During her tenure with the American Red Cross, she served as acting senior vice president of biomedical services from November 1993 to September 1994, where she was responsible for the operations of this \$1 billion revenue division engaged in the collection, processing and distribution of blood and tissues and blood components.

We will then hear from Dr. Edward Green, who is an applied medical anthropologist with 30 years of experience in developing countries, including numerous countries in sub-Saharan Africa. Dr. Green's sectoral experience includes AIDS and sexually transmitted diseases, primary healthcare, maternal and child health, child nutrition, water and sanitation. He has authored five books and over 350 peer-reviewed journal articles or book chapters, conference papers or commissioned technical reports.

Ms. Lipton, if you could begin.

STATEMENT OF MS. KAREN SHOOS LIPTON, CHIEF EXECUTIVE OFFICER, AABB (FORMERLY THE AMERICAN ASSOCIATION OF BLOOD BANKS)

Ms. LIPTON. Good afternoon, Chairman Smith and the other Members of the Subcommittee who might come in. On behalf of our members we thank you for the opportunity to testify on the critical role of the President's Emergency Plan for AIDS Relief and improving blood safety in sub-Saharan Africa and the Caribbean.

AABB is a professional society with over 8,000 individual professionals in the fields of blood banking, transfusion medicine, cellular therapies and cord blood, and 1,800 institutions including blood centers, hospital based blood banks and transfusion services. Twenty percent of our members are located outside of the United States in 80 countries around the world.

For over 50 years AABB has set voluntary standards for blood centers and transfusion services, and we have accredited those institutions against those standards. AABB standards are based on universally accepted quality principles, and they contain detailed technical requirements applicable to blood donor recruitment and evaluation, blood collection, blood processing, blood testing, blood storage and blood transfusion.

AABB was the original developer and author of what we call quality system essentials which are now used as the basis for many laboratory standards and accreditation programs. AABB has had significant experience globally in improving transfusion medicine. Our written testimony contains a list of our activities but for purposes of today's hearing I would like to tell you that AABB is the technical assistance provider for blood safety in 6 of the 14

PEPFAR focus countries, Guyana, Kenya, Mozambique, Rwanda, South Africa and Tanzania.

Written and oral testimony from other presenters has described the scope of the PEPFAR blood safety initiatives. From the technical assistance provider perspective all of us are engaged in the same activities, assessments, work plan development, training in all aspects of blood collection, processing and administration, advice on equipment purchase and rentals and assistance with the development of standard operating procedures and quality systems.

I know that we all believe that the need to improve blood safety and availability in all of the PEPFAR countries and in all of Africa is urgent and demands a powerful response. Today I would like to focus my comments on several critical issues that I hope might shape Congress' response to this tremendous need.

First, the acute shortage of human resources and by that I mean appropriately educated and trained healthcare professionals, specifically physicians and medical technologists, is a serious threat to real progress. In each country there are at best a handful of individuals who are qualified to manage a national blood program, and these individuals often have multiple responsibilities within the ministries of health, working with dozens of relief providers, governmental and nongovernmental.

In many cases, these individuals are so busy attending meetings that it is difficult to achieve the real work of operating and changing the system at the same time. The sad truth is that providing greater level of fundings without dealing with this serious limitation of capacity is simply not responsible. Outside the PEPFAR countries there is also a serious limitation globally of individuals who are truly qualified and competent to provide the necessary assistance.

Today in the U.S. there is a serious shortage of medical technologists, nurses and physicians in transfusion medicine making recruitment for PEPFAR a challenging task. Globally each of the technical assistance providers runs the risk of destabilizing another fragile blood system when we recruit trained professionals from the ranks of blood transfusion services in other African countries.

Second, sustainable blood safety and availability, unlike some of the other PEPFAR tracks, relies on infrastructures that do not exist or are at best weak. Poor roads, unreliable electricity and water and seasonal flooding that makes some parts of our countries inaccessible at certain times of the year are a serious threat to keeping blood, a perishable and temperature sensitive biologic, safe for transfusion.

The lack of appropriate curricula, qualified teachers and equipment in medical and technical schools threatens our ability to bring qualified workers into the blood centers, and the cumbersome tender procurement and hiring systems that slow the ability to access PEPFAR funds, that slow the ability to acquire the necessary equipment and reagents and vehicles and that slow the ability to recruit and retain qualified staff are barriers to real and sustainable change.

These barriers cannot be removed by throwing money at the problem. Removing them requires a long-term commitment of qualified technical assistants who work within the country to

change these systems. PEPFAR funding for improvements to the safety and availability of blood has saved countless lives mostly in vulnerable populations such as children and pregnant and postpartum women.

These improvements made under the mantle of HIV prevention have the added benefit of reducing the risk of many other transfusion transmitted diseases and the biggest risk of blood transfusion in Africa, the unit that is not there when it is needed.

Improvements to capability testing and transfusion practices are also improving clinical outcomes and reductions in the risk of transfusions related complications including death that far exceed the benefits of reducing the risk of HIV alone. For this reason, AABB supports the expansion of the Federal Government's efforts to improve the safety and supply of blood in Africa with the caveat that this expansion must be accomplished in a well-organized and deliberately phased approach that recognizes the capacity building nature of the programs that we are involved in, and the real limitations in the infrastructure and healthcare systems of these countries.

Providing massive funding to the countries' governments and the national blood transfusion services without recognizing a country's capacity to properly utilize the funds, without recognizing the country's ability to appropriately use blood and blood components and without strengthening supporting infrastructure will result in a failed effort in the long term. Moreover, if PEPFAR's blood safety program is expanded to cover additional African countries, careful consideration must be given to assuring that technical experts do not destabilize existing blood services in an attempt to find qualified individuals.

Existing national education and training systems must be strengthened in country to ensure a continual stream of properly trained healthcare professionals if these programs are to be sustainable. Finally, in order to fully benefit all patients, attention must be given to improving transfusion from what we call vein-to-vein, from the collection of the unit to the transfusion into the individual.

It is not enough that we improve infectious disease testing of blood. We must also work to ensure that the units are appropriately stored until the time of transfusion, and that each patient gets the right unit of blood. The wrong unit to the wrong patient or hemolysis of a unit of blood that is not stored in an appropriate temperature can kill more swiftly than any disease.

Blood transfusions are a significant therapy in the treatment of complications related to childbirth, pediatric anemia related to malaria and victims of trauma but absent the necessary improvements in every aspect of blood—donor recruitment, blood collection and processing, testing and blood administration—we will not achieve our goal of making blood safe and available for those patients in need.

AABB urges this Committee and Congress to support the development of a well-organized plan for the expansion of the blood safety program in three ways. One, incrementally expand funding to technical assistance providers in the 14 PEPFAR focus countries

based on realistic estimates of human resource capacity, and the country's ability to absorb the increased funding effectively.

Two, add nonfocus countries into an organized blood safety improvement program again in an incremental, organized and sustainable manner. Three, recognition of the current status of the blood safety programs and the substantial work that remains to be done in these countries, extend PEPFAR blood safety funding beyond the current March 10, 2010, deadline for development of sustainable blood programs. Thank you.

[The prepared statement of Ms. Lipton follows:]

PREPARED STATEMENT OF MS. KAREN SHOOS LIPTON, CHIEF EXECUTIVE OFFICER,
AABB (FORMERLY THE AMERICAN ASSOCIATION OF BLOOD BANKS)

Good morning Chairman Smith and members of the Subcommittee. My name is Karen Shoos Lipton and I am Chief Executive Officer of AABB. On behalf of AABB's members we thank you for the opportunity to testify on the important role of the Presidents' Emergency Plan for AIDS Relief (PEPFAR) in improving blood safety in Sub-Saharan Africa and the Caribbean.

AABB is a professional society at its core, representing approximately 8,000 individual professionals in the fields of blood banking, transfusion medicine and cellular therapies and 1,800 institutions, including blood centers, hospital-based blood banks and transfusion services. Approximately 20 percent of our members are located outside of the United States in 80 countries around the world.

For over 50 years, AABB has set voluntary standards for and accredited blood centers and transfusion services. In addition, we promote quality care for patients through our standard-setting and accreditation of cord blood and hematopoietic stem cell collection and storage facilities, immunohematology reference laboratories, and relationship testing laboratories. In fact, AABB, was the original developer and author of quality system essentials, which are now used by a number of organizations as the basis for their standards and accreditation programs.

Globally, in addition to our role as a blood safety "Technical Assistance" provider under the PEPFAR program, AABB has formal and informal liaison relationships with many organizations around the world and has been involved in numerous blood safety projects. For example, we are a founding and active member in the World Health Organization's Global Collaboration for Blood Safety. Jointly with the Pan American Health Organization, AABB assisted in the development of regional standards and implementation guidance for blood banks and transfusion services in the Caribbean region and delivered initial training on those standards to representatives from 22 countries. In 2004, we developed and delivered training for the Canadian government's blood bank regulatory inspectors. Through our voluntary accreditation program we perform assessments and accredit 49 blood collection and transfusion facilities in 16 countries.

More recently we signed two memoranda of understanding with the Chinese Society of Blood Transfusion and Shanghai Blood Center to develop professional education and technical programs in China and were selected as a subcontracting organization for a United States Agency for International Development (USAID) grant to improve blood safety in the country of Moldova.

AABB'S EXPERIENCE AS A TECHNICAL ASSISTANCE PROVIDER IN AFRICA

Under the President's Emergency Plan for AIDS Relief, AABB is the Technical Assistance provider to six of the 14 focus countries, Guyana, Kenya, Mozambique, Rwanda, South Africa and Tanzania.

As a Technical Assistance provider, AABB's role is to work with each country's Ministry of Health and National Blood Transfusion Service (NBTS) to strengthen the blood supply and address safety systems. The seven key areas identified by the Office of the Global AIDS Coordinator (OGAC) and the Centers for Disease Control and Prevention (CDC) as meriting attention include:

1. Infrastructure
2. Blood Collection
3. Blood Testing and Processing
4. Transfusion and Blood Utilization
5. Training
6. Monitoring and Evaluation

7. Sustainability

AABB's approach is, first, to conduct a complete assessment of the existing situation in each country. We perform a detailed "vertical" assessment of the country's infrastructures that impact blood transfusion, including:

- enabling legislation;
- regulatory systems;
- government policies;
- NBTS policies and organizational structure;
- financial support for the blood program;
- educational systems; and
- infrastructure (e.g., roads, electricity).

Concurrently, we assess horizontally the NBTS management, operational systems, and infrastructure, including:

- staff training;
- donor recruitment;
- donor evaluation and screening;
- blood testing and processing;
- storage and distribution; and
- transfusion practices and blood utilization.

Once the assessment is completed, it is shared with the Ministry of Health and the NBTS in each country and, together, we develop a customized five-year work plan targeted at each area requiring improvement. From our decades of experience in the United States, and more recently in other regions of the world, we believe a key to advancing transfusion medicine and blood safety is assisting each country in establishing national standards that are based on universally accepted quality principles, but tailored to the individual public health needs and resources of each country. Such standards allow the countries to implement their own quality systems that can be sustainable into the future, even with the inevitable transition of personnel in the country and after U.S. partners in this program have departed.

At this time, AABB is actively engaged in each of its six countries, working under organized and coordinated work plans for each. Each country, of course, is unique, but there are common problems that create significant challenges.

To provide some perspective about the complicating factors that need to be addressed, we would like to provide you with a few real examples from our experiences:

- *Standardized Testing and Collections:* 'As a general goal, AABB and others involved with PEPFAR's blood safety program are all working toward standardizing the collection and testing of blood and, in general, reducing the number of locations where these activities are performed. We have all witnessed, first-hand, some of the deplorable conditions—non-functioning or non-existent equipment, no standard operating procedures and barely trained staff—that exist in some of the blood collection and testing sites. In some countries, centralization of some of the activities, particularly of testing, can serve to increase the quality of practice. As a practical matter, however, this is not a solution that works in every country. The very real problems of lack of roads and transportation, including in some places, whole areas of the country that are inaccessible during the rainy season, and the difficulties of maintaining an effective cold chain for this perishable material, require that additional sites be established and maintained, if we are to ensure the availability of blood for all patients in need. The very basic challenge of providing this service in areas that have unreliable electricity and water is daunting.
- *Rapidly Expanded Funding:* Often, even the simple process of accepting and disbursing funds becomes a roadblock to success. As an example, in one of our countries, it took nearly 10 months to open a bank account to receive PEPFAR funds and establish the requisite authority to access the funds. Even more common is the concentration of signature authority for the disbursement of funds in one person who must approve every purchase, from equipment, to reagents, to pencils. Further complicating the situation in most countries is that the NBTS is generally required to utilize the tender and procurement system that typically resides in the Ministry of Finance, and which is often cumbersome and based solely on a principle of lowest bid, without regard to technical compatibility or quality.

- *Limited Senior Staff:* In most countries there is only one or, at best, a few senior staff with the education and experience necessary to manage the NBTS operations. And, many of the individuals in these countries hold several positions, including Ministry of Health or public health laboratory responsibilities. Their schedules are further complicated by the sheer number of foreign government and non-governmental organizations (NGOs) operating in many of these countries. It is not uncommon for these individuals to spend entire days and weeks just attending meetings with these funding organizations, leaving little, if any, time to actually implement the changes or manage the day-to-day activity. This very real problem limits the capacity of the country to effectively deal with funding opportunities.
- *Sustainability:* The ability to sustain the improvements in blood safety into the future beyond the PEPFAR funding period is dependent on recognizing many inter-related factors, some of which are outside of the control of the NBTS. Several examples include:
 1. *Need for sustainable financial systems for blood programs.* Most countries have a limited understanding of the costs required to maintain a safe and adequate blood supply. One solution may be to establish a per-unit cost recovery system whereby the per unit charges can be passed on to the patient, insurance and/or into the hospital budget on a rationale usage. This solution, however, will be extremely difficult to implement and may have the effect of undermining efforts to create a voluntary blood supply as donors question why patients must pay for something that is given for free.
 2. *Need for educational and training systems that properly prepare individuals for jobs and careers in the blood bank, transfusion medicine and/or laboratory fields.* In most NBTS's, the collection and laboratory staff are almost completely trained in an "on the job training" format, with minimal, if any formal education in the medical or laboratory field. Physicians often have had no, or very limited, instruction in transfusion medicine and proper blood utilization and administration. Even in those countries where training programs exist, the technical schools are often challenged by a lack of textbooks, materials and equipment required to teach the necessary skills.
 3. *Need for total systems and strategic approach.* On a day-to-day basis, the NBTS's are continually operating in a crisis-management mode, requiring them to focus their attention narrowly on solving each isolated, immediate problem, rather than looking at the overall systems and putting in place a more permanent system-wide solution. For example, if a facility runs out of test kits, it will most often "beg, borrow and steal" from another lab or facility, rather than focusing on improving the inventory and procurement process to avoid repeating the situation the following month.

AABB SUPPORTS GRADUAL EXPANSION OF THE BLOOD SAFETY PROGRAM

PEPFAR funding for improvements to the safety and supply of blood for transfusion has saved the lives of countless people, mostly children and women of child bearing age, in the 14 focus countries. Congress should also be aware that the improvements to blood safety and availability made under the name of AIDS/HIV prevention have the added benefit of reducing the risk of many other transfusion-transmitted diseases, most notably hepatitis B, and in reducing the biggest risk of blood transfusion—the lack of blood when it is needed. Additionally, improvements to compatibility testing and transfusion practices are providing significant improvements to the clinical outcomes and reductions in the risk of transfusion-related complications, including the potential for death, that far exceed the benefits of reducing the risk of AIDS/HIV alone. Finally, it is important to recognize that blood is a critical health care infrastructure. Without improvements to the safety and availability of blood, further improvements to health care, including treatment for cancer, malaria and surgeries, will not be possible.

AABB supports the expansion of the federal government's efforts to improve the safety and supply of blood in Africa but we need to also emphasize the need for a well organized and deliberately phased approach to such expansion that recognizes the real limitations in the infrastructure and healthcare systems of these countries.

Specifically, we would like to make three key points. *First, in our experience, each country's ability to make improvements is based on several limiting factors, most notably the lack of properly educated/trained human resources; limited existing*

healthcare delivery systems; and basic, often insufficient, infrastructures. Funding massive improvements to the NBTS without recognizing each country's capacity properly to utilize the funds, appropriately to utilize blood and blood components, or to build supporting infrastructure, will result in a failed effort in the long term. PEPFAR Technical Assistance providers and NBTS's work plans need to take a "complete systems" approach, and not an "emergency" or crisis management approach to addressing all of these substantial barriers. Moreover, the work plans need to address the blood supply needs of the entire country, which often requires time-consuming and deliberate efforts.

Second, the number of technical experts in the field of blood banking and transfusion medicine available globally to provide the necessary assistance is limited. There are a limited number of individuals from high human index development countries who are available to spend the time necessary to provide real assistance. Attempts to attract qualified individuals from other African countries with better blood systems only serves to de-stabilize those blood programs. Within the focus countries themselves, there are few qualified professionals who can extend that knowledge to the next generation of blood providers. If PEPFAR's blood safety program is expanded to cover additional African countries, careful consideration must be given to assuring that technical experts do not "desert" one country still in need in an effort to help another. Systems must be put in place to begin training sufficient numbers of blood banking and transfusion medicine providers.

Third, in order to fully benefit African patients, attention must be given to improving transfusion medicine "vein to vein"—from the collection of blood from volunteer donors, to the safe testing and processing of the blood components, to the act of transfusing these products into patients. It is not enough that we improve infectious disease testing of blood; we must also work to ensure that the units are appropriately stored until the time of transfusion and that each patient gets the right unit of blood. The wrong unit to the wrong patient or hemolysis of a unit of blood that is not stored at an appropriate temperature can kill as effectively as any disease. Blood transfusions are a significant therapy in the treatment of complications relating to childbirth, pediatric anemia related to malaria, and victims of trauma. Absent the necessary improvements in all aspects of blood—donor recruitment, blood collection and processing, testing and blood administration—we will not achieve our goal of making blood safe and available for these patients in need.

AABB urges this Committee and Congress to support the development of a well organized plan for the expansion of the blood safety program in three ways:

1. *Incrementally expand funding to technical assistance providers and the 14 PEPFAR focus countries based on realistic estimates of human resource capacity and the countries' ability to absorb the increased funding effectively.*
2. *Add non-focus countries into an organized blood safety improvement program, again in an incremental, organized and sustainable manner.*
3. *In light of the current status of blood safety programs and the substantial work to be done, extend PEPFAR blood safety funding beyond the current March 2010 deadline for development of a sustainable blood safety program.*

AABB would welcome the opportunity to work with Congress, OGAC, CDC and other interested parties to develop a comprehensive plan for blood safety in the PEPFAR focus and non-focus countries. Thank you for the opportunity to express our opinions and share our experiences in the development and implementation of blood safety programs globally.

Mr. SMITH. Ms. Lipton, thank you so very much. Dr. Green.

**STATEMENT OF EDWARD C. GREEN, PH.D., MEMBER OF THE
PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS**

Mr. GREEN. Mr. Chairman, thank you for inviting me to participate in this important hearing on the issue of blood safety in Africa. I am a Senior Research Scientist at the Harvard Center for Population Development and Studies, which has the mission to promote cross-disciplinary research on critical issues of population health and development that will advance the well-being of the global poor.

For most of my professional career I have not been an academic. I have worked in less developed countries, mostly in Africa, as an

applied behavioral science researcher, a designer and evaluator of public health programs mostly under the funding of USAID.

I have worked extensively in Africa and other resource-poor parts of the world. I have served as an in-country advisor to the ministries of health in both Mozambique and Swaziland, and I served on the advisory boards of several AIDS organizations, including the Presidential Advisory Council on HIV/AIDS.

I have worked on AIDS prevention since the mid 1980s, and I appreciate the attention that you are bringing to the issue of safe blood and prevention efforts. It is difficult to believe that in populations with extraordinarily high HIV prevalence rates, as high as 35 percent or more in some African countries, national policies, trained personnel and infrastructure are lacking or absent to ensure the blood collected and used for blood transfusions does not put the patient at risk for contracting HIV, hepatitis, malaria, et cetera.

I am aware of the limited resources that are available to address this overwhelming health crisis, and I am aware that it will take a considerable time before numerous infrastructural inadequacies, healthcare worker shortages and other long-term development challenges inherent in a safe blood solution can be achieved. However, I would submit that there are means to address this crisis that could be undertaken immediately that do not require significant resources, and that would have measurable impact.

Two such means to which I would like to draw your attention would require little more than a determination to put appropriate national policies into place, and to implement a follow-up strategy to ensure their proper and continued implementation. One is the importance of the screening and treatment of blood donors. Reports from the World Health Organization clearly demonstrate that donors who are unpaid volunteers and who donate regularly are the least likely to donate blood tainted with HIV and other life threatening pathogens.

The likely reason behind this phenomenon is that such donors are motivated purely by altruism, and have no reason to hide their HIV status or other conditions that might affect blood safety. Paid donors and relatives of the patient, on the other hand, could have such motives for obvious reasons.

One often overlooked factor in the recruitment and retention of voluntary blood donors is the treatment of donors within the medical system. Here in the United States we take for granted that when we go to give blood we will be greeted by a competent medical professional who has received adequate training for the proper taking of blood. We take for granted that the needle is sterile, and that being at the health facility will not threaten our own health, and we are relatively certain that if something goes wrong as a result of the blood donation, medical personnel are on hand to address the problem.

Our blood donor programs are also set up to make the processes as easy and efficient as possible. These are all assumptions that do not necessarily apply in Africa. Administrators of safe blood programs in Africa need to give attention in ensuring that competent, polite medical personnel draw blood from donors in a sanitary, welcome environment, and that any necessary follow-up is provided

immediately and within close proximity to the donor station. Such services also need to be consistent, since the volunteer blood donor station relies on its reputation to retain current donors and to attract additional ones.

Finally, I would emphasize the need for national policies and training to reduce the number of unnecessary transfusions. Several studies of African health facilities in the 1990s indicate that between 13 and 47 percent of all pediatric transfusions are unnecessary. According to one study in Kenya, almost half of all pediatric transfusions could have been avoided if prescribing practices had followed standard transfusion guidelines. Such guidelines and policies are readily available, for example, from international health organizations.

Transfusions could also be reduced significantly if increased attention and resources were directed to preventing maternal hemorrhaging and reducing the overall prevalence of malaria yet only half of the PEPFAR focus countries report having national guidelines that govern the clinical use of blood. I would therefore encourage U.S. agencies and organizations involved in blood safety to focus on these fundamental and essential elements that could be implemented now and at relatively little cost.

Thank you once again, Mr. Chairman and Members of the Subcommittee for focusing attention on safe blood in Africa, and particularly on means to prevent the transmission of HIV through blood transfusions.

[The prepared statement of Mr. Green follows:]

PREPARED STATEMENT OF EDWARD C. GREEN, PH.D., MEMBER OF THE PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

Mr. Chairman, thank you for inviting me to participate in this important hearing on the issue of blood safety in Africa. I am a Senior Research Scientist at the Harvard Center for Population and Development Studies, which has the mission to promote cross-disciplinary research on critical issues of population, health and development that will advance the well-being of the global poor. For most of my professional career, I have not been an academic. I have worked in less developed countries as an applied behavioral science researcher and as designer and evaluator of public health programs, mostly under funding of the US Agency for International Development. I have worked extensively in Africa and other resource-poor parts of the world. I served as an in-country advisor to the ministries of health in both Mozambique (1994–5) and Swaziland (1981–83), and I serve on the advisory boards of several AIDS organizations, including the Presidential Advisory Council for HIV/AIDS (2003–), the Office of AIDS Research Advisory Council, National Institutes of Health (until 2006), and AIDS.org. Internet portal for AIDS information. I have worked in HIV/AIDS prevention since the mid-1980s, and I appreciate the attention that you are bringing to the issue of safe blood in prevention efforts.

It is difficult to believe that in populations with extraordinarily high HIV prevalence rates—as high as 35% or more in some African countries—policies, trained personnel and infrastructure are lacking or absent to ensure that blood collected and used for blood transfusions does not put the patient at risk of contracting the disease. I am aware of the limited resources that are available to address this overwhelming health crisis, and I am aware that it will take considerable time before numerous infrastructure inadequacies, health care worker shortage, and other long-term development challenges inherent in a safe blood solution can be achieved. However, I would submit that there are means to address this crisis that could be undertaken immediately, that do not require significant resources, and that would have a measurable impact. Two such means to which I would like to draw your attention would require little more than a determination to put appropriate national policies into place and to implement a follow-up strategy to ensure their proper and continued implementation.

One is the importance of the screening and treatment of blood donors. Reports from the World Health Organization clearly demonstrate that donors who are un-

paid volunteers and who donate regularly are the least likely to donate blood tainted with HIV and other life-threatening pathogens. The likely reason behind this phenomenon is that such donors are motivated purely by altruism and have no reason to hide their HIV status or other conditions that may affect blood safety. Paid donors and relatives of the patient, on the other hand, could have such motives for obvious reasons.

One often-overlooked factor in the recruitment and retention of voluntary blood donors is the treatment of donors within the medical system. Here in the United States, we take for granted that when we go to give blood, we will be greeted by a competent medical professional who has received adequate training for the proper taking of blood. We take for granted that the needle is sterile and that being in a health facility will not threaten our own health. And we are relatively certain that if something goes wrong as a result of the blood donation, medical personnel are on hand to address the problem. Our blood donor programs are also set up to make the process as easy and efficient as possible. These are all assumptions that do not necessarily apply in Africa. Administrators of safe blood programs in Africa need to give attention to ensuring that competent, polite medical personnel draw blood from donors in a sanitary, welcome environment, and that any necessary follow-up is provided immediately and within close proximity to the donor station. Such services also need to be consistent, since a volunteer blood donor station relies on its reputation to retain current donors and to attract additional ones.

Finally, I would emphasize the need for national policies and training to reduce the number of unnecessary transfusions. Several studies of African health care facilities in the 1990s indicate that between 13–47 per cent of all pediatric transfusions are unnecessary. According to one study in Kenya, almost half of pediatric transfusions could have been avoided if prescribing practices had followed standard transfusion guidelines. Such guidelines and policies are readily available, for example from international health organizations. Transfusions could also be reduced significantly if increased attention and resources were directed to preventing maternal hemorrhaging and reducing the overall prevalence of malaria. Yet only half of the PEPFAR focus countries report having national guidelines that govern the clinical use of blood.

I would therefore encourage U.S. agencies and organizations involved in blood safety to focus on these fundamental and essential elements that can be implemented now and at relatively little cost. Thank you once again, Mr. Chairman and Members of the subcommittee, for focusing attention on safe blood in Africa and particularly on means to prevent the transmission of HIV through blood transfusions.

Mr. SMITH. Dr. Green, thank you very much for your testimony as well. I would like to hear from Chakah Fattah if he has any questions.

Mr. FATTAH. Dr. Green, let me ask you first, do you think that given the 45 countries in sub-Saharan Africa and given the problems with HIV that there would be resistance to some type of collaborative federation effort instead of going through each national health ministry in each country? Do you think that perhaps there could be a more area wide focus that would cross-fertilize a program?

Mr. GREEN. I think that would be feasible, yes.

Mr. FATTAH. Let me ask you another question. Do you think that an effort to make the public aware of the utility and the civic minded nature of blood donations over a period of time could penetrate African society in sub-Saharan Africa to encourage people who are healthy to voluntarily donate blood? As you have indicated here, that is something that we could start sooner rather than later.

Mr. GREEN. In principle, yes. There are some indigenous theories of disease where you might have to address some people's concerns about what might be done with their blood, but in principle, yes.

Mr. FATTAH. We have thousands of United States Peace Corps volunteers in Africa. Do you think that they could be utilized in some constructive way in terms of educating people and encour-

aging, particularly in communities where they are now working, building schools, doing other things, that they could be a part of an effort?

Mr. GREEN. I think that is a good idea, and as a matter of fact, it is my understanding that all Peace Corps volunteers working in sub-Saharan Africa have to do something related to AIDS. They may have some other job but they are all doing something related to AIDS. I did some training of Peace Corps volunteers in AIDS prevention in Swaziland a couple of years ago, and that is my understanding. I think that would work.

Mr. FATTAH. One last question. We have a few billion dollars that are sitting in the global AIDS fund and billions more sitting in the Millennium Challenge Account. Members of Congress who support these efforts—and I do too—have complained about the inability to get these dollars obligated more quickly and spent more quickly. Part of what we are talking about here is this particular effort and whether or not some additional resources focused at this.

Now, we heard some testimony earlier from Dr. Ryan that there was a problem at the country level, and as I would understand it, that has something to do with the requirements. We have required countries to come up with one strategy, and there is a sort of procedure bureaucracy that has been created. Are you aware of whether or not there have been any evaluations of whether or not there are alternative ways to utilize some of these dollars to proceed in terms of improving the blood supply?

Mr. GREEN. Well, sir, that is a broad and rather difficult question. There are bureaucratic realities that affect what we call the absorptive capacity. That is true. I think on the issue of ensuring safe blood and getting national safe blood policies and policies regarding transfusions in place I think that is an area where we could move relatively quickly but there are some problems with bureaucracies and national policies.

Mr. FATTAH. One last question, Mr. Chair. You state in your testimony that we could literally save lives doing this given your extensive experience. I do not know if you heard the earlier testimony. I believe you did. Some say it is 3 percent. Others say it is 5 percent. Health and Human Services say it could be 5 to 10 percent. Do you have any judgment about the data that is being used to make these judgments?

I have a lot of concerns about the empirical nature of the data that is being used as to the question of how many donors now. I mean how many units of blood that are being used for transfusion purposes in sub-Saharan Africa are tested at all or may be contaminated with HIV, given your experience.

Mr. GREEN. There are several questions there. I did actually notice that one of the questions that was asked—I do not think it was answered—the Chairman asked about the 3.2 percent. It is actually 3.19 percent of blood donors in all the PEPFAR focus countries except for Vietnam and Haiti. The average HIV prevalence rate was 3.19 percent. That was not the question. That 3.19 percent should not be confused with what percentage of the overall contribution to HIV infection comes from transfusions. I just want to clear that up.

I think what we heard from PEPFAR figures as WHO figures was 5 percent. That sounds reasonable, but there is no more efficient way to infect many people than with infected blood. It is something where a little effort could have a large impact.

Mr. FATTAH. Thank you. Ms. Lipton, you are a technical advisor in six of the countries you said?

Ms. LIPTON. That is correct.

Mr. FATTAH. Could you tell us whether or not you believe that the testing regime that is being reported by those countries is something we should rely on?

Ms. LIPTON. I think as Dr. Ryan earlier said it is a voluntary reporting system right now through the ministry of health.

Mr. FATTAH. I am familiar with what she said.

Ms. LIPTON. Right.

Mr. FATTAH. I am trying to ask you given your technical expertise whether you think we should rely on that data.

Ms. LIPTON. No. When we walk into a country, what we recognize is that most of what is being reported is being reported out of the public system, and in many places there is actually a private system that nobody knows what is happening with. I do think it would be very important for us to begin to collect data, and in fact, there will be data collected now by the technical assistance providers to try to get a better reality on what actually is going on in the countries.

Mr. FATTAH. You said a lot about infrastructure challenges, roads and difficulties to reach places. Where there are roads in the urban cities, where there is infrastructure in sub-Saharan Africa, are you suggesting that there is safer blood available?

Ms. LIPTON. I think there is no doubt.

Mr. FATTAH. Are the two related? I mean the infrastructure challenge and the safe blood challenge?

Ms. LIPTON. I think they absolutely are but it is not just infrastructure in terms of roads and electricity which is critically important too and water but also when I talk about infrastructure I mean training systems and education systems in the countries that help to develop experts in the country.

One of the things that happens to us in many situations is we train in on-the-job training and we get someone up to a certain competence level and they leave. If you do not have a system that continually feeds new people into a blood center or a hospital, you are correcting a problem for a day. You are not creating a system that allows it to be sustainable once we leave the country.

Mr. FATTAH. Is the biggest challenge the human capital infrastructure?

Ms. LIPTON. Absolutely.

Mr. FATTAH. How long, in your estimation, would it take us to create a system that could self perpetuate itself to train thousands and thousands of people repeatedly to be able to participate in a systematic delivery of safe blood?

Ms. LIPTON. I think you are realistically looking at a 5-year period. We have to go back and look at the medical schools and getting people trained in transfusion medicine in the medical schools, get their curriculum changed.

I cannot tell you how sad it is to go into the medical technical colleges even in a place like Kenya. We reviewed their curriculum because we were concerned about this and wanted them to help us. They have a wonderful curriculum. They have no books. They have no equipment to teach people. So essentially they are teaching medical technologists in a classroom, and then they are coming into the blood center expecting them to be able to do technical work.

Mr. FATTAH. If we had started 5 years ago, today we could have a system that could perpetually train people to provide for part of the system?

Ms. LIPTON. Yes. I think what is most important about this and you know everyone wants to do something on an emergency basis and I think we could move faster but if a country does not feel the problem themselves, and if they do not own it at the end it is just going to go away when we leave. A lot of what we do is I guess you might call it job owning if you will. We spend a lot of time in the ministries of health and the ministry of finance and the ministry of education really convincing them about the critical importance of blood, and that they need to set up policies, and they need to set up these clinical guidelines.

In most of our countries we have gotten them to adopt clinical transfusion guidelines. That is one step. That is 10 percent of the problem. Ninety percent is then educating the physicians on appropriate use. I think these are all very long-term efforts. We are in this for the long haul, and I really hope that when we talk about funding this we want and recognize we need to be.

Mr. FATTAH. But you agree we need to do it?

Ms. LIPTON. Absolutely.

Mr. FATTAH. Have we started doing it yet?

Ms. LIPTON. I think we have started. I think in many countries it has been a painful start up only because, an example, sometimes it took a long time for the governments to even set up the funding mechanisms. Every time we want to buy a piece of equipment, we have to go through the tender process in a country and not only go to the ministry of health but to the ministry of finance. One of the other things we are trying to do in these countries is gain a little bit of autonomy for the national blood transfusion service so that they have some control over their future and their sustainability.

These policies that we talk about that sound so simple and so realistic to us really take quite a bit of politicking to get through at that national level in the countries. I think the more visibility and the more we have countries talk to each other and recognize the success of other programs, I think we can gain some advantage. It is remarkable to me how little cross fertilization there has been in a lot of the African countries in the blood transfusion services, and that is something that from our perspective we are fortunate to have six countries.

We are really trying to build bridges and bonds, and actually get countries to partner one with the other. I think in the end that is what we need to do.

Mr. FATTAH. Let me thank you, and let me thank the Chairman.

Mr. SMITH. Thank you, Mr. Fattah. Ms. McCollum.

Ms. MCCOLLUM. Following along, it has been my observation that we need to train more birth attendants to identify high risk pregnancies to move people along quicker if there is even access to a regional hospital or someplace. I mean in some areas that we have traveled the access is limited.

You mentioned the shortage of some of the supplies in the room. When I am starting to hear of is the shortage of teachers, especially in nursing as more and more of the nurses leave and the nurses are not staying there to retire because they have either gone to England or to France or to Australia, wherever they are in high demand.

If you could maybe address the teaching shortage, and what you think we need to do. If you have any ideas of how we keep technicians and teachers in-country, and then about if you had the electricity, reliable electricity what would it cost to set up a blood bank? A minimal operational blood bank not in one of the larger district hospitals but the smaller hospital, referral hospital like in Tanzania. What would be the start up cost just in the equipment to do that if the electricity was reliable?

Ms. LIPTON. Let me address your first question first which is a real issue, the lack of teachers, the lack of individuals who remain in the country, and nurses in every country we have seen, if they are trained they leave because they can get better jobs. I think that is a very important issue.

One of the things that we struggle with is trying to make sure that the pay scale for people in the public sector who are working in the national blood transfusion services is sufficiently high to keep them working there so that when we train them they do not leave to get a better paying job in a private sector or elsewhere.

I think again a lot of that is going to have to be talking to the governments and getting them to understand that they need to invest in their own people and to make them stay in the system. Other than that, I am really not an expert in this area. I could only observe what I have seen.

What does it cost to set up a blood center? You know from top to bottom I guess in terms of American dollars it is not very much money. In terms of what is in their budgets, it would be huge. I think the problem is you could build a center, you could get the equipment in there but if that is all you are doing, and you have not fixed the rest of the problems, you have solved the problem for a day, and you have not ensured that when you walk out they are going to continue ordering the test kits, that they are going to continue training.

So that is why so much what we focus on is putting in place training systems and materials and training trainers so that when we depart there is a system that can carry forward, and is not dependent on one person leaving.

If I could just ask, do you have a sense—if I could ask my colleague, Mr. Riley—a sense of the dollar? I was going to say probably I mean I would think between \$500,000 and \$600,000 you could have. Now, that is assuming again that you are not trying to fix electrical problems which are significant.

Just as an example in Rwanda one of the places is so remote we are trying to do solar panels for electricity but the cost was just

prohibitive. So now we are just focusing on can we get one solar panel for the laboratory that would allow our refrigerator and some of the test equipment to run. You know I would love to see that as a solution that we could develop, and that is certainly something I think the U.S. could help in but that would require more funding efforts like that.

Mr. SMITH. Let me just ask some questions as well. I mentioned earlier the 2001 World Health Assembly Regional Committee and its targets and goals. Do you think that by 2012 at the current pace we are likely to reach—Ms. Lipton, this question would be for you—the goals that were articulated in that document? I mean it is obviously 11 years after bringing to the attention of the world that we have a plan. Is it being implemented?

Ms. LIPTON. I think if all the stars aligned correctly possibly but you also have to recognize that in some of the countries we are dealing with there is political unrest, and so when that happens I know in some of the countries our colleagues are working in they have to keep starting and stopping. I think by 2012 I think we should clearly be on a good start.

Mr. SMITH. Let me just ask you, you mentioned that we are in this for the long haul. What timeframe would you estimate is necessary to devise and implement a well-organized and deliberately phased approach? I understand the idea that capacity and infrastructure cannot be built overnight. You mentioned a moment ago the concern you have for the lack of books and the lack of machines and whatever is necessary. So you train up some motivated young men and women who then get sent out to the field and do not have the wherewithal to do what they have been trained to do.

How much faster do you think we could push this? We heard earlier and the submission as a result of Congressman Fattah's inquiry, the report that was written clearly shows that there is money just sitting there assumingly idle that needs to be put to good use so that more money can follow it. The question really is: How can we accelerate this timeframe without doing damage to infrastructure so we build it right but do it as quickly as possible?

Ms. LIPTON. I suppose the first thing I would say is that coordination of all the efforts that are going on in these countries is very, very important. You cannot have 20 different NGOs running around in a country not coordinating their efforts because everyone is working at cross purposes, and again there is no one there left to go and do the real work. I think we need to somewhat discipline ourselves when we go into countries, the U.S. and we need to work with the European Union and others to understand who is doing what, and that we all need to sort of work in a plan together.

I think that would actually speed things up as opposed to what is happening now when we are putting money in and getting people over there, and it is really very difficult to keep people on track and focused. Every time we have to pull somebody off in one of our countries we have planned training sessions that go for 2 weeks, every time we come in and they say, well we cannot do it that week because so and so is coming in here to do another project, we come to a dead halt. I do think coordination is important.

In terms of what would it take, I mean honestly and truly if I think about this I think it is going to take 10 years in each country

just to get us really so that we have the systems in place to sustain it, and I would really hope that this country could make that commitment and say, we will be there, and we will be there until we have put the system in place, until it is sustainable, and you know the thing that is so important about blood and everybody says this but it is so true, it is a critical healthcare infrastructure, and you cannot really improve a lot over the rest of the healthcare in a country.

You know you talk about cancer. Treating cancer victims, surgery. You cannot do that without a safe and reliable blood supply. This is a cornerstone of improved healthcare in African countries just as it was in the U.S.

Mr. SMITH. As you know there are an estimated 200,000 children who are born with sickle cell anemia every year in Africa, and those kids will require blood transfusions to lessen the impacts of sickle cell. It is a treatment which, each time, puts them at risk of one or the other blood-borne disease, including HIV/AIDS.

Given the fact that AABB has experience in standards setting in the area of cord blood accreditation in storage, collection, from deriving it from the placenta or the umbilical cord to actual transplantation, what is your sense as to when we might be able to begin to see cord blood being used to lessen or even cure sickle cell anemia? As I mentioned earlier, Keone Penn was perhaps the first to benefit. We are now creating in the United States a totally coordinated effort to collect and to make available this transplantation.

I have met with a number of health ministers, including most recently in Uganda with the health minister and gave them information about what we are trying to do here, and when we might be able to partner with that country, at least on a pilot basis. What would be your sense as to how we might get that off the ground?

Ms. LIPTON. Honestly and truly I do not think it is in the very near future. I think that what you have to recognize in the cord blood is when you go in to do the collections the conditions that you have to have and they have to be very controlled to get as you know good collections that are viable and that can really engraft.

It is a much more technical exercise. That does not mean that we could not assist with some cord blood units that we could even collect and could help with some of these pediatric patients but my experience in many of these countries is that the level of care for neonates really is not even at that level yet. That you know it really would be unusual for a child to be able to be whisked off to a setting where they could get a cord blood transplant. It is not to say we should not say that this is our goal but I do think it is perhaps a little bit further off than being able to get a safe and adequate blood supply.

Mr. SMITH. I understand your point about providing U.S. produced cord blood. Certainly, generated cord blood offers some hope for those who are suffering because it is very transportable, as you know. Let me just ask you with regards to women who are dying as a result of anemia and other problems. Obviously transfers of blood can save their lives as well.

My understanding is—and this is a WHO number—that 20 percent of all maternal deaths are attributable to anemia in preg-

nancy. Again, without supply those women are more likely to die as a result of it. We have heard from a number of health ministers in Africa that what is lacking in all of Africa when you talk infrastructure—and there are many things lacking—are midwives and mostly women who would be available to help with an obstructed delivery, but also to help with the maintenance of a long protracted pregnancy that needs care.

In the six countries in which you operate, what has been your experience with the partnership of midwives and skilled nursing, birth attendants and the like with the blood side of the equation?

Ms. LIPTON. We really have not had much interaction with midwives. In most of the areas we work in would be what you call district hospitals, and so the patients who are lucky enough to have some kind of prenatal care get to the district hospitals. I can tell you that their concern although we talk about safety there is no doubt that when you are in every hospital the biggest issue they talk to us is not about safety. It is about availability. That they would be transfusing and saving some of these patients but they do not have the blood there.

I think that again whereas we focus on safety and that is very important, the other side of this equation is clearly availability and motivating the volunteer donors and really getting them the safest people out to donate.

Mr. SMITH. Finally, I just asked earlier about the blood testing kits or the lack of those kits. In the six countries that you operate in, has that been a problem?

Ms. LIPTON. Yes. We have several issues that are going on. Right now most of our countries the purchases have to be approved through a tender process through the ministry of finance. The blood center up through the ministry of health will submit their purchasing order to the ministry of finance. The ministry of finance has a whole tender process where they might submit, you know they will put it out for an RFP and in some countries you may end up getting back a kit that first of all is not well integrated so you do not even know if the parts are working, and second you do not know when the tender process is going to go through.

I think that that is something that we absolutely need to fix. We need to bring greater autonomy to these blood transfusion services so that they can actually select the test kits and reagents that they need and buy them.

The other thing that we deal with is that we have a relatively unskilled group of people running a blood center who frankly do not really have a clue about inventory management. So one of the things we teach them is to talk about here is the test kits, and you need to remember to order them, and you need to think ahead. These are all skills that need to be imparted but yes, we have had difficulties.

Mr. SMITH. Finally, in the six countries that you operate in, what has been your experience with the UN Global Fund? One of the concerns we have had vis-à-vis PEPFAR, is that PEPFAR seems to get the money out of the door with a great deal of technical expertise much more swiftly. That is not to say the Global Fund will catch up at some point but even this year when the fiscal year 2007 appropriations bill came up, the Administration had asked for

\$300 million for the Global Fund. During the markup, \$245 million additional dollars were added to that but it was not like it was free money coming from nowhere. It was derived from the PEPFAR program and I believe from the maternal health account.

Those accounts had less to deal with these problems. Global Fund had more. But I was wondering what the situation was in your experience. Did you see or experience a focus on clean blood from the Global Fund?

Ms. LIPTON. I think any answer I would give you would just be terribly uninformed. I really focus primarily on technical assistance. I do not think I could give you a good answer.

Mr. SMITH. If upon reflection you do have some thoughts—because one of the points that this Subcommittee is dedicated to is oversight. We all want to get the money into the spigots and into these organizations, but if it is not being spent with the efficacy we believe it should be, we either want to know why and try to fix it or move it over to another pot. If you have any thoughts on that.

Finally, Dr. Green, if I could ask you: Are there studies to show what percentage of African blood donors are HIV positive? If so, what do they show? What percentage of donors in Africa are volunteers from your experience as opposed to those who are family members or paid donors in an emergency?

Mr. GREEN. I will address the first question. I have seen some data compiled by the Centers for Disease Control that show that—in fact, we have data from almost all the PEPFAR focus countries—and as I was commenting earlier, HIV prevalence is lower than we would expect. Let us round it off to 3.2 percent. Average HIV prevalence for sub-Saharan Africa is 7.2 percent, and that is down incrementally from a little bit higher.

In fact, in the last 3 or 4 years we have seen an incremental decline in the average prevalence rate in Africa, which is good news, but the average rate of blood donors is 3.2 percent. In no country do we see a higher HIV infection rate among blood donors than what the estimate is for the population as a whole, which is good news. It suggests that there is not some underclass of sick people, like injecting drug users that we might find in a country with an IDU-driven epidemic like Ukraine or Russia, who are selling blood and are more likely to be infected. That is basically good news.

As to what percentage of blood donors are volunteers, from the evidence I have seen from PEPFAR, less than half. This means, for reasons that have already emerged, that we need to get more voluntary donors and fewer who are donating or selling blood or who are family members.

One way to do that is to decrease demand by eliminating unnecessary transfusions. Another way is to make blood donation more confidence-inspiring.

Mr. SMITH. Thank you. Anything else any of our panelists would like to add? If not, I want to thank you for your testimony, especially for your extraordinary work. I apologize for these breaks as we have gone over to vote. It has been a long day for you, and we certainly do appreciate your patience. Thank you.

I would like to now just officially say that the hearing ends but that we now begin a briefing pursuant to a protocol that is necessary with our friends at the United Nations. I want to just say

that frequently during the last 2 years especially the UN has accommodated this Subcommittee and the Full Committee as well by providing expert witnesses to give us insight so that we can do our job better. I am very, very pleased and grateful to welcome Dr. Neelam Dhingra, who has been working in the field of transfusion medicine for the last 20 years.

Since 2000, Dr. Dhingra has been working at the World Health Organization, headquarters in Geneva, Switzerland, and leads the WHO blood safety program as coordinator of blood transfusion safety. We are privileged to have you here, and thank you especially for your patience. I want to assure you and our previous witnesses that the information you do provide will be provided to other Members.

It will be used in our deliberations, and I know my friend, Congressman Fattah and I, and Mr. Payne and others will take what you give us. I have already read your testimony. It was excellent. But I again want to thank you for again your patience in waiting and for your work. You are recognized.

**STATEMENT OF NEELAM DHINGRA, M.D., COORDINATOR,
BLOOD TRANSFUSION SAFETY, ESSENTIAL HEALTH TECHNOLOGIES, WORLD HEALTH ORGANIZATION**

Dr. DHINGRA. Good afternoon, Chairman Smith, Congressman Chakah Fattah and Members of the Subcommittee. My name is Dr. Neelam Dhingra, and I am coordinator of the blood transfusion safety program at the World Health Organization. I thank you for this opportunity to brief the Committee on the needs and strategies for making safe blood available in Africa, and I will be summarizing my prepared statement during my presentation.

There are two crucial issues which affect blood transfusion in Africa, and these are blood shortages and unsafe blood. In most of the African region today, access to safe blood when and where needed simply cannot be assured. Blood shortages have a particular serious impact on women and children.

As was mentioned earlier, 19 of the 20 countries with the highest maternal death rates in the whole of the world are in Africa where the risk of death is 1 in 16 mothers as compared to 1 in approximately 3,000 in rich countries. The most common cause of maternal death is severe bleeding which can kill even a healthy woman within 2 hours if not attended to. This contributes to almost half of the maternal deaths in Africa. Hundreds of thousands of these deaths could be prevented through access to safe blood.

Children are also particularly vulnerable to blood shortages because of the requirement of transfusion arising from life-threatening anemia caused by malaria or malnutrition. About 800,000 deaths occur each year in Africa due to malaria, the majority of them in children under 5 years, and up to half of the transfusions given to children are related to severe anemia due to malaria. Sufficient safe blood supplies could contribute to saving about half a million of these young lives.

Serious blood shortages also contribute to an increased risk of HIV and hepatitis by forcing a reliance on unsafe donors and increased pressure to issue blood without testing. Only 12 countries in Africa collect all their blood from voluntary unpaid blood donors

which presents much lower risk of transmitting HIV and hepatitis than family or paid donors.

The blood supply in Africa is currently very low, and less than 3 million units of blood are collected for the population of more than 700 million people, and only about half of these are collected from voluntary unpaid blood donors.

As far as testing is concerned, complete and accurate data on testing are simply not available, particularly in countries where blood services are fragmented. The majority of countries do not have reliable systems for testing due to shortages of trained staff, unreliable supply of test kits and lack of a basic quality system.

In Africa, almost 9 out of 10 units of blood are not tested for HIV in a way that meets quality requirements. The risk of HIV infection through unsafe blood is exceptionally high. Almost everyone who receives HIV contaminated blood will get HIV infection. The good news is that the transmission of HIV through unsafe blood is preventable and is the only approach to HIV prevention that is almost 100 percent effective.

The strategy for blood safety is well defined and has been successfully implemented even in resource-limited countries. It has three main components. First, collect blood only from the safest possible blood donors. Second, test all donated blood in accordance with basic quality requirements. Third, reduce unnecessary transfusions.

This strategy can only be effectively implemented with firm political commitment and support through national policies and plans, clear roles and responsibilities between different national stakeholders such as the ministry of health, the nongovernmental organizations such as Red Cross and the hospitals, and also through appropriate blood supply structures. In addition, quality systems governing all activities related to blood transfusion and an adequate number of trained staff are also required for effective implementation of this strategy.

The positive impact of this strategy has been seen in developing countries in all regions of the world including some countries in Africa. In Malawi for example after the establishment of the national blood service in 2003 a 60 percent decrease in deaths among seriously ill children and a 50 percent decrease in deaths in pregnant women with severe blood loss was recorded in the main hospital.

In addition, South Africa has demonstrated how in a country with HIV prevalence of 21 percent in the general population it has been possible to reduce the HIV prevalence to 0.03 percent in their blood donors. WHO works with U.S. Government support in three PEPFAR focus countries, two in Africa, these are Ethiopia and Namibia, to improve the safety and availability of national blood supplies.

Challenges are institutional as well as technical. That is: A fragmentation of blood transfusion services, poor institutional coordination and a lack of clarity of the roles and responsibilities amongst various stakeholders. The lack of sufficient trained staff is consistently cited as one of the main constraints faced by blood services.

This year's World Health Report of 2006 which is "Working Together for Health," also recognizes the same shortage of trained manpower in the developing world. Positive improvements in these

national blood systems have resulted from availability of funds and the development of trust and good working relations among ministries of health, national stakeholders and technical assistance agencies. Enhanced levels of commitment and support from governments demonstrated by the adoption of national policies and long-term strategic plans have paved the way for sustainable blood services.

WHO works with ministries of health, the blood services, with nongovernmental organizations and other international agencies to strengthen overall national health systems through evidence-based technical advice. I would like to highlight six strategies that WHO has learned are important for making safe blood available in Africa.

These are: Increased political commitment; institutional and technical capacity building; collaborations between national blood services and other programs at national level to reduce the need for blood transfusions; increase and sustain resources for blood safety and availability, recognizing that future requirements will be higher than current needs; resources for international technical assistance; and, last but not least, research and development to identify and implement innovative methodologies and appropriate technologies for blood safety in low-resource settings.

In conclusion, least developed countries and transitional countries in Africa do need technical and financial support in our experience for at least 5 years to develop sustainable systems which can meet the transfusion needs of their patient population.

Africa is in desperate need of a significant scaling up of efforts to make safe blood available to all patients whose survival and well being depends on this intervention. This is technically feasible in sub-Saharan Africa, lacking only the political commitment and the financial resources. Some countries are committed, but they also lack technical expertise and financial resources.

Considering the high effectiveness of HIV prevention through safe blood there should be a zero tolerance to any transmission of HIV or any other blood borne pathogen within the healthcare system.

I would like to leave all of you with this thought: That safe blood is a strategy which is truly cross cutting, from preventing deadly infections such as HIV and hepatitis, and promoting healthy lifestyle in blood donors to saving lives of people whose survival depends on timely access to safe blood. It is not rocket science. It is a simple strategy which can be easily implemented and is well integrated within the healthcare system.

Investments in making safe blood available in Africa will make tremendous difference by saving millions of lives. WHO appreciates this opportunity to brief the Committee on this important issue. I thank you for your attention, and will be happy to answer questions which you may have on this subject. Thank you very much.

[The prepared statement of Dr. Dhingra follows:]

PREPARED STATEMENT OF NEELAM DHINGRA, M.D., COORDINATOR, BLOOD TRANSFUSION SAFETY, ESSENTIAL HEALTH TECHNOLOGIES, WORLD HEALTH ORGANIZATION

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

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

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.

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

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

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

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

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

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

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

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.
- *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.

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 rela-

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

tions 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.

Mr. SMITH. Thank you so very much. Mr. Fattah.

Mr. FATAH. Thank you. Doctor, you have been at this for 20 years. Over the last 10 years in terms of the United States' efforts and other efforts in Africa in particular, where has safe blood and the safety of the blood supply ranked in the priority of our resources from where you sit?

Dr. DHINGRA. I would say in many countries, not only in Africa, HIV/AIDS brought the problems of blood safety to the forefront. Before that, blood banks were you know the shops sitting in a corner of a hospital which were included as "laundry." Literally blood banks were really not given any attention, and they were not seen as a source of so much of infection being transmitted through unsafe blood before HIV/AIDS came in the picture.

So in a way, HIV has been a driver for change for blood transfusion services across the world. However, if you see the other strategies for preventing HIV, it has been always a struggle in the countries to find suitable resources to invest in preventing sexual transmission or transmission through blood and other routes for prevention.

I think the U.S. Government initiatives have really been very important and drivers for major change in many developing countries, particularly in Africa, where, whether through global funds or through USAID or through CDC and the PEPFAR initiative, several of these initiatives have been able to bring forward the problem of blood safety, and have been able to get political commitment.

However, what is lacking even now is institutional coordination. There is a total lack of clarity in the roles and responsibilities amongst several stakeholders who are working at the country level. With my experience of Ethiopia and Namibia in the African region, these were the fundamental problems we had. We have been there for 20 months already, and the major achievement we have had is developing this coordination between different stakeholders because there are ministries of health who have not recognized that at all so far. They have not taken their leadership position and the ownership of the blood program as part of the healthcare system.

In some countries it has been delegated to the Red Cross or other NGOs, and they have not been supported adequately. So it is the lack of clarity of roles and responsibility which has led to this slow start in several of these countries including Ethiopia.

Mr. FATAH. You said in your testimony that you thought over a 5-year period of time you could take a country from nowhere to a safe sustainable blood supply in Africa.

Dr. DHINGRA. This has been seen in several countries in Africa and other regions where international assistance was provided and political commitment was there. There had been significant improvements in 5 years. I cited Malawi as an example where in 2000

when the funding was available through another international agency. For the first 2 years it was a very slow start because of all these institutional problems but after that with committed technical support provided by technical assistance there has been really a good improvement in blood safety.

However, the improvements have to be seen after 5 years, whether they are sustainable or not. Up to the time there is a system of sustainable finances and human resource it is difficult for the international assistance to pull out. So at least 5 years. It could be up to 10 years.

Mr. FATTAH. Let me ask the Chairman's question from earlier. He asked Dr. Ryan about the cost of creating a safe unit of blood in sub-Saharan Africa. He talked about \$55. Dr. Ryan says it would be about \$45 per unit. You would have to go through 33 units to find the one that was contaminated and so forth and so on.

It was somewhat confusing as to what the actual answer to this question was. If we were trying to create the number of units needed which is somewhere around 12 million units or so in sub-Saharan Africa per year, what would the cost per unit be given your expertise?

Dr. DHINGRA. WHO had undertaken an exercise to cost the blood transfusion services, and some of the developing countries were also included in this. This was done about 5 years back. At that time, on an average the cost of a unit of blood was about \$40 including the infrastructure costs. However, with the changes time and with inflation in our countries and changing economic situation, the recent costing would be approximately \$50 to \$60 with basic minimal strategies implemented which is volunteer blood donation and testing by simple serology tests.

If you introduce more and more technological advances, then the cost of unit goes higher but with the simple strategies for blood safety which includes voluntary blood donation and testing by simple serological testing it will be about \$50 to \$60 per unit of blood, and that does not include the processing of blood into different components. That is only a whole blood unit.

But when the future developments occur in medical care, there will be need for blood components and then it has to be relooked into how the component facility has to be developed and what more resources have to be invested in that.

Mr. FATTAH. If we were trying to get 14 million units, then at \$50 per unit we are talking about \$7 billion?

Dr. DHINGRA. The whole blood. Just for the whole blood units.

Mr. FATTAH. Right. \$7 billion.

Dr. DHINGRA. That is right.

Mr. FATTAH. Thank you, Mr. Chairman. We are spending \$9 billion a month in Iraq. It is probably give or take a dollar here or there. It might be doable. Thank you.

Mr. SMITH. Thank you, Mr. Fattah. Dr. Dhingra, you point out that 35 countries collect less than half the blood needed to meet the transfusion requirements of their populations. I am wondering what impact does the malnourishment issue have, the fact that so many people are sick themselves? It makes it even harder, I would think, to find even if you were able to motivate people to donate.

Does that account for a lot of the loss in addition to lack of infrastructure? Is that quantifiable as to what portion of the population base are candidates for donating blood?

Dr. DHINGRA. It has to be seen you know in the age of the population donating blood and the country demographics. The malnutrition currently seen in younger population and the population which is giving blood is usually 18 to 60 or 65 years. It has been seen in several developing countries where anemias and malnutrition and other infections and parasites are present that by selecting the population of potential donors who are healthy it is possible to develop good donor bases even in developing countries.

So, we have to just focus onto the population which is the least risk and the most suitable to give blood, and it is possible to get donors. In countries like Malawi, there are 100 percent volunteer donors, and they are youth clubs and they are all young donors who are giving blood. They are not anemic, and they are actually even promoting healthy lifestyle in the peer groups. In a way investing in volunteer blood donation programs again has a far reaching consequences on prevention of HIV through other routes also.

Mr. SMITH. Thank you. Let me just ask you: You quote in your testimony a WHO analysis of the cause of maternal death that was contained in Lancet on April 1 of this year that many of the deaths could be prevented through access to safe blood. You point out that in Africa severe bleeding during delivery or after childbirth contributes to up to 40 percent of the maternal deaths, which is a staggering number but it also gives hope that with resources and real political and medical will these deaths could be averted.

When you say many, how much of that? I know I may be asking a question that has no answer, but are we talking about most if they had access to a transfusion?

Dr. DHINGRA. Yes, I would say most, and there are two crucial factors to save lives of pregnant mothers who are having complications. One is attended by a trained midwife, and then access to safe blood. It would be most death could be prevented if there is safe blood supply available.

Mr. SMITH. Could you just explain to us what your sense is as to what the Global Fund is doing with regards to safe blood? Obviously they have a large pot of money. Have they, to your judgment, adequately integrated the mission of providing safe blood into their work?

Dr. DHINGRA. As far as I understand global fund in the countries, it is based on country requirements.

Mr. SMITH. Which they all have.

Dr. DHINGRA. In some countries they have identified blood safety as a priority over and above other requirements of the HIV program, and I know countries like Ethiopia has a program on global funds and the Philippines is now doing a proposal which has blood safety as part of it. Cambodia did a project in which blood safety was included. So there are several countries. I have not got the detail with me right now but there are countries which are asking for blood safety as part of the global fund also.

Mr. SMITH. Would it be possible for the record to get that kind of a breakout?

Dr. DHINGRA. Maybe.

Mr. SMITH. It would be very useful to see, especially since the U.S. is the major donor providing about one-third of that funding. I think Mr. Fattah and I and many others would love to see this money so well utilized especially as we put our arms around even further just how lifesaving this is. Your points about maternal deaths—I had heard about the mitigating factor of blood on maternal deaths. I never knew it was so dramatic. I do thank you for sharing that with us.

Mr. FATTAH. Mr. Chairman, could I ask one?

Mr. SMITH. Yes.

Mr. FATTAH. We heard a lot of comments earlier about the absorptive capacity which is a bigger question today I guess than the day before Warren Buffet gave the Gates Foundation \$32 billion. The inference is that we cannot with money do any more about this problem right now. What would be your comment to that?

Dr. DHINGRA. I mean I am not sure that I understand your question.

Mr. FATTAH. If Congress wanted to supply more resources to the question of safe blood in the world or in Africa or in sub-Saharan Africa, is there the absorptive capacity, this is the term of art that I have heard today, available so that something useful could be done with it so they could save some of the lives of these women or of these children or others whose lives are not being saved because of the absence of a safe, healthy blood supply or do we have so much money in the system and it is just a matter of kind of working out the politics and working out the stakeholders that money itself is not useful in this effort?

Dr. DHINGRA. I think PEPFAR is a very good example. The PEPFAR focus countries in initial 20 months have shown what are the problems and what needs to be done to address these problems. In WHO's experience of supporting the three countries, two of which are in Africa, Ethiopia and Namibia, it has really led to significant improvements in working situations.

I have got the key achievements with me. It is the infrastructure is strengthening and blood donation and collection has significantly improved. Blood testing and processing has improved, and in addition the emphasis has also been given to improving the transfusion practices, and more than 600 people have been trained, and also there are systems for national data collection within the country.

Until those resources are available to the country, within the country and also for technical assistance, this change would have never happened, and I think it is extremely important to support these countries by providing the required financial assistance and also technical assistance so that whatever changes happen is sustainable, and the countries can then take over the changes.

Mr. FATTAH. I guess through PEPFAR, Doctor, I think the number was \$32 million 2 years ago, \$50 million last year, about \$32 million or so this year to safe blood supply in Africa which is beyond the two countries you are working in but in all of Africa. Is it your impression that that is enough or that more resources would be useful? Do you have a sense of that?

Dr. DHINGRA. I think initial resources are required for a longer period of time in these countries. It is not only that these countries

because it has taken time to start the activities ongoing. It will take much more than 5 years, maybe total 10 years period to actually develop sustainable systems in these countries and definitely financial resources are going to be required. Initial resources are required for these countries as well as even non-PEPFAR countries in sub-Saharan region to bring about any change from the existing situation.

Mr. FATTAH. Do you think that either through the AU or through some other entity, that we could approach this problem as a sub-Saharan regional issue versus trying to deal with it country-by-country? Is it your sense that there may be some ability to create some federation of states in sub-Saharan Africa to address this one problem and kind of cut through the red tape of the individual nation-by-nation blood transfusion systems that have been set up?

Dr. DHINGRA. There are institutions existing. African Union is one of the existing system which could be utilized for this purpose. However, the requirements of each country are very specific, and it has to be addressed even if there are systems to coordinate the activities at the regional level. There is a great need to have national support for national systems and national coordination.

Mr. FATTAH. Thank you.

Mr. SMITH. Doctor, in your sixth recommendation you say there needs to be investment for research and development to enable developing countries to identify innovative methodology and appropriate technologies for blood safety. Are there innovative technologies that are being crafted that are specific to Africa where refrigeration may be a problem that you could speak to? Who is working on that? Who is providing the money for that?

Dr. DHINGRA. This is one area which needs to be further investment in this area but there is a lot of potential for this, and I would like to mention that there have been several lessons learned even in the developed world when the blood transfusion services have been set up. So developing countries do not have to go through the whole process of those lessons learned, and these lessons learned in the developed world should be applied to the developing countries. They should not take 30 years to reach a level where the developed countries have reached in 30 years. They should do it in maybe 5 to 10 years.

There are several methodologies and innovative technologies which could be explored and are available which are being used. In some countries, for example, where the refrigerator system is not working the big truck batteries have been used to create a system of refrigeration for transportation of blood and transportation of test kits. So similarly there is a need to look into those technologies which could be developed at the local level in these countries and investment needs to be done for this research and development in these areas.

Mr. SMITH. As far as transfusion-transmitted infections, I just share this because my father had malaria. He got it when he was a combat soldier in infantry in New Guinea during the Second World War, and he was barred from ever donating blood, and yet obviously some of the individuals who will donate blood have malaria. How threatening is that in modern day? Are there any other diseases, blood-borne, that are not on the list now like hepatitis B

and C and the like that could be a problem that might be caught with some additional detection?

Dr. DHINGRA. If we look into the diseases which are transmitted through blood and the severity, there are four infections which WHO recommends that each unit should be tested for, and that is HIV, hepatitis B, hepatitis C and syphilis. There are other regional infections like Chagas disease and HTLV which the countries screen for also.

Coming to malaria. Firstly, there are no good screening tests available for malaria particularly in the endemic countries where everybody would have had malaria at some stage or the other. Antibody tests are really not good and even antigen tests are not very cost effective to introduce for the screening of blood.

So what is currently done in the developing countries is a sort of donor selection procedure to test for the donors who have had history of malaria in the last 6 months or 3 months for example just to remove the possibility of acute anemia being transmitted through blood. However, the transmission introduced malaria does happen, and in many developing countries including India, Ghana and several other countries any fever after transfusion is considered as malaria and treated as fever and malaria. In some countries even prophylactic malarial treatment is being given.

It is a problem. However, it is not as serious a problem as HIV, hepatitis B is, and because of lack of good quality test kits which could be used as screening level for malaria in the endemic countries, screening of malaria is not recommended by WHO. But several countries are introducing antigen testing for malaria, and in non endemic countries antibody testing also is used and it is very useful.

Mr. SMITH. Let me just ask in terms of getting the word out that prospective donors are in great need as the system gets established. It was my experience in the early 1980s, when the child survival fund and Jim Grant from UNICEF was doing his great work, that travel to countries like El Salvador and Nicaragua, but especially El Salvador, and it was the church that provided the infrastructure to get the message out but also to provide volunteers. We all know, and I have given blood many times, churches often have blood banks and when a pastor or whatever the denomination may be gets behind the pulpit and says, this is a national need or a local need, people line up and they give blood.

Do you feel that in sub-Saharan Africa or anywhere else, but especially there, that the churches have been brought into the planning and implementation sufficiently? We were recently in Uganda, for example, and saw at Our Lady of Africa Church, there were 70 HIV positive people taking part in the PEPFAR program who were disseminating antiretroviral medicines. The reach of that ministry/health intervention was enormous, multiplied many times over by the church involvement. Are the churches involved as far as you know?

Dr. DHINGRA. I would like to take a step back here and just talk two issues, two big issues which are affecting the blood donating recruitment program particularly for volunteer donation. One is a lack of donor education and campaign which reaches the potential

donors, and the other is quality donor care which was also pointed out by other witnesses.

There is a need to develop customized messages for the prospective donors, and once we know a population—what are their current attitudes and behaviors and what are the myths and misconception in that community to give blood—the messages can be customized to go to the donor population, and there definitely churches and other organizations definitely play a role at different level in different countries but this is some approach which can be adopted at a much larger level in other countries, and I appreciate your comment.

Mr. SMITH. I appreciate that. It occurred to me that in El Salvador in 1984 they were admonishing the congregation, the mothers to bring their children in to get the MMR shots and to get the polio drops, and they were telling them up front, your child may develop a short fever but you have got to come back for the second one. So the reassuring statement from the pastor got most of those people, most of those moms to bring back their children.

There is credibility, I think, when the message is conveyed through a faith-based approach, which may expand the ability of WHO and all of us that are concerned about it to get that message out. I just would encourage that.

Dr. DHINGRA. Thank you.

Mr. SMITH. You point out that in Malawi the establishment of the national blood transfusion service in 2003 has led to a 60 percent decrease in mortality among seriously ill children and a 50 percent decrease in mortality in pregnant women with severe blood loss, recorded at the Queen Elizabeth Hospital. How did Malawi do it? Are they being looked up to by other ministries of health and other governments around Africa as well?

Dr. DHINGRA. Malawi also went through the same phase which other countries are going through in sub-Saharan Africa, and it was through the support of another international agency, the EU, provided support but for initial 3 years nothing much happened because of again the lack of clarity in roles and responsibility, poor institutional coordination but once with the technical assistance from outside those systems were established and the government commitment was sustained and stabilized, the things have really improved. This is the main teaching hospital where significant improvements and the impact of a strategy have been seen in a developing country.

Mr. SMITH. I just have two final questions. You point out cautiously that nearly 500,000 HIV infections through blood transfusion have already been averted each year in sub-Saharan Africa. That is great news, encouraging news. If you want to touch on that, that would be appreciated.

Finally, I will give you some background on this, but I mentioned this to some of our earlier witnesses, the cord blood effort which may be down the road a bit but I do not think it should be discounted as a possible way of helping to cure sickle cell anemia and other blood related diseases like leukemia. It does cure leukemia. There have been many instances where that has been recorded. It seems to me that this is ready-made, maybe somewhat in the future, but I think we ought to be thinking about how that might

look some years down the line and for some maybe right now. If you wanted to comment on that as well.

Dr. DHINGRA. The first about the infections averted I think that is a very important aspect which has been seen with the blood safety strategies. If we see the HIV prevalence in general population in some of these sub-Saharan countries and we see the HIV prevalence in donor population with the support of the technical assistance or even their own programs there is a significant difference and the HIV prevalence in blood donors is much lower than the general population.

So that is where infections are averted. If those strategies for volunteer blood donation were not implemented, all those infections for the general population would have passed through the blood supply, and even more infections would have occurred.

The second level is when the testing is done, and from there it further brings down and removes the units which are positive. So it is just through those donors who have been rejected from this, taken away from the system by good quality blood donor program and the blood which is being tested currently that 500,000 infections are being averted.

However, if you compare the risk of disease transmission in U.S. and in the countries in sub-Saharan Africa and the prevalence in the donor population, South Africa has brought it down from 21 percent to 0.03 percent in blood donors but even that is very high.

If you see in the U.S., for example, it is even less than 1 in 10,000, 20,000 donors, and the risk of transmission is 1 in 1.8 million or even less than that, maybe 1 in 2.5 million today risk of infection transmission of HIV through blood. There is need to even further avoid these infections which are passing through unsafe blood, and in many countries these systems have not been fully introduced to volunteer donation and proper testing.

A question on testing was asked earlier. No reliable data is available as mentioned in my statement. However, when we ask countries they say 100 percent is tested. Except two countries, everybody says 100 percent blood is tested but when we ask them about the quality systems, 33 countries out of these 46 countries said they have no quality systems.

So that is what gives us the figure. We have you know calculated the 90 percent of blood units are not actually tested in a quality assured manner, even of the countries say that they are testing 100 percent. However, there are no systems to collect the data so the reliability of this data is questionable. That is just one question.

The other question about the cord banking, I think it is a very good new technology which is emerging which will definitely give opportunities for treatment for leukemia and for sickle cell anemia and other conditions to cure the diseases. However, firstly whichever country has developed cord banking they will have built upon a good blood transfusion service. So first we have to look into establishing a sustainable blood transfusion service which addresses at least the proper testing and storage and transportation of blood because cord banking is going to require a good testing system and a good storage and transportation system.

Secondly, if we are going to treat patients in leukemias, we have to look into that the other blood components which are required for

leukemia management also available, that this country has the capacity to produce platelets and other blood products which are required to treat leukemia. So there is definitely a possibility of incorporating these new technologies even into the developing world particularly in the cord blood banking side.

Mr. FATAH. Thank you very much for your testimony and your work.

Mr. SMITH. Thank you so much for your testimony, for your insights, and your recommendations. The Subcommittee will really pour over your testimony. I have read it now twice. You have given us much to go on. I thank you for your exemplary work and look forward to working with you in the future.

Dr. DHINGRA. Thank you very much. Could I just clarify one thing?

Mr. SMITH. Sure.

Dr. DHINGRA. I did quickly calculate when we were talking about the——

Mr. SMITH. Would you hit the button please?

Mr. FATAH. The cost, yes. Did we do the math wrong?

Dr. DHINGRA. I did not calculate properly that time. My mental math was not that good. It is \$50 times \$15 million is \$750 million, not \$7 billion.

Mr. FATAH. Okay.

Dr. DHINGRA. \$750 million.

Mr. FATAH. It is even cheaper.

Dr. DHINGRA. Yes. That is achievable.

Mr. FATAH. All right. This is good. Thank you.

Dr. DHINGRA. Thank you very much.

Mr. SMITH. The briefing is adjourned.

[Whereupon, at 6:35 p.m., the Subcommittee was adjourned.]

A P P E N D I X



MATERIAL SUBMITTED FOR THE HEARING RECORD



THE SECRETARY-GENERAL

30 May 2006

Dear Congressman Fattah,

Thank you for your important efforts in support of improving the blood supply in Africa. The HIV/AIDS pandemic poses an unprecedented threat to human security and development in the continent. The epidemic demands an exceptional response and your Initiative on Safe Blood will play an invaluable role in benefiting the lives of millions of Africans.

I commend your leadership on this issue and look forward to hearing more about it in the weeks and months ahead.

Yours sincerely,

A handwritten signature in black ink, appearing to read "K. Annan".

Kofi A. Annan

The Honourable Chaka Fattah
Congressman
United States House of Representatives
Washington, D.C.



10 DOWNING STREET
LONDON SW1A 2AA

THE PRIME MINISTER

31 March 2006

Dear Mr. Fattah,

Thank you for your letter of 1 March about the Fattah initiative on Safe Blood.

During 2005, G8 leaders agreed to a set of commitments which should have a real impact on poverty in Africa and across the world. I believe it is vital to assist African countries to strengthen their health services – and this includes the provision of safe blood, integrated with comprehensive national HIV prevention strategies. We are committed to playing our part and have committed £1.5 billion over the next three years to tackling HIV and AIDS across the world.

The Department for International Development (DFID) takes the lead on this and other overseas development issues. I have asked the Secretary of State for International Development to ensure DFID officials follow up with you to discuss further and gain a better understanding of your initiative.

I wish you well with your efforts.

Mr Chaka Fattah

*Yours sincerely,
Tony Blair*



EUROPEAN UNION
DELEGATION OF THE EUROPEAN COMMISSION

Head of Delegation

Washington, 15 May 2006
D(2006) 990

Dear Mr Fattah,

I very much enjoyed the discussion we had on 9th March in your offices on various issues of common concern and in particular on how best to help Africa reach the Millennium Development Goals in the Health Sector. I consider that your Safe Blood Initiative is a very timely and important effort towards these goals, and I would be glad to support you in this.

The European Commission, as you know, is committed to working in partnership with the United States and the international community to reach the Millennium Development Goals, three of which relate directly or indirectly to health. In external action, our policy tackles the three infectious diseases related to poverty, namely, HIV/AIDs, Malaria and Tuberculosis.

The Commission's Action plan in this area emphasizes the need to strengthen country health systems and to support country led strategies. At global level, the Action Plan focuses on affordability, strengthening regulatory capacity, and the need or work in partnership. We support and work closely with other private partners such as the Global Initiative for Vaccines and Immunization (GAVI).

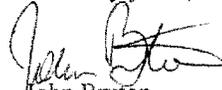
We are partners with the United States in the fight against contagious diseases and participate in the Global Fund for AIDs, Tuberculosis and Malaria (GFHTM). To date, the Commission has pledged a total of € 522 million for the Fund, covering the period of 2001-2006 of which € 432 million have already been disbursed.

We see your Initiative to protect the safety of blood in Africa as closely related to the fight of contagious diseases. In fact, we advocate that blood safety should be an integral part of any national strategy for HIV/AIDS prevention, as well as a standard component of national health policies. We believe that blood safety should be addressed as part of efforts to strengthen the national health systems, and that specific action to reduce the risk of HIV

transmission should include financing for strengthening systems for blood safety.

I trust that you will receive congressional support for your very crucial Initiative. It is my hope that this will raise awareness of the wider health system issues and that Africa – and the world as a whole – will be a safer place as a result.

Sincerely yours,



John Bruton
Ambassador

The Honorable Mr. Chaka Fattah
Member of Congress
Rayburn 2301
Washington, DC 20515

RESPONSES FROM JERRY A. HOLMBERG, PH.D., SENIOR ADVISOR FOR BLOOD POLICY, OFFICE OF PUBLIC HEALTH AND SCIENCE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, TO QUESTIONS SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HUMAN RIGHTS AND INTERNATIONAL OPERATIONS

Question:

In your testimony, you state that blood safety activities as they relate to malaria could become more feasible and cost effective as the background rate of the infection is reduced. Could you explain in more detail the inverse relationship between the two efforts (reduced malaria rates and increased efficacy of safe blood activities)?

Response:

If the background rate of malaria infection were greatly reduced to very low levels (i.e., approaching the levels seen in developed countries), it may become feasible and cost effective to consider donor screening as a way to reduce malaria transmitted by transfusion, as is done now in developed countries. However, most malaria-endemic countries in sub-Saharan Africa have a long way to go before reaching low levels of malaria infection. In these countries the high background prevalence of infection and disease overwhelmingly results from vector borne (mosquito) transmission. Limited resources must be focused on reducing the burden of malaria from this source. For now, blood safety efforts in sub-Saharan Africa will benefit from reducing cases of malaria-associated anemia and thus the overall number of transfusions needed to treat anemic malaria patients.

Question:

You also note the collateral benefits of blood safety programs in terms of education, risk assessment and laboratory screening. Could you elaborate and perhaps provide examples of how HHS/CDC has achieved these benefits?

Response:

In the course of blood collection, a national blood transfusion service (NBTS) puts a number of measures in place which can confer ancillary benefits to public health. First, all donors are given educational materials informing them of the clinical signs and symptoms associated with HIV infection and AIDS, high-risk activities for transmission, and the importance of refraining from donating blood if they have engaged in these activities or experienced associated signs and symptoms.

Donors are counseled on any abnormal test results, given information about alternative sites or other mechanisms to obtain HIV tests, and told where donors can seek further follow-up care.

A collateral benefit in most countries is the installation of incinerators at blood banks and blood processing labs. These incinerators prevent biohazardous waste from reaching local landfills. In Guyana, for instance, unused blood is simply trucked to the local dump and dropped off. There are no controls to prevent reuse of disposal items or prevention of exposure of biohazards to landfill workers, scavengers or the water table.

Some other examples of public health benefits include:

- Education: NBTS blood donor outreach activities can be integrated with other disease control and health promotion activities. Examples include:
 - In Rwanda, garden tools (nutrition), insecticide treated bed nets (malaria control) and bicycles (cardiovascular health) are offered as incentives to repeat donors. These incentives are accompanied with educational materials about the associated health benefits (e.g., malaria control).
 - In some sub-Saharan countries, donor groups such as *Club 25* have great outreach to the community and its younger population. *Club 25* is a youthful concept, promoting the value of saving lives by giving blood. Through *Club 25* young people are encouraged to attend a blood center, learn about healthy lifestyles and to give blood regularly, aiming for about 20 blood donations by age of 25 years. They also share what they have learned with their communities through health promotion activities to prevent HIV/AIDS, substance abuse and other health risk behaviors; in addition there are opportunities to be active in promoting first aid, good nutrition, physical exercise and road safety.
- Risk Assessment: The World Health Organization opines that repeat blood donors are less likely to engage in risky behaviors that can lead to HIV infec-

tion. As the pool of regular blood donors grows, the risk of contaminated blood entering the blood supply (i.e., HIV infected blood that is not detected by antibody testing due to the window period in early HIV infections) is reduced. Likewise, regular blood donors also have a lower risk profile for other sexually transmitted infections, e.g., syphilis or hepatitis B.

- Laboratory screening: Many focus countries do not have a dedicated laboratory for the NBTS or the reference lab. In many countries, one central laboratory performs both functions. In these settings, training laboratory technicians through a blood safety program will have a positive impact on these technicians' overall competency in the laboratory.

Question:

The PEPFAR inter-agency report on Blood Safety and HIV/AIDS notes that in South Africa, a highly-infected country, the National Blood Service did not find any evidence of HIV transmission by blood transfusion among the over 880,000 transfusions provided in 2000. What explains this successful record, and can it be replicated in other African countries?

Response:

South Africa is the richest and most developed country in sub-Saharan Africa. In FY06/07, the South African government committed \$8 billion to the health sector (36% of the national budget¹ or \$175 per capita). This level of public funding is supplemented by massive foreign aid, including \$190 million in PEPFAR funds in FY06. South Africa's success in protecting its blood supply is rooted, in part, in a steady stream of domestic funding to the South African National Blood Service (SANBS) over several decades. As a result, SANBS oversees a well-organized national blood program based on a national blood policy. Some of the successful activities implemented by SANBS include:

- In 1999, the SANBS adopted a standardized blood safety policy that included the closure of donation sites with high HIV prevalence, implementation of direct oral questioning using a stringent self-exclusion questionnaire that incorporates questions about heterosexual and homosexual contacts, intravenous drug abuse, and HIV risk behaviors, and a product triage system based on donation risk profiling. Prevalence of HIV in the donor population declined progressively.
- The development of effective strategies to recruit and retain voluntary, non-remunerated blood donors.
- The establishment of high-quality laboratories to ensure that every unit of blood donated has been screened for HIV, hepatitis, and syphilis. Negotiations between SANBS and the Minister of Health led to the implementation in October 2005 of a new Donor Status Risk Management Policy. This included the implementation of individual donation nucleic acid (ID-NAT) testing. This policy continues to use stringent donor selection, universal testing, and product triage to ensure blood safety. Note: This level of technology enabling use of ID-NAT is not available in most developing countries.
- The creation of educational and media-based initiatives to combat fears and rumors about blood donation and promote a culture of regular blood donation. These activities build public confidence and ensure a committed and low-risk pool of blood donors for the future.

While the reasons for South Africa's success are unique in sub-Saharan Africa, PEPFAR support has allowed several other African countries to rapidly strengthen their blood services and substantially increase the production of safe blood units. In Kenya, Zambia, and Cote d'Ivoire, for instance, Emergency Plan funds were directly responsible for a doubling of the number of safe blood units produced during the first 18 months of the initiative. These improvements were made possible by Emergency Plan funding for:

- New equipment and training to automate laboratory screening procedures.
- Enhanced outreach and donor mobilization efforts, particularly the use of mobile blood collection units.
- Continuing medical education for physicians to reduce the number of unnecessary blood transfusion orders.

¹ http://www.southafrica.info/doing_business/economy/fiscal_policies/budget2005-peoples-guide.htm

- World-class technical assistance to develop strategic plans, national blood policies and regulations, and training curricula.
- Procurement of consumables and other supplies (e.g., blood bags, reagents)

Other Emergency Plan countries in Africa face more significant challenges, including a lack of basic infrastructure (electricity, roads), poorly defined legislative and legal frameworks to enforce safe blood policies and regulations; and a scarcity of human capacity to fill key technical and administrative positions. Some of these barriers are being addressed with Emergency Plan funds. For example:

- Human resource capacity is being developed through training and educational programs.
- Best practices and ideas from countries with functioning policies and legal frameworks are shared with countries just beginning the process.
- Work is underway to identify blood banks, laboratories and transfusion centers that could benefit from solar electrification.

Because many infrastructure issues are not unique to blood safety, HHS/CDC and its U.S. Government (USG) partners work to integrate specific Emergency Plan objectives and activities with broader USG development assistance for each country.

Question:

The same PEPFAR report (see above question) states that Haiti has 95% voluntary unpaid donation for blood as opposed to only 5% in Uganda. What is the explanation for this extreme difference?

Response:

[PLEASE NOTE: The PEPFAR report states: "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 (from 5% in Uganda to 95% in Haiti)." The figures cited in this passage refer to donation rates from family/replacement donors, not voluntary, non-remunerated donors. Uganda receives 95% of its blood from voluntary unpaid donors and 5% from replacement family donors; while in Haiti the inverse is true, with 95% of the blood supply coming from replacement family donors and 5% coming from voluntary unpaid donors. We hope this note clears up any confusion caused by the wording of the report. We would also like to take this opportunity to explain why some countries, like Haiti, have not yet met the 100% voluntary, non-remunerated donor goal.]

The recruitment and retention of blood donors who are at low-risk of infection with HIV or other blood-borne pathogens is a critical part of any successful blood safety program. Evidence demonstrates that voluntary, non-remunerated (unpaid) donors have a lower risk profile than donors who give blood for financial gain. As a result, PEPFAR supports national blood transfusion services to increase the identification and participation of volunteer blood donors, particularly those who donate more than once per year.

Of the 14 Emergency Plan focus countries receiving blood safety funds, five reported in 2004 that 100% of the blood collected by the national blood service was donated by voluntary, non-remunerated donors. The proportion of donations from voluntary, non-remunerated donors in the remaining 9 countries covered a wide range, from a high of 95% in Uganda to a low of 5% in Haiti.

The extreme difference in the use of paid or family/replacement donors versus volunteer, non-remunerated donors can be attributed to several factors, including:

- A lack of personnel (e.g., nurses, phlebotomists, administrators) to conduct blood drives or staff fixed-site blood centers.
- Social or cultural anxieties about blood donation.
- Weak central controls over satellite blood collection centers in rural areas or cities outside of the capital.

In Haiti, political instability played a significant role in dissuading the public from volunteering to donate blood. In the Haitian capital, Port-au-Prince, the central blood collection center is located in an area that saw intense street violence and was considered off-limits by many potential donors. We are pleased to report that Haiti's numbers have improved steadily in 2006, following the successful presidential election and the introduction of new mobile collection units in the capital. In May 2006, the Haitian National Blood Transfusion Service reported 27% of donations were collected from voluntary, non-remunerated donors, up from 14% at the end of 2005 and 5% in 2004.

HHS/CDC and its USG/Emergency Plan partners remain committed to increasing the participation of voluntary donors in Haiti and are actively supporting the Na-

tional Blood Transfusion Service and its Haitian Red Cross partners in the following activities:

- Developing public awareness tools for blood safety.
- Organizing training sessions for donor recruitment in Port-au-Prince and Les Cayes.
- Introducing new legislation to return supervision of the blood transfusion system to the Ministry of Health.
- Planning for the renovation of 5 blood centers.
- Improving lab capacity to ensure 100% screening for HIV and hepatitis B and C.
- Training 172 clinicians and nurses in the clinical use of blood.

Collaborating with USAID to conduct solar power needs assessments on blood banks and clinics requiring reliable energy to support the cold chain.

RESPONSES FROM MS. KAREN SHOOS LIPTON, CHIEF EXECUTIVE OFFICER, AABB (FORMERLY THE AMERICAN ASSOCIATION OF BLOOD BANKS), TO QUESTIONS SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HUMAN RIGHTS AND INTERNATIONAL OPERATIONS

Question:

It has been asserted that cultural attitudes pose an obstacle to establishing voluntary blood donations in parts of Africa. Has your organization encountered this problem, and if so, could you describe those attitudes and any efforts that have been made to overcome them? Do government health officials share these attitudes?

Response:

Yes, we have encountered this problem in varying degrees in multiple countries. In most countries around the world, blood has a very important cultural meaning. It is sometimes viewed as a life force or a symbol of family and kinship ties. It may even be equated with personality and appearance. Several myths still remain regarding blood donation, including the belief that donating blood makes a person weak, infertile, or more susceptible to contracting AIDS or malaria. In addition, individuals with strong religious beliefs or racial/tribal ties may only wish to donate blood for individuals of the same religion/race/tribe, which is not consistent with a voluntary, non-remunerated blood program. Some cultures and religions require women to obtain consent from their husbands before donating blood, and oftentimes will not allow the woman to be interviewed for risk behaviors without the husband being present. A voluntary blood program requires a confidential interview to effectively screen for risk behaviors.

In general, volunteerism is not common practice in many African countries. In addition, in countries where family replacement donation is still practiced, family members may feel the need to "save their blood" in the event that a family member or friend should need blood, preventing them from donating as a volunteer for the general public.

In an attempt to overcome these obstacles, AABB is working with the National Blood Transfusion Services (NBTS) to gain a better understanding of the beliefs within each country regarding blood donation by conducting a Knowledge, Attitudes, and Practices (KAP) survey. Information obtained from this survey will be used to develop appropriate educational and public awareness information to promote the importance of voluntary blood donation. In addition, assistance will be provided to facilitate donations to accommodate specific cultural beliefs whenever possible (e.g., health history and interviews conducted by staff of the same gender). AABB is also working with the NBTS to educate government officials and hospital physicians and others about the importance of voluntary blood donation.

Question:

Are there other barriers unique to Africa that must be considered in the implementation of blood safety programs? If so, please include suggestions as to how these barriers can be overcome.

Response:

Financial sustainability is always a significant concern in Africa. Cost recovery systems, where a per-blood-unit transfused fee is passed on to the patient or insurer, are an option frequently considered. However, this solution may undermine

efforts to create a voluntary blood supply. A long-term strategy for funding is required.

An additional challenge is posed by a lack of knowledge, understanding, and/or sensitivity of the staff to openly discuss issues relating to sexual risk factors to effectively screen potential blood donors to ensure the safety of the blood supply.

The NBTS has a direct link to the national health system in each country, as the blood collected, tested and distributed by the NBTS is ultimately transfused into patients in public and private hospitals. As such, the inherent weaknesses of the national health scheme within each country have a direct impact on the financial sustainability of the NBTS. In addition, poor road conditions make it difficult both to collect blood within the rural communities and distribute blood to rural hospitals. Inconsistent electrical supplies also create challenges in maintaining consistent temperature of blood and blood components.

Question:

In your testimony, you refer to the problem of National Blood Transfusion Services being unable to examine and implement system-wide solutions because they are continually in crisis mode. What solution would you propose for this problem?

Response:

AABB is working closely with each country to develop country-specific national standards for blood transfusion. Following approval of the national standards, country-specific trainings will be conducted to assist the country in implementation of the national standards. This standards-based approach facilitates the development of processes and systems rather than stand-alone activities, thus building long-term capacity of the NBTS to manage the operations in a consistent, standardized manner rather than falling into crisis mode.

RESPONSES FROM EDWARD C. GREEN, PH.D., MEMBER OF THE PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS, TO QUESTIONS SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HUMAN RIGHTS AND INTERNATIONAL OPERATIONS

Question:

You lived for a considerable amount of time in Africa and worked with the health care systems. Did you have any personal experience with blood safety programs? If so, please describe.

Response:

I did once have some personal experience with being asked to donate blood in Africa. Two nurses I knew had set up a table at the entrance of a hotel, with the idea of catching people when they left the hotel or bar. Somehow, the setup did not seem very professional or confidence inspiring. The nurses were treating their efforts as something as a joke and they showed me the vials of blood that I would need to fill up. Since it was the AIDS era and it was southern Africa, I did not feel completely certain that the needle would be sterile, and I felt that the amount of blood being requested was excessive. So even though I knew the nurses, I declined.

I later thought: if someone who knew the nurses was unwilling to give blood—in fact, someone who works in the same field of public health—then think of what the average African would think. This underscores what I said in my Congressional testimony that the setting for blood donations must inspire trust and confidence. We Americans take for granted that the needle used in such donations is sterile. Africans often do not assume that.

Question:

Blood safety is one area of focus for prevention of HIV/AIDS transmission under the President's Emergency Plan for AIDS Relief, together with needle injection safety, mother-to-child transmission and sexual transmission. The United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 requires that 33 percent of PEPFAR prevention funds be spent on abstinence-until-marriage programs, which the Office of the Global AIDS Coordinator has interpreted to include "be faithful" programs. Some Members of Congress are advocating the elimination of this percentage spending requirement. Based on available evidence as to what prevention measures are resulting in reduced HIV/AIDS prevalence rates, would you support this effort to eliminate the abstinence-until-marriage spending requirement?

Response:

In January 2003, the United States pledged \$15 billion to global AIDS under the President's Emergency Plan for AIDS Relief (PEPFAR). The U.S. Agency for International Development (USAID) had recently adopted the ABC approach as the model of HIV prevention for generalized epidemics, using Uganda's success as a model. In 2003, PEPFAR also adopted the ABC approach. The first PEPFAR prevention strategy document to be released announced that "risk elimination" would be the "cornerstone" of prevention.¹ Risk elimination, also called risk avoidance, refers to sexual abstinence and to mutual fidelity between two uninfected sex partners. Risk reduction, on the other hand, refers to strategies such as condom usage that reduce but do not eliminate the risk of sexual transmission. PEPFAR, through the ABC approach, proposed to combat AIDS both ways, rather than only one way.

The Office of the U.S. Global AIDS Coordinator (OGAC) later released further guidance on the ABC approach.² Although this guidance has clarified the prevention approach to be followed by programs under PEPFAR, considerable confusion and controversy remain. Part of the reason for this seems to be the backlash coming from family planning and contraceptive-oriented organizations—and agencies including UNFPA and UNAIDS—which fear received smaller allocations of resources if some resources go to behavioral programs. In extreme forms, fear that condom programs might lose money have even led to formal proposals to eliminate primary prevention, behavioral programs altogether.

Amending the 2003 Act that requires that 33% of PEPFAR prevention funds be spent on abstinence and fidelity programs in a way that would remove this "earmark," would be an extremely bad move. It would return AIDS prevention to the era when HIV prevalence continued to rise in every country in Africa, with the exception of Uganda and Senegal, the first two countries in Africa to implement ABC programs, that is, programs that promote a balanced and targeted set of interventions that include Abstinence, Being faithful, and Condoms for those who cannot or will not follow A or B behaviors.

Since PEPFAR is implemented in countries with generalized epidemics (with the exception of Vietnam), its approach to AIDS prevention must be one that works with generalized epidemics. Risk reduction-only programs (condom promotion, treating STIs, and promotion of VCT) have been found to have little or no overall impact on generalized epidemics, if this is measured by declines in national HIV prevalence. This was the conclusion of the USAID ABC Study 2003,³ as well as two studies of UNAIDS: the multi-site African study (published in a special issue of *Journal AIDS*, 2001)⁴ and the 2003 Condom Effectiveness Review.⁵

By 2004, analyses of Uganda data were published in leading scientific journals concluding that decline in casual sex (the B of ABC) was the major factor associated with HIV prevalence decline in Uganda.⁶ Since then, evidence for a pivotal role for partner reduction has emerged for more recent HIV declines in Kenya and

¹ Office of the United States Global Aids Coordinator for AIDS Relief. *The President's Emergency Plan for AIDS Relief: U.S. Five-Year Global HIV/AIDS Strategy*. Washington, DC, Feb 2004.

² Office of the United States Global AIDS Coordinator for AIDS Relief. *ABC Guidance for United States Government In-Country Staff and Implementing Partners Applying the ABC Approach to Preventing Sexually Transmitted HIV Infections within The President's Emergency Plan for AIDS Relief*. Washington, DC, Mar 2005.

³ Bessinger, R., Akwara, P., and Halperin, D. (2003). *Sexual behavior, HIV and fertility trends: A comparative analysis of six countries; Phase I of the ABC study*. Measure Evaluation; USAID. (www.cpc.unc.edu/measure/publications/special/); Green, Edward C., Vinand Nantulya, Yaa Oppong (2003), "Literature Review and Preliminary Analysis of "ABC" factors in Six Developing Countries." Cambridge: Harvard Center for Population and Development Studies. July 2003.

⁴ Buve, A., Carael, M., Hayes, R., Auvert, B., Ferry, B., Robinson, N., et al. (2001). Multicentre study on factors determining differences in rate of spread of HIV in sub-Saharan Africa: methods and prevalence of HIV infection. *AIDS*, 15(Suppl.), S5–S14. White, R., Cleland, J., Carael, M. (2000). Links between premarital sexual behavior and extramarital intercourse: multi-site analysis. *AIDS*, 14, 2323–2331.

⁵ Hearst N, Chen S. Condom Promotion for AIDS Prevention in the Developing World: Is it Working? *Studies in Family Planning* 2004; 35(1): 39–47.

⁶ Shelton, James D, Daniel T Halperin, Vinand Nantulya, Malcolm Potts, Helene D Gayle, King K Holmes, "Partner reduction is crucial for balanced "ABC" approach to HIV prevention. *BMJ* 328(10) April 2004; Stoneburner RL, Low-Beer D. Population-level HIV declines and behavioral risk avoidance in Uganda. *Science* 2004; 304: 714–18; Halperin, DH, and Helen Epstein, "Concurrent sexual partnerships help to explain Africa's high HIV prevalence: implications for prevention." *The Lancet* Vol 364 July 3, 2004, pp. 4–6; Hearst, Norman and Sanny Chen, Condom Promotion for AIDS Prevention in the Developing World: Is It Working? *Studies in Family Planning* 2004;35 [1]:39–47).

Zimbabwe.⁷ This should not be surprising, considering that condoms are estimated to be between 80% and 85% effective against HIV when used consistently—that is, to reduce HIV transmission by 80% to 90% compared to non-use.⁸ Yet consistent use of condoms is rare and with “typical use” of condoms, risk reduction *at the population level* is minimal. In fact, there is a very disturbing association (whether or not causation can be established) in Africa between higher condom use and higher levels of HIV infection. This can easily be seen by simply looking at levels of both condom use and HIV prevalence in a list of African nations. It is noteworthy that while this disturbing association is widely recognized among AIDS professionals, such a table has never been published to my knowledge. Such a table showing condom availability and national HIV infection levels were presented in my testimony⁹ (Fig. 4). Consistent with this association, the first countries for which we have DHS behavioral data plus blood samples showing HIV status (Kenya, Tanzania, Ghana, Uganda) we see that condom users are almost always found to have higher HIV prevalence than non-users.

A “consensus statement” published for the 2004 World AIDS Day in *The Lancet*¹⁰ which was endorsed by over 150 global AIDS experts, including representatives of five UN agencies, WHO, World Bank, etc., as well as President Museveni of Uganda and various religious leaders including Archbishop Desmond Tutu, proposed that mutual faithfulness with an uninfected partner should be the primary behavioral approach promoted for sexually active adults in generalized epidemics. And abstinence or delay of age of “sexual debut” should be the primary behavioral approach promoted for youth. This represented a fairly marked departure from many previous prevention approaches, which emphasized risk reduction almost exclusively as the first line of defense for sexually active adults in all types of epidemics. A growing number of public and international health professionals including PEPFAR recognize that, before Uganda and Senegal, AIDS prevention lacked an essential primary prevention component. They see the AB components as logical, sensible, cost-effective, sustainable, culturally appropriate interventions for general, as distinct from high-risk, populations. Moreover, the evidence is clear that these components work and that risk reduction has not led to a single success in generalized epidemics.

Critics of ABC, if they work in AIDS or reproductive health fields, are invariably critics of these same AB interventions while favoring condoms. They point to rape, coerced sex, the powerlessness and lack of choice of African women, and they argue that promoting AB behaviors is quixotic, doomed to failure, or simply “irrelevant to women’s lives.” The logic seems to be: if not every woman is in a position to practice abstinence of fidelity, then we should not promote these risk elimination behaviors at all. But this makes no logical or public health sense, moreover we know from decades of experience that a great many women are not in a position to insist on condom use.

Another point of bitterness and contention are PEPFAR’s allocation guidelines, which specify that certain proportions of sexually transmitted HIV prevention funds must be spent on AB programs. This is unfortunate, since it appears to support a “one size fits all” approach. AB proponents argue with some justification that unless there is political pressure, few if any funds would be allocated to AB programs, since almost no funds were so allocated, prior to the US policy shift.

Still, any coerced allocations create a zero-sum game atmosphere, making AB critics feel that funds are being shifted away from familiar condom programs and perhaps away from organizations whose skills and experience center around contraceptives and who have been fighting the AIDS pandemic from the earliest years. Yet

⁷Gregson, Simon, Geoffrey P. Garnett, Constance A. Nyamukapa, Timothy B. Hallett, James J. C. Lewis, Peter R. Mason, Stephen K. Chandiwana, Roy M. Anderson, “HIV Decline Associated with Behavior Change in Eastern Zimbabwe” *Science* 311, 664 (2006); Cheluget B, Baltazar G, Orege P, Ibrahim M, Marum LH, Stover J. (2006). “Evidence for population level declines in adult HIV prevalence in Kenya.” *Sex Transmitted Infections* Apr;82 Suppl 1:i21–6; Hayes, Richard and Helen Weiss, “Enhanced: Understanding HIV Epidemic Trends in Africa.” http://www.sciencemag.org/cgi/content/full/311/5761/620?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=zimbabwe&searchid=1138923040026_15772&FIRSTINDEX=0&journalcode=sci

⁸Weller S, Davis K. Condom effectiveness in reducing heterosexual HIV transmission. *Cochrane database Systematic Review* 2002; (1): CD003255; Gardner, R., Blackburn, R. D., & Upadhyay, U. D. (1999). Closing the condom gap. (Population Reports, Series H). Baltimore: Johns Hopkins University.

⁹Green, E.C., “HIV/AIDS, TB, and Malaria: Combating a Global Pandemic.” Testimony on AIDS in Africa, for Committee Hearing, The House Committee on Energy and Commerce, U.S. House of Representatives, March 20, 2003. <http://energycommerce.house.gov/108/Hearings/03202003hearing832/Green1379.htm>

¹⁰Halperin DT, Steiner MJ, Cassell MM et al. The Time Has Come for Common Ground on Preventing Sexual Transmission of HIV. *The Lancet* 2004; 364: 1913–1915.

the last few years have seen an almost exponential growth in funds available for condoms and for AIDS programs in general. There should be enough resources for both sides. And viewed objectively, *both* sides of this debate are right, depending on whether high-risk or general populations are targeted. *Both* approaches are needed and *both* population segments need coverage. The condom intervention works best in concentrated epidemics with small, identifiable groups of core transmission where it is possible to achieve high rates of condom use, while AB is the approach that, when backed up by C, has had proven impact in generalized epidemics.

Who and how many are considered at high risk is also a point of contention. One side holds that “we are all at high risk; anyone can be infected.” Others point to DHS data that show higher levels of AB behaviors than many people assume, including those who ought to be familiar with the data:

- 1 23% of African men and 3% of African women reported multiple sexual partners in the last year
- 2 Among unmarried youth 15–24, 41% of young men and 32% of young women reported pre-marital sex in the past year

This means that *most* African men and women practice B behaviors (or do not have outside sexual partners) and *most* African teens do not report sexual intercourse in the past year. Moreover, the trend in Africa is towards *higher* levels of A and B behaviors and towards incrementally *lower* HIV prevalence (7.2% in 2005 compared to 7.5% in 2003).¹¹

What has been missing in this debate is a calm, even-handed, balanced viewpoint that recognizes that *some* resources clearly must be targeted to high-risk groups, while *some* must be directed to what survey and epidemiological evidence show are the majority of people. To target only those at high-risk is to effectively ignore the majority of any population. Targeting both minority (high-risk) and majority populations need not result in diminished quality or even quantity of prevention resources going to either group. If Uganda, with relatively few resources could design and implement a *balanced and targeted* ABC program, surely PEPFAR, with billions of dollars, can do as much.

In sum, it would be a tragic mistake to remove earmarks for fidelity and abstinence programs, one that would result in massive loss of lives. We would be removing the two interventions that have worked better than any others in generalized epidemics. American AIDS activists tend to think of AIDS patterns and challenges in New York and San Francisco when they make their demands, even if they shift the rhetoric to sound as if they are talking about Africa. These activists, who no doubt mean well for Africa and less developed countries, need to look carefully at the AIDS-related evidence from less developed countries.

Please do not undercut the one major donor agency in the world that is conducting effective AIDS prevention.

RESPONSES FROM NEELAM DHINGRA, M.D., COORDINATOR, BLOOD TRANSFUSION SAFETY, ESSENTIAL HEALTH TECHNOLOGIES, WORLD HEALTH ORGANIZATION, TO QUESTIONS SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HUMAN RIGHTS AND INTERNATIONAL OPERATIONS

Question:

Are you aware of countries that have continued blood safety programs with their own resources or have discontinued such programs once outside resources have been withdrawn? Do you perceive that this could be a problem in the future? If so, how can governments be convinced of the importance of continued support for blood safety programs?

Response:

The capacity of a country to maintain an effective blood safety program at the conclusion of a period of international assistance (financial and technical) is dependent on a sustainable infrastructure and systems being established during the project period. In all regions of the world, there are examples of developing countries (such as Chile) which, with the support of international donor and technical assistance agencies, have successfully established well-organized national blood programs with sustainable financial systems based on budget allocation, full or partial cost recovery or health insurance systems. There are also examples of countries which have

¹¹Data available at: <http://www.measuredhs.com/>

failed to establish sustainable systems and which consequently are either unable to ensure the safety or availability of the national blood supply or which remain precariously dependent on external financial support.

In the developing world, the major challenges to sustainability are the lack of tangible government support in the form of well-formulated national blood policies and plans with appropriate legislative frameworks, coupled with the fragmentation of blood transfusion services, a lack of clarity of roles and responsibilities between national stakeholders, poor institutional coordination and a lack of integration of blood programs within national healthcare systems.

An ongoing focus on systems development, good institutional coordination and the consolidation of key activities in major centers is crucial for the effective coordination and management of blood services and the efficient utilization of resources. The early stages of funding and technical assistance should focus on the development of national blood policies, capacity building, risk management and the development of systems for the sustainable financing of national blood programs as critical components of the health care systems and infrastructure. Depending on the existing situation, building a sustainable blood safety program in a country with a less-developed blood transfusion service will require a long-term commitment to international assistance for at least 5–10 years.

There are also countries such as Sri Lanka which have built up well-organized systems based on international financial and technical assistance and in 2006 are just reaching the point of transitioning to national support; sustainability of these programs will take several years to assess. The governments of the WHO Member States have expressed their commitment to blood safety in successive resolutions of the World Health Assembly, the annual policy-making meeting of ministers of health, and of WHO Regional Committees/Councils. However, there is a pressing need for ongoing advocacy by global partners in promoting wider understanding of the role of 'Blood Safety and Availability' in preventing the transmission of bloodborne infections. The urgency of the need for improved blood safety is highlighted by the response of governments to current lawsuits resulting from the transfusion of contaminated blood products. The recognition that it is more cost-effective to invest in developing safe blood programs than to face costly litigation is spurring on other countries to review and strengthen their blood safety programs. Advocacy is also required to call greater attention to safe blood as a core requirement in the health care system and its impact on other healthcare programs, including HIV/AIDS, safe motherhood, child health, malaria, surgical and medical care, and also in the management of patients with cancer, blood disorders and trauma.

Question:

How does WHO's work in the area of blood safety impact or how is it coordinated with WHO's work in other areas of global health?

Response:

The specific mandate of WHO is to support its 192 WHO Member States in the implementation of policies defined by the World Health Assembly and the achievement of their specific health goals. It works with ministries of health, nongovernmental organizations (NGOs) and other international agencies through its organizational structure and network at global, regional and national levels, each with distinctive, complementary roles and areas of expertise. WHO headquarters is responsible for developing global strategies, guidelines and tools and establishing mechanisms to support their implementation at regional and country level through advocacy, capacity building and technical cooperation. WHO regional offices adapt these strategies, guidelines and tools to meet specific country needs and provide direct support in their implementation through WHO country offices. Country offices, which have intimate knowledge of national health programmes, work with national health authorities in the context of the overall strengthening of national health systems. They also provide leadership in the coordination and monitoring of related activities, including HIV/AIDS prevention, treatment and care, by governments, bilateral and multilateral agencies and nongovernmental organizations. WHO also hosts and acts as the secretariat for the Global Collaboration for Blood Safety, a forum for about 60 internationally recognized organizations, institutions, associations, agencies and experts from developing and developed countries concerned with global blood safety and availability. This forum provides a platform for sharing expertise, identifying problems, seeking solutions and working towards the common goal of global blood safety and availability.

Within the United Nations family, the WHO Blood Transfusion Safety program takes the lead role in relation to blood safety and availability, working in collaboration with other WHO programs and initiatives, including HIV/AIDS prevention,

health action in crises, making pregnancy safer, communicable diseases, injuries and violence prevention, malaria, family and community health, healthcare waste management, evidence and information for policy, health systems and the Health Metrics Network. Blood safety is identified as one of the five elements of the Global Patient Safety Challenge by the WHO-hosted World Alliance of Patient Safety.

WHO also provides technical assistance to a number of country projects (Azerbaijan, Bangladesh, Burkina Faso, Cambodia, Ethiopia, Haiti, Namibia, Sri Lanka, Pakistan, Viet Nam) supported by other international development agencies, including the Asian Development Bank, Office of the U.S. Global AIDS Coordinator, U.S. Centers for Disease Control and Prevention, Global Fund, Gates Foundation, Japan Bank for International Cooperation, Japan International Cooperation Agency and the World Bank.

RESPONSE FROM ROBERT E. FERRIS, M.D., MEDICAL OFFICER, BUREAU FOR GLOBAL HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT, TO QUESTION SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HUMAN RIGHTS AND INTERNATIONAL OPERATIONS

Question:

USAID is to be commended for its efforts to make child birth safer and to reduce the incidence of malaria. What is the cost-effectiveness of such measures as compared to ensuring a safe blood supply? How do you think the two could best be coordinated in a single strategy to address maternal health, malaria and safe blood?

Response:

Low cost, high impact interventions exist to make child birth safer for pregnant women. For instance, external uterine massage, controlled umbilical cord traction, and the administration of medications like oxytocin to contract the uterus are widely accepted, inexpensive interventions that can prevent 50–60% of postpartum hemorrhages. A dose of oxytocin in a Uniject syringe costs approximately US\$0.50.

Several low cost, high impact interventions to reduce the incidence of malaria also exist. These include insecticide-treated bed nets (ITNs) which cost an estimated US\$5.00 each. Children are often the most vulnerable to the life threatening anemia caused by malaria. ITNs are highly effective in reducing childhood mortality and can cut the incidence of malaria by 50% in high prevalence areas. Approximately 5.5 lives per 1,000 children can be saved through the use of ITNs.

USAID is not aware of a direct cost-effectiveness analysis comparing these interventions with a safe blood supply. However, in the continuum of care, there are potentially significant synergies between prevention measures for the leading causes of blood transfusion (postpartum hemorrhage and severe anemia from malaria infection) and a safe blood supply. Maximizing prevention activities minimizes demand on already burdened blood supply systems. Theoretically, less demand would save scarce blood resources for severe cases that could not be prevented. More research is needed.

Investing in health systems is likely to be the best single strategy to address issues of safe blood, maternal health, and malaria. The critical infrastructures needed for a successful health system, like trained healthcare staff, reliable electricity, and secure supply chain, would allow a safe blood system to thrive. Maternal health and the treatment of malaria would also significantly benefit.

RESPONSES FROM CAROLINE RYAN, M.D., SR. TECHNICAL ADVISOR, DEPUTY DIRECTOR FOR PROGRAM SERVICES, OFFICE OF THE GLOBAL AIDS COORDINATOR, U.S. DEPARTMENT OF STATE, TO QUESTIONS SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HUMAN RIGHTS AND INTERNATIONAL OPERATIONS

Question:

Please describe the nature, location and grant level for programs funded by the Global Fund that address blood safety.

Response:

The Office of the Global AIDS Coordinator (OGAC) requested information regarding the nature, location and grant level of Global Fund programs that address blood safety from the Global Fund Secretariat. The information provided follows:

Experience has shown that Global Fund recipient countries include blood safety issues as part of general health systems strengthening activities and thus may fall outside the specific activities and selected indicators that are used to track progress for purposes of disbursement decisions in a number of grants.

- To date the Global Fund supports 36 grants which include indicators that relate to blood safety. The total amount signed for these grants is USD \$453 million, of which USD \$316 million have already been disbursed.
- Their geographical distribution is as follows: 20 in Sub-Saharan Africa and the Middle East, 7 in Eastern Europe & Central Asia, 6 in East and South Asia & the Pacific, and 3 Latin America & the Caribbean. Those countries are:
 - Jordan
 - Moldova
 - Tajikistan
 - Benin
 - Jamaica
 - Croatia
 - Kyrgyzstan
 - Haiti
 - Sudan
 - Swaziland
 - Sierra Leone
 - Azerbaijan
 - Guinea-Bissau
 - Eritrea
 - Chad
 - Mongolia
 - Zambia
 - Lao PDR
 - Afghanistan
 - Liberia
 - Pakistan
 - Georgia
 - Ethiopia
 - Armenia
 - Equatorial Guinea
 - Guinea
 - Togo
 - Mali
 - Multi-country Western Pacific
 - Niger
 - Papua New Guinea
 - Somalia
 - Yemen
- The 36 grants include a number of different specific targets related to blood safety. All 36 grants do have targets on “blood units screened” and additional targets refer to training of health personal in this area. Targets are formulated inconsistently throughout the grants, including “percentage of units screened” and “total numbers”, so that it is difficult at this stage to provide concrete results achieved to date (in terms of specific numbers).

Question:

The June 2006 PEPFAR Report on Blood Safety and HIV/AIDS indicates that “an incremental approach is the only realistic approach for establishing blood services in developing countries including sub-Saharan Africa.” However, would you not agree that incremental funding could be substantially increased over current levels to achieve the goal of a fully-implemented blood safety system in a shorter period of time? Please explain your response.

Response:

Because of the absorption issues noted in the 2006 PEPFAR report, the size of any increase should be carefully calibrated to ensure that countries can make effective use of the additional funds in a rapid timeframe. During the FY04–FY05 funding cycle, the 14 ministries of health (MOHs) receiving blood safety funds (\$60.2 million) absorbed these funds with different levels of success. On average, 55% of the Emergency Plan funds obligated for blood safety during this period were actually used by the grantees. However, this figure masks the dramatically higher ab-

sorptive capacity of some MOHs (e.g., Zambia, 97%; Nigeria 90%; Cote d'Ivoire, 85%) and the lower capacity of others (e.g., Ethiopia, 0%; Botswana, 8%; Guyana 30%). Several factors may limit a country's ability to absorb funds:

- Lack of trained personnel to implement activities on a national scale.
- Limited or poorly managed administrative structures within the Ministry of Health and/or other national government agencies/ministries.
- Complex internal procurement mechanisms and restrictions. On this note at least one country (Cote d'Ivoire) has also experienced problems obtaining a duty-free exemption for equipment and materials imported with Emergency Plan funds.
- A lack of suitable structures to renovate and the HHS prohibition on constructing new facilities. This has been a significant hurdle in Ethiopia, Botswana and Guyana.

In contrast, key factors contributing to a successful absorption of Emergency Plan funds in other nations include:

- Strong administrative systems in the Ministry of Health and the National Blood Transfusion Service.
- Adequate personnel to perform Emergency Plan-funded activities.
- Streamlined procurement policies.
- Adequate existing facilities with less need to build or renovate.

Based on these factors and the experience of the last three fiscal years, we believe it is wise that decisions to increase funding for blood safety be made on an incremental, country-by-country basis.

Question:

What is PEPFAR doing to ensure the regular monitoring of the blood safety programs in focus countries (and non-focus countries to the extent they exist)? What obstacles have focus countries encountered in monitoring the proper use of blood products?

Response:

The Emergency Plan uses a number of mechanisms to conduct routine and issue/site-specific monitoring of the 14 Emergency Plan-funded blood safety programs. These include:

- Most of the 14 focus countries have a program specialist on staff to "champion" blood safety issues and to interact with National Blood Transfusion Service (NBTS) partners on a daily basis.
- Emergency Plan-supported, nongovernmental technical assistance (TA) partners are increasingly basing staff members in the countries they serve. These in-country TA providers are often co-located with the Ministry of Health (MOH)/NBTS partners and provide daily program monitoring and guidance.
- Headquarters staff conducts routine site visits to blood safety programs in the 14 countries. Since the beginning of calendar year 2006, all 14 countries have received at least one monitoring, oversight and/or TA visit. During these support and supervision site visits, HQ staff use a standardized protocol to inspect all aspects of a program. Staff supplements and adapts this protocol as needed, based on their own subject-matter expertise and the country context.
- In April 2006, the Department of Health and Human Services Centers for Disease Control and Prevention (HHS/CDC) coordinated a meeting of the five TA providers and representatives from two of the 14 focus countries to develop a comprehensive list of program indicators covering the following seven key program areas:
 1. Infrastructure
 2. Blood Collection
 3. Blood Testing and Collection
 4. Transfusion and Blood Utilization
 5. Training
 6. Monitoring and Evaluation
 7. Sustainability

The indicator list includes contextual questions (i.e., items whose status is not expected to change year-to-year, such as number of hospital beds or whether a country has a Strategic Plan) and dynamic questions (i.e., items whose status would be expected to evolve over time, such as number of blood units collected). These indica-

tors will be deployed in a user-friendly Access database and will be collected and analyzed bi-annually.

Obstacles to monitoring the proper use of blood products include:

- A lack of trained local staff to oversee laboratory activities and clinical decisions on the use of blood.
- Few hospitals have functioning transfusion committees to monitor blood use, counsel/train physicians on the appropriate use of blood, and conduct hemovigilance activities.
- Weak enforcement of national policies and regulations.
- Limited data on the actual need for blood products. Example: An Emergency Plan-funded survey in Cote d'Ivoire in 2005 determined that significant wastage was occurring during the height of the malaria season when small amounts of blood from adult-sized blood bags were transfused into children suffering from anemia. Once these bags were opened, any remaining blood was discarded. Based on these findings, the Cote d'Ivoire blood service has increased the availability of pediatric-sized blood bags to reduce wastage during the rainy season.
- Private sector blood banks exist in all 14 focus countries. These banks often do not follow the national blood guidelines and do not submit blood they collect to the national screening program.
- War and civil unrest. Haiti, Cote d'Ivoire, Zimbabwe and Nigeria have all experienced disruptions to their blood services due to war and civil unrest.

Question:

According to WHO, about 40% of surveyed African countries have no line-item for blood transfusion services. Are there indications that the governments in the focus countries consider blood safety a priority? What exit strategies is PEPFAR planning to ensure the sustainability of blood safety efforts within focus countries?

Response:

By their actions over the last three years, all of the 14 focus countries receiving blood safety funds have indicated a significant commitment to maintaining and improving on the advances made possible through the Emergency Plan. A list of activities indicating this commitment follows:

- All 14 focus countries have developed and enacted national blood policies. These countries have also enacted (or are working with their legislatures to enact) legislation to support these policies.
- National Blood Transfusion Services have been established. In several focus countries (e.g., Haiti), blood services were historically managed exclusively by the national Red Cross. Emergency Plan funds have allowed governments in these situations to regain control over and consolidate administration of their national blood supplies.
- National Blood Transfusion Services in all 14 countries have published or are writing 10 year strategic plans for safe blood.
- Efforts are underway in all 14 focus countries to determine the cost of producing a unit of safe blood and to develop/enhance mechanisms to recovering some of these costs.

Ensuring the sustainability of these programs and activities is a priority for all USG agencies contributing technical and administrative support to the Emergency Plan's blood safety initiative. Emergency Plan exit strategies will need to be tailored to each country. These strategies will also, by necessity, need to be integrated into the USG's long-term development strategies and objectives for each country. Substantial thought will also need to be given to ways in which Emergency Plan-funded activities which still require external support may be supplemented by other sources of funding. For blood safety, Emergency Plan partners are working in the following areas to build administrative and technical capacity in the focus countries:

- Significant work is underway to identify and train energetic physicians, nurses, laboratory technicians, administrators, logisticians, and other allied healthcare workers to manage the scale-up during the Emergency Plan period and execute the strategic plans under development for the post-Emergency Plan era.
- Significant efforts are made to ensure that blood safety activities are effectively linked to other prevention, care and treatment programs. Staff also work to develop strong relationships with other funding partners and to facili-

tate new relationships between these partners and the ministries of health. For example, PEPFAR is working with ExxonMobil, Abbott and Safe Blood for Africa Foundation through a Public Private Partnership to implement a blood safety project with two major components, a National Blood Transfusion Service Training Laboratory and a Center of Excellence Blood Bank Facility in Nigeria's Federal Capital Territory. Additionally, support is provided for several regional blood banking centers throughout the country.

- PEPFAR has supported ministries of health, where appropriate, to leverage economies of scale. In countries with functioning procurement systems, this support includes technology upgrades and training.
- The Emergency Plan is also supporting coordination with Internews to create a blood safety training module for journalists and other media workers. The objective of this project is to leverage the media's existing communications networks to distribute blood donor education and mobilization information to the public without the costs associated with printed hand-outs and banners. Efforts are also underway to develop targeted messages using social marketing techniques. These activities are important for building the sense of local ownership so essential to sustainability.

Question:

As you know, the GAO recently submitted a report to Congress in early April regarding the impact of the 33% abstinence-until-marriage earmark for our Global AIDS prevention programs (Global Health: Spending Requirement Presents Challenges for Allocating Prevention Funding under the President's Emergency Plan for AIDS Relief, GAO-06-395, April 4, 2006).

Apart from finding that implementing the abstinence-until-marriage earmark challenged the ability of country teams to develop interventions that are responsive to local epidemiology and social norms, the GAO also found that one country team feared the earmark would force cuts in medical and blood safety activities and had sought an exemption from meeting the spending requirement.

Given the GAO report and some of the other associated challenges presented by the abstinence-until-marriage earmark, wouldn't eliminating the earmark give OGAC greater flexibility in spending our limited HIV prevention resources, so that we can put more money into blood safety and other areas, depending on local needs?

Response:

The legislation's emphasis on Abstinence and Be Faithful (AB) activities has been an important factor in the fundamental and needed shift in U.S. Government (USG) prevention strategy from a primarily condoms (C) approach prior to PEPFAR to the balanced ABC strategy. The Emergency Plan has developed a more holistic and equitable strategy, one that reflects the growing body of data that validate ABC behavior change. PEPFAR has followed Congress' mandate that it is possible and necessary to strongly emphasize A, B, and C, while also seeking to support prevention of medical transmission through programs to ensure a safe blood supply and safe medical injections, programs to prevent mother to child transmission and other critical prevention interventions.

At a recent briefing for Congressional staff and others, the Kenya director for a large program was asked if the 33% directive impacted his ability to program effectively. His answer, in paraphrase, was that ABC is the African approach and should be supported, that the directive had no adverse impact and in fact the enhanced emphasis on AB was beneficial in focusing programs on effective prevention. In a letter to the editor of Lancet the Minister of Health of Namibia and the CDC and USAID country directors presented opinions similar to the gentleman from Kenya. This joint letter reflects the reality that effective prevention programs must support national strategies; as long as the balanced ABC approach remains central to the strategies of host nations, it will necessarily be central to USG support for those nations.