AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

S. HRG. 108–294

SOLUTIONS TO THE PROBLEM OF HEALTH CARE TRANSMISSION OF HIV/AIDS IN AFRICA

HEARING

BEFORE THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

ON

EXAMINING SOLUTIONS TO THE PROBLEM OF HEALTH CARE TRANSMISSION OF HIV/AIDS IN AFRICA, FOCUSING ON INJECTION SAFETY, BLOOD SAFETY, SAFE OBSTETRICAL DELIVERY PRACTICES, AND QUALITY ASSURANCE IN MEDICAL CARE

JULY 31, 2003

Printed for the use of the Committee on Health, Education, Labor, and Pensions

U.S. GOVERNMENT PRINTING OFFICE

88–790 PDF WASHINGTON : 2004

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

JUDD GREGG, New Hampshire, *Chairman*

BILL FRIST, Tennessee
MICHAEL B. ENZI, Wyoming
LAMAR ALEXANDER, Tennessee
CHRISTOPHER S. BOND, Missouri
MIKE DEWINE, Ohio
PAT ROBERTS, Kansas
JEFF SESSIONS, Alabama
JOHN ENSIGN, Nevada
LINDSEY O. GRAHAM, South Carolina
JOHN W. WARNER, Virginia

EDWARD M. KENNEDY, Massachusetts
CHRISTOPHER J. DODD, Connecticut
TOM HARKIN, Iowa
BARBARA A. MIKULSKI, Maryland
JAMES M. JEFFORDS (I), Vermont
JEFF BINGAMAN, New Mexico
PATTY MURRAY, Washington
JACK REED, Rhode Island
JOHN EDWARDS, North Carolina
HILLARY RODHAM CLINTON, New York

SHARON R. SODERSTROM, *Staff Director*
J. MICHAEL MYERS, *Minority Staff Director and Chief Counsel*

C O N T E N T S

STATEMENTS

THURSDAY, JULY 31, 2003

	Page
Alexander, Hon. Lamar, a U.S. Senator from the State of Tennessee	1
Peterson, E. Anne, M.D., Assistant Administrator For the Bureau of Global Health, U.S. Agency For International Development: and Yvan Hutin, M.D., Medical Officer, Department of Blood Safety, World Health Organization	3
Ssemakula, John Kiwanuka, M.D., Medilinks: Holly Burkhalter, Physicians for Human Rights; and John Stover, Vice President, The Futures Group International, Glastonbury, CT	19

ADDITIONAL MATERIAL

Statements, articles, publications, letters, etc.:	
E. Anne Peterson, M.D.	40
Yvan Hutin, M.D.	47
John Kiwanuka Ssemakula, M.D.	50
Holly Burkhalter	60
John Stover	64

SOLUTIONS TO THE PROBLEM OF HEALTH CARE TRANSMISSION OF HIV/AIDS IN AFRICA

THURSDAY, JULY 31, 2003

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 10:35 a.m., in room SD–430, Dirksen Senate Office Building, Senator Sessions presiding.

Present: Senators Sessions and Alexander.

OPENING STATEMENT OF SENATOR ALEXANDER

Senator ALEXANDER [presiding]. The hearing will come to order. Our chairman, Senator Sessions, is in the midst of a press conference. Rather than keep you waiting, he asked me to go ahead and begin the hearing, which I am happy to do.

This is a very important topic in which Senator Sessions has taken a lot of interest. All of us in the Senate are focusing more of our attention on HIV/AIDS. Senator Sessions has looked especially at how AIDS is transmitted. Today, we are talking about the medical transmission of AIDS, what are some of the solutions for medical transmission and what policy makers should know and understand as we go about making decisions.

This all occurs against a backdrop where President Bush has announced with virtually unanimous bipartisan support in the Senate—the only disagreement is over who can support it the most, I think is the idea—our moral commitment as a country to working on helping to deal with the terrible problem of HIV/AIDS, especially in Africa, and that is what we are talking about today, one piece of the problem.

We have two panels of witnesses. I will introduce the first panel and ask them to go ahead and then Senator Sessions will be here and we will both have questions of both panels as time comes along.

Dr. Anne Peterson is our first witness. She is well known to us, Assistant Administrator for the Bureau of Global Health for the U.S. AID. It is the principal government agency providing economic and humanitarian assistance to transitioning and developing nations. Within U.S. AID, the Bureau for Global Health provides technical and program support to field interventions in areas such as HIV/AIDS, infectious disease control, and child and maternal health. Dr. Peterson knows what she is talking about. She has

lived and worked in Africa in different countries and we are delighted that she is here today. Dr. Peterson?

Before we begin I have a statement from Senator Kennedy.

[The prepared statement of Senator Kennedy follows:]

PREPARED STATEMENT OF SENATOR KENNEDY

I commend Senator Sessions for calling this hearing to highlight the AIDS crisis in Africa and the profound effects of this worldwide epidemic. We are now in the third decade of the epidemic, and every nation has an obligation to do more to end it. Almost 22 million lives have been lost to AIDS, and there is an urgent need to develop more effective means of prevention and treatment.

AIDS imposes its heaviest toll on developing countries. Of the 42 million people who are infected today, the overwhelming majority are in the poorest nations of the world. Sub-Saharan Africa is the region that has been hardest hit. The overwhelming majority of the thirteen million children who have been orphaned by AIDS live in that region. The United States has been far too silent while that enormous suffering goes on.

AIDS robs poor countries of hope. It robs them of workers needed to develop their economies teachers needed to combat illiteracy and train men and women for jobs and farmers needed to sustain their communities and feed their people. Year after year, because of AIDS, poor nations sink deeper into even more desperate poverty.

We know that challenges like these are not insurmountable, and that other governments can make the difference in battling AIDS in Africa. Thirteen years ago, we demonstrated our commitment to the care and treatment of Americans living with AIDS by passing the Ryan White Care Act. Since then, community-based care has become much more widely available. Public health campaigns have increased awareness of the disease, and the new awareness has made prevention a major part of our effort. That kind of model can be applied in other nations too, even in parts of the world that are reeling from the AIDS crisis.

In America, we have already made large gains in helping those infected by the virus to lead long and productive lives because of the miracle of prescription drugs. Drug treatments are available that nearly double the life expectancy of HIV-positive individuals.

Tragically, these advances are readily available only in wealthy nations. We have an obligation to continue fighting this disease at home, but we also need to share these enormous scientific advances with other nations. We must do all we can to provide access for everyone to today's life-saving therapies.

We must also take the lead on providing resources to developing nations. When governments obtain the necessary resources, infection rates have dropped by as much as 80 percent. They use these resources to carry out educational campaigns and improve the distribution of information to schools and health professionals. Mass media campaigns are needed to educate all sectors of society about the spread of AIDS and what each person can do to protect themselves against infection. Above all, poor nations need help in paying for necessary drug treatments and developing the local infrastructure to provide health care and get drugs to victims.

There is no silver bullet to solve the AIDS crisis. The solution must be wide-ranging and include steps to prevent unsafe sex practices, prevent transmission of the disease from mother to child, and prevent infections from contaminated blood and unsafe injections.

President Bush deserves great credit for his recently enacted $15 billion initiative over the next five years to combat the global AIDS epidemic. Lets be sure that these resources are delivered quickly and are available to prevent all methods of transmission with a particular focus on sexual transmission, which is widely recognized by all major national and international public health agencies as the most widespread type of transmission in both industrial nations and developing nations.

Dollars and common sense also mean that the use of the funds should not be based ideology. We have so little time to act, and we can't waste this opportunity. Working together, we can lead the world community in defeating one of the greatest threats of our time.

Again, I commend our Chairman for calling this hearing, and I look forward to the testimony of our witnesses.

STATEMENTS OF E. ANNE PETERSON, M.D., M.P.H., ASSISTANT ADMINISTRATOR FOR THE BUREAU OF GLOBAL HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT; AND YVAN HUTIN, M.D., PH.D., MEDICAL OFFICER, DEPARTMENT OF BLOOD SAFETY, WORLD HEALTH ORGANIZATION

Dr. PETERSON. Thank you. I very much appreciate the chance to be here today to speak on this important topic. The U.S. Government does acknowledge that there is medical transmission of HIV/AIDS and that this is an area that we need to take very seriously. I am not today going to try and talk about the epidemiology and how big the problem is, but more what kinds of things are we doing, where are we working in ways that can begin already to address the medical transmission of HIV/AIDS.

I was also asked specifically just to touch on the general epidemiology, how big is the epidemic and what is different in different parts of Africa. In your handout, you can see the slide that shows that Africa has a very high prevalence. Obviously, that is why we are here. But there is a difference in the epidemic from West Africa, East Africa, and Southern Africa. We don't completely know why there are those differences. It probably has to do with strains of HIV, response to the epidemic, maybe even things like male circumcision, a very interesting and new strongly supported area.

My experience is that medical transmission probably isn't the explanation for the differences between West Africa's slow growth and Southern Africa's very rapid growth, but I know that——

Senator ALEXANDER. Growth in AIDS, you mean.

Dr. PETERSON. For AIDS.

Senator ALEXANDER. HIV.

Dr. PETERSON. Yes. But that CDC/HHS is doing a study looking at what do we know about medical transmission and the epidemiology of that. So I expect in the new few months we will know more. We will be able to say which areas we can make the most difference.

Within HIV/AIDS, there are a host of strategies that we could be involved in. On the slide under "Comprehensive Approach," you will see that very many of them are in a medical and clinical setting, not all, but in each one of those areas, like ensuring blood safety, injection safety, postexposure prophylaxis, treating of STDs, even voluntary counseling and testing. Those are interventions in our AIDS program that happen in medical settings. Some of them are places where there can be medical transmission of HIV/AIDS and, therefore, they are areas where we want to reduce any potential transmission to the greatest possible extent.

In the next slide, we have a modeling that John Stover has done that—and I know he will be presenting to you later, and the most important point is that we truly have many and complementary strategies. Do you want me to——

Senator ALEXANDER. Please go ahead.

Dr. PETERSON. Thank you.

Senator SESSIONS [presiding]. Dr. Peterson, thank you for your testimony and I apologize for being late. We just had a big brouhaha and my good friend, the Attorney General of Alabama, and we find his nomination to be filibustered, so we got caught up in that. I am sorry. It was an important matter, but this is very important also and we are delighted to have you here.

Dr. PETERSON. Thank you very much.

Senator SESSIONS. Please continue.

Dr. PETERSON. And we have just started. The real point is that we have many and complementary strategies to address transmission of HIV/AIDS, especially within the medical setting, and prevention of medical transmission happens within our AIDS programming, the things like blood safety, postexposure prophylaxis, our mother-to-child transmission programs, but a lot of what is already happening that could address medical transmission of HIV/AIDS is being done through our general health programs, our injection safety programs, our immunization programs, our maternity care and delivery programs, the White Ribbon campaign, new protocols for delivery, malaria prevention—I will talk a little bit more about that, as well as the research that we do, the health systems training and quality assurance.

All of those things that are currently being done are predominately funded out of our child health and maternal health program funding, and as you can see, that is about 25 percent of our overall funding for U.S. AID's health programs. I am on the second page of the handout.

Injection safety is, I think, what really brought this issue to everyone's attention, and there is a lot already happening addressing injection safety. I sit on the board of the Global Alliance for Vaccines and Immunizations. Like the Global Fund, it is a public-private partnership that has had a lot of money put in, a lot of emphasis on immunization, both new and routine, and a portion of the funds that gets distributed to the countries is specifically for immunization system strengthening.

The U.S. contribution is $58 million in this year. It is a total of $160 million. And specifically, immunization services support has received $332 million through various of the countries and $77 million specifically for injection safety in the last 3 years.

U.S. AID has also been very involved in the technology development, the development of the auto-destruct syringe, so the single-use syringe, and the newest one, the Unijet, which is a small, very small—I should have brought it—syringe that can only be used once. It looks like a little bubble from bubble wrap. Part of what we are doing now is finding more and more of the immunizations and other kinds of injections that can be used using that modality. We had more than 400 million of the auto-disabled syringes that have been supplied to 40 countries and 22.6 million Unijet devices that have gone out worldwide since 1998.

We are also working in blood safety. In Kenya, we have $3.3 million to equip and construct a national and four regional blood transfusion centers to work with model transfusion projects and operational guidelines. In Nigeria, there is a newly-designed program, and in many places, we are working with countries to change their protocols for when do you transfuse.

That leads us really to both the maternal care and malaria issues. Maternity and delivery care is important for HIV medical transmission because postpartum hemorrhage is a major reason for anemia that leads to transfusion. There is the mother-to-child transmission, as well. Addressing the quality of maternity care protects the baby in mother-to-child, it protects the mother from receiving transmission, and it protects the health care workers, as well. If you can reduce the high-risk deliveries and you can reduce blood exposures, you are protecting all three of those populations in a medical setting.

So we have worked enormously there, both with changing protocols for delivery, working with improved postpartum and PAC care, working with getting Oxytocin, which is the drug that reduces bleeding into the Unijet, so again, it can be administered safety. We have done regional training in best practices, and again, dealing with when do you transfuse in those kinds of situations. All of this reduces HIV transmission in medical settings.

Similarly, malaria, which you know is a huge problem in sub-Saharan Africa, is a major contributor to the need of transfusion. Our malaria expert told me this morning he had just come back from Congo and 80 percent of the beds had to do—for young children—were there because of severe malaria and 80 percent of the transfusions were because of probably inappropriate transfusion of these children who were severely anemic. So we are working in our malaria programs, one, to reduce malaria. The primary prevention program is scaling up to national scale——

Senator SESSIONS. Dr. Peterson, you said 80 percent of what was caused by the transfusions?

Dr. PETERSON. Eighty percent of the children in the hospital had severe malaria, and 80 percent of those children were having inappropriate—well, a mix of appropriate and inappropriate transfusions. But he was very concerned and that was his "just returned" example. That is probably an exceptional case for the place that he had just visited, but it is an overall problem, that severe anemia is a common result of malaria and, in general, it has in the past been treated with transfusions. If we change the protocols for when you transfuse and if we can reduce the malaria burden for infants and children, we reduce, again, that risk of transfusion.

Malawi is fascinating in that a program to address the treatment protocol for malaria, get the right drugs to people who are sick with malaria, resulted in a 30 percent difference compared to other countries in the mortality for infants and children. It will equivalently change the amount of severe anemia. So primary prevention, correct treatment of malaria, and again, the changing of protocol for transfusions.

We also work in the science and technology. I mentioned the technical innovations like the auto-destruct syringe. But we also work in biomedical research, rapid diagnostic tests that let you know what you are dealing with so you can respond very quickly.

And since we are an implementing agency, one of the most important things we do is operations research. How do you know that what you are doing is being done well and is having the effects that it should have? And so things like are they doing their STD treatment properly, integrating family planning with PMCT, acceptance of medical waste protocols as we deal with immunization and medical waste and the potential transmission that you have in that kind of setting, and how do you get best practices in the medical setting for medical waste.

We have quality assurance projects that look at the protocols for doing treatment. This will be very important for the President's initiative in doing ARV treatment, but it will also be important for the mother-to-child transmission, for maternity care. In each one of these areas, having the right protocols and having people trained and following them correctly and the quality assurance and the oversight and management of that can make a real difference in medical transmission. We have seen that in the U.S. We certainly are seeing it also in international settings.

In the set of slides, I gave one example where in South Africa, and it would be wonderful if Senator Alexander got to see this project, in the Eastern Cape, which is the area of South Africa with the worst health indicators, very significant HIV, we worked in a management oversight information system type of program. We took $7 million of our U.S. AID money and we helped do technical assistance and management oversight and leveraged, really, the $420 million the South African provincial government was putting into their provincial health system and worked with them to recognize what they were doing and if there were problems to respond back.

If you walk through the slides, you can see that these were really poor settings. They didn't all have water and electricity. And over the course of 3 years, all of the process indicators improved. They did more counseling for HIV than they had previously. They got their TB drugs better into the clinics. They got their immunization drugs better into the clinics. They followed proper TB protocols. They followed proper management of STD protocols. And within 3 years, we saw a spectacular decline in syphilis and other disease outcomes and the beginning of the leveling off of HIV in the youngest age group in this whole province, and again, one of the poorest provinces in South Africa.

So this is a management oversight quality assurance program that we were doing to the provincial government that was having a profound impact on how the clinical care was being done and the

disease transmission and treatment and therapies within those settings. So the policy issues can make a huge difference.

There are still challenges. We need better data and surveillance to know where the greatest amount of medical transmission of HIV is happening. That is likely to change over time as we continue to implement programs and impacts. So we will have to continue to keep track of it.

Informal sector does contribute to "medical transmission" of HIV. There are many places in sub-Saharan Africa where you have non-medical providers doing injections and other therapies and that will be a hard sector to reach.

We also need to look at a major thrust of the President's initiative, the scale-up of anti-retroviral therapy, and recognize that we have a great potential and a caution, and that is as we do the scale-up for treatment of HIV/AIDS, we will necessarily have to work on the health systems. We can, as we plan it, either choose to be very narrowly focused and just make sure we have got the delivery systems and the protocols for ART, and like polio, perhaps get some diversion of attention. Polio has diverted in some places attention from routine immunization. Or we have the opportunity as we scale up and address health systems issues for the anti-retroviral treatment. We can make sure that it improves the health systems broadly for all of the different parts of medical transmission potential.

So it is a place to pay attention to as we go forward and make sure that the health systems work that we do specifically for the AIDS treatment does the best possible for all possible transmissions of HIV.

In the future, these are the things that I see going forward. Our health programs will certainly continue to pay attention to how can we deal with injection safety, delivery care, those kinds of things. The GAVI Board has just, really at our instigation, initiated a study looking at the immunization strengthening support dollars, the hundreds of millions of dollars that they are doing in ISS, to make sure that it is having a good impact and to make recommendations on that.

The Global Fund will similarly be scaling up their AIDS, TB, and malaria programs. They have the same opportunity that we do within our Presidential initiative to broadly assist in health systems strengthening and to address medical transmission of HIV/AIDS.

And as we have anti-retrovirals available, we will have more opportunities for introducing protocols that aren't done a lot currently in Africa, like postexposure prophylaxis. If you have the ARVs available, that will then be much more easily accessible to the health care workers and others on occasional exposure.

Senator SESSIONS. If you can wrap up——

Dr. PETERSON. Sure. And that is really it. If we can go forward, I think there is great scope for us to begin to make even more difference than in the past on medical transmission. Thank you.

Senator SESSIONS. Thank you.

[The prepared statement of Dr. Peterson may be found in additional.]

Senator SESSIONS. Dr. Yvan Hutin works for the Department of Blood Safety and Clinical Technology of the World Health Organization in Geneva, Switzerland. He attended medical school at the University of Nancy in France before going on to complete his Master of Science in clinical and tropical medicine at the University of London, a diploma of specialized studies in hepatology and gastroenterology in Paris, and a Ph.D. in epidemiology at the Swiss Troppen Institute.

Dr. Hutin has extensive experience in epidemiology and injection safety. He has spent over 10 years studying the epidemiology of infectious diseases, including a number of years specifically focused on the assessment of African nations. His service in epidemiology includes acting as a medical epidemiologist specializing in hepatitis B prevention with the CDC, as well as his present position at the World Health Organization. He is presently the project leader of the Safe Injection Global Network of WHO, which acts to assist member states in assessing, planning, implementing, and evaluating policies for the safe and appropriate use of injections.

Dr. Hutin, we thank you, and thanks to WHO for allowing you to take time out of your busy schedule to share with us. We are, for both of you, we are going to be spending a tremendous amount of additional funds. As I know both of you agree, it is a moral imperative that we apply those funds as wisely as possible to get the greatest possible reduction of this terrible disease in Africa. Dr. Hutin?

Dr. HUTIN. Thank you. Mr. Chairman, distinguished members of the committee, the World Health Organization appreciates the opportunity to brief the committee on the prevention of HIV through health care practices in Africa and appreciates the interest of the committee in this important public health issue.

Senator Sessions, members of the committee, I am Dr. Yvan Hutin from the World Health Organization in Geneva, Switzerland. WHO is an international organization, the technical specialized agency for health of the United Nations system, which currently has 192 member states. The United States has been a member of the WHO since it was founded in 1948.

As a clinician, I have experience in the care of individuals with HIV infection and viral hepatitis both in Europe and in Africa. As an epidemiology, I served in the Epidemic Intelligence Service of the United States Centers for Disease Control and Prevention. As you mentioned, I am now project leader for the Safe Injection Global Network.

In addition to my statement, I have provided the committee copies of two reports entitled, "The Cost Effectiveness of National Policy for the Safe and Appropriate Use of Injections," and "Progress Towards the Safe and Appropriate Use of Injections Worldwide 2000-2001," and I would request that these two reports be made part of the record.

A number of health care procedures may lead to the transmission of HIV. These include transfusion of infected blood, unsafe injections, and other skin-piercing procedures that would be conducted in the absence of universal precautions. Thus, health care services should offer to their users selection and testing of blood donors, and when applicable, viral inactivation of human material for

therapeutic use, safe and appropriate use of injections, and procedures that are conducted according to the universal precautions.

In Africa, for a population of 0.6 billion, which is about ten percent of the world, only 2.4 million blood units are collected annually. That is against an estimated annual need of six million units. About one-third of the blood is donated by family replacement or paid donors that we consider to be a high risk for HIV transmission when we look at the incidence of prevalence of HIV in Africa. In addition, 50 percent of collected blood is not tested, either for HIV, hepatitis B, hepatitis C, or syphilis. The high efficiency of the transmission of HIV through the transfusion of infected blood, which is about more than 90 percent, leads to a substantial burden of infection among the patients who receive blood transfusions.

Senator SESSIONS. Does that mean if you are transfused with infected blood, you have a 90 percent chance of——

Dr. HUTIN. Yes. If you receive an infected blood transfusion, your risk of becoming infected yourself is 90 percent. The risk is much smaller for unsafe injections. However, unsafe injections are a more common procedure than blood transfusion, so this is how the difference plays out.

For the remainder of the statement, I will focus primarily on the issue of unsafe health care injections, which I have been asked by the committee to address.

WHO estimates that in developing and transitional countries, 16 billion health care injections are administered each year, an average of 3.4 injections per person per year. This high figure, along with evaluation reports indicating inappropriate use of injections, suggests that injections are overused to administer medications. The causes of this overuse may include a preference for injection among patients. However, the key cause is a desire from the health care provider to satisfy what they believe is a preference for injection among the clients, and in fact, research suggests that most patients are very open to oral medications when you explain to them that they are just as effective as injections.

In addition to being overused, injections may also be administered by unsafe procedures and cause infections. A safe injection should not harm the patient, the health care worker, or the community at large. However, an injection may harm the patient when injection devices are reused in the absence of sterilization. Injections may harm the health care workers when dirty needles are collected in the absence of safety boxes. And injections may harm the community at large when health care facilities are surrounded by sharps, health care waste, mostly dirty syringes and needles.

Reuse of injection devices in the absence of sterilization is a problem of greatest concern that we have to address as it leads to the largest burden of disease. A mathematical model developed by WHO suggests that in 2000, in developing and transitional countries, reuse of injection devices accounted for an estimated 22 million new cases of hepatitis B infection, which is about a third of the total, two million cases of infection with the hepatitis C virus, which is about 40 percent of the total, and about a quarter-million of HIV infection, which is about five percent of the total for the whole world. These infections acquired in 2000 alone are expected

to lead to an estimated nine million years of life lost, and this is adjusted for disability, between the year 2000 and the year 2030.

As the committee is certainly aware, there has been a recent controversy over the role that unsafe health care injections play in the transmission of HIV infection in sub-Saharan Africa. While WHO estimates that, worldwide, about five percent of all HIV infections are transmitted through unsafe health care injections, this estimate is only 2.5 percent for sub-Saharan Africa. Although there is uncertainty around these figures, WHO and our sister program, the U.N. AIDS, believe that these are in the right order of magnitude and that the vast majority of HIV infections in sub-Saharan Africa are transmitted via unsafe sexual practices.

The public health issue of unsafe injection may appear daunting. Yet, evidence indicates that the death and disability associated with unsafe injections is highly preventable. First, interventions conducted to improve communication between patients and health care workers and intervention to improve the rationality of the prescription of the prescribers are effective in decreasing injection overuse.

Second, interventions to ensure the injection device security, and what we mean by that is to make sure that single-use syringes are available reliably in every health care facility, are effective in preventing reuse of injection devices. Some of the poorest countries in the world, Burkina Faso, for instance, have actually achieved substantial progress through ensuring that all injectable medications are made available with sufficient quantities of single-use syringes and needles.

In addition to being highly effective, policies and plans for the safe and appropriate use of injections are a very sound investment in health. In the scientific paper that I presented to the committee as part of my statement, WHO has estimated that interventions implemented in 2000 for the safe and appropriate use of injection would have cost about $102 for each year of life saved, and that is also adjusted for disability. This cost is under the threshold of 1 year of average per capita income, which is considered by the WHO Commission on Macroeconomics and Health to be the threshold to consider health intervention as highly cost-effective health intervention.

Thus, implementation of safe and appropriate use of injections as part of HIV prevention and care programs is highly desirable and can be accomplished with only a modest shift in the assignment of resources for two reasons. First, injection safety is not that of a costly intervention. The scientific paper on the cost effectiveness that I submitted to the committee as part of my statement includes an estimate of what it could cost to ensure injection safety in each of the world regions, and so you can check the figures. Second, the large majority of HIV infections worldwide are caused by unsafe sexual practices. Thus, the emphasis of HIV prevention programs must remain on preventing sexual transmission.

Among prevention opportunities, single-use injection devices with reuse-prevention features deserve a specific mention. These have been also referred as auto-disable or auto-destruct syringes. These syringes inactive themselves after one use through either plunger breaking or plunger blocking or needle retraction and are now the

norm for immunization services and they are becoming also the norm for other programs that are supported by international donors or lenders.

I just thought it would be useful for you to see how these devices work. This is an example of a device that works through plunger breaking, so if I give an injection once, then I can't pull back the plunger because it has been blocked by a metal clip.

The second type of device that I have here would work through a plunger breaking, and here, I can give one injection and once I have given it, if I try to give a second injection, the plunger has been broken off.

The third type of device that we can use is based on a system by which the needle retracts after the injection, so here I am giving one injection, and if I want to give another one, the needle has disappeared. I will clean my toys afterwards, I promise. [Laughter.]

So in addition, we have new single-use syringes with reuse-prevention features that have now been developed for general curative health care services and not only sort of donor and lender funded programs. These devices that are very promising require field evaluation so that we can define the exact future role that they will have in public health.

Since the establish of SIGN at WHO in 1999, great progress has been made toward the safe and appropriate use of injection. In the progress report that I have attached as part of my statement, you will see that actually the Government of the United States has supported very strongly WHO's effort in this area through the Division of Viral Hepatitis of the Centers for Disease Control and Prevention, the United States Agency of International Development, and the United States National Vaccine Program Office. Additional support will be needed in the future to prevent death and disability through key interventions at a country level.

Four key interventions are needed for injection safety. These include increasing the awareness of the population so they can know that when they are exposed to a dirty syringe, they can get HIV; making sure there is enough quantities of single-use injection devices and safety boxes in every health care facility where injections are administered; ensuring that all donors and lenders who support the supply of injectable substances in developing and transitional countries also support the provision of injection devices with reuse-prevention features and safety boxes—we don't believe it is ethical to send to a country injectable substances if you don't have the syringes that go with it; and finally, manage the waste associated with dirty syringes and needles in a safe and appropriate way.

The four key interventions for blood transfusion safety are the national blood transfusion service; the collection of blood from voluntary, nonremunerated blood donors from low-risk populations; the testing of all donated blood; and the reduction of unnecessary transfusion.

WHO appreciates the opportunity to brief the committee on this important issue and I would like to thank you for your attention and will be happy to answer any questions that you may have on the subject.

Senator SESSIONS. Thank you, Dr. Hutin.

[The prepared statement of Dr. Hutin may be found in additional material.]

Senator SESSIONS. Thanks to you and thank you, Dr. Peterson. Those were very worthwhile comments that you made and I would like to raise a few questions.

First, I think we ought to deal with the question of injections, Dr. Hutin, and where we stand on that. Have you had the occasion to study Dr. Gisselquist's study of the transmissions by injection? I know he has numbers extraordinarily higher than the two percent or 2.5 percent WHO has come up with.

Let me ask you this. When WHO has a number like 2.5 percent transmitted by dirty needles, injections, does that figure include—that only includes that transmission. It does not include the possibility that the person unknowingly infected may infect other people, is that right?

Dr. HUTIN. Yes. I think that would be very difficult to take into account. I am familiar with Dr. David Gisselquist's work and I think his work has been useful to bring light to this important public health issue. We have done the math and done a mathematical model that suggests that there is a certain amount of uncertainty about the proportion of HIV that comes from unsafe injections, but that it would be about five percent globally and 2.5 percent only in Africa.

As I say, there is a certain amount of uncertainty around that and our number may be slightly on the lower side, but it is very clear from a WHO point of view that the very large majority of HIV transmission in sub-Saharan Africa is caused by sexual transmission. However, I would like to add that we do not believe it is a question of fighting for percent, and I agree with your comments. There is all this issue of secondary transmission that is difficult to address. It is not like we can cut a pie with a proportion that we can definitely assign to a mode of transmission.

We have now consensus at WHO to say that whatever the mode of transmission of HIV, all modes of transmission should be prevented. Sexual transmission should be prevented. Health care transmission should be prevented. And because, as I have said in my statement, because injection safety is not that expensive and because the major issue is sexual transmission, we do not believe that the shift of resources should be of a major magnitude. However, it is clear that injection safety is a low-hanging fruit that really needs to be taken care of.

Senator SESSIONS. Thank you. I would agree with that. I would just say, WHO's leadership on SARS was extraordinary. I think you moved decisively, courageously. You moved based on sound science and apparently have curtailed this dangerous disease. I would like to see all of us do a better job of being that decisive, that courageous, and that effective on AIDS, which is an even more deadly disease.

In your report, I notice that WHO was insisting on its lower figure earlier this year in reference to Dr. Gisselquist's report, but in your report for the WHO, the global burden of disease attributable to contaminated injections given in health care settings, you concluded that in AFR E, is that Africa——

Dr. HUTIN. Yes.

Senator SESSIONS. Africa East?

Dr. HUTIN. It is one of our acronyms for a subregion in Africa.

Senator SESSIONS. That subregion, at least, you reported that where prospective studies are available, the lowest attributable fraction calculated on the basis of the data provided by the authors was eight percent. In looking at your footnotes, you note that three other studies came in, in addition to the eight, 15, 41, and 45 percent. What could you tell us about those numbers and what implications they may have for us?

Dr. HUTIN. What I have done is we have done a mathematical model which has suggested that the proportion of HIV that comes from the unsafe injections is about 2.5 percent. We have compared this figure with epidemiological studies that have been conducted in the field, and when we look at these epidemiological studies, they give figures of a slightly higher order of magnitude.

So the conclusion that I have made is that probably our number is slightly on the lower side. However, as I have said earlier in my statement, we do not believe that the medical transmission—the injection-associated transmission of HIV could be of an order of magnitude of more than ten percent. The vast majority is sexual transmission. So we may be on the lower side with 2.5 percent, but that remains our best estimate, together with the margin of uncertainty that is mentioned in this report, and clearly, the majority of HIV is transmitted by sex.

Senator SESSIONS. It is just strange to me that you did report and your conclusion was that the 2.5 percent was probably conservative, I believe were your words, so that would indicate it is more than that. As I understand it, 2.5 percent translates into 50 or 100,000 infections per year in the continent, would that be correct?

Dr. HUTIN. I want to make sure I have the right figure. I know it is a quarter-million worldwide. I don't have the exact figure right here.

Senator SESSIONS. I believe that was the figure from one of the WHO numbers.

Dr. HUTIN. Right.

Senator SESSIONS. I guess what I am saying is, if it were to be ten percent, even, and Gisselquist has it higher than that, that would be four times as many, and so we would be talking about in, I believe, in Africa, 400,000 maybe infections a year.

Dr. Peterson, you raised and shared with us your concern about transfusions in particular because your studies deal only with injections, that that may be even higher. I believe you relied on WHO numbers that suggested that five to ten percent of the infections in Africa came from transfusions. Would you share any comments you might have about that?

Dr. PETERSON. Sure. I am really looking forward to where the study that I know has commissioned goes on this. The data that they have always is looking retrospectively, and on something like blood supply and safe transfusion, we get samples. So again, very similar to what you have heard on injection safety, you have your best estimate and you have an area of uncertainty around it. The most often quoted is five percent. Five to ten percent is probably blood safety or blood transfusion related.

But that is the working number for a number of years, and part of what has happened in the last two or 3 years which would not yet be reflected in any of the data we have in hand is we are trying to address that, both in the protocols and all of our other programs, to reduce that amount——

Senator SESSIONS. Yes.

Dr. PETERSON. —both dealing with the blood banking issue itself, but also dealing with how often you transfuse and the need for transfusion. So we have got several years of intervention where we have known that the blood has not been safe and people have been responding to that.

I will give a personal example. My third child was born in Kenya. I had a c-section, and what I did, given the very known unsafety of the blood supply in Kenya, was made sure I had a blood donor of my blood type available should I need a transfusion. Those are the kinds of things that people have been doing in response.

So what we need now is more up-to-date data on how much is actually—how much transmission is actually happening. We have better ideas of how much of the blood is unsafe, but how much transmission is actually happening is something we need to find out, address, and keep track of, and continue to address very strongly.

Senator SESSIONS. We did place in the global AIDS authorization bill a requirement that HHS conduct a study, but from what I am hearing from you, we may need to do more than study studies. We may need to develop a very intense study and move on it, and I would just share this thought, that this is a life-and-death matter.

I still shudder every time I think of a German study that came out in May that found that there were 670,000 children in South Africa, 670,000 from age two to 14, infected with AIDS, and most likely the majority of that would have come from either transfusions or injections, from what we understand. It is just a stunning, stunning number. To me, we need to move on this rapidly. It is just so important.

So studies don't need to be a two- or three-year study. They need to be absolutely prompt and get the best data we have got and we are going to have to act without absolute clarity in some of these issues, it seems to me.

Senator Lamar Alexander, we appreciate you starting this meeting off. As a university president, reviewer and hirer of scientists, we would be delighted to have your insights at this time.

Senator ALEXANDER. Thank you, Mr. Chairman. University presidents work for the scientists. That is the way it really works. [Laughter.]

What interests me especially, Dr. Hutin, is this huge number of injections—16 billion health care injections in developing and transitional countries, an average of 3.4 injections per person per year in all the countries that you are talking about. Now, in a country like the United States, what would be the average injection per person per year?

Dr. HUTIN. That is a very good question. Unfortunately, I am unable to answer it. We think that it is probably much lower, but unfortunately, we don't have very accurate data.

Senator ALEXANDER. As I understand your testimony, injections are by far the largest part of the health care transmission of HIV/AIDS, is that right?

Dr. HUTIN. We have done the global burden of disease exercise for the injections. We have not completed it for the blood transfusion. We are in the process of doing this.

Senator ALEXANDER. OK.

Dr. HUTIN. So I can't release any official number, but the order of magnitude is about the same. In other words, we are talking under ten percent and——

Senator ALEXANDER. You mean about as much transmission of HIV/AIDS from blood transfusions as from injections?

Dr. HUTIN. Injections, about the same order of magnitude.

Senator ALEXANDER. OK. Sixteen billion injections, and while it might be a relatively small percentage of the transmission of HIV/AIDS, according to your figures, it is a large percentage of the transmission of hepatitis B and C, a huge, disturbing percentage.

Dr. HUTIN. Absolutely.

Senator ALEXANDER. So rather than Safe Injection Global Network, maybe we need a "Less Injections Global Network." Is there a major effort to try to discourage the use of injections as a way of administering medicines in transitional and developing countries?

Dr. HUTIN. You are absolutely right and this is why, in fact, you will see throughout this statement that I use the phrase "safe and appropriate use of injection." If you have a look at this paper, we have actually estimated the cost of intervention to reduce injection overuse and the cost of intervention to make injections safe, and the cost of the combined interventions.

Senator ALEXANDER. Which is the cheapest? I guess, less injections?

Dr. HUTIN. What we think is that both should be done, because if you reduce injection overuse, then you use less injections, it is actually less expensive to make them safe, so——

Senator ALEXANDER. Many people prefer the injection to taking a pill orally, is that what you are saying?

Dr. HUTIN. Not exactly. What I am saying is that most doctors imagine that this is what is in the patient's head and, therefore, they give injections to the patient while, in fact, the patient would be pretty happy with a pill.

Senator ALEXANDER. Do you have a rough estimate of how many of the 16 billion health care injections administered each year in developing and transitional countries may only be done by injection?

Dr. HUTIN. You mean the proportion that would be necessary?

Senator ALEXANDER. Would it be half? How much of that medicine could be taken in some other form?

Dr. HUTIN. I can't back this up with very good scientific numbers, but if you want a ballpark estimate, I would say about a half or 75 percent are unnecessary.

Senator ALEXANDER. So for maybe a half or more, half to 75 percent of the injections, instead of an injection, you could take a pill.

Dr. HUTIN. Actually, if you will allow me, I will give you an anecdote that will make it extremely clear.

Senator ALEXANDER. That would be helpful.

Dr. HUTIN. I visited a place in South Asia that people refer to as "Doctor's Bazaar," where you have an informal lay health care provider who has no formal qualification and they have a line of patients who are there and they come and they say, "Doctor, I have generalized body pain," and the provider will take a syringe, will make a mixture between three different multidose vials, take the syringe from his ear—I actually have a photo where the provider put the syringe on his ear—he prepares the injection, give it to the patient. The interaction between the patient and the provider lasts less than 1.5 minutes, and then he recaps the syringe, puts it back on his ear for the next patient. I have seen that with my own eyes and it is very common in South Asia.

Senator ALEXANDER. And the reason for that? [Laughter.]

I mean, are doctors selling things? Is that an attractive way to do things?

Dr. HUTIN. These informal lay health care providers that I am referring to are very often in the private sector and there is a financial incentive for them to make the patient happy through the prescription of these injections that are not justified.

Senator ALEXANDER. Dr. Peterson, do you have any comment on this?

Dr. PETERSON. I have seen very similar. In Zaire, there were informal providers that were injecting gasoline into people and they would come to the clinic then with huge ulcerative lesions. The problem is, this informal sector is much harder for us to intervene in and either cut out completely, because they are doing it for profit, or improve their practices if that were possible. So the informal sector is a large part of these unsafe injections and it was part of the reason I said the challenges we will be addressing in this informal sector.

In the formal sector, the public sector hospitals, the charity and faith-based hospitals and proper protocols, we have got ways to address that. The informal sector is harder to do the training. We have got some programs that try and address that, as well.

Senator ALEXANDER. Thank you. Thank you, Mr. Chairman.

Senator SESSIONS. We are going to have testimony in our next panel, Dr. Peterson, from a doctor and he will present dramatic evidence that we are reusing needles right now in Africa and other places in the world, as you have testified is occurring.

I just note that in a news article in the French press in March of this year, a Botswana nurse injected 170 school children with the same needle during an immunization campaign. They then said that should any of the children test positive, we will follow up with HIV-negative children and retest them to determine their status. It has caused a scare in the country. Then the article notes that at least 330,000 of the country's 1.6 million people are infected with HIV or have full-blown AIDS, which is 20 percent, while 65,000 children have been orphaned by the disease. So it is really a stunning thing.

We were discussing the number of 2.5 percent. The best data that I have, Dr. Hutin, I think this is WHO numbers, is that there are 3.5 million new cases a year in Africa, 3.5 million people given a death sentence. At 2.5 percent of those being injections, that is

88,000 a year. If that number is conservative and is considerably higher, we are talking about probably 100,000, 200,000, 300,000, maybe even more. It could be even greater.

Doctor, I will just ask you this. You know, I am not in the medical profession. I haven't lived with these difficulties like you have. I don't believe you always have to do things perfectly and get everything in control and run a perfect program. What if we were to make a consensus decision with the world leadership and the African leadership, the United States money that we are putting up, and say we are going to supply nonreusable needles for every clinic in Africa and we are going to do it within 6 months and we are going to tell people with clarity that they should never have an excuse to reuse a needle again.

Is that the low-hanging fruit we are talking about? Could we make a dramatic difference? Sure, we could train and have all kinds of other things to go even further, but couldn't we do that on a fairly short basis?

Dr. HUTIN. Absolutely. In fact, in the paper that I have submitted as part of my statement, what we are trying to say is that it is not an issue about 2.5 percent or five percent or one percent. We have actually done a sort of worst-case scenario and we have said in this paper, let us say we have overestimated the 2.5 percent and let us say, in fact, we need even more needles than what we have estimated and we have actually underestimated the cost.

Even under the sort of worst-case scenario in our approach, safe and appropriate use of injections remains a very highly cost-effective health intervention. We remain, in terms of cost per deadly averted, under the threshold of one-year per capita income. So we are talking of an extraordinarily simple thing.

At a moment when we are talking about other sophisticated health care intervention, here we are talking of making sure that in a dispensary in Africa, when you have a vial of penicillin, well, next to the vial of penicillin there is also a syringe that is being provided, and if possible, a syringe with a reuse-prevention device. It is extraordinarily simple. You have the cost figures in this paper. It is not high——

Senator SESSIONS. Could you share with us your ranges?

Dr. HUTIN. The cost figures? Yes, absolutely. For Africa, for the combined safe and appropriate use of injection policy would be, for the reduction of unsafe use—I am sorry, the combined safe and appropriate use of injection policy, which includes reduction of overuse and safety, it would be $22 million. And for AFRE, $22 million also. So you are talking $44 million——

Senator SESSIONS. For the nonreusable safe needles, or for the whole program?

Dr. HUTIN. Forty-four million dollars in total in Africa to reduce injection overuse and to make these injections safe.

Senator SESSIONS. Overuse——

Dr. HUTIN. And make them safe.

Senator SESSIONS. I have been told that for every injection in Africa bought in bulk, the safe nonreusable needles could be supplied for $100 million a year. When you consider that we will probably be spending $2 to $3 billion a year over the next 5 years, that may

just in itself—but you are saying that if we really knock down the unnecessary injections, you could get an even bigger saving.

Dr. HUTIN. Exactly.

Senator SESSIONS. Obviously.

Dr. HUTIN. And as I say, the cost, as you see, is not that high. So it wouldn't call for a major shift in resources and the emphasis can remain on the prevention of sexual transmission of HIV.

Senator SESSIONS. Would you comment on the urgency of that, and Dr. Peterson, should we line up, get serious, have a generalized conference on this issue and urge every leader in every African Nation to institute dramatic change?

Dr. PETERSON. I would say we are already pretty serious about it. The GAVI Board has been working, getting immunization out at a much better level, and all of those vaccines are provided in auto-destruct. So a lot of the gear-up of immunization practices in the last couple of years has already said this is really important. We need to be dealing with injection safety.

Similarly, I mentioned the Unijet. One of the places we are doing research is to find not just the vaccines, but other drugs that can be used in the Unijets. We are looking at the contraceptives, the Depo-Provera that women get every 3 months, that it would be available in these little Unijets that can only be used once.

So we are very actively looking for as many different places to do injections much more safely than in the past. Our quality assurance programs, when we work in hospitals and clinics on what are their protocols, proper use of medical equipment, we are working on sharps and appropriate auto-destruct syringes availability.

Senator SESSIONS. And one more thing. Likewise, I assume, it would not be cost prohibitive to develop a much, much more effective program in dealing with transfusions, to make sure that all blood is tested. It may be difficult managerially, but it would not be a huge cost in terms of the overall cost of fighting AIDS, would it?

Dr. PETERSON. I would have to go and get that data for you. This is something that CDC/HHS does even more than we do. One of the issues is not just how much does it cost to make sure that the blood supply is safe, but do you have enough blood donors, as well, and there are some trade-offs there.

But we are, frankly, working both on improving the blood supply, and again, similar to the injections, reducing unnecessary transfusions or even—it would be good to have a transfusion, but the risks are higher of having a transfusion than not having one and setting those protocols in ways that reduce medical transmission through blood, as well.

Senator SESSIONS. Well, thank you, both of you, for your service to the world. Your commitment is extraordinary and total. At times, I know you are having to deal with difficult choices and limited resources.

This chart on the wall, though, has sort of hit me very hard. It says, "Fast Track to Global Disaster," the San Francisco Chronicle, and the subheading there is, "For decades, researchers warned that contaminated syringes could transmit deadly viruses with cruel efficiency, but efforts to defuse the crisis failed and today it has be-

come an insidious global epidemic, destroying millions of lives every year."

What I would note that is most dramatic about that article is that it is dated October 27, 1998, and we are not there yet. I think those of us in public policy have got to get you the resources, create some public and world interest, and it has got to be intensive. I have no doubt that the leadership in the African countries are more and more attuned to the crisis that is facing them, and if we give them good sound science and a good sound plan that will work, such as providing on an immediate basis nonreusable needles, I think we could save a lot of lives.

Do either of you have any comment on that before we go to the next panel, or any thoughts?

Dr. HUTIN. Actually, I just wanted to mention about blood transfusion safety because I am in the Department of Blood Safety and Clinical Technology at WHO. WHO conducted a systematic review of the cost effectiveness of all the various interventions in the field of HIV that was published by Dr. Andrew Creese in the Lancet recently, and blood transfusion safety was actually one of the most cost effective of the various interventions against HIV. So it is a small—it is exactly like injection safety. You are a small piece of HIV burden, but it is actually an inexpensive one that you can fix pretty rapidly.

Senator SESSIONS. Well, I thank you for that. That is where we need to be heading, it is pretty obvious to me. Thank you so much.

We will go to the next panel. We will have Dr. John Ssemakula of Medilinks, Holly Burkhalter of Physicians for Human Rights, and John Stover of The Futures Group International.

Dr. John Ssemakula is the founder of Medilinks, an online source of health information for Africa. He is also a public health consultant with the Africa-America Institute, where he serves as program manager and adviser on the AAI HIV/AIDS Initiative. Dr. Ssemakula trained at Ibadan University Medical School in Nigeria and Makerere University in Uganda, where he received his M.D. He subsequently received an M.P.H. degree at Dundee University Medical School in Scotland, where his master's thesis was entitled, "HIV/AIDS and the Health Care System in Uganda."

Dr. Ssemakula has extensive on-the-ground experience as a practicing physician in Uganda and was able to witness firsthand the impact on HIV on his home country. He has published multiple articles on HIV/AIDS, including a March 2003 article on the role of unsafe medical care in continuing spread of HIV in Africa.

I will start with you, Dr. Ssemakula.

STATEMENTS OF JOHN KIWANUKA SSEMAKULA, M.D., M.P.H., MEDILINKS; HOLLY BURKHALTER, PHYSICIANS FOR HUMAN RIGHTS; AND JOHN STOVER, VICE PRESIDENT, THE FUTURES GROUP INTERNATIONAL, GLASTONBURY, CT

Dr. SSEMAKULA. Thank you very much. Senators, thank you for affording me the honor and privilege to address this Senate hearing committee on the very important subject of safe health care in Africa.

Senator SESSIONS. Dr. Ssemakula, I will note that we will try to keep our statements to five minutes. We can go over a little if need

be, but we would like to do that so everybody will have a chance to speak.

Dr. SSEMAKULA. I have had a professional personal relationship with HIV and AIDS throughout my tertiary education, as you said, both in medical school and then my on-the-ground experiences as a young physician, first undertaking medical internship as a medical officer in the early 1990s during the peak period of the HIV/AIDS crisis in Uganda.

My interest in HIV and AIDS, though, is not just professional. It is also on an intensely personal level. I have lost several cousins who were like brothers and sisters to me over the years.

I have been following the issue of unsafe health care and its role in the spread of HIV and AIDS in Africa for a year now, from the time David Gisselquist sent me a draft of his groundbreaking paper almost a year ago and the controversy that ensued when it was published in the International Journal of STD and AIDS. But as far as I was concerned, people who are discussing the issue in terms of controversy were missing the point completely, for there wasn't a controversy. It was not about the percent of HIV and AIDS that was transmitted by unsafe needles, be it 2.5 percent, ten percent, or 40 percent. It was really simply about health care, the first and most basic thing as a doctor one should provide.

I have since learned that there are relatively cheap technologies, such as auto-disable syringes made by BD or companies like Starr, or such as retractable syringes as you saw Dr. Hutin demonstrating.

I have just come back from Uganda—in fact, I came back on Monday this week—where I have been talking to people about the issue of unsafe health and the possibility of getting AIDS through needles. None of the people I talked to saw any hint of a controversy. No one jumped to the conclusion that providing safe health care would lead to more unsafe sex. They had equal concerns about safe health care and safe sex, saying we need both.

While in Uganda, I also attended the Uganda Bishop's Council, where they were taking landmark decisions on adolescent youth sexual and reproductive health. They were very excited to hear that I could be testifying before the Senate. They all agreed that the issue of reuse of needles was very important, just as important as safe sex. They told me, "We are sending you as our emissary to the USA and we are trusting you to tell the Senators about this. Tell the Senators we are also working very hard. We appreciate any and all help you can give us in our fight against HIV and AIDS."

I also visited health centers in Uganda, first in Rakai District, where AIDS was first seen in Uganda. That is my mother's and my cousin's home district, and then in Luwero District. While in Rakai District, I was taken around to one of the health centers by Sister Namperwa of Kakuto Health Center and she told me, "We don't reuse needles here. But," she said, "if you have these auto-disable syringes and you can bring them to Uganda, it would be good. Doctors are worn out fighting AIDS day in, day out, and it will help all those doctors at those clinics further up-country because they are just stuck."

While at Luwero Health Center, I was also taken around by another doctor and sister, a Sister Margaret Serunjoji, the "in charge" of the maternity wing. I asked her, among other things, if they had a problem with the reuse of needles. She said in immunization there was no problem because of the provision of the UNEPI program and auto-disable syringes, except if they were running low on supplies, they may have a few difficulties. But, she said, they have nothing similar for curative services.

When I told her about the existence of auto-disable syringes that may be made available and the moves to make them available in Africa for curative services, she became excited. Sister Serunjoji told me, "This is just what we need. Even though we don't reuse needles here at the clinic because supply is generally good, sometimes we run out. When that happens, patients are forced to buy syringes. But the problem is, even at 300 shillings," which is equivalent to 15 cents, "it is still too expensive for most villagers. So when a patient comes with their own syringe, they will tell the doctor," and I will use this in my language, [spoken in Ugandan], which means, "Doctor, give me back my needle so I can go and boil it again so I can reuse it." They don't want to buy a syringe every time because it costs too much.

I remarked, isn't this particularly dangerous, especially with the danger of AIDS in Uganda? Isn't there a possibility of it being spread this way? The doctor who was also taking me around replied, "This is a very real problem. It is even more urgent if one realizes that when a patient buys a needle, sometimes they share it among the family. It is a common practice, using it over and over again, or being good neighbors, they may even share it with their neighbors. Auto-disable syringes that are cheap enough and supplied in enough quantities would help prevent this by using technology as a control. This is not just an issue of health, but it is also an issue of poverty."

On my visit, every single doctor and nurse I met in the past few weeks were concerned about HIV transmission in health care settings, because as health care workers today, they are still living many of the same experiences that I lived through as a practicing doctor in Uganda. As a medical student, a junior house officer, and a medical officer, I witnessed the reuse of needles in the late 1980s and 1990s. I witnessed the reuse of needles constantly. Thankfully, that is not the case today, which shows how much Uganda has done.

But back then, sometimes the needles were so blunt they could actually cause trauma to the patient and blood would flow, and many of my colleagues still recall some of the stories. And at that time, so concerned were we as junior doctors, doing most of the work and on the front line, we went on a work to rule demanding equipment such as disposable needles and gloves that would allow us to do our jobs in a safe environment, both for the protection of ourselves and our patients.

I remember one time a colleague and I decided just to do an informal survey, because at the time, we didn't have the means to do testing on everybody. We just decided to do an informal survey to see how many of our patients were HIV-positive. We were shocked to discover that up to 50 percent of our patients were HIV-

positive. In fact, at the time, people felt it was so unsafe practicing as a doctor, even my aunts, cousins begged me to go into other lines, branches of medicine that would expose me less to any of these hazards.

Also, it is also at this time while I was working in pediatrics, I and a colleague, Dr. Madewo, started noticing children that were presenting as HIV-positive when the mother was not, and some of these children were quite old. This is going back 10 years and this was not in the data that WHO was giving out. So we tried to theorize what was happening and we thought perhaps they were being infected through immunizations, either injections or unsafe blood, and the reason we thought this was because for a lot of patients who came, and if you asked them a question, they would always tell you they are being given an injection by a doctor.

Now, a "doctor" is a quotation. The word is [in Ugandan] in my language. It could be anybody from a lay health worker, traditional birth attendant, or whatever it is. An injection is given as a means of treatment, and it may or may not contain any medicine at all. Unfortunately, at that time, for various reasons, we were unable to investigate further, but I believe this was a missed opportunity to investigate the possibility of HIV being spread in a medical setting.

I will say there is no denying that unsafe sex is probably the major route for transmission of AIDS, but other routes, such as the reuse of needles and other unsafe health care practices, are just as significant. The message of safe sex and behavioral changes to safeguard people is of paramount importance because this is something the individual has control over, but they have no control over what happens in a hospital or clinic. In this, they put their trust in I as a doctor or the nurse or the clinical officer to provide the safest health care.

Knowing this and the danger of AIDS and other bloodborne diseases, should we then not be striving to achieve the safest health care? I say again, as I have said to people, how in all honesty can I stand in front of people in rural areas in the rural health clinics and villages to address them on practicing safe sex when I know that I am not giving them the highest possible standard of health care. How can I just say that you should not have this as a basic choice?

It is not really a case of choice between safe sex or safe health care. It is quite simply, and this came out of my visit to Uganda, the health care workers, that the people who have been and continue to be on the front line of the fight against HIV and AIDS, who despite battling huge difficulties and odds have succeeded in doing tremendous work, and they are simply asking for tools that will help them in the fight. It is about the fight for the future. In this and this, there is no controversy.

Whatever help can be given should be provided, and can anyone in all honesty give a reason in this case why such equipment and help or assistance should not be rendered? I say, if you can't, if so, let them come to these health clinics that I visited, look at these health workers and their patients, and look and say why they can't get these things. Thank you very much.

Senator SESSIONS. Thank you, Dr. Ssemakula, for those eloquent comments from the heart and from your scientific experience. We appreciate that.

[The prepared statement of Dr. Saemakula may be found in additional material.]

Senator SESSIONS. Dr. Burkhalter, let me introduce you. I haven't done that yet. Dr. Burkhalter is the U.S. Policy Director of Physicians for Human Rights, a Boston-based human rights organization specializing in medical, scientific, and forensic investigations of violations of internationally recognized human rights. Her group has evaluated the problem of health care transmission of HIV in Africa, the very subject we are talking about, and has developed a comprehensive plan with associated cost projections to address the issue.

Ms. Burkhalter graduated Phi Beta Kappa from Iowa State University in 1978 and subsequently worked for 4 years on the staff of then-Senator Tom Harkin—I guess Representative Tom Harkin then. She subsequently staffed the House Foreign Affairs Subcommittee on Human Rights and International Organizations before going on to work for 14 years as the Advocacy Director and Washington Office Director of Human Rights Watch. She has published extensively on human rights and human rights law, as well as on the problem of HIV/AIDS in the regions she has studied. I suppose, Ms. Burkhalter, that it is an important human right in that a young person getting an inoculation or a person going in for a shot not be unnecessarily subjected to a deadly disease.

Ms. BURKHALTER. Yes, indeed it is, Senator Sessions. Thank you very much for having me. I am not a doctor, actually, but thank you for the promotion. I work for a lot of doctors, though. [Laughter.]

And I am privileged to say that Physicians for Human Rights, over the course of the last several years, has put together an advisory committee of the preeminent HIV/AIDS experts in the United States, most of whom are engaged in overseas activities involving prevention, care, and treatment of the disease. They advise us and I try as best I can to speak for them.

I am the chair of an informal network of nongovernmental groups that has joined together—Dr. John is one of our members—to promote safe health care, particularly in the context of HIV/AIDS and other infectious disease transmissions. We are privileged to be here and thank you very much for your kind attention to this long-neglected issue.

I will be very brief. I have an extensive and detailed testimony that I would appreciate having included in the record, and I thank my research assistant, Eric Friedman, for his wonderful assistance in producing it.

Senator SESSIONS. We will make that a part of the record.

Ms. BURKHALTER. Thank you, sir. I would note that even though you have brought this issue to our attention in these times, it has been on the agenda for some time, and the U.N. Declaration on AIDS 2 years ago committed governments to having universal precautions available by the year 2003 and blood safety and injection safety by 2005, but we are very far from achieving those goals, nowhere close to meeting it, upwards of half-a-million AIDS infec-

tions, at a minimum, from unsafe blood and unsafe injections, 20 million-plus hepatitis infections in health care settings. Only 13 of some 46 countries in Africa with safe blood policies, 25 to 50 percent of blood units in Africa not screened for AIDS. You could go on. Yvan Hutin is the expert and his recitation of what is left to do was absolutely chilling.

Experts disagree on the numbers of transmissions, as you have heard and as we know. But I think all agree that this is a form of AIDS transmission that is completely preventable. It is not tolerated in rich countries. It is not tolerated in the West and I wonder why it is tolerated in poor countries. Asian and African life are not cheap, and 500,000, at a minimum, preventable transmissions worldwide is not trivial. It is not a rounding error. It is not trivial. It is not a write-off. Therefore, it is somewhat of a mystery to me why there has been some opposition to engagement on this within the international health establishment.

One of the possible explanations is fear that leaders and publics in AIDS-burdened countries cannot address two issues simultaneously, the notion being somehow if the issue of safe health care and ending unsafe injections and cleaning up the blood supply are raised up in a very prominent way, that someone people will immediately begin to neglect safe sexual practices. I don't see any reason whatsoever why African governments and others can't do exactly what our government and Western governments have done, which is, of course, both.

And you look at cases of some of the poorest countries in Africa, such as Burkina Faso, where they have under their own leadership, for example, made nonreusable injection technology part of their essential medicines list and reduced by a huge percentage, from 50 percent unsafe injections to four percent. They did not neglect their safe sexual prevention programs in the context of doing that. Nor did Senegal, for example, which has a very comprehensive blood safety and injection safety program. They did so without neglecting other needed aspects of prevention. It should be promoted among all of the countries of high risk.

I have a number of recommendations to the U.S. Government and I am not going to go through them now. They are all in the testimony. But I would say that a lot of what the United States can do is political. We can urge, for example, that when countries are putting together their national strategies to apply for global AIDS Fund funding, each one should include a safe health care provision.

Countries vary in terms of what they have. Some have safe blood. Some have good education. But all countries should have a plan and a request for technical assistance if they need it, as well as supplies, in this area.

We can raise up this issue internationally. A good opportunity to do so will be at the Bangkok AIDS meeting a year from now, in July of 2004.

We can promote assessments in every country. It is cheap as can be, $20,000 to do an assessment of safe or unsafe health care, to allow governments, to encourage them to make these assessments, to pay for them if we need to to identify the problems and craft solutions to them.

Encourage countries to include safe health care in their national AIDS strategies. Promote education. Provide supplies and logistics. I have a back-of-the-envelope costing for it if you would like to hear from that.

I would just conclude by saying that 20 years into the AIDS pandemic, it is a disgrace that the world is so far behind the curve on safe health care. I give you again as an example, Uganda has only just recently called in experts, such as Dr. John, to help them develop a national safe blood and injection safety program. Uganda is a model of national leadership on AIDS prevention. They have long been held up as a model, quite rightly so. But many, many years after they had developed the best practices with regard to safe sex, they are only now developing national strategies to deal with safe blood.

The rest of the world is far behind. It is proposed that India, for example, one-quarter of the new infections from AIDS will be attributable to unsafe needles. The fact that this is still going on and it is entirely preventable is just vital.

Let me just add one quick thing, though I know I am out of time. It is really—and this should have been the focus of my remarks as a human rights activist—it is really vital that universal precautions and safety of health care workers and doctors, no many how many transmissions occur in health care settings, be held up as a real goal, because much of the discrimination against people with AIDS, including in the health professions, comes from people's fear of unwitting infection.

We recently carried out a very extensive survey of doctors and nurses in Nigeria and asked them their attitudes about people with AIDS, where there is much discrimination within the medical profession against people with AIDS. And much of their reluctance to treat people with AIDS or to deal with them in a kind and humane way, as they would any other patient, comes from their fear of them and their fear of unwitting transmission.

When you are in health care settings where midwives are delivering ten babies a day and don't have enough gloves, or you are in a situation where doctors are hoarding their supplies, their injection equipment or their gloves or the protective gear, they are hoarding it and only using it with people they think might have AIDS, thus identifying them to people around them, this contributes to stigma and discrimination and it just should not be.

I would conclude to say that there are many ways that the world falls short of affording the right to health that all people deserve, but surely the most important among the right to health should be people's right to enter a health care setting and not come away with a deadly disease from health care providers who are doing their best in an environment of scarcity.

These are, as Yvan Hutin mentioned in the previous remarks, among the most cost-effective interventions one can make to shore up a beleaguered medical establishment that is fighting the worst pandemic in human history and I am very pleased at the leadership you have provided that will put the United States in a leadership role. Thank you.

Senator SESSIONS. Thank you very much. I guess that great oath, the first part of it is, first, do no harm. That is an important concept.

[The prepared statement of Ms. Burkhalter may be found in additional material.]

Senator SESSIONS. John Stover is the Vice President of Futures Group, International, as well as a Director of the Group's Connecticut office. In this capacity, he is responsible for computer applications and modeling and directs the Group's efforts in the area of HIV/AIDS.

Mr. Stover has substantial experience in developing and applying population-related models in developing nations. He has published articles on topics ranging from population and family planning to AIDS modeling, intervention analysis, and demographic impact analysis. In this field, he is noted for having developed an AIDS impact model used to evaluate the effectiveness of AIDS interventions.

Mr. Stover, it is a delight to have you with us and to hear from you at this time.

Mr. STOVER. Thank you very much for the opportunity to be here today. Much of the work that I have been doing with colleagues at U.N. AIDS, WHO, and other research institutions in the past couple years has focused on estimating what needs to be done now to achieve the goals that we have all set for ourselves. The Declaration of Commitment of the U.N. General Assembly Special Session on AIDS called for a 25 percent reduction in infection levels among young people in the next few years. WHO has set a goal of having three million people on ARV therapy by 2005. And the President's emergency plan for AIDS relief aims to prevent seven million new infections, treat two million infected people, and care for ten million people and orphans in 14 priority countries.

So our work is focused on what is required to achieve those goals. What do we need to do? And we have some good ideas of what we need to do in the areas of care and treatment, in terms of expanding access to health care, providing more training for health care providers, and expanding supplies of drugs, and changes in policies and regulations.

We also have some ideas of what needs to be done to prevent new infections. It is clear to us that no single intervention will be enough, but that a comprehensive approach that reaches people with different risks and with a variety of information and services can be effective.

So we have looked—we have done an analysis, a country-by-country analysis of 135 low- and middle-income countries to look at the prospects for the future. Our analysis indicates that if current trends continue, there will be about 45 million new infections between now and the year 2010, and that is what you see here on this bar on the left part of the chart labeled "Baseline." The majority of these new infections will be in sub-Saharan Africa, where HIV prevalence levels are the highest, and also in South and Southeast Asia, where populations are large and the epidemic is growing rapidly.

But this somber projection is not inevitable. Our estimates indicate that the implementation of a comprehensive package of pre-

vention programs in these countries by 2005 would reduce the number of new infections by 29 million, in other words, averting about two-thirds of the infections that would otherwise occur.

This is shown in the second bar here, labeled "Expanded Response." The benefits will be large in sub-Saharan Africa, where almost 60 percent of projected infections could be averted, and the gains could be even larger in Asia, where early action can be especially effective.

Well, what do we need to do to achieve these results? In order to achieve these, we need to expand the coverage of a variety of HIV/AIDS services and information. We need to—our estimates assume that we can achieve relatively full coverage of some services, such as mass media, AIDS education, treatment of sexually-transmitted diseases, voluntary counseling and testing, and coverage for maybe two-thirds of the population for such services as condoms, workplace interventions, programs for out-of-school youth, prevention of mother-to-child transmission.

Achieving these results will be a big effort, however, because today, globally, perhaps only one in five people have access to these important services, and in Africa, it is even less. Perhaps one percent have access to anti-retroviral therapy and programs to prevent mother-to-child transmission. Only maybe about five percent have access to voluntary counseling and testing, and 70 percent of infected people in sub-Saharan Africa don't have access to even the basic level of care as defined by the World Health Organization.

But we believe that we can achieve this and the next chart looks at estimates of what it will require in terms of costs, financial resources, to achieve these goals. This represents resources from all sources, so it is national governments, it is international and bilateral donors, it is also individuals and households. And from the chart—I don't know whether you can read that there, but you can see the range of different services that we included in this analysis.

Total resources required will go from about $6 billion today to $10 billion by 2005 and $15 billion or so by 2007. For Africa, the resources will more than double, from about $2.5 billion today to $5.5 billion by 2007. And for the 14 countries of the Presidential initiative, requirements would double, from about $2 million today to about—$2 billion today, sorry, to $4 billion by 2007.

The largest amount, as you may be able to see from this chart, would be required for anti-retroviral therapy and treatment of opportunistic infections because these are relatively expensive. Support for orphans and vulnerable children also requires significant funding. And in the area of prevention, the greatest needs are for programs for youth, voluntary counseling and testing, condom programs, workplace programs.

The red line here is blood safety, and from the red line upwards, you can see blood safety and safe injection, universal precautions, and postexposure prophylaxis, which together in this estimate account for about four to five percent of total spending. I should mention that these figures look at countries with prevalence above one percent. So countries with lower levels of prevalence would have additional needs for safe injection and universal precautions that are not shown here.

About half of the required resources are for prevention and half are for care. Globally, this level of spending would provide prevention services for over 270 million people in low- and middle-income countries and would provide needed care and treatment for an additional 13 million.

Senator SESSIONS. Mr. Stover, this crazy Senate is so frustrating. Today has been one of the worst days of the year. But I have got to do something that will take me 15 minutes. With great apologies, I would sincerely ask if you could suspend now. We will be back in 15 minutes, and I have some questions I would like to ask this panel also and allow you to elaborate in any way you would like on the points you have made. It is very, very frustrating for me to have to ask you to do this, but it is just one of those unavoidable things and I will try to be right back. Thank you.

We are adjourned for 15 minutes.

[Recess.]

Senator SESSIONS. I am just terribly, terribly sorry. You know, the problem in the Senate is you never have time to think. You are always being jerked around here or there. You are causing us to think about policy and the billions of dollars that we will—new billions that we will be spending, in addition to the amounts of money that people all over the world are spending on AIDS and we have got to get it right. Lives are at stake.

Mr. Stover, I am so sorry to have interrupted you, but I shall be pleased if you would complete your remarks.

Mr. STOVER. Thank you. I was actually just coming to the end, so I will just say a couple of words.

One, on the issue of injection safety and blood safety, from the figures that we have estimated here, if we look just at sub-Saharan Africa, our estimates would be that the total requirement for injection safety and blood safety would be somewhere in the order of maybe $130 million today, increasing to $250 million or so in the next few years. That would be the total requirement. It wouldn't be the U.S. share of it. We would hope that lots of donors would contribute to that.

But speaking of the total funding of $6 to $10 billion over the next few years or increasing to $15 billion beyond that, we have also tried to take a little bit of a look at what might be the fair share of the U.S. to contribute to that total figure, because the total figure includes national spending by national governments as well as individuals and other donors. It all depends on the assumptions that you make about how much national governments should be paying for themselves and how you would allocate the international share, whether using some formula based on the U.N. or WHO allocations or whatever. But generally, the figures come in around $2 to $3 billion today as the U.S. fair share and increasing to somewhere between $3.5 and 5.5 billion over the next 5 years.

So just to conclude, we recognize that the full implementation of this expanded response presents many challenges. U.N. capacity to deliver the required interventions needs to be scaled up greatly and improved infrastructure will need to be developed to meet the demands of expanded services. Meeting these challenges will require both financial and political commitment.

The costs of scaling up are great. However, without this effort, we will not achieve our goals, and the costs of doing nothing are even higher. So thank you very much for your attention.

Senator SESSIONS. Thank you very much.

[The prepared statement of Mr. Stover may be found in additional material.]

Senator SESSIONS. The President said—I was with him yesterday in a private conversation and he made clear his commitment to go beyond just prevention and that we are going to put money out for treatment, life preserving, extending treatment, which is very, very expensive.

Of course, as a doctor, Dr. Ssemakula, nothing good happens if you contract that virus. The best thing is to prevent it if possible, is it not?

Dr. SSEMAKULA. I quite agree, and one of the things that people tend to forget, they are looking at providing these safe needles as a curative thing. It is actually preventive in the sense that you are preventing the person from getting an infection so they can infect some other people. Sometimes also giving treatment, if it cures a person, is also part of prevention. If a person has TB, you can prevent a person from getting TB by immunizing them, but if they actually contract the disease, you give them treatment and they don't go and infect another person.

In the case of anti-retrovirals, it is not a cure. It is the person will always be infected for the rest of their lives, and until we get some kind of cure, we will have to rely on methods that can prevent people from getting infected. One of these, of course, is behavioral sex, but the other is just a simple thing, safe needles. I mean, that is such a simple thing that already exists. Unlike anti-retrovirals, 16 billion injections already exist in existence. So you can just provide this technology and change it to safe practices.

Senator SESSIONS. Does anybody else want to comment on that subject? Ms. Burkhalter, why hasn't more been done to address the issues of blood safety and injections? What are your observations as one involved but somewhat on the outside of the official program? I know you are not wanting to be critical, but let us be frank about what is happening and what we can do.

Ms. BURKHALTER. Obviously, some of the best—the leading work on this issue is done by the WHO in the form of Yvan Hutin, and at the same time, the International AIDS Establishment from the same institution, I think has been less in the forefront, and U.N. AIDS perhaps has been less in the forefront. You don't see, for example, in the kind of protocols of best prevention practices. This is kind of the orphan stepchild.

I wouldn't want to speculate, nor would I want to impugn either medical professionalism or ethics of the principal actors. I do think that there is such a well-meant concern about the principal mode of transmission that there is a concern that if the message is to—and indeed, you can find quotations from WHO leadership saying that if this message about safe sex is diluted, is diverted or diluted. If attention is somehow turned to something else, that then there will be careless with regard to safe sexual practices.

And I appreciate the attention to the very important means of both behavior change and provision of supplies, particularly to

those most vulnerable to sexual transmission, as well, I might add, to a neglected area of sexual transmission, which is violence, rape, and trafficking. I appreciate it very much. But I think that this just so obviously needs to be a part of what is considered to be bets practice and it needs to be promoted as such and lifted up very actively, particularly among the health establishment that deals with international AIDS.

You see, for example, that the immunization community has really embraced this and led the safe needle, safe health care initiatives, but the AIDS community seems to think that this is a diversion or a red herring. I just think we need to take a look at what Africans themselves are doing and what they are asking for and then provide the kind of leadership in technical assistance and procurement and supplies that will allow them to have what we take for granted, which is safe health care.

Senator SESSIONS. I thank you for that. I guess you would agree, and I am not one to claim that everything bad that happens in the world is a human right, but when 170 kids go down to be given an inoculation with the same needle, that is a right of humanity, I think, to assume that those people giving those inoculations understand the dangers that are being risked and would not take them. Those children come in entrusting their lives and their health to a health care giver, and that is important.

You indicated, Ms. Burkhalter, that you had some, I think, back-of-the-envelope numbers about what you thought it would take to make some immediate inroads into this problem. Could you just share with us your thoughts?

Ms. BURKHALTER. Well, this is just kind of—of course, they are all based on Yvan's work, so you should really get him up here, and again——

Senator SESSIONS. Well, maybe we should. Maybe he should come back up.

Ms. BURKHALTER. When I make a mistake, I will depend upon him to correct me.

Senator SESSIONS. As a matter of fact——

Ms. BURKHALTER. John is really more expert than I, as well, and——

Senator SESSIONS. Dr. Hutin, why don't you pull up a chair, if you will.

Ms. BURKHALTER. I will just start you off, sir, and then I can be corrected when I make an error.

Senator SESSIONS. You can defend yourself, since they are talking about you.

Ms. BURKHALTER. We should take Mr. Stover's advice, however, and understand that there are multiple providers of foreign assistance and that governments themselves will want to and need to take a leadership role. There are a whole bunch of these interventions that are virtually free—law, regulation, putting nonreusable injection technology on essential medicines list. This is not costly at all and it requires political leadership, and let us not overlook that.

But just looking at what you asked for, which is what actually is the cost for Africa, you can extrapolate a little bit from some of what was already said today. I noted that Dr. Peterson described

the cost of putting together a safe blood program for Kenya was $3.3 million. WHO has not yet released its own studies on what the price tag for safe blood for Africa, though Yvan might want to give us some under-the-table estimates.

But if you just extrapolate from what it cost for Kenya, $3.3 million, and I believe the EU provided safe blood—now, this is just one component of the overall safe health care price tag, but we noted in our testimony that the EU supported a Ugandan safe blood program that was $1.5 million. I don't know. You can't expect every country's cost to be the same, but it looks to me like a ballpark for a blood safety program might be somewhere from $2 to $3 million. There are 14 countries identified on the President's list, and you can do the mathematics.

WHO has estimated that the price tag for the African region for injection safety, which I had always assumed would be a very big price tag, is actually very affordable, coming in at about $45 million. Dr. Hutin can give you the detail about what that includes, but it does include provision of supplies as well as education and training.

Senator SESSIONS. If you did those two things, if those two plans would occur, I will ask you and Dr. Ssemakula and Dr. Hutin, couldn't we expect rather significant reductions in medical transmissions just by those two steps, even though there may be other things that——

Ms. BURKHALTER. It seems important to me, we are neglecting—and don't neglect universal precautions, which has a much bigger price tag, and Yvan can explain where some of those costs come from. But the injection safety and the blood safety will help you keep your health providers safe. But we need to make sure we have waste management, sharps disposal, gloves, and all the other protection for health care workers that is an added cost.

I will let Yvan take over from here, or——

Senator SESSIONS. Dr. Ssemakula?

Dr. SSEMAKULA. Yes. The introduction of that technology would have tremendous effects. I take what Ms. Burkhalter said about waste disposal and the management, and these were all the questions when I went to Uganda. All the health workers asked me, how do we dispose of this? But at the same time, their concern was having safe health care. That was the first and paramount thing. They said, we will find a way of how to dispose of these things.

But we have this risk. Partly because they don't have the opportunities like I have to tell people, the outside world about this, they said, if you can tell people that we need this, it will have a tremendous effect.

I mean, for instance, the story I told you about people sharing needles, I mean, that is just frightening. All it needs is one infected person to share it, infect the entire family, infect the neighborhood. I mean, that is all it needs. Just one auto-disable syringe can prevent that, and this will have a tremendous effect.

If you think about the number of people that have died in Africa of HIV and AIDS over the past—let us not just talk—over the past 5 years, it is almost 15 million, and you just do an extrapolation of how many could have been saved. And this is not just their lives, their families and the orphans that have come as a result. This is

such a small cost and it is something that you don't even have to think about. The effect would be so much greater than just the amount that is spent.

Senator SESSIONS. Let me congratulate Uganda for the good work they have done. I had an occasion to meet with the first lady of Uganda and get a briefing on what you have accomplished. It is terrific and I am glad to see you step up to the plate on medical transmissions.

Let me ask you. Do you think there are other areas in Africa that are not as up-to-date as Uganda is today on medical transmissions and do you think many of them are operating as you were years ago when you were operating there still?

Dr. SSEMAKULA. Oh, certainly. I lived in Nigeria for 5 years, and that is where I first started my medical school. Nigeria is a much larger country. It has much wider disparity and much more poverty and their health care system is almost nonexistent in the rural areas.

I know my friends who are doctors, we all know the same thing. These are people I am talking to. And they said, yes, these practices go on. They go on there. And part of the problem is that they are still very far behind Uganda in terms of opening up in HIV and AIDS. So people are still operating in a complete environment of ignorance, still practicing unsafe health care, unsafe practices, be it behavioral or such.

There was a similar thing in Kenya, which should be more advanced than Uganda, but they still have the same problems, and even in Tanzania, where I visited a couple of years ago. They still had similar problems.

So I would say, taking Uganda as a model, then you take that back to all the other African countries. You must realize that there is a problem and we need to do something about it.

Senator SESSIONS. Dr. Hutin, would you like to make any general comments on what we have heard so far?

Dr. HUTIN. Two quick comments, the first one about what is currently the situation in Africa. In our paper, you have our estimates of about 18 percent of injections being reused in the absence of sterilization for sub-Saharan Africa. I just want to make a brief comment about the reliability of this number.

This is based on ten systematic injection safety assessments that we, WHO, coordinated in ten countries of the region. This is a standardized WHO methodology where you go in a country, you visit 80 health care facilities selected at random. You send an investigator there. You have health care workers who know they are not supposed to be reusing injection equipment, and here, under the eyes of the investigator, you will see that 18 percent of injections will be administered with reused injection equipment. That is the history behind this number.

Senator SESSIONS. So you would say that is a conservative number?

Dr. HUTIN. That, I think, providing that we are using a methodology where it is direct observation of the health care worker during an investigation, I am confident in saying that the reuse of injection equipment is probably on the conservative side, because you send an investigator where people are supposed to know they

should not reuse injection equipment, and here during an assessment they will do that in 18 percent of the cases. That, as I say, is based on basically 80 health care facilities in each country times ten. So we visited 800 health care facilities in Africa to come up with that number in randomized fashion.

And I think that we are not talking about whether it is 2.5 percent or one percent or ten percent. I think that 20 years into the HIV epidemic, knowing that roughly one injection out of five in Africa is given with a reused needle, is unacceptable. Nobody would question these numbers would want to go in an African dispensary and say, oh, the risk is small and I will take an injection with a reused syringe because it is only one percent.

Senator SESSIONS. Wouldn't it also be important to note that when you talk about a country that may have a 30 percent infection rate, that reusing needles is even more dramatically risky than in a country where the infection rate is much lower than that?

Dr. HUTIN. Yes, of course, although what we have seen is that because precisely the bulk of the transmission is caused by sex and not by injection, sometimes the country with the highest prevalence of HIV, such as the Southern cone of Africa, will not have the worst practices. So the worst practices and the worst prevalence rate will not necessarily match because the driver is elsewhere.

Senator SESSIONS. Ms. Burkhalter?

Ms. BURKHALTER. Could I just say something that hasn't been talked about very much, but it is a cheap intervention that I think could actually have disproportionate value, and that is public education about unnecessary injections. Some of the data we looked at showed that 70 to 90 percent of injections are unnecessary. Some of these are given in the nonformal sector. You cannot drive people out of these doctor bazaars, drive them out of the nonformal sector by saying it is unsafe unless the formal sector is itself safe.

It is very important, the way that consumer demand for a clean needle, a clean syringe being taken out of a sealed package can itself drive the market. At the same time, you don't want to create a demand for something that literally doesn't exist, but demand creation can itself help take care of this problem.

I noted in something that Yvan has put together that is not even released yet, but I was speaking with the WHO about this, there is 100 percent awareness that dirty needles can cause HIV/AIDS in the country of Romania. Why? Because of the terrible epidemic of pediatric AIDS that occurred in that country because of this totally wacky medical practice that is completely unsupported by modern medical literature of injecting sickly orphanage babies and children with plasma and other vitamins and antibiotics and all kinds of crazy stuff, but with blood during the Ceaucescu years when Romania was completely cut off from international medical discourse and all other kinds of, you know, sort of the modern world.

Romania ended up with this extraordinary and totally anomalous pediatric AIDS epidemic from children who were infected through needles and blood in their orphanages. I know the medical doctor at Baylor University who now manages a caseload over there of 800 kids who are on anti-retrovirals, and doing brilliantly, I might

add. But because of this terrible tragedy of medical transmission in these hundreds and hundreds of children, everybody in Romania knows about this and nobody in Romania would ever consent to getting a shot from anything but a needle that came out of a package.

Accordingly, a very cheap intervention and one that AID knows how to do, as well as a whole host of NGOs, is create this demand for clean health care on the part of consumers. And I just think it would help develop health infrastructure and help put the power of safe health care into the hands of health consumers, which is where it belongs.

Senator SESSIONS. Dr. Ssemakula, let me ask this. We heard Dr. Hutin mention that there are markets in Southeast Asia where people come in and just get shots as they go by and they are not really official medical places. They don't use medical standards and they are not part of the government health care system. Do you have those in Africa and is that likewise a difficult group to control?

Dr. SSEMAKULA. They do exist. It is not as organized, but in Africa, they do exist. As I said, in a lot of the patients who come to see me in the hospital, I would ask them, have you received any treatment, and they would say, "I have had an injection from a doctor." Now, that doctor could be anybody. A lot of people just call themselves a doctor. They will get a white coat from the hospital. It could just be someone in the village and that is what they do for a living, they give injections.

It could be water, it could be all sorts of substances. In some cases, the children would come in poisoned. A lot of the injections were for children because they frequently suffered malaria and vomiting so they couldn't swallow pills, or they had pneumonia. But this practice exists, and they are a difficult group.

But the introduction of this technology, I mean, we tend to think, because if you are really educated, you tend to think the people in the village don't have common sense. They do. They know what the best drug is in the hospital, what the best practices are. They see that you are using auto-disabled syringes, then they will have a market. They will go to these people and say, look, I want the best syringe, and they will force them to create that. It may drive the price up, obviously, being a market, but it will introduce a better practice even within these unsafe people, because if they want to keep their market, they will have to use auto-disabled syringes.

Senator SESSIONS. Let me ask you this. I am a free market person, but what would happen if every country was provided a sufficient supply of needles for all the reasonably necessary injections in the country, so that every clinic had an abundant supply of reusable needles. What incentive would there be for any health care worker not to use a clean needle every time?

Dr. SSEMAKULA. There would be none. There is no excuse. It is a simple thing. If the supply—that is what they say. If the supply is there, they will use it. There will be no excuse at all. And, in fact, it is criminal if they are doing otherwise.

Senator SESSIONS. In fact, the health clinic leaders and health department leaders could impose discipline if people failed under those circumstances.

Dr. SSEMAKULA. Yes.

Senator SESSIONS. And if they made that a clear message, in your opinion, if the health care system and the governmental leaders and the WHO and all made this clear that these are standards that cannot ever be violated, you always must use safe injections, don't you think that we could achieve pretty dramatic results with this problem?

Dr. SSEMAKULA. I certainly think so. I mean, as I said, it is one thing that a patient does not have control over, is what happens to them in a clinic. That is incumbent on the doctor or the health care provider and they must be providing the best health care. If they don't do that, then they are liable, and it must be made clear, if the technology exists, it becomes part of policy, that if you fall short of those standards, you must expect to be tried by the law, whatever it is, be it in court or in the health care setting. But I think that would have a tremendous effect.

Senator SESSIONS. Dr. Hutin, do you see any significant impediments to an immediate decisive action by governmental leaders to strive to take the injection transmission mode down to zero and spending the money and would it be a good use of their money?

Dr. HUTIN. As I said, a good use of the money, there is no question. The cost-effectiveness analyses support that. But even more important, it is extraordinarily effective.

My colleague has just raised the issue of Romania, which in 10 years has wiped out the HIV transmission in the medical setting because of a very strong consumer demand that came out of the big scandal.

I would just like to share with a little bit more detail the story of Burkina Faso. In 1995, there was an injection safety assessment done by WHO and Burkina Faso that showed a high proportion of reuse of injection equipment. In 2000, we redid it and we saw almost no reuse of injection equipment, much to our surprise, much to the surprise of the people in Burkina Faso.

We tried to understand why, so we sent a consultant to try to understand what had happened. What we found is the difference between 1995 and 2000, in the meantime, the essential drug program had decided that in every health care facility, there would be a community-based pharmacy and that the community-based pharmacy would make syringes available at low cost and only make the syringes available in a country like Burkina Faso, which is one of the poorest countries in the world, wiped out the reuse of syringes and needles in the course of 5 years in such an easy and effective way, if I may say so, that nobody was even aware that the problem had been fixed before we did the assessment.

It was done as an essential drug common sense intervention, not even to improve injection safety, because somebody in the Ministry of Health said, we can't send the penicillin to the dispensary without the syringes, and they fixed the problem in the course of 5 years. As I said, I am talking with one of the poorest countries on the planet. So I think it can be done extremely easily.

Senator SESSIONS. Mr. Stover, you have really given us some insight into the complexity and the things that we need to do around the world that could make a big difference in the AIDS fight. Do you think we could come in with a targeted program less expensive

than yours focusing on the immediate low-hanging fruit situation and make a big difference, and shouldn't we act there even if we are not able to do everything that needs to be done?

Mr. STOVER. I definitely do think that a program to promote injection safety and blood safety would be something worth doing and it would make a large contribution. I think that perhaps the reason—one of the reasons that it hasn't been done in the past is if it is done as part of an AIDS program, in the past, AIDS programs have been very under-funded. There has not been enough money for anything. So it is not so much that people were against the idea of injection safety. It is just that with so limited funds, you have to decide, well, where will we put these limited funds, and the decision was not always to give the highest priority to injection safety.

I think that could also be true going forward in the future. But the amazing thing that has happened in the last couple years is that the total resources available for HIV/AIDS have expanded dramatically and the President's initiative is a good example of that, in which resources are not going to be the major limitation. If that is true, I don't think you will find any opposition to programs to provide injection safety throughout the world. Everybody is going to support that because it is an important component.

The fact that there will also be money for all the other things that need to be done to address the AIDS pandemic makes it much easier, but I don't think there would be any objection from anybody to pressing forward with that program, and it would have many benefits, not only for HIV/AIDS, but also for other disease transmission and for——

Senator SESSIONS. Yes. We aren't talking about hepatitis and——

Mr. STOVER. Absolutely. Absolutely.

Senator SESSIONS. Would either one of you like to comment on the debilitation caused by hepatitis and the extent of that? I assume we have the same transmission rate numbers from needles and blood transfusions, or relative numbers.

Ms. BURKHALTER. Much higher. Much higher for hepatitis. Dramatically higher——

Senator SESSIONS. Why would that be?

Ms. BURKHALTER. Some 20 million cases or something like that.

Senator SESSIONS. You have more cases, and therefore you would be more likely when injected with a reused needle to be infected? Is it transmitted as easily?

Dr. HUTIN. With respect to HIV, as I have said before, there is a certain amount of uncertainty about the proportion of HIV that comes from unsafe injections. That is why there has been this controversy.

With respect to hepatitis B and C, there is much less uncertainty, and I can say with a lot of confidence that for about a third of hepatitis B in the world in developing countries comes from unsafe injections, about 40 percent of hepatitis C. In addition——

Senator SESSIONS. Those are stunning numbers.

Dr. HUTIN. Yes, and in addition——

Senator SESSIONS. Precautions for HIV would be just as effective in reducing the hepatitis.

Dr. HUTIN. Yes. And in addition, we have solid evidence to say that in countries where hepatitis C has become a huge problem,

like Egypt, for instance, this transmission has been very largely driven by medical injections. Even industrialized countries that are industrialized today that have had a lot of hepatitis C transmission in the past, such as Italy and Japan, these outbreaks have been driven by health care injections.

So the link between viral hepatitis and unsafe injections is even clearer than for HIV, and this is actually the reason why this whole injection safety initiative was initially spearheaded by the Division of Viral Hepatitis of the Centers for Disease Control, where I used to work before I came to WHO.

Senator SESSIONS. Very important numbers. I remember one anecdote that was told, that in Russia, a group of people had been infected with HIV and an investigation was conducted to find out what happened, and they found 250 people infected from one dirty needle transmission. Is that possible? Could the numbers be that high? Dr. Hutin?

Dr. HUTIN. Yes. The capacity of hepatitis B to be transmitted through unsafe injection is 100 times higher than the capacity of HIV. In other words, if you have a patient who was infected with hepatitis B, you use a syringe on this patient and then use it on a second patient, the second patient has 30 percent probability of getting hepatitis B, whereas for HIV we are talking 0.3 percent. So hepatitis B and hepatitis C are viruses that are almost engineered to be transmitted through syringes.

Senator SESSIONS. Dr. Ssemakula?

Dr. SSEMAKULA. I was going to say, yes, hepatitis B is a problem. I mean, the focus, obviously, the overwhelming number of patients we would see in Uganda were HIV and AIDS, but we used to see a lot of people who were in the end stages of liver disease.

Senator SESSIONS. Tell me about the progression of hepatitis for the patients you saw in Africa, what their life was like and how it affected their quality of life.

Dr. SSEMAKULA. I mean, it was actually pathetic because there was nothing we could do for them. We would see people in the end stages of liver failure, because hepatitis, it is a disease that progresses much like HIV and AIDS. You can have it for many years and then it manifests itself. It is a systemic disease. Your body begins to break down. And they would die much like AIDS patients. There was nothing we could do for them. They would come in jaundiced, with fever, unable to look after them, and it was a similar thing. We would just try and treat them and then they will die. It is a problem, you know.

But, you see, we have been focusing on HIV and AIDS because that has been the more immediate issue, but again, I say, if we can protect people from any disease, then let us do it. This is what we should be doing. We don't want people to get infected in a health care setting.

Senator SESSIONS. This has been a most fascinating discussion. I have had occasion to talk with senior administration officials to just share this general information that we are learning and met with Mr. Tobias this morning and Dr. O'Neill at the White House yesterday.

I believe that we need to, as the United States, be aggressive on this issue, and I think if we can reach an accord with WHO and

the nations in Africa, if we work it correctly, we can have an impact on the number of people that are infected with AIDS and hepatitis. I don't think there is any doubt about that, and it is a moral imperative. The numbers we are hearing, Dr. Burkhalter, if you take WHO numbers on needles and your numbers, $44 million I guess U.S. AID came up, or that was WHO, on blood transfusion, you are not looking at much over $100 million a year for doing what would be the largest part, would you say, Dr. Hutin, dealing with the largest part of the problem?

Dr. HUTIN. With respect to health care transmission of HIV, I think it is fair to say that the bulk is caused by injection and transfusion. If we were to fix these two, we would fix the majority. Universal precaution, as was said, would cost more money for a smaller benefit in terms of HIV, but actually a huge benefit also for other diseases, such as SARS, for instance. We have seen with SARS how hospitals can actually be disease amplifiers. With the implementation of universal precautions, you could actually address that, too, but maybe that is the purpose of another hearing.

Senator SESSIONS. There are a lot of factors. Am I incorrect, Dr. Ssemakula, that I think you indicated that people who come into the clinics are even more likely to be AIDS patients than the normal person who would be more healthy. So because they are ill, they are more likely to come in, so you have a higher likelihood that when you are reusing a needle, that you are taking it from a person who may be infected than in the population as a whole.

Dr. SSEMAKULA. That is absolutely correct. And in that sense, I heard this term "super-spreaders" from SARS, about how one person can infect a lot of people, and you have just mentioned—Dr. Hutin has just mentioned that the health care setting can become that. Because you have such a large number of HIV-positive people, the likelihood—I mean, those studies done in Kenya a long time ago about people who were getting infected from hospitals and the likelihood was that much greater, the risk is that much amplified because of the nature of the environment.

Ms. BURKHALTER. I don't want you to—I don't want any of us to skip over the universal precautions because even if the immediate impact on AIDS transmission is not as great as the bang for the buck with the two identifiable, blood and injection safety, which I strongly, strongly support directing funds toward, I do think it is worth mentioning that the continent of Africa is losing its doctors and nurses in very large numbers. They cannot graduate enough new health professionals to even account for the brain drain that is occurring because we are taking their health professionals to work in our clinics and hospitals.

Those that are there, a dwindling number who themselves get sick from a variety of means, but some of them get sick from needle-stick injuries, are just beleaguered. All their patients are dying. They can only provide actual treatment to keep them alive for a handful that can afford the ARVs. They are just psychologically traumatized all the time and they are working way too hard and they are scared of their patients and they are at risk. They don't have enough gloves to even deliver babies safely.

I just think that even though it is the more expensive piece, that the public health model alone of maximum bang for the buck, we

need to also be aware of just the human costs on these front-line activists who are trying to save their people from the worst epidemic in human history should not be avoided. Let us get better cost estimates for what it would cost to work with med schools and hospitals and clinics in Africa, work with suppliers, provide those technical and systems management services like Anne Peterson was providing in the East Cape to include distribution and dissemination and education of gloves and masks so we don't have such a terrible burden on these heroes.

Senator SESSIONS. Thank you very much. We certainly have not focused on all the problems in dealing with the transmission of AIDS in Africa. This is an issue I raised with Chairman Judd Gregg and he urged me to have these hearings and pursue it and see what we would discover. I think we have been affirmed in the idea that we can do better and that it would save hundreds of thousands of lives. I believe it is our responsibility to do so.

I thank all of you on the panel for your commitment to that. Thank you, Ms. Burkhalter, for preparing a thoughtful paper, which we will be looking at, on some of your ideas on a more comprehensive program. We shall continue to work on it. If you have any suggestions, I would be pleased to receive them.

Ms. BURKHALTER. Thank you.

Senator SESSIONS. If there is nothing else, we are adjourned.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF E. ANNE PETERSON, M.D.

SOLUTIONS TO THE HEALTH CARE TRANSMISSION OF HIV/AIDS IN AFRICA

Good morning. Thank you for inviting me to testify on the important topic of the transmission of HIV/AIDS during medical care.

USAID recognizes that HIV and other infections do occur in medical settings. Clearly, potential transmission is greatest in countries that have a high burden of disease and poor quality of medical services. The higher the general HIV prevalence, the greater the risk of transmission through all modalities will be. Risks of transmission by medical procedure will depend on local practices and implementation and is widely variable. Utility and cost-effectiveness of any intervention depends on not just the direct costs but system needs and how common the problem is.

Injection safety and medical best practices can play an important role in preventing unintentional spread of certain blood-borne diseases, including HIV, during medical care. I welcome the attention this committee is giving to this mode of HIV transmission.

Not every contaminated injection transmits HIV. In the U.S. the post-exposure transmission rate is 3 in 1,000 needle stick injuries for health care workers. Hepatitis is much more infectious. The extent of HIV transmission through other routes in a medical setting in Africa are not nearly as well documented. I am sure later testimony will give more detail, and we all look forward to the Centers for Disease Control study on the relative contribution of medical setting transmission.

Proper safety procedures can reduce HIV transmission through transfusion of blood products and contaminated needles. However, addressing healthcare safety in much of the developing world is a complex endeavor that requires much more than simply providing supplies. It includes behavior change among providers and patients, careful supply chain management, addressing poor distribution systems, poor forecasting of supplies, inappropriate use of supplies by providers, and poor waste management practices.

USAID is the implementation arm of the U.S. Government in foreign aid and development. I would like to describe USAID's work in the areas of injection safety, blood safety, safe delivery practices, and quality assurance.

USAID has a long history of strengthening health systems and improving the quality and safety of health care in developing countries. USAID's programs in child survival, maternal health, infectious diseases, and HIV/AIDS have improved the safety of medical practices through technological innovations, clinical training, policy guidance in best practices and appropriate protocols, and strengthened management and logistics systems. Most of these interventions are currently funded out of our non-AIDS child survival budget but contribute to the prevention of HIV in medical settings.

Injection Safety

Over 16 billion injections are given every year in developing countries for immunizations, therapeutic purposes, transfusion of blood and blood products, and injectable contraceptives. These injections, if contaminated with infected blood, can transmit hepatitis B, hepatitis C, and HIV.

While there is significant variation between countries, WHO estimates that in sub-Saharan Africa approximately 18 percent of injections are given with reused syringes or needles that have not been sterilized. However, unsafe medical injections are believed to occur most frequently in South Asia, the Eastern Mediterranean, and the Western Pacific Regions. Together, these account for 88 percent of all injections administered with reused unsterilized equipment.

USAID has been a global leader in support of immunization safety as part of comprehensive routine immunization programs in developing countries since the early 1980s and remains committed to injection safety. Raising the focus on immunization safety is a top priority for USAID global health programs. USAID has provided leadership to change country policies and procedures to improve medical practices; promote behavior change by recognizing the role of unsafe medical practices; create a research agenda to identify risk factors in poorly covered areas; reduce unnecessary injections; and further work in technical development.

USAID has worked with its partners to document the extent of the unsafe injection practices and the cost-effectiveness of interventions to improve the safety of injections in the developing world. USAID's efforts in this area led to the development of the World Health Organization's Safe Injection Global Network (SIGN). USAID has provided technical assistance to SIGN to establish injection standards that are

not only scientifically sound, but which also are designed to change the behavior of health care providers.

In addition, USAID through the Program for Appropriate Technologies for Health (PATH), has developed and introduced single-use injection devices, and is currently developing and introducing systems for safely disposing of contaminated needles. Uniject, a new smaller single-use device, will reduce costs, medical waste, and the risk of unintentional needle sticks. USAID is supporting research to expand the number of injections that can be given with Uniject. USAID currently "bundles" Depo-Provera with a single use syringe and a safety box to improve the safety of disposal.

Finally, USAID has been a lead partner in the effort which resulted in the Global Alliance for Vaccine and Immunizations (GAVI). Five-year commitments to immunize children in the world's poorest countries through the GAVI and The Vaccine Fund topped $1 billion in July, bringing to 71 the total number of countries receiving support for health infrastructure, vaccines and supplies from The Vaccine Fund. The U.S. contribution to The Vaccine Fund, GAVI's financing arm, has increased annually, from $48 million in fiscal year 2001 to $53 million in fiscal year 2002 and $58 million in 2003—resulting in a total U.S. contribution over the past three years of nearly $160 million. GAVI is providing safe injection supplies to all of its participating countries as well as supporting the development of waste management plans. GAVI has estimated commitments for support of $332 million for immunization services support over 5 years and $77 million for injection safety over three years. USAID was the instigator at the last GAVI meeting for insisting on a review of how ISS funds are being used.

Blood safety

Each year, countless lives are saved through necessary blood transfusions, but various limitations in how the blood is collected and tested put many people at risk of infection with HIV. Interventions to make the blood supply safer have led to a significant reduction in HIV transmission by blood transfusion in industrialized countries, and USAID is working to extend these practices to the developing world.

In Kenya, USAID played a leadership role by helping the national blood safety program address challenges to the blood supply, including problems of limited training and experience with blood transfusion science among health care personnel and the need for quality monitoring. HIV transmission through unsafe blood transfusions was reduced through the system put in place by USAID/Kenya following the 1998 Nairobi bombing. The new system, made up of 5 regional blood transfusion centers, trained staff, new equipment, policy guidelines, and donor recruitment activities, met its primary objective, preparedness for future disasters, by providing safe blood to the victims of the Thanksgiving Day terrorist attack in Mombasa. USAID continues to support the government of Kenya in developing its blood safety program and blood transfusion services.

Through the new Safe Blood for Africa project, USAID will help develop a blood collection and distribution center in Abuja, Nigeria to help combat the crisis of HIV transmission through blood transfusion in Nigeria. USAID will provide funding for staff, equipment, and review of operating systems and organizational structures. In Abuja, blood services are severely understaffed, underfunded and are far from meeting standards for blood collection and distribution set out by the WHO. Not only does the substantial probability exist for HIV infection from blood transfusion, but also, adequate stocks of blood for routine medical requirements are not available. USAID anticipates that this new project will significantly reduce the transmission of HIV through blood transfusion in the area and increase the safe blood supply in the Abuja Region. USAID support for this initiative will contribute to the long range goal of implementing a National Blood Policy and establishing a Nigerian National Blood Transfusion Service.

Major reasons for transfusion include severe anemia, malaria, or bleeding after childbirth. A little recognized contribution to reducing HIV transmission is some major changes in the rate of giving transfusions. We can substantially reduce the number of transfusions through changing transfusion criteria, reducing the need for transfusions by addressing delivery care and through our extensive malaria prevention and treatment programs.

Safe Delivery Practices

USAID supports two levels of HIV prevention during delivery care. The first level is focused interventions for prevention of mother-to-child transmission, and the second is protecting medical workers from exposure by implementing proper sharps disposal and universal precautions.

The USAID-funded Maternal and Neonatal Health Program works in 10 countries in Africa on infection prevention practices for safe motherhood and newborn health. We 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. The program focuses on the prevention of mother-to-child transmission of HIV (P–MTCT) and safe motherhood service delivery. In addition, we emphasize several key infection prevention behaviors: injection safety, universal precautions, handwashing, clean, safe delivery, avoiding of unnecessary medical procedures, proper sterilization of instruments, proper disposal of hazardous waste, and newborn umbilical cord care.

USAID funded the Program for Appropriate Technology in Health to test the feasibility of putting the drug oxytocin in Uniject pre-filled, auto-disposable injection devices. Oxytocin 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.

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.

USAID has also supported the development of protocols for postpartum hemorrhage and delivery by caesarian section.

QUALITY ASSURANCE IN MEDICAL CARE

Quality assurance can be defined as the development and promotion of cost-effective methods to strengthen health care services and systems. Examples of activities include accreditation of facilities, supervision of health workers, or other efforts to improve the performance of health workers and the quality of health services. Applying the principles of quality assurance to our work in the health care sector is critical to ensuring that our programs are effective and do not cause risks to health care workers or their patients.

USAID supports programs to introduce modern quality assurance practices into the health systems of developing countries. In Zambia, we developed a hospital accreditation program, which included criteria for blood transfusion, infection control, quality assurance activities, and incident reporting and analysis.

In Tanzania, our program supported a quality improvement collaboration in which Tanzanian hospitals learn from one another's experience in infection prevention and the use of universal precautions during procedures.

USAID has supported studies of how the stigma of HIV/AIDS affects health provider behavior in Rwanda. As a result, we have made recommendations for the use of post-exposure prophylaxis, protective equipment and other preventive measures.

In addition, USAID has supported infection prevention training programs in several countries around the world, including Malawi, Ghana, Kenya, Honduras, Guatemala, Nepal, Indonesia, Haiti, Senegal, Uganda, Guinea, Bolivia, Mali, Burkina Faso, the Philippines, and the Ukraine. These courses include basics on disease transmission, hygiene, processing instruments, safe injection practices, gloves and other items (decontamination, cleaning, high-level disinfection, sterilization), and waste disposal (a universal precautions approach to protect both healthcare workers and clients/patients). The training on safe injection practices includes teaching about how to dispose of needles and syringes safely using locally available resources.

The Development of the HIV/AIDS Epidemic in Africa

In addition to discussing medical transmission of HIV, I was also asked to address the question of why the AIDS pandemic has affected Africa more severely than other regions, and why are there such disparities between regions in Africa.We can track the trends that differ between the regions but why the epidemic has followed such different patterns is much less clear.

Most West African countries continue to have relatively low prevalence levels. Meanwhile, in the newer epidemics of southern Africa, the prevalence has exploded to nearly 40 percent in many countries. The highest prevalence countries are all located in southern Africa.

Although studies show a high rate of knowledge about HIV in Africa, there is a very low rate of knowledge on how to protect oneself from acquiring HIV infection.

There is low prevalence of male circumcision in these countries. New, very strong evidence shows an association of increased risk of HIV with not being circumcised. Circumcision varies geographically and by tribal group in Africa and is a possible contributing factor to the differences in the growth of the epidemic. Western Africa

has very high rates of male circumcision and southern Africa variable but generally low rates of circumcision. Differing sexual practices may also contribute or strains of HIV may be contributing factors.

Certainly, behavior change response to the epidemic (the ABCs: Abstinence, Behavior change, and correct and consistent Condom use) varies by country. Decreasing number of partners (being faithful) is beginning to look like the most important factor in turning around the epidemic. USAID will soon be publishing a baseline ABC study in six countries showing some of the contrasting behaviors.

Conclusion

In conclusion, I would like to emphasize that USAID is committed to HIV/AIDS prevention. We will continue to ensure that risky medical practices, risky sexual behaviors, and mother to child transmission are all addressed as part of the overall response to the HIV/AIDS pandemic. We look forward to being a key partner in implementing the President's Emergency Plan for AIDS Relief and continuing to achieve results in HIV/AIDS prevention, care, treatment, and support.

I believe very firmly that it will be impossible to do the prevention of mother-to-child transmission and treatment envisioned in the President's initiative without systems strengthening that will improve delivery care, drug and commodity logistics, and clinical protocols. All these improvements will directly impact and reduce HIV transmission in medical settings.Thank you again for inviting me to speak on this important topic.

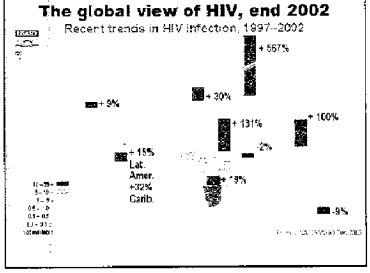
Prevention of Medical Transmission of HIV/AIDS

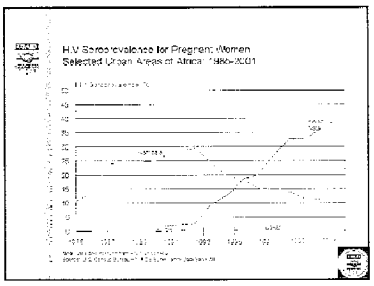
E. Anne Peterson, MD, MPH
Assistant Administrator
Bureau for Global Health, USAID

July 30, 2003

The global view of HIV, end 2002

Recent trends in HIV infection, 1997–2002





A Comprehensive Approach

Prevention

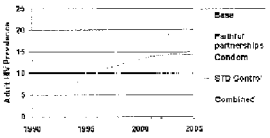
- Ensure **blood safety**
- **Ensure injection safety**
- **Post-exposure prophylaxis**
- Sexual risk reduction
- Condom social marketing
- **Treat other sexually transmitted diseases**
- **Voluntary counseling and testing**
- **Prevent mother-to-child transmission**
- **Surveillance and monitoring systems**

Care and Mitigation

- Basic care and support for HIV infected persons
- Nutrition & on ARV Rx
- **Rx of Opportunistic infections**
- **Use of anti-retroviral drugs in introductory sites**
- Support for orphans and vulnerable children
- Other mitigation activities

No Magic Bullet

- Many & complementary strategies
- Synergies between strategies
- Varies by epidemiology & culture
- Ethical & balance issues abound

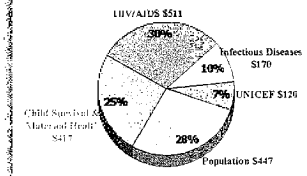


Based on hypothetical model using typical net prevalence urban areas.

Prevention of Medical transmission of HIV

- AIDS programs
- Health programs:
  - Injection safety
  - Maternity care: white ribbon, PAC, oxytocin, protocols for safe delivery/C-section
  - Malaria prevention & care: protocols – Malawi, ITNs-coverage for GM people
- Research: biomedical, applied, OR
- Health systems, training & Quality Assurance
- Surveillance

Global Health
FY 2002 - All Accounts



Injection Safety

- GAVI Global Alliance for Vaccines & Immunizations
  - U.S. contribution to Vaccine Fund: $58 million in 2003, nearly $160 million over past 3 years
  - GAVI has estimated commitments of $332 million for immunization services support over 5 years and $77 million for injection safety over three years.
- PATH
  - USAID:$19 million/ 5yrs for technology development in injection safety issues; autodestruct syringe, unijet,
  - More than 400 million SoloShot auto disable (AD) syringes supplied to over 40 developing countries since 1992
  - 22.5 million Uniject devices supplied worldwide since 1998

Blood safety

Kenya: $3.3 million to construct and equip a national and four regional blood transfusion centers, strengthen model blood transfusion services and develop operational guidelines

Nigeria: newly designed program for staff, equipment, and review of operating systems and organizational structures to improve blood safety in the Abuja region

Change transfusion protocols

Maternal Health/Delivery Care

- Protects newborn, mother and health workers
- Prenatal care decreases high risk deliveries & unknown HIV status
- Change protocol for delivery for HIV+
- Improved post partum and PAC decreases need for transfusion and HW blood exposure
- Oxytocin: decreased bleeding, unijet delivery
- Use of skilled attendants at birth increased by 18% between 1989-99
- Regional training centers for treating obstetric emergencies established in Africa, Asia, & LAC
- Standards for managing maternal and newborn complications developed and distributed world wide

Malaria Control

Severe Anemia due to malaria a major contributor to need for transfusion in Africa

- Reduce burden of malaria:
  - national scale bednets
  - Surveillance & best Rx protocol - Malawi
- Change transfusion protocols

Science & Technology: USAID roles

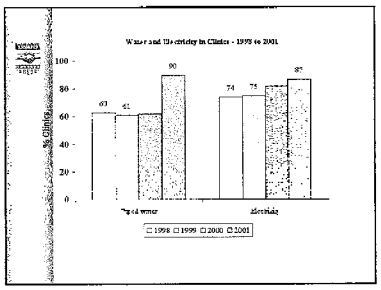
- Biomedical Research: rapid diagnostic tests, male circumcision ~HIV
- Technical Innovation: vaccine vial markers, autodestruct syringe, Unijet
- Operations research: impact of STD Rx on HIV, integration of family planning with PMCT, acceptance of medical waste protocols, best practices transference

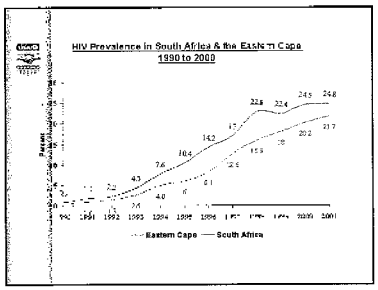
Quality Assurance

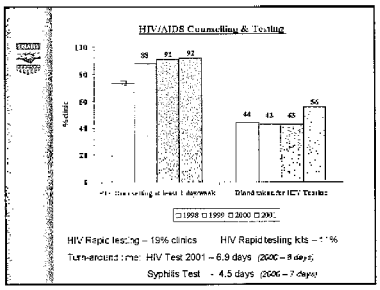
- Quality Assurance Project: $8.2 million in FY 2002 to develop effective guidelines, systems for monitoring quality of care, strategies for promoting compliance with guidelines, and problem solving capacity.
- Management oversight & Information systems assistance – S Africa

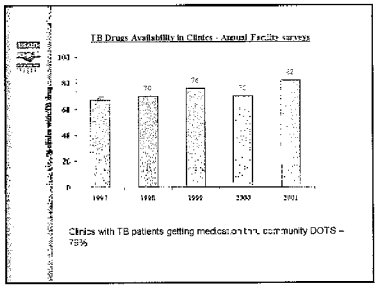
Management Oversight/ Information Systems (Eastern Cape, S Africa)

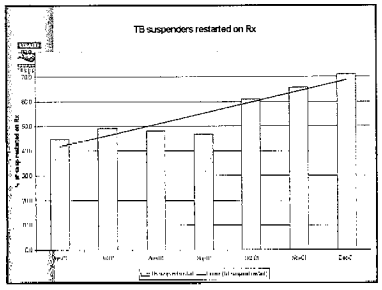
- Worst health indicators in S Africa
- HIV+ rate is greater than 20%
- USAID's Equity project: $7M/yr
- S Africa gov't: $420M/yr
- Our funding insignificant on its own
- Management training/oversight & health information system investment
- Guiding larger investments leads to much greater impact: process and outcome

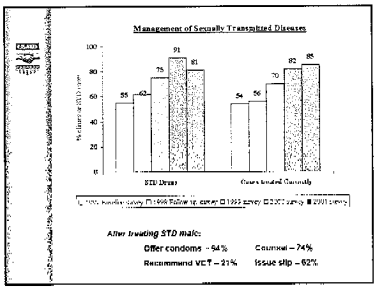


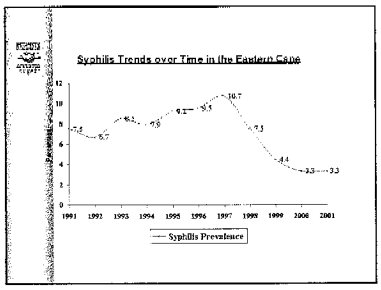


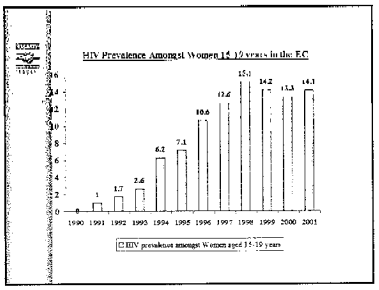


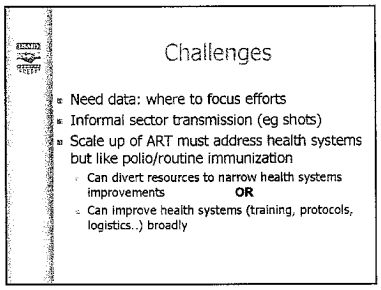


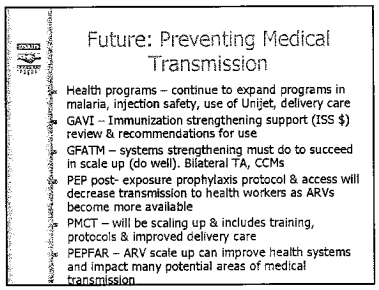












PREPARED STATEMENT OF YVAN HUTIN, M.D.

Mr Chairman, distinguished Members of the Committee, the World Health Organization (WHO) appreciates the opportunity to brief the Committee on the prevention of HIV through safe health care practices in Africa and appreciates the interest of the Committee in this important public health issue.

Senator Sessions and Members of the Committee, the World Health Organization in Geneva, Switzerland. WHO is an international organization—the technical specialized agency for health of the United Nations system—which currently has 192 Member States. The United States has been a member of WHO since it was founded in 1948. As a clinician, I have experience in the care of individuals with HIV infection and viral hepatitis. As an epidemiologist, I served in the Epidemic Intelligence Service of the United States Centers for Disease Control and Prevention. I am now Project Leader of the WHO-based Safe Injection Global Network (SIGN) which is an international coalition of stakeholders working together to make injections safe. In addition to my statement, I have provided the Committee copies of two reports

entitled "The cost effectiveness of national policies for the safe and appropriate use of injections" and "Progress towards the safe and appropriate use of injections worldwide, 2000-2001" and I request that these two reports be made a part of the record.

A number of health care procedures may lead to the transmission of HIV. These include (1) transfusion of infected blood, (2) unsafe injections and (3) other skin-piercing procedures performed in the absence of universal precautions. Thus, safe health care services should offer to their users (1) selection and testing of blood donors, and when applicable, viral inactivation of human material for therapeutic use, (2) safe and appropriate use of injections and (3) procedures conducted according to universal precautions.

In Africa, for a population of 0.6 billion (10% of the world), only 2.4 million blood units are collected annually against an estimated need of six million units. About one-third of blood is donated by family replacement or paid donors considered at high risk for HIV transmission, considering the incidence and prevalence of HIV in Africa. In addition, 50% of collected blood is not tested either for HIV, HBV, HCV or syphilis. The high efficiency of transmission of HIV through transfusion of infected blood (>90%) leads to a substantial burden of infection among transfused patients. For the remainder of this statement, I will focus primarily on the issue of unsafe health care injections which I have been asked by the Committee to address.

WHO estimates that in developing and transitional countries, 16 billion health care injections are administered each year (an average of 3.4 injections per person, per year). This high figure, along with evaluation reports indicating inappropriate use of injections, suggests that injections are overused to administer medications. Causes of this overuse may include a preference for injections among patients. However, the most important cause is a desire by health care providers to satisfy what is believed to be a preference for injections among clients. In fact, research suggests that most patients are open to use of oral medications.

In addition to being overused, injections may also be administered by unsafe procedures and cause infections. A safe injection should not harm the patient, the health care worker or the community. However, injections may harm the patient when injection devices are reused in the absence of sterilization. Injections may harm the health care workers when dirty needles are not collected in safety boxes. Injections may harm the community at large when health care facilities are surrounded by sharp health care waste—mostly dirty syringes and needles. Reuse of injection devices in the absence of sterilization is the problem of greatest concern that we have to address as to leads to the largest burden of disease. A mathematical model developed by WHO suggests that in 2000, in developing and transitional countries, reuse of injection devices accounted for an estimated 22 million new infections with the hepatitis B virus (a third of the total), two million new infections with the hepatitis C virus (40% of the total) and 260 000 new HIV infections (5% of the total). These infections acquired in 2000 alone are expected to lead to an estimated nine million years of life lost (adjusted for disability) between 2000 and 2030.

There has been a recent controversy over the role that unsafe health care injections play in the transmission of HIV infection in sub-Saharan Africa. While WHO estimates that, worldwide, about 5% of all HIV infections are transmitted through unsafe health care injections, this estimate is only 2—5% for sub-Saharan Africa. Although there is uncertainty around these figures, WHO and our sister program, UNAIDS, believe that they are in the right order of magnitude and that the vast majority of HIV infections in sub-Saharan Africa are transmitted via unsafe sexual practices.

This public health issue may appear daunting. Yet, evidence indicates that the death and disability associated with unsafe injections are highly preventable. First, interventions conducted to improve communication between patients and doctors and interventions to improve prescriptions through monitoring of providers have proven effective in decreasing injection overuse. Second, interventions to ensure injection device security (i.e., make single-use syringes available reliably in each health care facility) are effective in preventing reuse of injection devices. Some of the poorest countries in the world have actually achieved substantial progress through ensuring that all injectable medications are made available with sufficient quantities of single-use syringes and needles.

In addition to being highly effective, policies and plans for the safe and appropriate use of injections are a sound investment in Health: In the scientific paper that I presented to the Committee as part of my statement, WHO has estimated that interventions implemented in 2000 for the safe andappropriate use of injections would have cost $102 per year of life saved (adjusted for disability). This cost is under the threshold of one year of average per capita income in developing countries used by the WHO Commission on Macroeconomics and Health as a criterion for an

intervention to be considered very cost-effective. Thus, implementation of safe and appropriate use of injections as part of HIV prevention and care programmes is highly desirable and can be accomplished with only a modest shift in the assignment of resources for two reasons:

(1) Injection safety is not a costly intervention. The scientific paper on the cost effectiveness that I submitted to the committed as part of my statement includes estimates of what it would cost to ensure injection safety in each of the world's regions;

(2) The large majority of HIV infections worldwide are caused by unsafe sexual practices, thus the emphasis of HIV prevention programmes must remain on preventing sexual transmission.

Among prevention opportunities, single-use injection devices with reuse-prevention features deserve a special mention. These have been also referred to as auto-disable or auto-destruct syringes. These syringes that inactivate themselves after one use through plunger blocking, plunger breaking or needle retraction are now the norm in immunization services and are becoming the norm in other international donor and lender-supported services (e.g., family planning and tuberculosis treatment). In addition, promising new single-use syringes with reuse-prevention features have now been developed for general curative services. These devices now require field evaluation to define their future role in public health.

Since the establishment of the Safe Injection Global Network (SIGN) at WHO in 1999, great progress has been made towards the safe and appropriate use of injection worldwide. In the progress report that I have attached as part of my statement, you will see that the government of the United States has supported WHO's effort in this area through the Centers for Disease Control and Prevention (CDC), the United States Agency of International Development (USAID) and the United States National Vaccine Program Office (NVPO). Additional support will be needed in the future to prevent death and disability through key interventions at country level.

Four key interventions are needed for injection safety:

(1) Increasing the awareness of the population regarding the risk of HIV and other infections associated with unsafe injections;

(2) Making sure there are sufficient quantities of single-use injection devices and safety boxes in every health care facility where injections are administered;

(3) Ensuring that all donors and lenders who support the supply of injectable substances in developing and transitional countries also support the provision of injection devices with reuse-prevention features and safety boxes;

(4) Managing the waste associated with dirty syringes and needles in a safe and appropriate way.

Four key interventions are needed for blood transfusion safety:

(1) Establishment of a nationally-coordinated blood transfusion service;

(2) Collection of blood only from voluntary non-remunerated blood donors from low-risk populations;

(3) Testing of all donated blood, including screening for transfusion-transmissible infections, blood grouping and compatibility testing;

(4) Reduction in unnecessary transfusions through the effective clinical use of blood, including the use of simple alternatives to transfusion.WHO appreciates the opportunity to brief the Committee on this important issue. I thank you for your attention and I will be happy to answer questions you may have on this subject.

Senate Hearing Committee on Unsafe Health Care and the HIV/AIDS epidemic in Africa
Testimony of Dr. John Kiwanuka Ssemakula (MD, MPH)
Washington DC, USA, 31st July 2003

Senators, thank you for affording me the honor and privilege to address this **Senate Hearing Committee** on the very important subject of **Safe Health Care. My name is** John Kiwanuka Ssemakula a Ugandan Doctor currently working as a Public Health Consultant with the Africa-America Institute (AAI), where I am the Programme Manager and Advisor on the AAI HIV/AIDS Initiative. I trained as a Doctor at Ibadan University Medical School, Nigeria, and Makerere University, Kampala in Uganda where I received my medical degree. I subsequently took a Masters Degree in Public Health at Dundee University Medical School in Scotland, for which my Masters thesis was titled "HIV/AIDS and the Healthcare system in Uganda."

I have had a professional and personal relationship with HIV/AIDS during my tertiary education, through medical school, then my on-the-ground experiences as a young physician first undertaking a medical internship, and then as a medical officer in the early1990's, during the peak period of the HIV/AIDS crisis in Uganda.

But my interest in HIV/AIDS is not just professional, but is also on an intensely personal level. I have lost several cousins, who were like brothers and sisters to me over the years. One was a doctor, another was an engineer doing a masters, others were in university. I have also lost aunts and uncles who left behind orphaned children that we have helped educate and bring up over the last 15 years.

The issue of unsafe medical practices and re-use of needles is a subject that I as a Doctor have always had in my mind, but in Africa the focus in the fight against HIV/AIDS has always been on sexual transmission and prevention methods primarily by behavioural changes. Nonetheless over the years myself and many of my colleagues have discussed what was it that led to HIV spreading so fast in Africa, why Africa and not elsewhere in the world. Many researchers from the West attributed it to the promiscuity of Africans, but for those of us who have and do live in the West, nothing compares to Western Europe and the US, places like Ibiza, or Summer break in places like Cancun where "Girls gone wild" is filmed.

My interest in other routes of transmission rose in me again when I was doing research for an article on new and emerging infections and whether African nations were adequately prepared to identify early enough the emergence of a new epidemic like the AIDS epidemic. In the course of my research I came across a paper called the *"The injection century: massive unsterile injections and the emergence of human pathogens"* by Drucker E., Alcabes P. Marx P. (December 2001) published in the Lancet Medical Journal in 2001, which drew a link between the rapid rise in injection use in the world and the emergence of HIV/AIDS.

Shortly after publishing my article I received an email from David Gisselquist asking if I was interested in looking at risks for HIV transmission through unsafe health care in Africa. He went to tell me he had been working with some people to estimate proportions of HIV from health care and from sexual transmission and that they'd found a lot of evidence that unsafe health care may be an important factor. In this same email he also added an attachment that included a draft of his ground-breaking paper ***"HIV infections in sub-Sahara Africa not explained by sexual or vertical transmission"*** that was soon to be published in the International Journal of STD AIDS.

The paper seemed to contain all the information in terms of HIV/AIDS that had been missing. As soon as the article came out in October 2002 I was moved to write an article commenting on this very possibility. The paper proved and has continued to be controversial. I was invited to write a letter for an International Journal of STD AIDS special issue on the subject of unsafe medical practices contributing to the spread of HIV/AIDS which was entitled **"The Missing Link? "The Spread of HIV/AIDS in Africa through Unsafe Medical Care"** and was published in the March 2003 edition of the International Journal of STD AIDS. The article resonated so strongly with me because it seemed to explain so much of what had been mysterious about the spread of HIV/AIDS in Africa. I also published extracts and comments on a number of international listservs such as Afronets that deal with African Health.

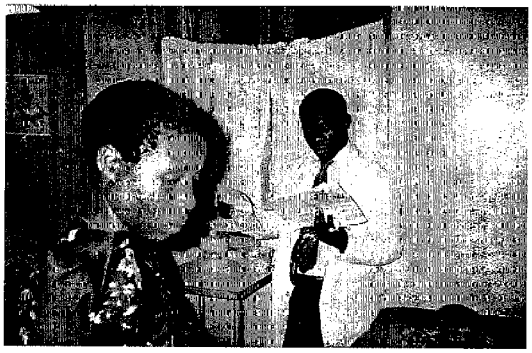
Why did I believe that HIV inadvertently spread through needles in Africa to be the case? Quite simply, it makes sense. Working as a clinical doctor I often had to rely on my gut instinct to diagnose cases that did not meet any clear clinical parameter mentioned in the books. In this I was always reminded of a statement that one of my lecturers said "diseases do not read books". What he meant was as a doctor one must always be vigilant of a disease not presenting with common accepted symptoms but in an unusual manner that was not in the books. As soon as I saw the article I knew this could entirely be the missing link.

Over the next few months as the controversy surrounding the article erupted, I discussed the implications with many of African colleagues in the USA and in Africa by email. I was struck by the similarity of opinions and views held by people who had grown up and worked in African nations for any length of time and those who worked in international organizations such as the WHO, CDC and the UN. Many people in Africa had similar experiences that they could relate about having received immunizations where only one syringe was used and where sometimes blood flowed freely from a particularly difficult injection. Others talked of how they would go to hospitals and only accept injections if they were syringes they had bought and brought themselves. Whenever I explained to them about the issue and the controversy many were surprised because they knew what the conditions were like in hospitals and instantly realized that HIV could very well have been spread in medical settings.

As a medical student and a Junior House Officer in Mulago hospital in Kampala in the late 80's and 90's I witnessed the re-use of needles constantly. Sometimes the needles were so blunt they would actually cause trauma to the patient and blood would flow. We used sterilizers which sometimes did not reach the correct temperature or sometimes power would go out unbeknownst to us ,and the medical equipment we thought had been sterilized were actually still unsterile. We resorted to also putting instruments in a 5% solution "Jik," a type of bleach which at the time was recommended as a method for sterilizing equipment to kill the HIV virus. Unfortunately, sometimes the bleach solution was not up to strength or the bleach was a batch that was not of the right grade (a practice that still continues today in some hospitals I am told). So concerned were we as junior Doctors doing most of the work and in the frontline, we went on a work to rule demanding equipment such as disposable needles and gloves that would allow us to do our jobs in a safe environment, both for the protection of ourselves and our patients. I worked in surgery department, where we often had multiple victims from major road traffic accidents, people with gunshot wounds, and other traumas. I remember one time a colleague and I decided to do an informal survey of the rate of HIV on our patients. We were shocked to discover that up to 50% of our patients were HIV+ve.

I also worked in Paediatrics, which if possible was even more intense than working in surgery. The wards often had 100 in patients and on admission days which was every third day I saw on average 200 patients and often up to 400 patients a day. It was at this time I and my fellow doctor Dr Madewo

noticed an unusual phenomenon, we started seeing children presenting as HIV+ve when the mother was not. We also noticed infants presenting with unusual signs, such as necrosis or gangrene of the extremities, with no other presenting symptoms. We discovered most were HIV+ve and we wanted to do research into this, because we thought perhaps this was one more manifestation of HIV that differed from the classical presentation described by the WHO, and we wondered how the children could have become infected when sometimes the mothers were not. One of the possible routes we thought of at the time was perhaps through immunisations or somehow infected by either injections or unsafe blood. Unfortunately we were unable to get the funding to do this and lack of time and other constraints did not allow us to pursue this. We were told that the mother's were very likely in the early stages of HIV infections and would likely sero-convert so that the virus would show up later. I believe this was a missed opportunity to investigate the possibility of HIV being spread in a medical setting.



Dr John Kiwanuka Ssemakula with mother and sick child, Nsambya Hospital, Kampala, Uganda (1992)

I then worked in Nsambya Hospital an NGO hospital which was then considered one of the best hospitals in Uganda as a Medical Officer in charge of the Casualty Out-patients department. Nsambya also had one of the first AIDS clinics in the country. Even here needles were occasionally still boiled and re-used though practices were much better than at Mulago. At the time HIV had reached such proportions in Uganda, my parents, Aunts and cousins actually feared I'd get infected in hospital. And remember, these were better equipped hospitals in an urban setting.

This is why as soon as I learned of the research being done on unsafe healthcare in Africa, it immediately struck me this could be another way that HIV had been spread in Uganda and other countries in Africa. We corresponded back and forth during which time I also joined the Safe Health Care /HIV Working Group which was started by the Physicians for Human Rights to find ways of getting more attention about the issue. I'd followed the first Senate hearings on the issue as well as the meeting the UN/ WHO had convened to discuss the subject and was quite disappointed at the outcomes.

At the beginning of June I received a call from a person called Renuka Gadde who said she was working for a company called BD, Becton Dickinson. She asked me if I'd heard about them, and I said no. She told me that BD was the biggest manufacturers of needles, syringes and other medical equipment. Until then I'd never really thought about where needles and syringes come from. As a doctor they are just one of these implements that you use all the time, but I'd never really stopped to think about who made them. On the Wednesday of that same week I was in DC being interviewed as a potential witness to testify in the senate hearings. During the course of this process I was asked if I was being paid by BD and I said until two days ago I'd never heard of them! I thank Edwina Rogers and Senator Sessions for having the confidence in me to give this rare honor to testify before the senate.

I jumped at the chance to testify because I'd been disappointed at the outcomes of previous official hearings on the subject. As far as I was concerned people who were discussing the issue were missing the point. It was not about the percent of HIV/AIDS that was transmitted via the unsafe use of needles. It was about safe health care, the first and most basic thing as a health worker one should do, "Do no harm to the patient." The WHO's figures stated 2.5%, other figures were saying 8-10%, some figures were as high as 40%. I said even if it were only 2.5%, it is 2.5% too much, if should be 0%. Saying 2.5% is acceptable goes against all the promises of tackling the HIV/AIDS problem. At the meeting with BD I was shown some remarkable technology that they had developed, auto-disable syringes for developing countries. I was amazed. I said to them if this exists why is it not made available, it at least gives a tangible way of preventing the spread of AIDS and not just AIDS, other blood borne diseases such as Hepatitis B and C. This strengthened my resolve to find a way of participating in the process, to raise awareness about the issue and make sure this technology became available.

For me, there was no controversy, it was a simple black and white issue, that of providing safe health care. I said, "Can I honestly go into my home village in Uganda and tell my relatives there they should not have access to safe health care. They trust me for this. The arguments that if people thought HIV was spread through needles would encourage them to go and practice unsafe sex were absurd. Were all these officials saying that African's should have a choice between practicing safe sex or getting safe health care, but not both?" I was astonished at such assertions.

Immunisation using auto-disable syringes in Mali, UNICEF EPI Programme

I pointed out that the UN/WHO already appreciated the risk of spread of AIDS in medical and health settings, specifically to children. Which was why they had made the use of auto-disable syringes the standard for the UNEPI immunization programme, which has been extremely successful. Why then I asked could they not do the same for curative services? Did it make sense to give a child life saving immunizations on a Monday, only for them to come back ill with malaria the next day and possibly receive unsafe injections? Were people who received injections for curative purposes not allowed the same standards?

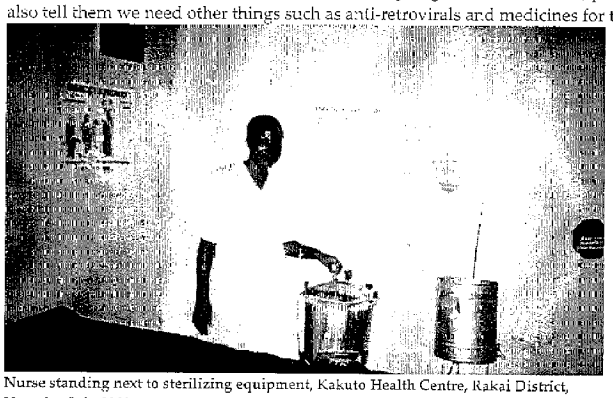
The clincher for me was when the SARS epidemic started. The response by the WHO and public health officials around the world to contain the epidemic was unprecedented dramatic and ultimately successful. Bu it was while reading an article discussing the SARS epidemic and how it was spread that I came across the term "superspreader".

One of the more unusual features of this virus that emerged from the research of Asra Ghani of the Department of Infectious Disease Epidemiology at Imperial College, London. She found that most people who get SARS do not infect anyone else, but some individuals appeared to be responsible for transmitting the disease to dozens and sometimes hundreds of others. Such individuals are known

as "superspreaders", and these superspreaders have some role in transmission of the disease. Another disease that exhibits this kind of classic transmission heterogeneity is HIV. In the case of HIV most people have just a few sexual partners and so transmit the virus to one or two other individuals, but a small number of people have a large number of partners, and spread the virus widely. I theorized that this could have been how HIV was spread widely through needles and injections. It only needed to happen a few times, cases where perhaps through some kind of vaccination campaign or an outbreak a large number of people received contaminated injections, thus ensuring there was a large enough pool of people to spread the disease in the general community. Perhaps this could be one explanation for the rapid spread of AIDS.

I have just come back from a 10 day visit to Uganda to see my family. I also took the opportunity to visit health clinics in Rakai district, almost all the way to the Tanzanian border, and Luwero district, a rural area about 50 miles from Kampala. I went to Rakai, because it was the area that was first and hardest hit by AIDS in Uganda, it was also the area my mother's family comes from. I wanted to see how they had been coping with AIDS and perhaps at the same time to get their views on the issue of re-use of needles and provision of safe health care. I went on the Monday, two days after I'd arrived in Uganda. In my first visit, I met the LC 5 Chairman and the District Commissioner at Rakai District HQ. They told me about the work they are doing in Rakai. The Chairman told me how the HIV prevalence rate which had reached up to 40% was now down to 12% in some areas, and as low as 6% in other areas. They had done tremendous work on sensitizing and informing people about the need for behaviour change but there was still a lot of work to do. He said the most important thing is to continue with the message about the need for safe sex as the most important thing. He also acknowledged the need for safe healthcare practices. There was no issue of controversy for him.

"Of course, we must continue with our messages to continue practicing safe sex as our priority" he said "but it is also important that we use whatever means to fight AIDS. We know AIDS can be spread by needles. If there are syringes like these available, please, please bring them to us. Here in Rakai we are constantly thinking about the future of AIDS, how do we just keep it at the level it is now, or even reduce it to lower levels. We were very happy President Bush came to visit Uganda and has promised this money on the Bush AIDS bill. If there is money to give us safe needles, please give them to us. But also tell them we need other things such as anti-retrovirals and medicines for the people."

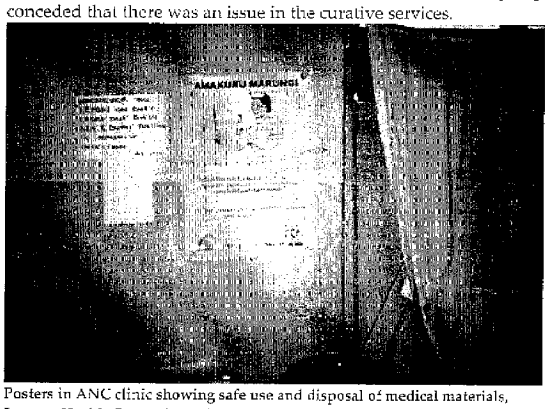


Nurse standing next to sterilizing equipment, Kakuto Health Centre, Rakai District, Uganda, July 2003

Following the meeting with the at the District HQ, I then went to Kakuto Health Centre accompanied by Sister Judith Namperwa, a senior Public Health Nurse. Kakuto Health Centre which is some 40km from Rakai District HQ is a health centre 4, rural referral facility. It was originally designed to serve 23,000 people, but its catchment area in reality is four times greater than that, because people come from neighbouring districts and even from across the border in Tanzania.

We were met by Michael Kaweze the Health Management Information Systems Officer (HMIS) who took us round with Sister Namperwa as well as the duty nurse. The health centre is well designed and has a staff of 45, which is not enough one considers they work in shifts, some go for training, and others are on holiday. They provide a comprehensive range of services, including out patient and in-patient, ANC and maternity, family planning, Dental and Eye clinic, TB, leprosy, immunization, VCT and lab facilities. They see on average 80-100 out patients a day, the commonest conditions are malaria, URTI's and LRTI's, GIT and STI's and of course HIV/AIDS. The difficulties the health centre has include lack of drugs especially ARV's especially since they have been very successful on sensitizing the local population to come in for VCT and mothers to register for the MTCT programs, lack of equipment. Sister Namperwa said "we still have a problem of lack of equipment, and the abasawo "doctors" are just worn out with dealing with HIV/AIDS day in day out!"

I asked Sister Namperwa if re-use of needles was a problem. She retorted, "That is pre-AIDS, here we use auto-disable syringes especially in immunization. Re-use is not done." But when I talked to her in more details about the issue of safe health care and how I was going to testify before senate. She conceded that there was an issue in the curative services.



Posters in ANC clinic showing safe use and disposal of medical materials, Luwero Health Centre, Uganda, July 2003

Sister Namperwa said to me " If you have these auto-disable syringes and you can bring them to Uganda it will be good. It will help Doctors because for those in clinics further up country, they are just stuck. This is a problem they have no means to deal with!" The duty nurse and HMIS also agreed that this was an issue, but there was nothing to be done about it.

I got the impression from my visit and the replies given that the all staff recognized them issue of re-use as a problem and potentially a big problem, but it just was not their priority and moreover until now, there was little they could do about it anyway. Even if they recognized it as a problem that needed some intervention, it was not seen as such a huge priority as such.

That evening I was sitting with my brother Paul Kiwanuka Mukiibi, also a physician and consultant working in Uganda discussing what I'd seen that day. He told me when he'd first heard of the subject, he was mystified as to why there was any controversy, saying "This is just an issue of basic health care, the most basic things we as doctors do. How can people see this as controversial in anyway". Like me he was angry that the whole subject was being treated in what appeared such a dismissive way. Later we were joined by a former classmate of mine in medical school, who was now a Surgeon at Mulago Hospital in Uganda. We started discussing the issue, unsurprisingly he agreed with our views. He said "It is time we started looking at AIDS in a bigger way. This issue is a real problem especially in up country clinics where equipment is hard to come by." As an aside he complained that "Quite often when we go for conferences and presentations abroad, because we African's do not have such big entourages or as much visibility as our counterparts in the West, no one listens to us when we start talking about AIDS in a different way, to the way people outside view it." Both Paul and I agreed,

that this is indeed part of the problem, an African perspective of AIDS and what to do about it were not often given enough due consideration.

In the Tuesday, while taking a relative to the hospital, I also had the opportunity to visit Mulago hospital, where I trained as an Medical student and Intern and where ten years ago, we had complained of lack of facilities including access to gloves and needles. There was no evidence of any sterilizers in use which was very encouraging. I discussed the issue of re-use of needles with a consultant Dr Myers Lugemwa and he also agreed that despite the fact that it did not appear to be an issue in Mulago, did not mean it was not a problem elsewhere, especially the rural areas and these were the places where HIV was increasing most rapidly. He told me while working in Northern Uganda, he had seen needles and syringes soaked in buckets of "Jik" bleach for re-use later. He said "I have seen people just soaking needles in Jik , but there have been problems with Jik in the past which is not up to the required strength, and this means that the syringes won't even be sterilized at all!"

The following day, I visited a private clinic and here I saw disposable needles and what was possibly a sterilizer. I could not confirm whether it was also used in re-use of needles, but I counted it as a strong possibility. While discussing this with my brother, he reminded me that more than 50% of all spending on health in Uganda was in the private health sector. I also recalled how working as a junior house officer an a medical officer, quite often the patients that I saw at out patients had already visited a "musawo" who could have been anyone from a real doctor to nursing aide posing as a doctor. More often that not they had already received initial treatment that included an injection.

Auto-disable syringes and SHARPS box for safe disposal, Luwero, Uganda, July 2003

The most dramatic testimony concerning the hazards and dangers of re-use of needles came in my up country visit to the Luwero District Health HQ Centre which is about 50 miles from Kampala. I first met up with Dr. Joseph Okware, the District Director of Health for Luwero and explained to him the purpose of my trip, how I wanted to see have a tour and see another example of a health clinic in Uganda. I told him a little about what I had been doing in the US, how I had an opportunity to testify before the US Senate on an issue that concerned HIV/AIDS. He instantly grasped the importance of the subject and directed me to one of the Doctors on duty, Dr Umaru Ssekabira, who explained that the Luwero health centre was a referral centre (much like the Kakuto clinic in Rakai) designated a Health Centre 4. The health centre provided similar services including in-patient and out-patient services, maternity and ante-natal services, a disability clinic and orthopaedic workshop, an eye clinic and theatre services. We started off at the immunization centre where they had just concluded immunizing children as part of the UNEPI program. There were some syringes on the table which were quite clearly auto-disable syringes. Next to the immunization table was the PMTCT clinic which was adjoined to the maternity wing.

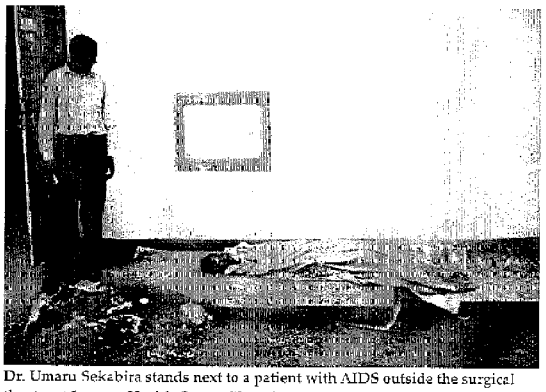
They were just signing up the first 10 people for the VCT/PMTCT counseling including the first couple. The program had in fact just started, training of the first few counselors had only concluded in June. As we went around the maternity clinic, we were joined by Sister Margaret Serunjoji the In Charge of the maternity ward. She explained there were 10 maternity beds, and one delivery bed.

ANC and immunization services were offered and they were soon going to add the VCT and PMTCT to the services.

I asked Sr. Serunjoji if there was a problem with the re-use of needles. She said in immunization there was no problem, except when they were running low on supplies. Dr. Ssekabira agreed saying "At the moment we are running low on supplies, we may have to resort to obsolete technology." But in general they used disposable needles which were disposed of in SHARPS boxes that were provided by the UNEPI program. Dr Ssekabira said "We are a happy that UNEPI agreed otherwise we would have had difficulties" I asked them if they used any similar technology in curative services. They said they had nothing, but if anything existed it would be very useful. I explained part of the purpose of my visit they become very interested that it was partly to see about providing auto-disable syringes and needles for curative services.

Sr. Serunjoji said "This is just what we need. Even though we do not re-use needles here because the supply is generally good, sometimes we run out. When that happened patients are forced to buy syringes. But the problem is even at 300 shs it was still too expensive for most villagers. So when a patient comes with their own syringe they will tell the doctor to give them their needle so they can go back and boil it and re-use it. They do not want to buy a syringe every time because it cost toomuch. "

I remarked "Isn't it particularly dangerous especially with the danger of HIV/AIDS in Uganda, isn't there the possibility of it being spread this way?"



Dr. Umaru Sekabira stands next to a patient with AIDS outside the surgical theatre at Luwero Health Centre, Uganda, July 2003

Dr. Ssekabira replied " This is a very real problem. It is even more urgent if one realizes that when the patient buys a needle sometimes they share one needle among their family, using it over and over again or may even share with their neighbours. Auto-disable syringes that were cheap enough and supplied in enough quantities would prevent this. This is not just an issue of health, but also of poverty."

I said "If that is the case, doesn't it make sense to do something about this? Why are we teaching and preaching to people about practicing safe sex and behavioural changes yet they can still get infected by this other route." Sr Serunjoji and Dr Ssekabira agreed saying "That is why if this technology exists we should use it"

I also attended the Uganda Bishops Council where they were taking landmark decisions on Adolescent and Youth Sexual and Reproductive Health. They were very excited to hear that I was testifying before the senate. All agreed that the issue of re-use of needles was very important. "We are sending you as our emissary to USA are trusting you to tell the Senators about us. Tell the Senators, we are also working very hard. We appreciate any and all help you can give us in our fight against HIV/AIDS"

You may notice that I have not talked about the issue of re-use in terms of the "controversy" about what proportion it has played in the spread of AIDS, be it 2.5%, 10% or 30%, because as far as I'm concerned there is no controversy. It is a question about providing safe healthcare to people who seek it, the most basic tenet of healthcare provision. Do no harm to the patient. It is not just an issue of protecting people from getting HIV which is very important, but also at protecting them from the risk of getting other blood borne diseases, such as hepatitis B and C or ebola.

However if you were to ask me to give an estimate or guestimate of how much unsafe healthcare has contributed in the spread of AIDS I'd have to give it in terms of my own personal experience because I know of no study in Uganda that has investigated this.

Graduating Class, Makerere Medical School, 1990 outside Mulago Hospital, Kampala (note Dr Kiwanuka Ssemakula in centre)

In my graduating class there were 120 students, I know of at least 12 or 13 of my colleagues who have since died of HIV/AIDS. The significance of this is that of those who died at least five were friends who in know way could be described as leading any sort of promiscuous lifestyle, there was at least one monogamous couple who had been together from high school, through medical school for years and tragically got AIDS. They most likely got it through exposure in medical settings. This would mean that at least 30% of those who have died got AIDS through routes other than sex.

And these were not the only ones, we would hear of students who had died of AIDS even though they had been very religious, not just Christians but Muslims also. And when these people died, it was always assumed that they had been lying and practicing unsafe sex which led to a lot of finger pointing and stigmatization. Another consequence was that it perversely encouraged some students to start practicing unsafe sex! Their reasoning was that if their colleagues who were leading a life of practicing safe sex and not indulging in wild behaviour were getting AIDS, why should one bother doing so, if there was a risk of getting it anyway, particularly in the healthcare conditions we were working doing our work in. This also led to some of my colleagues to abandon clinical medicine where there was a danger of exposure to hazards such as getting pricked by needles, getting splashed by blood for other safer branches of medicine. I recall getting accidental needle pricks on several occasions or getting splashed with blood when doing surgery, because our gloves and needles were so old, they leaked or were blunt through constant re-use.

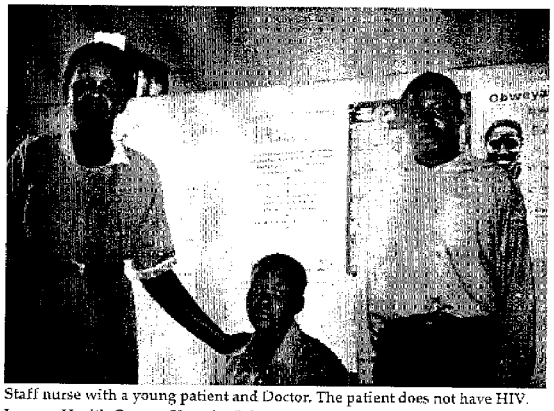
The issue of re-use of needles and syringes though important has not necessarily been given the as much concern as it deserves, because in recent years it has been sidelined by so many other issues. During my visit I asked several of my colleagues and the people I talked to, "Why is it, if you all agree this is an important subject is know one talking about it? Have you not heard of what is happening outside on this whole subject?" The reply was that "Often we don't have time to look into everything, it is hard enough just dealing with what we are already doing. But even if we wanted to talk about it,

if one asked for funding for a research project to investigate the issue, no one is interested. Especially foreign donors, they are just interested in sex and behavioral changes."

I was asked one curious question "Are people out there (in the US) open about AIDS, how do they compare to us Ugandans who have been so open about talking about this disease?"

I said "How do you mean open about AIDS, you mean discussing it on TV or in the news? I'm not sure what you mean?" The person replied "Well if they are so open as they claim to be, why aren't they telling us about such things? Why are they not telling us about these dangers so we can do something about them?"

There is no denying that unsafe sex is probably the major route for transmission of AIDS, but other routes such as re-use of needles and other unsafe healthcare practices are just as significant. The message of safe sex and behavioural changes to safe guard people is of paramount importance this is something the individual has control over. But they have no control over what happens in a hospital or a clinic, in this they put their trust in the doctor, nurse of clinical officer to provide the safest possible healthcare.



Staff nurse with a young patient and Doctor. The patient does not have HIV. Luwero Health Centre , Uganda, July 2003

Knowing this and the dangers of AIDS and other blood borne diseases, should we not then be striving to achieve this? I said it before and I say it again, how in all honesty can I stand in front of the people in rural health clinics, in villages to address them on practicing safe sex, when I know that I am not providing the highest standard of health possible. How can one in all sincerity argue against making the safest healthcare equipment available?

During my visit to Uganda I talked with a quite number of other people where the subject of the spread of HIV/AIDS through needles was discussed either specifically or generally. I was struck by the fact none of the people I talked to saw any controversy. No one jumped to the conclusion that providing safe health care by preventing re-use of needles would lead to more unsafe sex. It was not a case of choice of safe sex or safe health care, it was quite simply the people who have been and continue to be on the frontline of the fight against HIV/AIDS, who despite battling huge difficulties and odds have succeeded in doing tremendous work, simply asking for tools that will help in the fight. It is about the fight for the future and in this there is no controversy, whatever will help should be provided. Can anyone in all honesty give a reason why such help or assistance should not be rendered? If so let them come to these health clinics, look these health workers in the eye and say so.

PREPARED STATEMENT OF HOLLY BURKHALTER

Thank you, Mr. Chairman, for holding this important hearing. I am honored to be here. My name is Holly Burkhalter, and I am the Director of U.S. Policy for Physicians for Human Rights, a Boston-based human rights organization. Since forming our "Health Action AIDS" campaign two years ago, Physicians for Human Rights has engaged in extensive activities to mobilize the medical, nursing, and public health communities in the United States to confront the global HIV/AIDS pandemic. Our Health Action AIDS advisory board includes this country's leading specialists in HIV/AIDS prevention, care, and treatment, many of whom are engaged in overseas programs.

A particular focus of our work on the global HIV/AIDS pandemic is to promote "best practices" to prevent the transmission of the disease, as well as the right to care and treatment. Best medical practices in preventing transmission of AIDS include providing access to education, counseling, testing, and prevention supplies, especially for those in high-risk groups. It also includes protecting women and girls from violent transmission of AIDS through rape and sexual violence and enhancing their right to education, health care, and legal equality.

The topic of today's hearing—assuring that the disease is not transmitted in health care settings—is a "best practice" in preventing HIV/AIDS and other disease transmission that has been, for the most part, overlooked by the international AIDS establishment, by governments of AIDS-burdened countries, and by wealthy donor nations. Thanks to your interest, Chairman Sessions, and the pioneering work of such leaders as Yvan Hutin, who is with us at today's hearing, the issue is now being given the prominence that it deserves. It is our hope that these hearings will contribute to the United States becoming a leader in promoting safe health care and integrating injection safety, universal precautions, and a safe blood supply in all health programs.

It is important to note that the issue of preventing HIV/AIDS infections in health care settings has been identified by the United Nations. The June 2001 U.N. General Assembly Special Session on HIV/AIDS final document, the Declaration of Commitment on HIV/AIDS, called upon all countries to implement universal precautions in health-care settings to prevent transmission of HIV infection by 2003 and to implement a wide range of prevention programs by 2005, including sterile injecting equipment and safe blood supply.[1] Yet it is now the year 2003 and this year—and every year—at least half a million people will become infected with HIV/AIDS through unsafe medical injections and blood transfusions,[2] and approximately 8.0-20.6 million people will become infected with hepatitis B and 2.0-4.7 million with hepatitis C because of unsafe medical injections.[3] A report cited at a 2000 World Health Organization (WHO) meeting of directors of national blood transfusion services in Africa stated that only 13 of 46 countries in the WHO African Region had implemented national blood safety policies.[4] The financial, political, and technical

[1] See Declaration of Commitment on HIV/AIDS, United Nations General Assembly Special Session on HIV/AIDS (UNGASS), adopted June 27, 2001, at para. 51-52. Available at: http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html.

[2] See Anja M. Hauri, Gregory L. Armstrong & Yvan J. F. Hutin, "Contaminated injections in health care settings." In M. Ezzati et al. (editors) Comparative quantification of health risks: global and regional burden of disease attributable to selected major risk factors (Geneva: World Health Organization, 2003) (attributing 260,000 HIV infections in 2000 to unsafe medical injections); World Health Organization, Department of Blood Safety and Clinical Technology, Blood Safety Clinical Technology Progress 2000-2001, 2002, at 1. Available at: http://www.who.int/bct/Main—areas—of—work/Resource—Centre/General—docs/BCT%20Progress%20Report.pdf (estimating that 5-10% of new HIV infections are caused by unsafe blood transfusions). In 2002, there were 5 million new HIV infections. See UNAIDS, Estimated number of adults and children newly infected with HIV during 2002, Dec. 1, 2002. Available at: http://www.unaids.org/worldaidsday/2002/press/EpiCoreSlides2002/EPIcore—en/Slide5.GIF. Since 5% of 5 million equals 250,000, unsafe blood transfusions cause at least 250,000 new HIV infections every year. Therefore, at least half a million new HIV infections from unsafe blood transfusions (250,000) and unsafe medical injections (260,000) occur every year.

[3] See A. Kane et al., "Transmission of Hepatitis B, Hepatitis C and Human Immunodeficiency Viruses through Unsafe Injections in the Developing World: Model-Based Regional Estimates." Bulletin of the World Health Organization (1999) 77(10): 801-807, at 803 (estimating 8-16 million hepatitis B and 2.3-4.7 million hepatitis C infections every year from unsafe medical injections); Anja M. Hauri, Gregory L. Armstrong & Yvan J. F. Hutin, "The Global Burden of Disease Attributable to Contaminated Injections Given in Health Care Settings." International Journal of STD & AIDS (2003) (in press) (estimating 20.6 million hepatitis B and 2.0 million hepatitis C infections every year from unsafe medical injections).

[4] See J.B. Tapko, Workshop of the Directors of National Blood Transfusion Services, May 2-5, 2000, Harare, Zimbabwe, at 1. Available at: http://www.afro.who.int/bls/pdf/blsworkshop1.pdf.

support required for the development of safe health care in the developing world has not begun to keep pace with the commitments reflected in the UNGASS document.

Some AIDS experts have expressed reluctance at acknowledging the importance of unsafe injections, in particular, for fear that attention to this widespread problem in Africa and Asia will divert attention from safe sex education and condom promotion and dissemination. Interestingly, no WHO or UNAIDS official ever admonished rich countries for addressing the problem of iatrogenic HIV/AIDS transmission in health care settings, where even one such infection is cause for serious investigation and correction of the problem. This is the attitude that should be assumed towards iatrogenic HIV/AIDS infections in poor countries. Each case of an HIV infection in a young child whose mother is HIV negative, or in sero-discordant, monogamous couples should be the cause of concern and immediate investigation, and national governments, donors, and international development agencies should make the wholly preventable transmission of HIV/AIDS and other infectious disease through unsafe needles and blood and occupational injuries a top priority.

WHO's latest estimates indicate that 17-19% of injections in Africa are unsafe,[5] though other studies estimate higher levels of unsafe injections.[6] WHO's Regional Office for Africa reported in 2001 that about 25% of blood units transfused in sub-Saharan Africa are not screened for HIV, more than half of the units are not being screened for hepatitis B, and 81% are not being screened for hepatitis C.[7] Yet because of a lack of emphasis on the importance of assuring injection and universal precautions, it may well be the case that many poor governments are not aware that they have a problem. A review of nearly all of the proposals of the 90-plus countries that have received funding from the newly-formed Global Fund to Fight AIDS, Tuberculosis and Malaria, found only one—Ethiopia—requested funding for implementing universal precautions.

Poor countries, like their Western counterparts, are fully capable of absorbing a variety of prevention best practices and virtually eliminating iatrogenic transmission without diverting attention and resources from prevention of sexual transmission. In Burkina Faso, for example, single-use syringes were included on the country's essential medicines list and within five years, the proportion of non-sterile injections in health care settings plunged from 50% to 4%. In Senegal, experts were invited to develop a comprehensive safe injection system, and have done so without neglecting other aspects of HIV/AIDS prevention, including safe sex education and programs.

Addressing health care transmissions of HIV, besides preventing new infections, will help counter something nearly as deadly—discrimination against people living with HIV/AIDS. Doctors, nurses, and midwives who are at risk of needlestick injuries or who are delivering babies without gloves are afraid of patients with HIV/AIDS and sometimes refuse them health care. Alternatively, health care workers whose supply of gloves, masks, sterile needles, and other equipment is limited sometimes adhere to universal precautions only for those suspected of having HIV/AIDS or segregating them. Such measures, in the context of a disease that carries with it immense social stigma, contributes to discrimination against people with HIV/AIDS.

The United States can play a vital role in helping eradicate medical transmissions and discrimination in health care settings. This testimony includes detailed recommendations on many aspects of safe health care, including specific activities and infrastructure to fund. One of the most important things the U.S. Government can do, however, will be to raise the issue of safe health care within international agencies and insist that "best practices" to eliminate disease transmission to and from health care workers in the workplace, to assure injection safety and a clean blood supply, and promote public education to discourage unnecessary injections be included in prevention strategies and programs.

DISEASE TRANSMISSION IN HEALTH CARE SETTINGS

In countries with common unsterile conditions in health care, public and professional education and selected items and logistical support are required to establish

[5] See Anja M. Hauri, Gregory L. Armstrong & Yvan J. F. Hutin, "The Global Burden of Disease Attributable to Contaminated Injections Given in Health Care Settings." International Journal of STD & AIDS (2003) (in press).

[6] See L. Simonsen et al., "Unsafe Injections in the Developing World and Transmission of Bloodborne Pathogens: A Review." Bulletin of the World Health Organization (1999) 77(10): 789-800, at 792. Available at: http://www.who.int/bulletin/pdf/issue10/simonsen.pdf.

[7] See World Health Organization Regional Committee for Africa press release, Ensuring blood transfusion Safety in Africa, Aug. 27-Sept. 1, 2001. Available at: http://www.afro.who.int/press/2001/regionalcommittee/rc51004.html.

new standards of safety that will decisively stop transmission of HIV and other blood-borne pathogens in health care settings. The components of a comprehensive program are well understood and include infection control ensuring safe injections and other health care procedures, universal precautions to protect healthcare workers and their patients, and safe blood. Injection safety and blood safety are among the most cost-effective HIV prevention interventions.

The high proportion of unsafe and unnecessary injections in many developing countries, where as many as 70%-90% of injections are unnecessary, means that public education and health care worker training to ensure that injections are both safe and appropriate are crucial. A safe injection strategy should also ensure adequate supplies of new syringes through health facilities and pharmacies, and should include sharps waste management. A complete program for infection control requires attention to other health care procedures such as dental care and minor operations, where sterilization is crucial.

Universal precautions, simple infection control measures to protect health care workers and their patients, require both a consistent and sufficient supply of protective gear and adequate training.

Blood safety, which has already been achieved in at least several low-income countries, requires a national transfusion service, a system to recruit voluntary, unpaid donors, blood screening, and the appropriate use of blood transfusions.

Using the best available estimate from WHO, the annual global cost of a global injection safety program is $905 million ($45 million in WHO's African Region), decreasing significantly over time as fewer inappropriate injections are administered. Ministries of public health will contribute, and particularly in the private and informal sectors, some of the cost of increased injection safety will be borne by consumers aware of the importance of sterile care. Donors also have an important role to play, both because of the resources they can direct at the problem and through their leadership and technical expertise. Based on UNAIDS estimates, the incremental global cost of blood safety is about $200 million per year, and the incremental cost of implementing universal precautions in countries that have an HIV prevalence of more than 1% is about $600 million in 2004, increasing to about $1.1 billion in 2007.

ASSESSMENT AND PLANS FOR INJECTION SAFETY AND OTHER INFECTION CONTROL

A first step for any country where sterile health care practices may be spreading HIV and other blood-borne pathogens is to assess its own situation with respect to injection safety. The World Health Organization (WHO) has developed several survey guides—or tools—to assess injection safety. Perhaps the more important of the two generates nationally representative quantitative information on injection practices in health care facilities, and can be completed in about 3 weeks at a cost of $20,000. The other tool, which costs about $10,000 to use, provides a more qualitative analysis.[8] A health care waste management rapid assessment tool also exists.[9]

WHO does not have an equivalent tool for universal precautions and other aspects of infection control, though at least one country, Egypt, has developed several assessment tools. A proper assessment is important for developing sound policy. By highlighting the very fact that a problem exists, an assessment may also be crucial in generating political will to address the problem. Ethiopia, for example, has pioneered using the Global Fund to Fight AIDS, Tuberculosis and Malaria to support the implementation of universal precautions. Ethiopia drafted national guidelines on universal precautions and sought funding from the Global Fund to begin to implement the guidelines because a rapid assessment of injection practices found that 30% of injections were unsafe.[10]

While injection equipment security, health care provider training, and public education are all elements of a safe injection strategy, different countries have varying capacities in these areas, and therefore have different needs. There is no single ideal distribution of funds between these areas; a flexible approach is required. Countries should develop injection safety strategies and strategies to minimize other health care exposures to HIV and other blood-borne pathogens. WHO, through the Safe Injection Global Network (SIGN), has an excellent guide to helping countries formulate national injection safety strategies, including budgeting, in their booklet "Man-

[8] See World Health Organization, Managing an Injection Safety Policy (2003), at 7.

[9] See World Health Organization, Online documents on Health-care waste management, http://www.healthcarewaste.org/htmlpages/onlineDoc.html. Accessed July 27, 2003.

[10] See Ethiopia Country Coordinating Mechanism, The Global Fund proposal to reduce HIV/AIDS and malaria in Ethiopia, July 2002, at 30. Available at http://www.globalfundatm.org/proposals/round2/files/ethiopiahivuk.doc.

aging an Injection Safety Policy."[11] WHO has also developed draft guidelines on developing a national action plan on health care waste management.[12]

To help ensure that national policies on blood safety, universal precautions, and injection safety are implemented, countries should guarantee blood safety, universal precautions, and injection safety through their legal systems, whether through legislation or regulation. It is critical that sufficient resources be allocated to these areas if the legislation or regulation is to be successful. For example, Amit Sen Gupta, an Indian doctor, told us that India's rigorous blood safety legislation can have a negative impact of making blood unavailable in some areas. Clinics in many rural areas, without the resources to ensure safe blood as required by Indian law, often have no blood available for transfusions. To be successful, a blood policy must be designed so as to meet a country's need for blood transfusions—while minimizing that need through rational clinical use of blood transfusions—while ensuring that all blood that is transfused is screened for HIV and other blood-borne pathogens. And the policy must receive the resources required to succeed.

Recommended U.S. action: The United States should encourage countries to assess their injection safety situation, as well as that of other aspects of universal precautions. In advising countries on developing HIV/AIDS strategies, for example, U.S. agencies can encourage countries to conduct an injection safety assessment and, based on findings, to develop a safe injection strategy. If needed, the United States can provide funding for these assessments. Along with the value of assessments in forming policy, by revealing a lack of injection safety, they can motivate countries to address injection safety.[13] The United States, whether through its own initiative or as part of a World Health Organization (WHO) or other multilateral initiative, should develop, or help develop, an inexpensive and rapid assessment tool that countries can use to evaluate their situation with respect to universal precautions not addressed by the injection safety assessment guides. The Egyptian instruments could be a useful starting point. This tool should be made widely available.

The United States government can also provide technical assistance in helping countries develop laws and adequately budget programs on blood safety, universal precautions, and injection safety. A related and inexpensive undertaking that the United States could take through field offices of USAID, the CDC, and other relevant agencies that could ease national efforts to develop legislation and regulation on blood safety, universal precautions, and injection safety, as well as on numerous other AIDS-related legislation and regulations, would be to develop a database for these and other AIDS-related laws and regulations. No such central database now exists. Such a database, which should be easily accessible to the public, would be very useful in national efforts to develop critical legal tools to ensure sound and effective HIV/AIDS policy.

INJECTION EQUIPMENT SECURITY

Ensuring that sufficient quantities of safe injection equipment, including new single-use syringes, new needles, and safety disposal boxes, are consistently available at all points of injection is central to an injection safety strategy. In Burkina Faso, WHO attributes a rapid fall in the proportion of unsafe injections through the late 1990s—50% of injections were unsafe in 1995, down to 4% in 2000—primarily to increased availability of single-use syringes because they were included in Burkina Faso's essential drugs program.[14]

Certainly, behavior change response to the epidemic (the ABCs: Abstinence, Behavior change, and correct and consistent Condom use) varies by country. Decreasing number of partners (being faithful) is beginning to look like the most important factor in turning around the epidemic. USAID will soon be publishing a baseline ABC study in six countries showing some of the contrasting behaviors.

---

[11] WHO, Managing an Injection Safety Policy (2003).

[12] See World Health Organization, Online documents on Health-care waste management, http://www.healthcarewaste.org/htmlpages/onlineDoc.html. Accessed July 27, 2003.

[13] Ethiopia, the only country that we are aware of to have included injection safety in a proposal to the Global Fund to Fight AIDS, Tuberculosis and Malaria, had conducted an injection safety assessment in 2000. The assessment revealed a 30% syringe re-use rate, a likely motivator for policymakers to include universal precautions, including injection safety, in the country's second round application to the Global Fund.

[14] See Safe Injection Global Network (SIGN), Annual Meeting Report, 30-31 August 2002, 2001, of HIV with not being circumcised. Circumcision varies geographically and by tribal group in Africa and is a possible contributing factor to the differences in the growth of the epidemic. Western Africa has very high rates of male circumcision and southern Africa variable but generally low rates of circumcision. Differing sexual practices may also contribute or strains of HIV may be contributing factors.

Conclusion

In conclusion, I would like to emphasize that USAID is committed to HIV/AIDS prevention. We will continue to ensure that risky medical practices, risky sexual behaviors, and mother to child transmission are all addressed as part of the overall response to the HIV/AIDS pandemic. We look forward to being a key partner in implementing the President's Emergency Plan for AIDS Relief and continuing to achieve results in HIV/AIDS prevention, care, treatment, and support.

I believe very firmly that it will be impossible to do the prevention of mother-to-child transmission and treatment envisioned in the President's initiative without systems strengthening that will improve delivery care, drug and commodity logistics, and clinical protocols. All these improvements will directly impact and reduce HIV transmission in medical settings.Thank you again for inviting me to speak on this important topic.

PREPARED STATEMENT OF JOHN STOVER

Thank you for the opportunity to be here today to address the important issue of confronting the global HIV/AIDS epidemic. I will focus my remarks on the goals we have set for ourselves, what needs to be done to achieve those goals, and the cost of implementing these programs.

Goals

Much of the work that my colleagues and I have done in the past couple of years has focused on estimating what needs to be done to achieve the goals we all have set for ourselves. The Declaration of Commitment of the UN General Assembly Special Session on AIDS calls for a 25 percent reduction in infection levels among young people in the next few years. WHO has set a goal of having 3 million HIV-infected people on ARV (anti-retroviral therapy) by 2005. The President's Emergency Plan for AIDS Relief aims to prevent 7 million new infections, treat 2 million HIV-infected people and care for 10 million infected people and orphans in 14 priority countries.

How Will We Achieve These Goals? What Needs To Be Done now and how Much Will it Cost?

We do have a good idea of what needs to be done to achieve the care and treatment goals. We need to expand access to health care, provide more training for health care providers and expand supplies of drugs and equipment.

We also have a good idea of what needs to be done to prevent new infections. It is clear that no single intervention will be enough, but a comprehensive approach that reaches people with different risks with a variety of information and services can be effective. A comprehensive approach includes mobilization of communities and civil society, behavior change interventions, service delivery (such as treatment for sexually transmitted infections, condoms and voluntary counseling and testing), medical precautions, care and treatment, and mitigation of the impact of AIDS on orphans and other vulnerable children.

We have done a country-by-country analysis for 135 low and middle-income countries to look at the prospects for the future. Our analysis indicates that if current trends continue there will be about 45 million new HIV infections between 2002 and 2010. You can see that figure in the first bar of the chart, labeled "Baseline." The majority of these new infections will be in sub-Saharan Africa, where HIV prevalence levels are the highest, and in South and South-East Asia, where populations are large and the epidemic is growing rapidly.

But these projections are not inevitable. Our estimates indicate that the implementation of a comprehensive prevention package in these countries by 2005 would reduce the total number of new infections by 29 million, averting about ⅔ of the infections that would otherwise occur. As shown in the second bar in the chart, labeled "Expanded Response," the benefits will be large in sub-Saharan Africa where almost 60 percent of projected new infections can be averted. Note that the gains could be even larger in Asia, where early action will be especially effective.

Effects of delay

It is important to expand our prevention efforts as rapidly as possible. Delayed implementation will lead to large reductions in the benefits. Just a 3-year delay in achieving full implementation of this program would reduce the total number of new infections averted by 2010 by 50 percent.

What Do We Need To Do To Achieve This Result?

These results can be achieved by expanding the coverage of HIV/AIDS services. In our estimates we assumed that full coverage would be achieved in high preva-

lence countries for programs such as mass media, AIDS education, treatment of sexually transmitted infections, voluntary counseling and testing, safe blood and safe injections. Coverage of 50–60 percent was assumed for services such as condoms, workplace interventions, out-of-school youth and prevention of mother-to-child transmission of HIV.

Achieving this result will require a large effort. Currently the coverage of key services is very low in most countries. We estimate that fewer than 20 percent have access to basic prevention services. In Africa the figures are even lower:

- Only 1 percent have access to anti-retroviral therapy.
- Only 1 percent have access to "Prevention of mother to child transmission" programs.
- Only 6 percent have access to voluntary counseling and testing.
- 70 percent do not receive even the basic level of care as defined by the World Health Organization.

What Will It Cost?

The second chart shows you our estimate of the total resource required to achieve these goals between now and 2007 by year and by program. This represents resources from all sources: national governments, individuals and households, bi-lateral and multi-lateral donors, foundations and the Global Fund.

From the chart you can see the range of programs considered and the relative funding required by each.

The resources required will increase from about $6 billion today to $10 billion by 2005 and $15 billion by 2007. For Africa the resources required will double from $2.6 billion today to $5.5 billion by 2007. For the 14 countries of the Presidential Initiative, requirements will double from just under $2 billion in 2003 to $4 billion by 2007.

The largest amount will be required for anti-retroviral therapy and treatment of opportunistic infections. Support for orphans and vulnerable children will also require significant funding. In prevention, the greatest funding needs are for programs for youth, voluntary counseling and testing, condoms and workplace programs. About 4 percent is required for safe injections and universal precautions.

Through 2005 about half of the resources are needed for prevention and half for care and treatment. After that, the share required for treatment increases as more people are maintained on ARVs. Eventually the share for care and treatment will decrease as the prevention efforts reduce the number of new infections.

Globally, this level of spending by 2005 would provide prevention services for over 270 million people in low- and middle-income countries and would provide needed care and treatment for an additional 13 million.

How Much Is Currently Available?

We do not know exactly how much funding is currently available for HIV/AIDS programs in these countries. But our best estimate is that of the $6 billion needed today, about $4 billion is actually available. This includes about $2.6 billion from bi-lateral and multi-lateral international donors, $0.5 billion from national governments and nearly $1 billion from household and employer-financed spending. Thus there is currently a gap of nearly $2 billion dollars that will only grow larger in the next few years unless we can mobilize significant new resources.

How Much Funding Should the U.S. Provide?

Various estimates of the "fair share" the United States should contribute to the global need can be developed depending on assumptions about how much developing countries can and should pay themselves and how the international contribution is allocated. Our calculations suggest that the U.S. share should range somewhere between 25–35 percent of the total. This translates into $2.0–2.8 billion today and $3.7–5.2 billion in 2005.

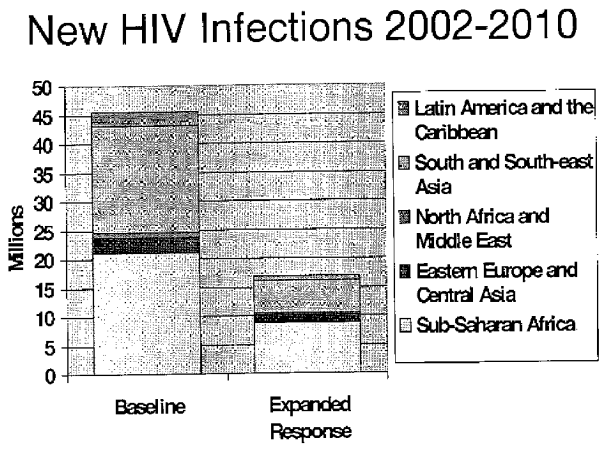
The Cost of Doing Nothing

We recognize that the full implementation of this expanded response presents many challenges. Human capacity to deliver the required interventions needs to be scaled up greatly and improved infrastructure will need to be developed to meet the demand of expanded services. Meeting these challenges will require both financial and political commitment.

The costs of scaling up programs as indicated here are large. However, without this effort we will not achieve our goals of rolling back the AIDS pandemic. The costs of doing nothing are even higher.

Thank you for you attention.

But these projections are not inevitable. Our estimates indicate that the implementation of a comprehensive prevention package in these countries by 2005 would reduce the total number of new infections by 29 million, averting about two-thirds of the infections that would otherwise occur. As shown in the second bar in the chart, labeled "Expanded Response," the benefits will be large in sub-Saharan Africa where almost 60% of projected new infections can be averted. Note that the gains could be even larger in Asia, where early action will be especially effective.



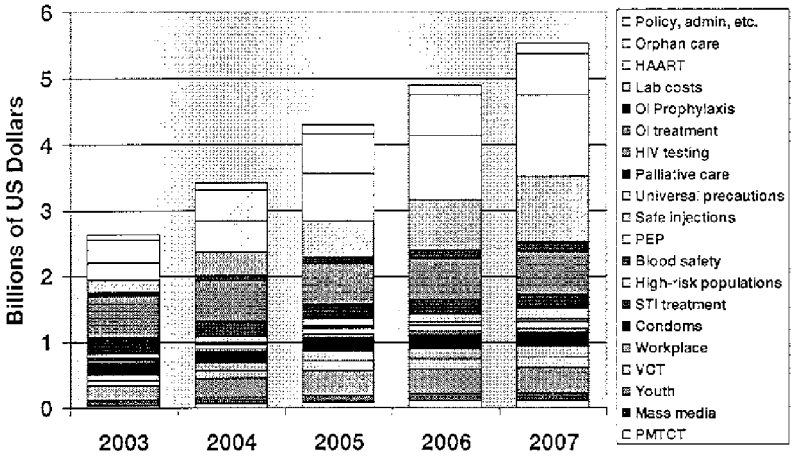
Effects of delay

It is important to expand our prevention efforts as rapidly as possible. Delayed implementation will lead to large reductions in the benefits. Just a three year delay in achieving full implementation of this program would reduce the total number of new infections averted by 2010 by 50%.

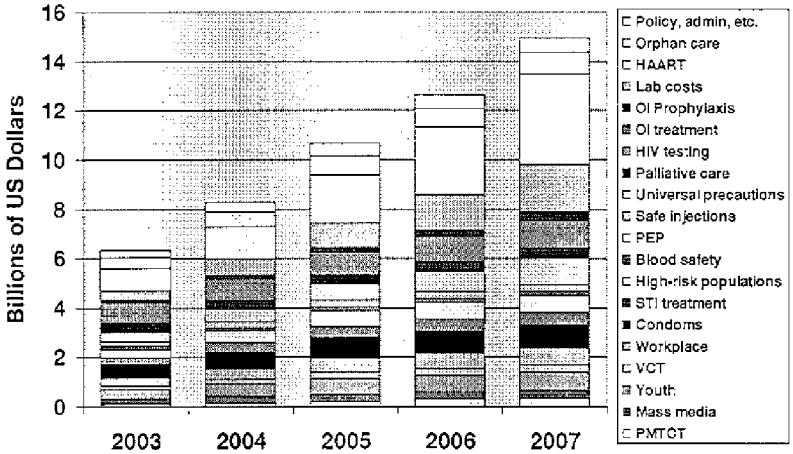
What do we need to do to achieve this result?

These results can be achieved by expanding the coverage of HIV/AIDS services. In our estimates we assumed that full coverage would be achieved in high prevalence countries for programs such as mass media, AIDS education, treatment of sexually transmitted infections, voluntary counseling and testing, safe blood and safe injections. Coverage of 50-60% was assumed for services such as condoms, workplace interventions, out-of-school youth and prevention of mother-to-child transmission of HIV.

Resources Required in Sub-Saharan Africa for HIV/AIDS Prevention, Care and Mitigation



Resources Required in Developing Countries for HIV/AIDS Prevention, Care and Mitigation



[Whereupon, at 1:19 p.m., the committee was adjourned.]

○