

AIDS Crisis in Africa: Health Care Transmissions

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Testimony:

Mr. Chairman and Members of the Committee, I am Claude A. Allen, Deputy Secretary of the

U. S. Department of Health and Human Services. I am pleased to be here today to provide an overview of the Department of Health and Human Services' activities to combat the global spread of HIV/AIDS, Tuberculosis (TB), and Malaria. I bring greetings from Secretary Thompson, and his thanks, as well, for your tireless efforts to address these worldwide pandemics.

At the outset, I would like to acknowledge that we, at HHS, are in your debt, Mr. Chairman, and in the debt of your colleagues on this Committee, and others in this Chamber, for your support of prevention, care, and treatment of these diseases. The leadership of this Committee has been crucial to the U.S. Government's response to these devastating diseases, and will continue to be, as Congress and the Administration work together to support the Global Fund for AIDS, TB and Malaria, implement the President's Emergency Plan for AIDS Relief, announced in the State of the Union address in January, and implement his international Mother and Child HIV Prevention Initiative, announced last summer. The broad bipartisan support that these initiatives enjoy – as well as the strong public support – speaks to their vital importance. I look forward to continuing to work with each of you to make them reality.

The United States has a long history of assisting other countries in need. And I am pleased to report that the Department of Health and Human Services is continuing that humanitarian tradition in a variety of ways, but most particularly in helping developing countries address the devastation caused by AIDS, TB and malaria.

From Tanzania to Vietnam to Haiti, HHS employees are on the ground, working with Ministries of Health, nongovernmental organizations (NGO), faith-based groups, and – equally important – with other U.S. government entities, such as the Department of State and the U.S. Agency for International Development (USAID), to develop country-specific solutions to the ravages of AIDS. Together with USAID, we are working with 16 countries and with international organizations such as the World Health Organization (WHO) to address TB – which infects nearly eight million persons per year. Worldwide, TB kills two million people each year and is the leading cause of death for one-third of persons infected with HIV, causing fully one-third of all AIDS deaths. Further, we work with the WHO and other partners to address malaria, which kills an estimated one million children in the developing world each year.

Today, I will provide you with an overview of HHS activities and, I hope, reinforce your long-standing, demonstrated commitment to U.S. support in this essential endeavor.

Three HHS operating divisions are most actively involved in fighting AIDS, TB, and

malaria worldwide. The National Institutes of Health (NIH) has a strong portfolio of basic research in the areas of HIV and TB, including vital efforts to develop a vaccine to prevent HIV infection and new treatment technologies and strategies. NIH also trains U.S. and foreign scientists as a critical part of its mission. The Centers for Disease Control and Prevention (CDC) has engaged in international applied AIDS research and programmatic efforts since the beginning of the pandemic and supports bilateral and multilateral efforts to address TB and malaria. And the Health Resources and Services Administration (HRSA), through a cooperative agreement with CDC, works to train health care workers internationally to care for people living with HIV and AIDS. While there is not time today to go over all that we do to address HIV, TB and malaria, permit me to briefly illustrate how, at HHS, the pieces fit together into a strategic plan to combat AIDS around the globe.

Research on AIDS

Guiding principles for the National Institutes of Health's global research are to:

1. Target research efforts to develop prevention and therapeutic strategies adapted for the unique needs of developing countries;
2. Develop multidisciplinary research programs on AIDS, TB, and malaria;
3. Build and sustain research capacity in developing countries;
4. Stimulate scientific collaboration and global, multi-sectorial partnerships; and
5. Work with scientists in countries hardest hit to develop training, communication, and outreach programs.

The United States has been the world's leader in research and practical assistance to battle HIV/AIDS, and NIH's budget confirms that commitment. In fiscal year 2003, NIH will devote over \$2.7 billion to AIDS research, with over \$250 million to be spent on AIDS research and training efforts abroad.

To conduct clinical research on vaccines for HIV/AIDS, the NIH supports the HIV Vaccine Trials Network – or HVTN – a network of 16 domestic and 13 international sites. Directly and through collaborations with investigators, mostly university-based, the HVTN also supports laboratory research worldwide to ensure that vaccines are efficacious against a variety of HIV strains found in different parts of the world. The HVTN currently is conducting a phase II clinical trial in Haiti, Brazil, and Trinidad/Tobago. NIH is working with the CDC in several countries to identify cohorts of populations at risk for HIV infection and build the infrastructure necessary to conduct large-scale efficacy trials of potential vaccine candidates worldwide when they become available.

NIH supports a growing portfolio of university-based biomedical and behavioral research for the discovery, development, preclinical testing, and clinical evaluation of interventions to prevent HIV transmission, slow disease progression, and limit disease mortality. NIH-sponsored programs target studies in Africa, Asia, Latin America and the Caribbean on factors related to HIV transmission and the mechanisms associated with HIV disease progression. The HIV Prevention Trials Network – or HPTN – is a worldwide collaborative network designed to conduct research in 16 international and nine domestic sites on promising and innovative biomedical/behavioral strategies for the prevention or reduction of HIV transmission among at-risk adult and infant populations.

A critical element of NIH's research portfolio is efforts to strengthen – or create – the research infrastructure of developing countries as well as the capacity of in-country investigators to conduct clinical trials of therapeutic and preventive therapies. These therapies include treatment for opportunistic infections, such as TB, which kills a third of those infected with HIV, AIDS vaccines, microbicides, and interventions to prevent mother-to-child transmission.

Capacity-building for international research is a critical issue in all the countries where NIH funds research activities. NIH focuses its efforts in three essential areas:

- **Training Research Scientists** – It is critical to the success of international studies that foreign scientists be full and equal partners in the design and conduct of collaborative studies. To help build capacity in developing countries, NIH, through the Fogarty International Center, funds the AIDS International Training and Research Program (AITRP). The AITRP provides research training to foreign scientists through grants to U.S. universities. The program has provided training in the U.S. for scientists from developing countries in Africa, Asia, Latin America and the Caribbean, 85 percent of whom return home, and training courses have been conducted in 60 countries. Over 200 senior investigators and health officials in Africa have been trained through the AITRP, and thousands at more junior levels. With 85% of trainees returning home, the AITRP is a model of capacity building. It is no wonder that Dr. Salim Abdool-Karim, Deputy Vice Chancellor for Research and Development at the University of Natal in South Africa, and Principal Investigator of a highly successful Fogarty AITRP grant has described this program as the pre-eminent model of capacity-building for developing countries.
- **Laboratory Capacity** – NIH-supported HIV-related research helps to build laboratory capacity in developing countries, where the research is conducted, through purchase of laboratory equipment and transfer of research technology.
- **Comprehensive International Program of Research on AIDS (CIPRA)** – NIH has launched CIPRA to provide long-term support to developing countries to plan and implement a comprehensive HIV/AIDS prevention and treatment research agenda relevant to their populations, and to enhance the infrastructure necessary to conduct such research. Through this initiative, funding will be provided directly to foreign institutions for HIV research that is relevant to the host country.

A safe and effective HIV preventive vaccine is essential to controlling the AIDS pandemic. But, while we have made tremendous progress in vaccine development, the deployment of a vaccine is likely years away. Other biomedical interventions, such as microbicides, are likewise not yet proven or ready for widespread use.

In the interim, the world's best – and only – hope for controlling the epidemic is through sound prevention programs. And care and treatment programs are essential to helping the millions already infected to diminish the likelihood of infecting their partners, furthering the aims of prevention and helping to keep productive workers and citizens alive.

I will now discuss some of the prevention, care, and treatment work HHS staff are performing in countries hardest hit by this terrible disease. HHS scientists, public health experts, and specialists in AIDS care and treatment form a critical component of the U.S. Government's inter-agency response to the international HIV/AIDS pandemic.

Prevention, Care and Treatment

Through the HHS Global AIDS Program, CDC works directly with 25 countries in Africa, Asia, Latin America, and the Caribbean to prevent new infections, provide care and treatment to those already infected and develop the capacity and infrastructure needed to support these programs. We calculate that these 25 countries account for more than 90 percent of the world's AIDS burden, based on prevalence estimates released at the end of last year by the WHO and UNAIDS. Targeting our resources to those countries most in need makes sense, and allows us to achieve the greatest results for our modest investment. For this fiscal year, the budget for the Global AIDS Program is \$143 million, plus \$40 million directed by Congress to the President's international Mother and Child HIV Prevention Initiative, jointly implemented by HHS and USAID. In addition, CDC supports approximately \$11 million in applied prevention research to support these programs.

CDC's highly trained physicians, epidemiologists – who have special training in the causes, distribution and control of disease in populations – virologists and other laboratory scientists, and public health advisors – who are experts in the science and practice of protecting and improving the health of a community through a variety of measures, including preventive medicine, health education, disease control, refugee health, and sanitation, for example – are providing technical assistance to host-country governments and others working to prevent and control HIV/AIDS.

CDC staff is often located directly in host-country Ministries of Health or their affiliated National AIDS Control Programs. Working in close proximity with public health and medical colleagues for both government and non-governmental organizations allows CDC experts to enhance their services to host-country programs. They are also co-located with USAID colleagues, promoting complementary programming between the two agencies.

In addition to CDC employees, the HHS Global AIDS Program currently has nearly 400 locally employed staff, who serve in a range of capacities, from research scientists, laboratory technicians, nurses, and midwives to computer specialists, statisticians, sociologists, and support staff. One of the primary goals of the HHS Global AIDS Program is to develop in-country capacity to address HIV/AIDS. Local staff are employed to form a national cadre of trained professionals who can share their knowledge with others, developing an ever-growing cadre of trained personnel.

The Global AIDS Program was first funded in fiscal year 2000. It builds on HHS's long and successful history of global initiatives to promote health, in areas such as immunization. For example, in Thailand, CDC staff worked with the Thai government to develop a national mother-to-child HIV prevention program, the first of its kind in the developing world. As a result of this effort, testing has been implemented in all public hospitals and it is estimated that perinatal transmission has been reduced to less than 10 percent preventing more than 1,000 HIV infections in children each year.

All of this work now forms the foundation for HHS support for and involvement in the President's Emergency Plan, which is focused on 14 of the hardest-hit nations, accounting for 50 percent of all HIV infections. This five-year plan is expected to prevent seven million new infections - 60 percent of the projected new infections in the targeted

countries. Two million HIV-infected people will be treated with anti-retrovirals, and care will be provided to 10 million HIV-infected individuals and AIDS orphans. Implementation will be based on a “network model” being employed in countries such as Uganda: a layered network of central medical centers that support satellite centers and mobile units, with varying levels of medical expertise as treatment moves from urban areas to rural communities. The model will employ uniform prevention, care, and treatment protocols and prepared medication packs for ease of drug administration. It will build directly on clinics, sites, and programs established through USAID, HHS, non-governmental organizations, faith-based groups, and willing host governments.

Let me emphasize that all persons who receive HIV diagnostic testing through the President’s Emergency Plan for AIDS Relief and who meet the medical criteria for anti-retroviral therapy will receive it.

Now, let me explain how we derived that goal of putting two million people on anti-retrovirals, which some people have tried to claim is too small, given the more than 20 million people estimated to be HIV-positive in our 14 target countries. First, let us remember that the World Health Organization endorsed a world-wide target to put three million people on anti-retrovirals by 2005.

Second, our goal is based on field experience and research. The President’s Plan projects that 50 percent of patients who are HIV-infected in the 14 countries will enter voluntary counseling and testing programs during the five years of the program, an optimistic projection, but one supported by data from Brazil and here in the U.S. So, approximately 10 million of the 20 million HIV-infected persons in our 14 target countries will be diagnosed with HIV-infection and receive counseling. All of these persons will receive appropriate medical care through the Emergency Plan.

Most important, according to medical criteria and international guidelines, an estimated 20 percent of HIV-infected persons in resource-limited settings at any one time require anti-retroviral therapy. Twenty percent of 20 million infected would be four million, but remember that we estimate that only half of the infected population will come in to receive testing to find out their status and receive medical attention. Therefore, approximately two million of the 10 million persons who are diagnosed with HIV infection in our 14 countries will require anti-retroviral therapy during the five years of the program.

Because those with advanced disease who are very sick are most likely to come in for care through the plan, it is possible our partners in the Plan will treat more than two million people with anti-retroviral therapy; if more than two million people require such therapy, the Emergency Plan will provide it. If this scenario were to occur, economies of scale should allow for a reduction in the price of anti-retroviral medications and certain laboratory tests to keep the Plan within the budget the President has requested.

Although the President’s Emergency Relief Plan will not begin until next fiscal year, the first stage of this unprecedented effort is his Mother and Child HIV Prevention Initiative, which has already begun in the same 14 countries and is jointly implemented by HHS and USAID. HHS and USAID staff have worked with host governments and NGO’s to develop preliminary country-specific plans of action that will target one million HIV-infected women annually within 5 years or less, provide them with HIV counseling and

voluntary testing, essential prenatal care and support services and – most importantly – with the life-saving drugs that will help their babies be born free of HIV infection. We expect that this initiative will reduce mother-to-child HIV transmission by 40 percent among the women treated. A second goal of the initiative is to improve health care systems to provide care and treatment not only to mothers and babies, but to fathers, other children, and the broader community as well. Strengthening health care systems is essential to the success of the President’s broader Emergency Relief Plan.

HRSA is lending its strength to this initiative through the training of health care providers and the facilitation of partnerships between U.S. hospitals and clinics and their counterparts in the 14 countries (“twinning”). HRSA also supports broader HIV/AIDS international training initiatives through a cooperative agreement with CDC.

The President’s Emergency Plan also increased our pledge to the Global Fund to Fight AIDS, Tuberculosis and Malaria to \$1.65 billion, 50 percent of the total \$3.36 billion pledged to date. Our fiscal year 2003 commitment alone accounts for 45 percent of all resources available to the Fund this year (\$350 million of a total \$780 million pledged or in the bank), and the U.S. is responsible for 37 percent of the Fund’s cash on hand. With the exception of Germany and Ireland, major donor countries have not increased their initial pledges, which in most cases extend over several years. Secretary Thompson, who was elected to serve a one year term as Board Chair during the last Global Fund Board meeting in January, is committed to mobilizing additional resources from both donor nations and the private sector. The U.S. supported strongly the creation of the Global Fund and continues to support its efforts through technical assistance to partnerships as they develop proposals for the Fund and helping to implement and monitor Global Fund financed programs.

For too long, people in the developing world have seen a diagnosis of HIV infection as a death sentence. And it has been. But with the promise of care and treatment, for the first time, learning your HIV status can be seen as a stepping stone to needed care. An HIV test will be the gateway to services. For those who are infected, they will be able to receive treatment – and essential prevention and support services to keep from transmitting the virus to others. For those who are not infected, they can receive vital prevention services to learn how to remain HIV-free, emphasizing the ABCs of HIV prevention. “A” is for abstinence in young people, “B” is for being faithful within a relationship, and “C” for condom use in high risk populations with the knowledge that condoms are not as effective in preventing all sexually transmitted diseases as they are with HIV. I have traveled to Uganda, and I have seen that ABC is working. Uganda is the only country in Africa with an increasing life expectancy. The ABC prevention concept is something that we should seriously examine in our own country.

All this is possible because of the hope of care and treatment. We at HHS, in partnership with USAID and other organizations, are making good on this promise. We are providing the essential training, technical assistance and financial support to governments and scientific institutions around the globe to help them help their people. None of this would be possible without the continued support of members of this Committee and your colleagues in the House and Senate.

HIV Transmission through Unsafe Medical Practices

As the focus of today's hearing, I will now briefly speak about recent reports that unsafe medical practices, including unsafe injections, are responsible for a more significant percentage of HIV infection in Africa than previously thought.

A clear understanding of the modes of HIV transmission will contribute to achieving our goal of turning the tide of this epidemic. We at HHS are committed to exploring all avenues of inquiry that may hasten the achievement of that goal. We acknowledge, and have acknowledged publicly, the contribution of unsafe medical practices to HIV in resource-limited settings. HHS, through CDC, has been a major proponent of the need for safe blood practices and provides technical assistance in this regard throughout the world. However, it is important to acknowledge that the contribution of such practices to HIV infection in resource-limited settings is unknown. There are a few key points regarding the recent publication in this regard.

First, the publication was not a study, it did not perform primary research and did not perform actual surveillance. Rather, the authors reviewed previously published data and came to conclusions different from the authors of those studies, and of the global scientific community in general.

Second, I should note that the vast majority of scientists, and we at HHS, accept the premise that the contribution of unsafe injection and medical practices discussed in the paper does require further evaluation. However, the preponderance of experts reviewing the same data have concluded that the author's estimate that medical practices are responsible for 20 to 40 percent of infections in Africa is likely a significant overestimate.

Finally, however high the percentage of infections in Africa contributed by unsafe injections and medical practices really is, I want to assure you that the President's Emergency Plan for AIDS Relief in Africa and the Caribbean has a component to reduce transmission from unsafe injections and medical practices. Each and every infection with a dirty needle is wholly preventable and should be prevented. Under the President's initiative, prevention activities will be directed at all modes of transmission, including improving safe blood supplies, and the Emergency Plan will have the flexibility to adjust resource allocation based on scientific data as it becomes available.

In addition, the Emergency Plan will enhance the medical capacity and infrastructure in the countries participating in the program; these activities in and of themselves should have a "spill-over" effect to promote safer medical practices. Finally, it is important to note that the Emergency Plan is committed to providing medical care and treatment, including anti-retroviral therapy, for those who are infected with HIV regardless of how they acquired the virus. However a person obtained HIV, the President's bold and compassionate Plan will provide the necessary care and treatment.

An important target of HHS HIV prevention activities is to prevent the infection of children. Although the contribution of unsafe medical practices to the infection of children has not been fully quantified, there is no question that transmission of HIV from mothers to their infants is the most significant cause of infection among children. For this reason, the Congress has supported the President's Initiative to prevent vertical

transmission of HIV. As noted above, this Initiative hopes to prevent 40% of HIV infections from mothers to their infants. However, one of the most effective ways to prevent a mother from infecting her infant, and to protect the child from becoming an orphan, is to prevent the mother from becoming infected in the first place. The President's Emergency Plan provides broad prevention activities that have had great success in reducing infections of mothers in Uganda, Senegal, Brazil, and Thailand. It is important that we continue to support these proven strategies.

Global Control of TB and Malaria

Thus far, I have focused on HIV and AIDS in this testimony. Let me now make a few comments regarding HHS's contributions to the global control of tuberculosis and malaria. HHS's approaches to both TB and malaria are similar to that of HIV/AIDS, but are more limited in terms of scope and resources.

Both NIH and CDC work to address TB. TB is a global emergency and a leading infectious killer of young adults worldwide. Approximately one-third of the world's population is infected with the bacterium that causes TB and 80 percent of active TB cases originate in 22 high-burden countries. As I noted earlier, TB accounts for one-third of deaths among persons with AIDS. Basic research on TB, including research on a vaccine, is conducted at NIH. CDC supports applied research, including operational research to improve programs and clinical research to evaluate new drugs and diagnostics, and program implementation.

In addition to addressing HIV and TB coinfection through the Global AIDS Program, CDC works closely with USAID, international organizations, and 16 countries around the globe to control TB. International partners include the WHO and the International Union Against TB and Lung Diseases (IUATLD). Collaborative efforts include the Stop TB Partnership, technical support to USAID, and technical assistance to specific countries. Technical assistance is focused on countries that contribute most to U.S. cases, are high burden countries, have high rates of multi-drug resistant TB (MDR-TB), are of strategic importance (e.g. countries participating in the HHS Global AIDS Program), or provide opportunities to improve diagnosis and treatment of TB, MDR-TB, and HIV-associated TB.

Spearheaded by the WHO and its international partners, including HHS, a proven effective national case management strategy has been applied increasingly in developing nations. This strategy is termed DOTS—Directly Observed Therapy, Short-Course—which emphasizes consistent drug supply, microscopic based diagnosis, and direct observation of each dose of life saving medication. The World Bank has ranked DOTS as one of the most cost-effective of all health interventions. CDC works with WHO and other partners to expand the current DOTS strategy so that people with TB have access to effective diagnosis and treatment, and to adapt this strategy to meet the challenges of HIV and multi-drug resistance.

CDC and NIH are also involved actively in research on global malaria prevention and control. NIH is engaged in research both domestically and globally with a focus on malaria vaccine development and optimal use of the information on newly characterized malaria genome and the mosquito vector genome. CDC continues to work on U.S. domestic prevention and monitoring and on global collaborations with Ministries of

Health, U.S. universities and schools of public health, and non-governmental and faith-based organizations in the prevention and control of malaria in malaria-endemic settings – mostly in sub-Saharan Africa. In fact, much of the HHS global work on malaria is in the same setting where HIV prevention work is underway.

The HHS effort in malaria is widely collaborative with the Department of State, USAID and the Department of Defense. The U.S. leadership in the Global Fund to Fight AIDS, TB, and Malaria has been especially well-received in the malaria community.

Currently available control strategies for malaria have proven to be highly effective in saving lives. Effective antimalarial treatment exists that cures infection and disease. Effective prevention exists, as evidenced by the 20 percent reduction in child mortality with the use of insecticide-treated bed nets in Africa. Use of insecticide treated bed nets and preventive treatment can alter the impact of malaria dramatically in pregnant women and their newborns, improving newborn birth weight and reducing anemia in the mother and the newborn, and saving lives.

Finally, as with TB, malaria must also be seen in the context of HIV and AIDS prevention and control. Recent studies have shown that malaria and HIV interact broadly. Malaria causes anemia and the needed blood transfusions can be a source of HIV transmission. HIV-infected pregnant women contract the disease disproportionately and exhibit more severe complications, conferring a greater risk to the developing fetus and the newborn. Most recently, studies suggest that malaria is more severe in HIV-infected adults and that malaria may stimulate HIV viral replication, with potentially greater increased risk for HIV transmission. The widespread co-existence of malaria and HIV in Africa likely means that each is making the other worse and that addressing both is a good policy.

I thank you again, and welcome any questions you have for me.