

Full Committee Hearing Notice - Solutions to the problem of Health Care Transmission of HIV/AIDS in Africa

Bill Number: Oversight

Hearing Date: July 31, 2003 - 10:00 AM

Witness:

Holly Burkhalter

Physicians for Human Rights

Testimony:

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. 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, 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. 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. The financial, political, and technical 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, though other studies estimate higher levels of unsafe injections. 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. 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 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. A health care waste management rapid assessment tool also exists.

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.

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 “Managing an Injection Safety Policy.” WHO has also developed draft guidelines on developing a national action plan on health care waste management.

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. 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.

Key elements of injection equipment security require health systems to purchase enough equipment to meet injection needs and to have an effective distribution and logistical system to distribute that equipment in a consistent manner. The distribution system is needed to ensure that adequate quantities of the equipment are consistently available at all health facilities and other locations where injections are given. A country might have enough equipment, but this will be of little help if it is poorly distributed, leaving some health facilities with shortages.

One successful strategy is including injection equipment on essential medicines lists, as Burkina Faso has done. Or, a country might have a separate essential supplies list that includes injection equipment.

In public health programs where donors and governments pay for or distribute injectable medications, bundling policies help ensure that particular injectable substances will be given with new syringes and needles. Bundling may be physical, where an injectable substance is packaged together with equivalent quantities of new syringes, needles, and safety disposal boxes. Or, bundling may be conceptual, where the same entity that funds the injectable substance also funds equivalent quantities of new syringes, needles, and safety disposal boxes, and so contributes to the country's injection device security.

Recommended U.S. action: The United States could help countries improve injection equipment security both by providing funding for the injection equipment itself and by helping develop effective distribution systems. U.S. agencies may be particularly adept in helping with the logistical needs of injection security. Helping to develop effective distribution systems for injection equipment could have enormously valuable spill-over benefits for health infrastructure. Since these distribution systems are likely to be those used to distribute essential medicines as well, enhancing these systems could ensure the consistent availability of all essential medicines at health facilities. Once it becomes

available, appropriate agencies of the U.S. government (such as USAID and the CDC) should strongly consider endorsing the WHO's "Guiding Principles to Ensure Injection Security." U.S. agencies that assist countries in developing HIV/AIDS strategies should encourage them to include injection equipment security as part of those strategies. The United States should also integrate injection security, as well as other safe health care practices, into the prevention, care, and treatment programs it funds. For example, if the United States funds facilities that offer voluntary counseling and testing, the appropriate U.S. agencies should ensure that the facilities are connected to supply lines that can provide a consistent and adequate supply of single-use syringes, safety disposal boxes, gloves, and other items required for safe injections and universal precautions. Health care workers, in particular those involved in testing the blood, should be trained on safe injection practices and other universal precautions. Adequate supervision should be provided to ensure that health care workers consistently adhere to these policies. The facility should have a sharps waste disposal policy and the means to implement it. The United States should provide any needed financial or technical assistance to ensure that these conditions are met. Besides promoting safe health care, these investments will strengthen the health infrastructure more generally. The same supply lines that provide an adequate and consistent supply of injection equipment and gloves will also provide proper quantities of essential medicines. The same supervisor that ensures that health care workers are adhering to universal precautions can provide the health care workers extra training in other areas of their practice.

TRAINING AND PUBLIC EDUCATION

Training and education are key components of a safe injection strategy. Health care consumers – the general public – should also be educated on the risks of injections, the importance of injection safety, and the appropriate use of injections. The education can take various forms including pamphlets, group education sessions, mass media, and other information, education, and communication (IEC) techniques. Injection safety information should be incorporated into other material on HIV/AIDS prevention.

Public education can be informed by successful instances of injection safety education efforts that have already been implemented. For example, in 1994 the Aga Khan Health Services, Pakistan (AKHSP) conducted community-based education to address hepatitis C transmission through unsafe medical injections in Pakistan. The education included group information sessions and the distribution of colorful pamphlets. A follow-up study conducted in 1997-1998 revealed the impact of the education, as patients were more likely to use syringes and needles from sealed packages (60% of patient respondents) than they had been during a pre-intervention study in 1994 (24% of patient respondents). Also in Pakistan, an intervention in nine villages that combined community awareness with health care provider education led to dramatically improved injection practices. Use of new disposable syringes rose from 27.9% before the intervention to 70.9% after it, and the use of injections fell from 73.2% to 54.2%.

Health care providers should be trained in safe injection practices, including on the appropriate use of injections. This training should be provided both in medical and nursing training institutions (pre-service training) and to health care providers during the course of their service (in-service training). Where safe injection practices and other aspects of universal precautions are not already incorporated into the curricula of training institutions, they should be so incorporated. U.S. agencies can help design and fund

training programs. Through SIGN, considerable training materials are already available, including a health care waste management training guide and brochures and posters on injection safety.

One education strategy is to develop and educate community members on Patient Observed Safe Treatment (POST) practices. These are practices that, if followed, will ensure the health care consumer that the injection or other equipment to be used on them is sterile. For example, patients would insist that their health care provider open in front of them a sealed package containing a single-use syringe and taking the injectable substance from a single-dose vial.

Training of health care providers in and public education on injection safety is also crucial because of the effect they will have on the informal and private health sectors. In many developing countries, private sectors provide a significant proportion of health care, and many people receive injections in informal health settings. It will be difficult for governments to create injection equipment security for private sector facilities that are not linked to government distribution networks, and they will be unable to provide injection equipment security for informal sector providers.

Training and education will help address injection safety in the private and informal health sector. Many of the health care providers who provide injections in the private and informal sectors are also public sector employees. Their public sector training should therefore carry-over into their private and informal sector practice. Perhaps even more importantly, if a strong enough consumer demand is created for safe injections, private and informal sector health care providers will have to improve their injection practices if they want to continue to receive business. Consumer demand can force injection practices to change.

Recommended U.S. action: The United States could help fund training and education and provide technical assistance. U.S. agencies involved in helping countries formulate and revise national HIV/AIDS strategies should encourage countries to include training and education on injection safety among the prevention measures in those strategies.

INAPPROPRIATE USE OF INJECTIONS

As many as 70-90% of injections in developing countries are unnecessary, either because the substance injected is simply inappropriate – such as injecting vitamins to address fatigue – or because the substance can be given in non-injectable (primarily oral) form. One reason for the prevalence of unnecessary injections is health care consumers' unfounded belief that injections are more powerful or otherwise better than other forms of delivery. Public education is necessary to counter this belief, and should be incorporated into other education on injection safety.

Although consumer demand does exist for injections even when they are not necessary, health care providers frequently believe that this demand is even greater than it actually is, a second reason for unnecessary injections. Providers therefore might prescribe an injection because they believe – incorrectly – that this is what the patient wants. Dialogue between health care providers and consumers is therefore necessary to rid health care providers of their misperceptions.

To aid health care providers, national treatment guidelines – which guide health care providers in treating specific diseases and conditions – should be revised to substitute injectable with oral medications wherever possible. National treatment guidelines draw

on the WHO's standard treatment guidelines, which should therefore be revised to eliminate injectable medications where non-injectable alternatives exist. Similarly, WHO's Essential Medicines list should be revised to replace injectable medications with non-injectable alternatives wherever feasible. This revision is in process, and we understand that the WHO Department of Essential Drugs and Medicines Policy is committed to removing unnecessary injectable medicines from the list.

Strategies to reduce the inappropriate use of injections can be extremely effective. A study in Indonesia that involved interactive group discussions and seminars reduced the proportion of health care visits with injections from 75% to less than 20%. In five hospitals in Laos, management, training, and planning reduced the proportion of prescriptions with an injection from 60% to 20%.

Reducing the number of unnecessary injections has a number of benefits. It eliminates a certain share of overall – and therefore, unsafe – injections. It reduces the cost of an injection safety program by decreasing the number of syringes and other injection equipment needed. Indeed, if enough unnecessary injections are eliminated, a comprehensive injection safety program can be expected to lead to lower overall injection-related costs than before the program began.

Reducing unnecessary injections will also reduce drug costs, which account for 20-40% of national health budgets. And reducing the use of antibiotics – one of the prime culprits of unnecessary injections – will help address the problem of resistance to antibiotics.

Recommended U.S. actions: Ensure that all public education and health care worker training on injection safety incorporates education and training on the rational use of injections. U.S. agency field offices should encourage governments to revise national treatment guidelines to replace injectable substances with oral or other noninjectable version wherever possible, and to ensure that the rational use of injections is covered in medical and nursing training institutions.

SYRINGES WITH RE-USE PREVENTION DEVICES

If injection security, training, and public education were all perfect, there would be no need for anything but standard single-use syringes. However, since it will take time for health care providers to change their habits and health care consumers to assert their right to safe health care, an important additional safety measure to ensure safe injections is syringes with re-use prevention devices. Even when a health care worker does not recognize the danger of re-using a syringe, that worker will only be able to use a syringe with a re-use prevention device once. Auto-disable syringes are being used increasingly for immunizations – WHO has a goal of having auto-disable syringes used in all immunization programs in developing countries by the end of 2003.

Similar syringes for curative injections, which represent about 95% of all injections, are being developed, and many already exist. Syringes with re-use prevention devices have already been developed that could cover the vast majority of curative injections, and once produced in high quantities, will cost less than 10-cents each. Syringes also exist that include both re-use prevention devices and technologies (such as needle guards) to protect health care workers from needlestick injuries. These, too, will cost less than 10-cents each when produced in sufficient quantities.

Countries where injection equipment re-use is a problem should strongly consider purchasing syringes with re-use prevention devices, and the United States can help fund this equipment. In areas that opt for syringes with re-use prevention devices, the injection

equipment security concept would therefore apply to syringes with re-use prevention devices.

Recommended U.S. actions: The United States can provide syringes with re-use prevention devices to countries where injection equipment re-use is a problem. If the United States directly supplies these syringes, U.S. agencies should provide manufacturers through open, competitive, transparent bidding policies and practices to ensure encourage innovation and ensure highest quality at lowest cost. The United States should also strongly encourage technology transfer to Africa and developing countries elsewhere of standard single-use syringes and syringes with re-use prevention devices to enable local production of these technologies. Local production would both help stimulate local economies and enhance injection equipment security. Along with encouraging technology transfer, the United States should provide the technical assistance to develop quality standards and other mechanisms to ensure the quality of these syringes.

SHARPS WASTE MANAGEMENT STRATEGY

Any injection safety strategy would be incomplete without a sharps waste management strategy. There are two main risks: that a needle that is inadequately disposed will injure someone, whether a health care worker, a janitor, or children who might play with improperly disposed of sharps, and that scavengers will repackage and re-sell used syringes as new.

Countries should therefore develop a policy for sharps waste management. They should also ensure that medical and nursing training institutions include in their curricula information on managing sharps waste and provide health care providers in-service training and sharps waste management.

Two of the primary safe disposal methods are incineration and burial in a concrete-lined pit. Both methods have drawbacks. Incineration pollutes the air and involves equipment that frequently breaks down and goes unrepaired. Burying waste in concrete-lined pits requires space and really burying the waste in concrete-lined pits, not just in pits that will easily be uncovered. Other low-cost methods are being developed. As a general rule, injection waste should be disposed of as close to the point of use as possible where safe and effective means of disposal exist.

Recommended U.S. actions: The United States could provide funding and technical assistance to aid countries in developing and implementing sharps waste management policies and provide health care workers the appropriate training.

OTHER INFECTION CONTROL

The current practice of other medical procedures, such as blood tests and dental exams, entail risks for infections. Risks to patients in many of these procedures can be addressed with a similar shift to disposable equipment and other simple procedures (such as hand washing and using disposable gloves), but many other medical procedures require re-use of equipment, such as forceps, scissors, and suture needles.

Ensuring that health care providers have and use equipment for sterilization correctly is therefore necessary, and requires at least three steps. First, health care providers should be trained in proper sterilization techniques, including how to properly handle sterilized devices to maintain their sterility before use. Second, spare parts for sterilization equipment, such as steam sterilizers (autoclaves) – and the equipment itself – must be available. Electricity or fuel to heat water to operate the equipment used in the

sterilization process must be accessible. The equipment available for sterilization should be compatible with local power supplies. And third, to ensure that sterilization was successful, a time-steam saturation-temperature (TST) indicator should be used. This indicator affirms that an instrument has been properly sterilized by changing color only when sterilization conditions have been met.

As with injection safety, health care consumers should demand proper sterilization procedures for these other health care practices. Different procedures will require different techniques. Patient Observed Safe Treatment (POST) practices can be developed for different procedures to enable consumers to ensure that they are treated with properly sterilized instruments.

Recommended U.S. actions: The United States could provide funding and technical assistance for training and sterilization equipment. The United States could also fund NGOs and other organizations involved in developing and disseminating POST procedures.

UNIVERSAL PRECAUTIONS

Safe injection practices, including sharps waste management, are important aspects of universal precautions. Broadly speaking, there are two aspects to universal precautions, supplies and training. Health care providers must have supplies, such as gloves, eyewear, and soap, to protect themselves and their patients from blood-borne pathogens. They also need training, both pre-service and in-service, on universal precautions, so that they are cognizant of safe practices, and understand their importance.

This training must include a strong message that health care providers should to the maximum extent possible adhere to universal precautions at all times with all patients. It is crucial that health care providers do so not only because someone might have HIV/AIDS whom the health care provider does not suspect, but also to help combat discrimination against people living with HIV/AIDS. Without proper training or adequate supplies, health care providers' often reasonable fears for their own safety frequently lead them to refuse to care for people they believe are infected with HIV or otherwise treat them differently from patients who are HIV-negative, thus contributing to discrimination against people with HIV/AIDS. One Nigerian policymaker told a Physicians for Human Rights researcher, "Most hospitals don't have protective supplies. There is no incentive for Health Care Providers to risk infection."

The human rights implications of inadequate supplies to for health care workers to adhere to universal precautions for all patients, whether or not suspected or known to be HIV-positive, are powerfully illustrated by disconcerting news from India of health professionals opposing legislation that would protect the rights of people living with HIV/AIDS. Legislation is being drafted in India that would protect the rights of people living with HIV/AIDS, including requiring people's consent before being tested for HIV, protecting the confidentiality of HIV test results, and protecting people living with HIV/AIDS from discrimination and segregation in health care settings. Some health professionals argue that they must be able to perform HIV tests, with or without the patient's consent, so that they can protect themselves. Said one doctor, "If we are supposed to treat patients who refuse HIV test, then it would be tantamount to safeguarding the rights of the protected at the cost of exposing the protectors' life to the risks of getting infected during the surgery." Knowledge of patient's HIV status rarely

remains confined to health care workers. According to the director of a hospital in Mumbai, “We are extra cautious about not disclosing the HIV status of the patient. However, most of the times, we are forced to segregate patients because the relatives of other patients find out about the status.”

The consequences of inadequate supplies to adhere to universal precautions for all patients is that health care workers test patients even without their consent, so that they can use their limited supplies for the patients who pose the most risk of infecting health care providers with HIV. As a result, whether through the use of protective gear for these patients, through the segregation of these patients, or other means, those living with HIV/AIDS are clearly marked. Their families, and quite possibly their communities, are likely to learn of their HIV-positive status, putting them at risk of the range of discrimination experienced by people living with HIV/AIDS, including being turned away by their own families, losing their jobs, and being shunned by the community. Thus, the discrimination that a person with HIV/AIDS initially experiences in the health sector may be the decisive event that subjects a person to the full force of societal discrimination against people living with HIV/AIDS.

Recommended U.S. actions: The United States could both provide training and funding for supplies, such as disposable gloves and other protective gear. Indeed, USAID has already providing training on universal precautions in hospitals in a number of countries. Along with funding for the supplies themselves, the United States could provide technical assistance to help countries improve their distribution systems for key health care items to help ensure a consistent, steady supply of the items needed for health care workers to adhere to universal precautions.

The United States could also help develop a standard list of essential supplies for universal precautions, or use its role on the World Health Organization’s Executive Board to encourage the WHO to develop such a list. The list could be a universal precautions supplies equivalent to the Essential Medicines list, guiding government policy in purchasing these items, as they recognize that these are key items for which health facilities require a consistent and adequate supply. Also either through its own experiences or through the WHO, the United States should help develop information, education, and communication (IEC) material to promote adherence to universal precautions. SIGN has already developed IEC material to encourage and aid adherence to safe injection practices.

BLOOD SAFETY

More attention has been given to blood safety in developing countries than to injection safety, and developing countries including Uganda, Namibia, and South Africa have achieved a very high degree of blood safety. Many other countries, however, have been slow to prioritize blood safety, even though blood transfusions are the most efficient way of transmitting HIV. A 2000 report from WHO stated that only 13 of 46 countries in the WHO African Region had implemented national blood safety policies. The elements needed for a safe blood supply are well documented, and include a national blood transfusion service (including a national quality system), a pool of voluntary, non-remunerated donors, blood screening, and guidelines, training, monitoring, and evaluation on the appropriate clinical use of blood.

Recommended U.S. actions: The U.S. government can help countries improve their blood safety in several ways. These include helping fund blood safety programs, encouraging

countries to prioritize blood safety, and providing technical assistance to help countries develop blood safety programs. With political will and adequate and sustainable funding, even impoverished countries can develop blood transfusion services that virtually eliminate HIV (and other blood-borne pathogens) from the blood supply.

U.S. GOVERNMENT AND UNAIDS, WORLD HEALTH ORGANIZATION, AND THE GLOBAL FUND

Along with encouraging countries to address safe health care and providing technical assistance and funding to do so, the United States can use its role in international forums to significantly advance the case of safe health care. As an influential member of WHO and UNAIDS, the United States should encourage those organizations to place a higher priority on safe health care as a means of preventing HIV transmission. For example, the United States should support efforts to add injection safety to the core components of WHO's 2003 Global HIV/AIDS Strategy for the Health Sector, which was released several months ago.

The United States should work through WHO and UNAIDS to ensure that the goals of the United Nations General Assembly Special Session on HIV/AIDS (UNGASS) Declaration of Commitment on HIV/AIDS are achieved. These goals include implementing universal precautions in health care settings by 2003 and safe blood supplies and the availability of sterile injection equipment by 2005. Also, the United States should encourage WHO and UNAIDS to include injection safety messages in all prevention materials, as appropriate, and to collect and disseminate information on best practices in injection safety, including training, public education, injection equipment security, and sharps waste management.

The United States should also encourage countries to add sections on universal precautions, including injection safety, and blood safety to their proposals to the Global Fund to Fight AIDS, Tuberculosis and Malaria. The United States should offer any necessary technical assistance countries require to enable them to effectively include blood safety, universal precautions, and injection safety in their proposals to the Global Fund.

While a number of countries have included blood safety in their proposals, a review of most of the first and second round proposals to the Global Fund have revealed only one country, Ethiopia, that has included universal precautions in its Global Fund proposal. This strategy has a two-fold advantage. It should get high-level officials in developing countries to address these issues – they would have little hope of getting funding without a sound strategy – and could tap a potential source of funding. The United States could also propose that the Global Fund Board adopt a rule that as a prerequisite to receiving money for injectable substances from the Fund, countries must have safe injection policies. Entities in a position to do so, including the United States and WHO, should provide any needed technical assistance to enable countries without such policies already in place to develop them. This rule should in no way affect the approval of proposals, nor should it affect the disbursement of funds for anything other than injectable substances. The United States should also support research that will help improve safe health care interventions. The National Institutes of Health should add health care risks as a new research area for their HIV Prevention Trial Network.

OTHER PARTICIPANTS

This memo has focused on the United States government role in preventing HIV transmission in health care settings. The important role of other participants in the health system should not be lost. For example, a commercial code of conduct could be developed under which participating companies would refuse to sell injectable substances to countries that do not have injection safety policies. Religious institutions affiliated with health facilities in developing countries could bundle any injectable substances with single-use syringes (preferably with re-use prevention devices), clean needles, and safety disposal boxes, particularly important if the host countries do not have effective injection equipment security policies. Injection device manufacturers should continue to develop syringes with re-use prevention devices, and increase production of those already available.

COSTING

Based on a study by WHO published in April 2003, the global cost of an injection safety program is about \$905 million. Because of the population size of Asia, the large number of injections given in many Asia countries, as well as the high proportion of syringe re-use in much of Asia, most of this money would be for South East Asia and the Western Pacific Region. According to this study, the cost of an injection safety program for WHO's African Region is about \$45 million. The study calls both blood safety and policies for the safe and appropriate use of injections "in the range of the most cost-effective interventions for preventing HIV infection" in sub-Saharan Africa.

The cost should decrease over time as education and training on the appropriate use of injections takes effect, and the total number of injections is reduced. UNAIDS has estimated that the overall number of injections could fall by 25% by 2007. Since \$826 million of the \$905 million (and \$37 million of the \$45 million for Africa) is for injection safety equipment, of which less would be necessary as the overall use of injections decreases, the cost of injection equipment should decrease by at least 25% of \$826 million by 2007, to less than \$699 million globally (and less than \$36 million in Africa). In a certain respect, the cost of an injection safety program could become substantially lower still. According to the WHO study, the syringe re-use level in Africa is 17-19%. (This may be an underestimate.) Assuming this re-use rate is correct, it is less than the postulated 25% reduction in overall number of injections. This means that the total number of syringes used would be fewer in 2007 than at present, and so the regions should achieve overall cost savings on injection equipment (though funding for education, training, and logistical support would likely still be necessary).

If a 25% reduction in overall injections is achieved globally by 2007, total global spending required on injection equipment would fall very significantly, but remain above present levels. According to the WHO costing study, 39.8% of injections are unsafe. The cost of injection equipment globally, then, should fall by about 60%. How the reduced spending required on injection equipment in Africa and elsewhere would affect donors such as the United States would depend on which safe injection activities the United States most heavily supports and how the savings of the reduced injections are shared between donors and host countries.

Based on UNAIDS estimates, the incremental cost needed to achieve blood safety globally is an additional \$200 million per year. UNAIDS has estimated the cost of implementing universal precautions in all countries with an adult HIV prevalence of more than 1% at about \$600 million in 2004, increasing to about \$1.1 billion by 2007.

Total financial needs of safe health care interventions

Total cost 2004: \$1.705 billion

U.S. share (25-33%): \$426-\$568 million

Total cost 2007: \$1.999 billion (This estimate uses a figure of \$699 million for injection safety, based on the assumption that by 2007, the overall number of injections will be reduced 25%. As explained above, the actual figure could be significant less than this, depending on how savings from the reduced number of injections are allocated.)

U.S. share (25-33%): \$500-\$666 million

This total cost does not include universal precautions for countries with HIV prevalence below 1%, such as India and China.

Total estimated financial needs of HIV/AIDS interventions

To put the costs of safe health care in perspective, below are the total financial needs for HIV prevention activities and for most HIV/AIDS interventions, including treatment.

None of these figures include costs of scaling up health infrastructure or certain other interventions, such as food security/nutritional support, NGO capacity building, programs to reduce and prosecute sexual violence and otherwise promote women's rights, programs to create economic opportunities for people left destitute by HIV/AIDS, and efforts to replace lost capacity in education, agriculture, health, and other sectors. Nor do they include research. They incorporate only low coverage for educational and other support for children orphaned by HIV/AIDS. They therefore understate total need.

The increase in costs is a function of increasing coverage. To achieve a goal of expanding coverage faster, the costs will increase faster. Also, infrastructure costs should be frontloaded – the sooner health facilities are built and rehabilitated, the sooner doctors, nurses, counselors, and other health care workers are trained, the sooner supervision systems are upgraded, the sooner HIV/AIDS treatment and other activities can take place and the more effective they will be. The incremental increase reflected in the figures below is therefore misleading.

UNAIDS cost estimates, incorporating WHO injection safety estimate

2004: Prevention: \$5.0 billion (U.S. share of 25-33%: \$1.3-\$1.7 billion)

Total: \$9.0 billion (U.S. share of 25-33%: \$2.3-\$3.0 billion)

Safe health care interventions are 34% of the prevention cost and 19% of the total cost.

2005: Prevention: \$6.1 billion (U.S. share of 25-33%: \$1.5-2.0 billion)

Total: \$11.1 billion (U.S. share of 25-33%: \$2.8-\$3.7 billion)

Safe health care interventions are 28% of the prevention cost and 15% of the total cost.

2007: Prevention: \$7.0 billion (U.S. share of 25-33%: \$1.8-\$2.3 billion)

Total: \$15.4 billion (U.S. share of 25-33%: \$3.9-\$5.1 billion)

Safe health care interventions are 29% of the prevention cost and 13% of the total cost.

Safe health care interventions make up a significant portion of the prevention costs, and even of the total costs.

The UNAIDS total estimated need for 2004-2007 is about \$46.8 billion. UNAIDS does not have official estimates for funding needs for 2008, but based on the upward trend of

2003-2007, the need can be expected to be about \$17 billion (U.S. share of 25-33%: \$4.25-\$5.6 billion). Thus, the five year total of 2004-2008 would be about \$63.8 billion. The U.S. share would be \$15.9-\$21.2 billion (25-33%), or \$3.2-\$4.25 billion per year, excluding health infrastructure, research, and other costs described above. This total also excludes the funding needed for HIV/AIDS research and for tuberculosis and malaria control and treatment programs.