

HIV Transmission in Health Care Settings: A White Paper by Physicians for Human Rights

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About Physicians for Human Rights

The Boston-based Physicians for Human Rights (PHR) promotes health by protecting human rights. PHR believes that respect for human rights is essential for the health and well-being of all members of the human family.

Since 1986, PHR members have worked to stop torture, disappearances, and political killings by governments and opposition groups and to investigate and expose violations, including deaths, injuries, and trauma inflicted on civilians during conflicts; suffering and deprivation, including denial of access to health care, caused by ethnic and racial discrimination; mental and physical anguish inflicted on women by abuse; exploitation of children in labor practices; loss of life or limbs from landmines and other indiscriminate weapons; harsh methods of incarceration in prisons and detention centers; and poor health stemming from vast inequalities in societies. PHR also works to protect health professionals who are victims of violations of human rights and to prevent medical complicity in torture and other abuses.

PHR's Health Action AIDS Campaign, in coordination with Partners in Health (PIH), mobilizes the health professions to support a comprehensive HIV/AIDS strategy and advocate for the United States to contribute US\$3.5 billion annually to combat the disease, while developing ways for health professionals in the United States to support health providers and activists around the world. The Campaign brings together the best available medical and scientific understanding of the disease, using that understanding to direct policy choices. The PHR/PIH partnership takes advantage of PHR's ability to organize health professionals and combines it with PIH's extraordinary knowledge and experience, having led the MDR-Tuberculosis campaign, its leading role in the development of the Harvard University AIDS statement, and its work in developing countries.

Visit <http://www.phrusa.org> or <http://www.healthactionaids.org> for more information.

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EXECUTIVE SUMMARY

Even as prevention programs aimed at sexual transmission require greater funding, the high risk of HIV transmission in health care settings requires immediate and sustained attention from national and multilateral organizations involved in HIV/AIDS prevention activities. Every year, because of violations of core aspects of the right to health, at least half a million people – and possibly many more – contract HIV through unsafe medical injections¹ and blood transfusions.² Throughout the developing world, health care providers, health facility staff, patients, and the community at large are placed at risk of contracting HIV because of a lack of supplies, poor training, poor awareness about the danger of unsafe injections, and lack of incentive to observe good practices.

A foundational principle of medical ethics is that physicians must “first, do no harm.” A central tenant of the right to health is that health care must be safe. People in every country, rich and poor, have the right to a health system that improves people’s health, not one that creates grave risks to health. Yet unsafe medical injections and unsafe blood transfusions contribute significantly to the greatest health crisis of our time, the HIV/AIDS pandemic. Inadequate efforts by donors, multilateral organizations, and the governments of impoverished countries themselves to ensure safe health care for people in poor countries suggest a tacit, widespread acceptance of a two-tiered health system: health care must observe the highest standards in wealthy countries, but not necessarily in poorer countries. Under human rights law, health care must be safe in every country. Until the discriminatory perception ends, unsafe medical injections and unsafe blood transfusions will continue to contribute considerably to the HIV/AIDS pandemic, as well as to the spread of other bloodborne pathogens such as the hepatitis B and hepatitis C viruses.

Discrimination against people living with HIV/AIDS is also fueling the pandemic. The widespread inability of health care providers in developing countries to implement universal precautions necessary for them to protect themselves from contracting HIV from their patients contributes to that discrimination. Without proper training or adequate supplies, health care providers’ often reasonable fears for their own safety frequently have devastating consequences. The fears can lead health care providers to refuse to treat people infected with HIV, or to follow

¹ As used in this paper, “unsafe medical injections” refers to injections both in formal and informal health care settings, given by both medical and non-medical personnel. The injections covered by this phrase and this paper do not include illicit drug use.

² A model endorsed by the World Health Organization (WHO) estimates that 260,000 HIV infections are caused annually by unsafe medical transmissions. 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). WHO estimates that 5-10% of new HIV infections are caused by unsafe blood transfusions. See 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. 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 health care (260,000 through unsafe injections and 250,000 through unsafe blood transfusions) occur every year.

safety precautions only for people they suspect are infected, thus contributing to the stigma and isolation of people living with HIV/AIDS. This discriminatory treatment of people living with HIV/AIDS violates a core aspect of the right to health, everyone's right to access health care on a non-discriminatory basis. Until universal precautions become universally implemented, such discrimination seems destined to continue.

Discrimination that HIV-positive people face in the health system has lethal consequences. It discourages them from seeking health care, such as treatment for opportunistic infections and nutritional counseling, speeding people's passage from infection to death. Discrimination in the health care sector and the stigma and discrimination that people with HIV/AIDS face throughout society also discourages people from seeking voluntary counseling and testing services, which might reveal that they are HIV-positive. Yet these services provide HIV/AIDS education and strategies that enable people infected with the virus to take precautions against transmitting the disease to others, and voluntary counseling and testing services are the gateway to interventions that can improve the health of people with HIV/AIDS. Every step towards ending discrimination against people living with HIV/AIDS is a step towards stopping the spread of the disease. Providing the training and supplies to enable health care providers to adhere to universal precautions, including injection safety, is one such step.

To assure people's human rights and to help slow the HIV/AIDS pandemic, strong, immediate efforts must be made to improve the safety of blood supplies and health care providers' adherence to universal precautions, including safe injection practices.

Since the late 1980s, the World Health Organization (WHO) has not emphasized the risks of HIV transmission in the health care setting, though it has recognized the dangers of unsafe blood supplies.³ Renewed interest in these risks has begun to surface in the past several years. In late 2002, UNAIDS recognized universal precautions and safe injection practices as important interventions by including them for the first time in an estimate of the cost of a global response to the HIV/AIDS pandemic.⁴ A year earlier, the United Nations General Assembly Special Session's Declaration of Commitment on HIV/AIDS urged the nations of the world to implement universal precautions to prevent HIV transmission in health care settings by 2003, and to expand access to sterile injecting equipment by 2005.⁵

The urgency to act to reduce the risks of transmitting HIV in the health care setting does not suggest any lessening in the importance of decreasing sexual transmission. Indeed, efforts to do so must be scaled up significantly and urgently. Encouraging broad recognition of the importance of universal precautions, including injection safety, along with a renewed focus on blood safety, is simply an attempt to open up another front in the war against HIV/AIDS. The

³ See David Gisselquist, John J. Potterat, Stuart Brody & François Vachon, "Let it be sexual: how health care transmission of AIDS in Africa was ignored." *International Journal of STD & AIDS* (March 2003) 14: 148-161, at 148.

⁴ See UNAIDS press release, *New figures show AIDS fight under-resourced: Existing funds insufficient to keep pace*, Oct. 10, 2002. Available at: http://www.unaids.org/whatsnew/press/eng/pressarc02/GlobalFund101002_en.html.

⁵ See *Declaration of Commitment on HIV/AIDS*, United Nations General Assembly Special Session on HIV/AIDS (UNGASS), adopted June 27, 2001, at paras. 51-52. Available at: <http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html>.

experience of Uganda demonstrates that it is possible to educate people on the risks of infection through unsafe injections while still achieving significant behavioral changes to reduce HIV transmission through sexual behavior.⁶

Unsafe medical injections

Unsafe medical injections are probably the most significant route of HIV transmission in the medical setting.⁷ Medical injections are procedures that pierce the skin and introduce a substance into the patient for curative or preventative medical purposes, including immunizations. The infections they cause each year will lead to more than a million deaths from hepatitis B, hepatitis C, and HIV/AIDS.⁸ Injections are unsafe when syringes are re-used without being sterilized properly or at all. When a syringe is used on an HIV-positive patient, that syringe can be contaminated with HIV-infected blood, which can then be passed on to the next person if re-used. The danger is especially great because of the extensive, often unnecessary and irrational use of injections in developing countries. Studies have estimated that as many as 70-90% of injections in developing countries are unnecessary.⁹ Re-use of injection equipment is especially high in Asia and sub-Saharan Africa, where syringes may be re-used as frequently as 50% or more of the time.¹⁰

According to a very recent model, unsafe injections cause 260,000 HIV infections globally every year.¹¹ This number may be understated since it is based on a lower proportion of unsafe

⁶ See Susan A. Cohen, "Flexible but Comprehensive: Developing Country HIV Prevention Efforts Show Promise." *Guttmacher Report on Public Policy* (Oct. 2002) 5(4), at 2. Available at:

<http://www.guttmacher.org/pubs/journals/gr050401.pdf>; Harriet Birungi, "Injections and self-help: Risk and trust in Ugandan health care." *Social Science & Medicine* (1998) 47(10): 1455-1462, at 1458-59.

⁷ The Safe Injection Global Network (SIGN) has estimated that 5% of global HIV infections are caused by unsafe medical injections. 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). Estimates place the proportion of HIV infections in Africa as high as 20-40%. See David Gisselquist, Richard Rothenberg, John Potterat & Ernest Drucker, "HIV infections in sub-Saharan Africa not explained by sexual or vertical transmission." *International Journal of STD & AIDS* (2002) 13: 657-666, at 657. Unsafe blood transfusions probably cause 5-10% of HIV infections in developing countries. See 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.

⁸ See M.A. Miller & E. Pisani, "The Cost of Unsafe Injections." *Bulletin of the World Health Organization* (1999) 77(10): 808-811, at 808-09. Available at: <http://www.who.int/bulletin/pdf/issue10/miller.pdf>.

⁹ See Anne V. Reeler & Lone Simonsen, *Bill and Melinda Gates Child Vaccine Program Occasional Paper #2, Unsafe Injections, Fatal Infections*, May 2000, at 1. Available at:

http://www.childrensvaccine.org/files/CVP_Occ_Paper2.pdf; Safe Injection Global Network (SIGN), *Annual Meeting Report, 24-26 October 2002*, 2002, at 4. Available at:

http://www.who.int/injection_safety/sign/meetings/past/2002MeetingReport.pdf.

¹⁰ 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>.

¹¹ 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).

injections in Africa than probably exists;¹² it uses an arguably low estimate of the efficiency of HIV transmission through unsafe injections,¹³ and; studies from Africa indicate a greater importance of HIV transmission through unsafe injections than the model generates.¹⁴ A large study in South Africa found high levels of HIV in children ages 2-14, about 70% of which could not be explained by mother-to-child transmission.¹⁵ Low levels of sexual experience for these children suggest that many of these infections may have been caused by unsafe injections and other modes of medical transmission. Several studies have shown significant HIV levels among adults who reported never having any sexual experience, or who reported having had only one sexual partner, who was HIV-negative.¹⁶ Also, a data-driven model found that sexual activity can explain only about one-third of the epidemic's growth.¹⁷ This suggests that a relatively high proportion of infections may be attributed to unsafe injections and other forms of transmission in the health care setting, including blood transfusions and modes of transmission whose importance is not yet be well understood.

Along with transmitting HIV, unsafe injections are responsible for significant proportions of hepatitis B and C infections. Every year, about 8-20.6 million people become infected with hepatitis B and 2.0-4.7 million with hepatitis C because of unsafe medical injections.¹⁸ Of those people infected with hepatitis B and hepatitis C every year through unsafe injections, an estimated 1.2 million will die from these infections.¹⁹

¹² 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>.

¹³ See David P. Gisselquist, "Estimating HIV-1 Transmission Efficiency through Unsafe Medical Injections." *International Journal of STD & AIDS* (2002) 13: 152-159, at 154-155; 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* (in press).

¹⁴ 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).

¹⁵ See Centre for AIDS Development, Research and Evaluation (CADRE), *Nelson Mandela/HRSC Study of HIV/AIDS, South African National HIV Prevalence, Behavioral Risks, and Mass Media, Household Survey 2002*, 2002, at 47; David Gisselquist, *Estimate of the Proportion of Non-MTCT HIV Infections in South African Children 2-14 Years Old*. (Unpublished) Dec. 13, 2002.

¹⁶ See, e.g., Basia W. Zuba et al., "Adjusting Ante-natal Clinic Data for Improved Estimates of HIV Prevalence among Women in Sub-Saharan Africa." *AIDS* (2000) 14(17): 2741-2750, at 2744 (reporting Zimbabwe study that found 2.1% HIV prevalence among women who reported no sexual experience); Susan Allen et al., "Effect of Serotesting with Counselling on Condom Use and Seroconversion among HIV Discordant Couples in Africa." *BMJ* (1992) 304: 1605-1609, at 1607 (Rwanda study reporting that 15 of 25 HIV-positive women with HIV-negative partners reported only one lifetime sexual partner).

¹⁷ See David Gisselquist & John J. Potterat, "Heterosexual Transmission of HIV in Africa: An Empiric Estimate." *International Journal of STD & AIDS* (March 2003) 14: 162-173, at 170.

¹⁸ 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).

¹⁹ See M.A. Miller & E. Pisani, "The Cost of Unsafe Injections." *Bulletin of the World Health Organization* (1999) 77(10): 808-811, at 808-09. Available at: <http://www.who.int/bulletin/pdf/issue10/miller.pdf>.

Inexpensive technology exists to make injections safe, in particular single-use and auto-disable syringes. Single-use syringes are meant to be disposed of after one injection. Auto-disable syringes have the added advantage of being automatically altered so that they cannot be re-used. Along with the availability of this equipment, health care providers and the general public need to be educated about the dangers of unsafe injections, as well as about the appropriate use of injections, so as to reduce the number of unnecessary injections. Annual cost estimates for a global injection safety initiative range from about \$300 million to \$900 million,²⁰ with the higher estimate probably more accurate.

The public needs to be encouraged to insist that their health care providers always use a new, sterile needle and syringe. Because syringes will be used only once, the number of syringes disposed of will increase, at least until health care worker training and public education reduces the number of unnecessary injections. This means that safe injection waste management will be particularly important. The potentially hazardous waste must be contained in safety boxes and destroyed to avoid putting health facility staff and community members at unnecessary risk of needlestick injuries and bloodborne infections.

In 1999, the WHO-sponsored Safe Injection Global Network (SIGN) became the central organization in advocating safe injections.²¹ UNICEF, the U.S. Agency for International Development (USAID), and others have contributed to increased use of auto-disable syringes in immunization and family-planning programs.²² A “bundling” policy for immunizations encourages donors and lenders who finance vaccines to also finance auto-disable syringes and safety boxes for their disposal.²³ However, comparable progress in using safe injection equipment has not been made for curative injections, which account for the vast majority of medical injections.²⁴ Recognizing the important connection between unsafe medical injections and HIV/AIDS would likely accelerate efforts to ensure injection safety for curative injections. At present, most HIV prevention initiatives fail to give adequate attention to the risks of contracting HIV through medical injections. Some countries, though, such as Uganda and Senegal, have included or are beginning to include injection safety as part of their HIV/AIDS strategies.²⁵

²⁰ See UNAIDS, *Financial resources for HIV/AIDS programmes in low-and middle-income countries over the next five years*, Nov. 28, 2002, at 7, 13. Available at:

http://www.unaids.org/about/governance/files/PCB13_FinancialResources_en.doc; Gerald Dziekan et al., “The Cost-Effectiveness of Policies for the Safe and Appropriate Use of Injection in Healthcare Settings.” *Bulletin of the World Health Organization* (2003) 81(4) (in press).

²¹ See World Health Organization, *The SIGN Alliance*, http://www.who.int/injection_safety/sign/en/. Accessed Feb. 21, 2003.

²² See World Health Organization, United Nations Children’s Fund (UNICEF) & United Nations Population Fund (UNFPA), *WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services*, Dec. 1999. Available at: http://www.who.int/bct/Main_areas_of_work/SIGN/pdf_documents/policy.pdf; U.S. Agency for International Development, *Global Health: Child Survival: Health Technologies*, http://www.usaid.gov/pop_health/cs/healthtech.htm. Accessed Feb. 22, 2003.

²³ See World Health Organization, United Nations Children’s Fund (UNICEF) & United Nations Population Fund (UNFPA), *WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services*, Dec. 1999. Available at: http://www.who.int/bct/Main_areas_of_work/SIGN/pdf_documents/policy.pdf.

²⁴ See World Health Organization, *Safety of Injections Fact Sheet*, April 9, 2002. Available at: <http://www.health.fgov.be/WHI3/krant/krantarch2002/kranttekstapr2/020409m02a-who.htm>.

²⁵ See Harriet Birungi, “Injections and self-help: Risk and trust in Ugandan health care.” *Social Science & Medicine* (1998) 47(10): 1455-1462, at 1458-59; Ibrahim Ndoye (Executive Secretary, National Council on

Multi-dose vials

Multi-dose vials also have been implicated in transmitting bloodborne infections, including hepatitis B, hepatitis C, and HIV.²⁶ Multi-dose vials contain multiple doses of an injectable substance, meaning that the health care provider will insert syringes into the vial multiple times. Both the high levels of syringe re-use and the high prevalence levels of HIV increase the possibility that multi-dose vials could be responsible for transmitting HIV when the vials are contaminated with the virus. These risks can be eliminated by replacing multi-dose vials with single-dose vials. Immunization programs that are financed by national governments might be unable to afford single-dose vial use without international assistance.

Sterilization of equipment

Even if syringes are never re-used, some instruments, such as scissors and forceps, will continue to be used on multiple patients. This makes it critical that health care providers are trained in proper sterilization techniques and have the necessary equipment, such as steam sterilizers and time-steam saturation-temperature indicators, to properly sterilize these instruments and verify their sterility.

Blood transfusions

Blood transfusions are another significant mode of HIV transmission in the health care setting. They appear to be responsible for 5-10% of new HIV infections.²⁷ According to WHO's Regional Office for Africa, only about 75% of blood transfused in Africa is screened for HIV, with far lower proportions screened for hepatitis B and hepatitis C.²⁸ As of 2000, most countries in Africa did not have safe blood policies, though WHO and other organizations have been working with countries to help them develop such policies.²⁹

It is well within the capacity of African nations to implement effective blood transfusion policies. Countries including South Africa, Zimbabwe, Namibia, and Uganda have achieved a

HIV/AIDS/Senegal), *Senegal Experience on HIV/AIDS Control*, presentation at conference on Fighting HIV/AIDS in Africa: What Works, Jan. 8, 2003, Washington, DC, at 11-12. Available at:

<http://www.cgdev.org/events/ndoye.ppt>.

²⁶ See Safe Injection Global Network (SIGN), *Best Infection Control Practices for Skin-Piercing Intradermal, Subcutaneous, and Intramuscular Needle Injections, Background Paper for the WHO Working Group Meeting, 19-20 October 2000, Salle A*, 2000, at 10, 26-28.

²⁷ See 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.

²⁸ 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>.

²⁹ 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>; World Health Organization African Region press release, *Health in Africa 2000-2001: A Balance Sheet*, Oct. 8-12, 2002. Available at: <http://www.whoafr.org/press/2002/pr20021008-12rc01.html>.

safe blood supply.³⁰ Key elements of a safe blood policy include careful selection of voluntary, unpaid blood donors, and health infrastructure that includes blood banks, training for donor recruiters, counselors, blood collectors, laboratory staff, and quality managers, blood test kits and reagents, a robust supply chain, and refrigeration capacity. UNAIDS has estimated that about an additional \$200 million per year is needed to ensure a safe blood supply in all low- and middle-income countries.³¹

The potential for blood transfusions to cause large numbers of HIV infections is apparent from the epidemic in Henan Province, China, where as many as one million or more people became infected through blood selling practices in the 1990s, which involved unsterile blood donation procedures.³² China has included an investment of about \$115 million in its five-year plan to build more blood collection stations, though increasing the number of voluntary blood donors is also critical to improving blood safety in China.³³ India too has taken measures to improve blood safety, following the identification of transfusions as a significant cause of HIV transmission there.³⁴

Universal precautions

To protect health care providers, as well as to prevent HIV and other infectious diseases from being transmitted from health care providers to their patients, universal precautions must be implemented. Universal precautions are infection control measures aimed at preventing the transmission of HIV and other pathogens in blood and other body fluids in the health care setting. They include safe injection practices and measures to create physical barriers such as wearing gloves, goggles, and other protective gear. UNAIDS has estimated the cost of implementing universal precautions in all countries with an adult HIV prevalence of more than 1% at about \$500-600 million in 2003, rising to about \$1.1-1.2 billion by 2007.³⁵

³⁰ See PANOS Institute, *Safe Blood: an affordable right*, June 10, 1996. Available at: <http://www.aegis.com/news/panos/1996/PS960601.html>.

³¹ See UNAIDS, *Financial Resources for HIV/AIDS Programmes in Low- and Middle-Income Countries over the Next Five Years*, Nov. 28, 2002. Available at:

http://www.unaids.org/about/governance/files/PCB13_FinancialResources_en.doc. The information is presented graphically, so the figure is an approximation.

³² See UNAIDS (UN Theme Group on HIV/AIDS in China), *HIV/AIDS: China's Titanic Peril*, June 2002, at 28. Available at: <http://www.unaids.org/whatsnew/newadds/AIDSchina2001update.pdf>.

³³ See "Hospitals asked to be alert in taking blood." *China Daily*, Aug. 6, 2001. Available at: <http://www.china.org.cn/english/2001/Aug/17039.htm>.

³⁴ See World Bank, *India's National AIDS Control Program*, Sept. 1999. Available at: <http://wbln1018.worldbank.org/SAR/sa.nsf/All/0C8B13C927927CA3852567F4005394FC?OpenDocument>; See "Avoid taking blood from strangers." *Ludhiana Tribune (India)*, Nov. 9, 2000. Available at: <http://www.tribuneindia.com/2000/20001109/ldh3.htm>.

³⁵ See UNAIDS, *Financial Resources for HIV/AIDS Programmes in Low- and Middle-Income Countries over the Next Five Years*, Nov. 28, 2002. Available at:

http://www.unaids.org/about/governance/files/PCB13_FinancialResources_en.doc; UNAIDS, *Global HIV/AIDS-specific resource needs at October 2002*, Oct. 2002, at table 3. Available at:

http://www.unaids.org/publications/graphics/GlobalresourcesOct02/GRfigures_1002.doc. The information is presented graphically, so the figures are an approximation.

The greatest risks for occupational infections appear to come from needlestick injuries.³⁶ One study estimated that the risk of occupational acquisition of HIV for surgeons practicing in Zambia was fifteen times that of their Western colleagues, primarily due to the high HIV prevalence in Zambia. That study found that most injuries to surgeons occurred through needlestick injuries caused by suture needles.³⁷ Replacing sharp suture needles with blunt needles could prevent many injuries caused during suturing.³⁸

Universal precautions are frequently not followed in both sub-Saharan Africa and much of Asia because of both a shortage of supplies and inadequate training. Dangerous diagnostic equipment, such as nonretracting finger-stick lancets and glass capillary tubes, is often used in developing countries, in spite of the fact that safe alternatives exist.³⁹

Healthy health care providers are an absolute necessity for a strong health care system and universal precautions will contribute to protecting their well-being. Many countries, particularly in Africa, are facing severe shortages of health professionals and other health care providers. Minimizing reductions in the health care workforce by improving occupational safety through the implementation of universal precautions is an important step in retaining qualified and experienced staff.

Implementing universal precautions will help strengthen health care systems. Many countries, particular in Africa, are facing severe shortages of health professionals and other health care providers. Universal precautions can help save their lives. The potential for a fast, significant impact on the HIV/AIDS pandemic should help convince policymakers to seriously address the risks of HIV transmission in health care settings. It is critical that they act now, for the dangers of unsafe injections and failing to implement universal precautions increase as HIV prevalence increases. The longer countries wait to address these dangers, the greater the amount of HIV transmission in health care settings will occur.

Call to action

The number of people who become infected with HIV through unsafe injections and other medical procedures is a controversial question. While the discussion of the number of people who become infected through these modes is one that should take place, Physicians for Human Rights urges WHO, UNAIDS, national health and HIV/AIDS organizations, donors, and others who are responding to the pandemic to focus their energies not on debating numbers, but on implementing programs and initiating new, life-saving policies without delay. In particular, PHR calls upon the international community to live up to its pledge in the Declaration of Commitment on HIV/AIDS to implement universal precautions in all nations by 2003. PHR

³⁶ See, e.g., Hans Veeken et al., "Occupational HIV infection and health care workers in the tropics." *Tropical Doctor* (Jan. 1991) 21: 28-31.

³⁷ See Esther C.J. Consten et al., "A prospective study on the risk of exposure to HIV during surgery in Zambia." *AIDS* (1995) 9: 585-588, at 587.

³⁸ See M. Mendelson et al., "Evaluation of Blunt Suture Needles in Preventing Percutaneous Injuries Among Health-Care Workers During Gynecologic Surgical Procedures — New York City, March 1993–June 1994." *Morbidity & Mortality Weekly Report* (Jan. 17, 1997) 46(2): 25-29.

³⁹ See Charles Sagoe-Moses et al., "Risks to Health Care Workers in Developing Countries." *New England Journal of Medicine* (Aug. 16, 2001) 345(7): 538-541, at 538.

further calls upon the international community to endeavor to ensure that all health facilities have safe injection equipment by the end of 2003, given the significance of HIV transmission through unsafe injections and the relative ease with which this problem can be solved.⁴⁰

RECOMMENDATIONS

Injection Safety

The international health community can take a variety of steps to help ensure that a comprehensive safe injection strategy is successfully implemented and to help ensure that the proportion of medical injections that are safe increases rapidly:

- Donors should provide funding to make auto-disable and single-use syringes, single-dose vials, and safety disposal boxes available in all health care settings. Auto-disable syringes and safety boxes should be distributed for vaccinations, family planning services, and those curative injections for which the effectiveness of auto-disable syringes has been demonstrated. For other curative injections, single-use syringes should be used. Injectable substances should be “bundled” with auto-disable (or single-use) syringes, single-dose vials, and safety disposal boxes. Although bundling does not require that the products are packaged together, they must be available in complementary quantities throughout the supply chain. Donors and local authorities should work together to develop a robust supply chain to ensure that adequate supplies of these critical devices are available at all health care service delivery points.⁴¹ It is particularly critical that adequate supplies of single-use syringes are available so that health care providers do not re-use these syringes because of low supplies.⁴²

Countries in Africa, Asia, and elsewhere where unsafe injection practices exist should immediately begin to develop and implement training and education programs for health care providers and the general public on the dangers of unsafe injections, the importance of using only single-use or auto-disable syringes, the importance of using only single-dose vials, and the proper use of injections. Members of the public should be encouraged to demand a new, sterile needle and syringe, and to insist on a non-injectable treatment when one is available. Although health systems are responsible for providing new syringes to each patient, when health facilities fail to do so, members of the public should be encouraged, as a last resort, to purchase and bring their own new, sterile syringes to the health facility. Donor countries and multilateral organizations, such as WHO, should provide technical assistance to facilitate countries’ efforts in developing these programs

⁴⁰ Although the Declaration of Commitment calls for increased access to sterile injecting equipment by 2005, the danger of unsafe injections is far greater than the drafters and signers of the Declaration probably realized, necessitating a faster transition to safe injection equipment than the Declaration calls for. *See Declaration of Commitment on HIV/AIDS*, United Nations General Assembly Special Session on HIV/AIDS (UNGASS), adopted June 27, 2001, at para. 52. Available at: <http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html>.

⁴¹ E-mail from Paula V. Nersesian, Public Health Specialist, John Snow, Inc., March 12, 2003.

⁴² A survey of injection practices in Ethiopia found that only 28 of 51 (55%) health facilities had a one-week supply of disposable injection equipment. *See Yemane Berhane & Jules Millogo, Report of Injection Safety Survey in Ethiopia*, Oct.-Nov. 2000, at 11.

and to ensure a consistent and adequate supply of sterile single-use injection devices and disposal containers.

- Safe injection equipment, health care worker training and education, and public education on injection safety should be universal. But to the extent that international funding and other resources are inadequate, those resources that are available should be directed to the countries or regions with high HIV prevalence. Priority should also be given to clinics and other health facilities where the concentration of HIV-infected people are (or can be expected to be) high. These include treatment clinics for sexually transmitted diseases (STDs) and clinics frequented by populations engaged in high-risk behaviors (for example, health facilities used by large numbers of commercial sex workers).
- WHO, perhaps with SIGN taking the lead, should develop and disseminate health care procedures that allow patients to see for themselves that needles, syringes, and other injection equipment are safe. These procedures could include such elements as the health care provider removing a new auto-disable or single-use syringe from its packaging in front of the patient and showing the patient that the provider is using a single-dose vial. These procedures could be adjusted as needed to meet local circumstances.
- For all multilateral and bilateral assistance programs that directly provide, or provide funding for, medicines and other injectable substances, donors should incorporate a bundling policy that includes auto-disable or single-use syringes, single-dose vials, and safety disposal boxes with the injectable substance. Additional safety boxes should be provided so that each site receiving injection equipment also receives a safety box for disposal.⁴³

A bundling policy should exist for all injectable drugs on the WHO essential drug list. As of late 2001, the “WHO Model List of Essential Drugs specific[d] that 137 of 306 drugs or active ingredients could be made available in injectable form, [but] the list [did] not specify the need to ‘bundle’ injection equipment and safety boxes.”⁴⁴ “[A]ll authorities and organizations in charge of drug supply and drug donations” – both those of donor countries and of developing countries, and both public and private suppliers – “should ‘bundle’ all orders and deliveries of injectable medications with adequate number of disposable syringes, needles and safety boxes.”⁴⁵

- Medical, nursing, and medical officer (or equivalent) training institutions should include in their curricula information on the proper use of injections as well as the proper

⁴³ In a USAID bundling initiative for the contraceptive Depo-Provera, only four boxes are provided for every 400 auto-disable syringes. If the syringes are distributed among more than four health facilities, some will not receive a safety disposal box. Phone conversation with Paula V. Nersesian, Public Health Specialist, John Snow, Inc., March 11, 2003.

⁴⁴ Safe Injection Global Network (SIGN), *Improving Access to Injection Equipment to Improve Injection Safety: Policy Analysis*, Nov. 27, 2001, at 2. Available at: http://www.who.int/medicines/organization/par/edl/policy_analysis.pdf.

⁴⁵ *Id.* at 3.

destruction of injection waste.⁴⁶ In-service training should also be provided. Along with the training, behavioral change programs should be implemented to give health care providers an understanding of the importance of following safe injection practices and the motivation to do so.

- Developing countries should include injection safety (and universal precautions generally) in their national HIV/AIDS strategies, and should devise separate injection safety policies and procedures.⁴⁷ UNAIDS, USAID, and other relevant organizations and agencies should strongly encourage developing countries to revise their national HIV/AIDS strategies in this way, and provide any assistance needed to do so.
- WHO's Department of Essential Drugs and Medicine Policy and other members of the International Network for Rational Use of Drugs (INRUD)⁴⁸ should develop easy-to-use protocols on the rational use of injections. These organizations should work with local health authorities to adapt them to each country's circumstances and to widely distribute the protocols to health care providers. The protocols should address inappropriate uses of injections (such as for fatigue or to deliver vitamins) and list alternative preparations and formulations of medicines commonly irrationally given through injections.

These (or more generic) protocols should also be distributed to pharmaceutical and equipment industry companies that sell injectable medicines or vaccines or injection equipment in developing countries (both to private and public buyers). WHO and other organizations, as well as donor countries, should encourage these companies to manufacture and market their products based on these protocols. They should also encourage these companies to join the movement to promote single-dose medications and auto-disable syringes for all injections, and help to coordinate their efforts.

- Syringe manufacturers should continue to develop new designs for auto-disable syringes for curative injections so as to increase the number of curative injections for which auto-disable syringes are available.⁴⁹ Manufacturers should also increase production capacity for auto-disable syringes now in use.⁵⁰ WHO, other multilateral organizations, and donor

⁴⁶ Even if these health care workers will not be destroying the waste themselves, they are likely to be responsible for oversight of the waste disposal and destruction activities. Comment from Paula V. Nersesian, Public Health Specialist, John Snow, Inc., March 21, 2003.

⁴⁷ Laos, for example, has a five-year plan of action for improving injection safety and safe disposal of injection equipment. See *Lao PDR Plan of Action to Improve Injection Safety and Safe Disposal of Injection Equipment (2000-2004) Draft*, <http://www.healthcarewaste.org/linked/countryinfo/Asia/Laos/LaosPA.pdf>. Accessed Feb. 20, 2003.

⁴⁸ International Network for Rational Use of Drugs (INRUD), homepage, <http://www.inrud.org/>. Accessed March 12, 2003.

⁴⁹ As of October 2002, "two auto-disable syringe designs with capacities exceeding 1 ml [were] available on the market." Safe Injection Global Network (SIGN), *Annual Meeting Report, 24-26 October 2002*, 2002, at 29. Available at: http://www.who.int/injection_safety/sign/meetings/past/2002MeetingReport.pdf.

⁵⁰ The Safe Injection Global Network (SIGN) has recently stated that "the production capacity for auto-disable syringes is estimated at 2-3 times the quantity being procured through UNICEF. These figures are still far less than the estimated quantity of auto-disable syringes that would be required for all immunizations worldwide." Safe Injection Global Network (SIGN), *Annual Meeting Report, 24-26 October 2002*, 2002, at 28. Available at: http://www.who.int/injection_safety/sign/meetings/past/2002MeetingReport.pdf.

countries should assist in technology transfer to enable local manufacturers to produce auto-disable syringes.⁵¹

- USAID should coordinate injection safety efforts among all of its health projects.
- WHO, possibly with other organizations, should compile best practices on safe injection programs to guide training, behavioral change communications, and public education programs.
- WHO, UNAIDS, USAID, and other organizations involved in forming HIV/AIDS prevention strategies should become more vocal proponents of the need for injection safety as a strategy to stem the spread of HIV and other bloodborne pathogens.
- Organizations such as USAID and the International Council of Nurses, which have endorsed the use of auto-disable syringes for immunizations, should also endorse the use of single-use syringes, including auto-disable syringes where available, for all preventative and curative injections.
- UNICEF, WHO, and donors should pressure countries to adhere to all existing bundling policies – such as for immunizations – in their own programs, and provide them assistance in doing so.⁵²
- Along with the work of governments, multilateral organizations, and the pharmaceutical and equipment industry, the medical community in the United States and other wealthy nations, where safe injections are the norm, should advocate for their counterparts in the developing world to have access to the same safe injection equipment as is available in their own countries. They should encourage WHO, UNAIDS, and other multilateral institutions, as well as their own governments, to ensure that health care providers in developing countries have the equipment and training necessary to enable them to adhere to the profession’s time-honored pledge, “first, do no harm.”
- Donors and international organizations should support the development and implementation of safe and effective destruction mechanisms for injection waste.

Blood Transfusion Safety

To ensure that HIV infections through blood transfusions are eliminated:

⁵¹ *See id.* (“Technology transfer supports auto-disable production in India and is possible or under consideration in other regional countries, including Indonesia and Bangladesh.”)

⁵² In their 1998 measles campaign, Botswana, South Africa, and Zimbabwe did not adhere to the WHO-UNICEF 1997 bundling policy for mass immunizations, while other countries were unable to adhere to the policy because of poor planning and distribution, which led to shortages of auto-disable syringes. *See* M. Dicko, “Safety of Immunization Injections in Africa: Not Simply a Problem of Logistics.” *Bulletin of the World Health Organization* (2000) 78(2): 163-169, at 166. Available at: <http://www.who.int/bulletin/pdf/2000/issue2/bu0269.pdf>.

- WHO, UNAIDS, and other health and development organizations should work with developing countries that currently lack national blood safety policies to devise such policies. WHO recommends that all blood be screened for HIV, hepatitis B, and syphilis, and that where appropriate, it is also tested for hepatitis C, Chagas disease, and malaria.⁵³
- Donor nations should provide funding to assist developing countries in implementing their national blood safety plans.⁵⁴
- Countries lacking national blood transfusion legislation should develop and enact such legislation.
- Once their national blood safety policies have been implemented, and for those nations with blood safety policies already in operation, countries should conduct on-going monitoring and evaluation to determine whether the policies are being adhered to. If not, donors and multilateral organizations should provide technical assistance to assist countries in translating the policies into practice.
- As WHO has recognized, regional training centers could be established to train managers in national blood transfusion services, and information could be shared regionally.⁵⁵ Developing nations should consider their own training needs and capacities under their blood safety programs and, if they decide it useful, should build one or multiple regional training centers to train blood system managers in quality management. If such centers are established, donors should assist in funding them.

Universal Precautions

- Donor nations should work with developing countries to contribute the funding and expertise to fulfill the pledge in the Declaration of Commitment on HIV/AIDS to make universal precautions truly universal by the end of 2003.⁵⁶

⁵³ See World Health Organization, Department of Blood Safety and Clinical Technology, *Blood Transfusions Safety, Questions and Answers*, http://www.who.int/bct/Main_areas_of_work/BTS/Questions_and_answers.htm. Accessed March 25, 2003.

⁵⁴ USAID is currently providing assistance to Kenya and the Democratic Republic of Congo to improve blood safety. See U.S. Agency for International Development, *Global Health: HIV/AIDS, Countries, Kenya*, http://www.usaid.gov/pop_health/aids/Countries/africa/kenya.html. Accessed Feb. 22, 2003 (“In addition to helping develop a national blood policy, USAID is assisting the government of Kenya to revamp its blood transfusion system through building and renovating five transfusion centers, providing equipment and training technical staff”); U.S. Agency for International Development, *Global Health, HIV/AIDS, Countries, Democratic Republic of Congo*, http://www.usaid.gov/pop_health/aids/Countries/africa/congo.html. Accessed Feb. 22, 2003 (“Through Catholic Relief Services, USAID introduced rapid HIV diagnostic tests to improve blood safety in rural health delivery sites”).

⁵⁵ See World Health Organization, Department of Blood Safety and Clinical Technology, *Blood Safety and Clinical Technology, Strategy 2000-2003*, May 2001, at 33-37. Available at: http://www.who.int/bct/Main_areas_of_work/Resource_Centre/General_docs/BCT_Strategy_2000-2003.pdf

⁵⁶ See *Declaration of Commitment on HIV/AIDS*, United Nations General Assembly Special Session on HIV/AIDS (UNGASS), adopted June 27, 2001, at para. 51. Available at: <http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html> (“By 2003, implement universal precautions in health-care settings to prevent transmission of HIV infection”).

- In ensuring that universal precautions are respected, donors and developing countries should give special attention to precautions necessary to prevent transmission of HIV through needlestick injuries, including providing proper training and ensuring consistent availability of sharps disposal containers, auto-disable and single-use syringes, and disposable gloves. Priority should be given to providing training and protective gear, including gloves and goggles, to health care providers most likely to be exposed to large amounts of blood and other body fluids, including surgeons, midwives, traditional birth attendants, operating theater staff, and laboratory technicians.
- Medical, nursing, and medical officer (or equivalent) school curricula should incorporate material on universal precautions, and current health care providers should receive in-service training on these protections. Health care providers “should understand the need to use universal precautions with all patients, at all times, regardless of diagnosis.”⁵⁷ Along with the training, behavioral change programs should be implemented to give health care providers an understanding of the importance of adhering to universal precautions and the motivation to do so.
- Internationally-supported programs on preventing HIV/AIDS and other infectious diseases should incorporate protective measures for health care providers.⁵⁸
- Countries should enact and implement laws that guarantee health care providers and patients the protection of universal precautions.
- For surgical procedures for which blunt suture needles are appropriate, blunt suture needles should replace sharp suture needles.⁵⁹ When blunt suture needles are produced in sufficient volume, they will not be more expensive than sharp suture needles.⁶⁰
- Nonretracting finger-stick lancets and glass capillary tubes should be replaced with automatically retracting lancets and plastic or plastic-wrapped capillary tubes.⁶¹

Additional Recommendations

- National HIV/AIDS strategies should cover the risk of HIV transmission in health care settings. UNAIDS, USAID, and other organization that work with countries to create national strategies should ensure that HIV transmission in health care settings is included in the strategies.

⁵⁷ World Health Organization, *Universal Precautions, Including Injection Safety*, <http://www.who.int/hiv/topics/precautions/universal/en/>. Accessed Dec. 13, 2002.

⁵⁸ See, e.g., Charles Sagoe-Moses et al., “Risks to Health Care Workers in Developing Countries.” *New England Journal of Medicine* (Aug. 16, 2001) 345(7): 538-541, at 540.

⁵⁹ Conversation with Dr. Janine Jagger, Health Care Worker Safety Center, University of Virginia, Dec. 6, 2002. See also Janine Jagger, Melanie Bentley & Patricia Tereskerz, “A study of patterns and prevention of blood exposures in OR personnel.” *AORN Journal* (May 1998) 67(5): 979-996.

⁶⁰ E-mail from Dr. Janine Jagger, Health Care Worker Safety Center, University of Virginia, Jan. 29, 2003.

⁶¹ See Charles Sagoe-Moses et al., “Risks to Health Care Workers in Developing Countries.” *New England Journal of Medicine* (Aug. 16, 2001) 345(7): 538-541, at 538.

- Public and private research institutions should conduct further research on how HIV is transmitted in health care settings, with a particular focus on means that remain unknown, under-recognized, or insufficiently understood.
- The U.S. National Institutes of Health (NIH) should add research on health care risks and HIV transmission as an additional focus in their HIV Prevention Trials Network.⁶²
- The public should be educated on the risks of HIV transmission in health care settings generally, along with the specific risks including those of unsafe injections and multi-dose vials.
- WHO, UNAIDS, bilateral development agencies, and independent health care professionals and their advocacy groups should encourage patient-advocacy activities and organizations in developing countries to continually question and monitor the safety of health care.
- WHO, UNAIDS, and bilateral development agencies should encourage public discussion on the risks of HIV transmission in health care settings, and encourage and cooperate with private initiatives to investigate and publicly discuss evidence of specific cases of HIV transmission in these settings.

⁶² The HIV Prevention Trials Network is a worldwide network of clinical trials that test the efficacy and safety of HIV prevention interventions. A division of the NIH established it in 1999. They currently focus on six areas: therapies, behavioral interventions, microbicides, perinatal, STD control, and substance use. See HIV Prevention Trials Networks, *HPTN Prevention Science*, http://www.hptn.org/prevention_science.htm. Accessed Feb. 18, 2003.

INTRODUCTION

Every year, at least half a million people contract HIV in health care settings – through unsafe medical injections, unsafe blood transfusions, and HIV transmission between patient and health care provider – because of underlying violations of core aspects of the right to health.⁶³ A central tenant of the right to health is that health care must be safe. People in every country, rich and poor, have the right to a health system that improves people’s health status, not one create grave risks to health. Yet unsafe medical injections and unsafe blood transfusions contribute significantly to the greatest health crisis of our time, the HIV/AIDS pandemic. Inadequate efforts by donors, multilateral organizations, and the governments of impoverished countries themselves to ensure safe health care for people in poor countries suggest a tacit, widespread acceptance of a two-tiered health system: health care must be safe in wealthy countries, but not in poorer countries. Under human rights law, health care must be safe in every country. Until the discriminatory perception ends, unsafe medical injections and unsafe blood transfusions will continue to contribute considerably to the HIV/AIDS pandemic.

Discrimination against people living with HIV/AIDS is also fueling the pandemic. The widespread inability of health care providers to implement universal precautions necessary for them to protect themselves from contracting HIV from their patients contributes to that discrimination. Without proper training or adequate supplies to protect themselves, health care providers’ often reasonable fears for their own safety frequently have devastating consequences. The fears can lead them to refuse to treat people infected with HIV, or to follow safety precautions only for people they suspect are infected, thus contributing to the stigma and isolation of people living with HIV/AIDS. This discriminatory treatment of people with HIV/AIDS violates a core aspect of the right to health, everyone’s right to access health care on a non-discriminatory basis. Absent universal precautions, such discrimination seems destined to continue.

Discrimination that HIV-positive people face in the health system has lethal consequences. It discourages them from seeking health care, such as treatment for opportunistic infections and nutritional counseling, speeding people’s passage from infection to death. Discrimination in the health care sector and the stigma and discrimination that people living with HIV/AIDS face throughout society discourages people from seeking voluntary counseling and testing services, which might reveal that they are HIV-positive. Yet these services provide HIV/AIDS education

⁶³ A model endorsed by the World Health Organization (WHO) estimates that 260,000 HIV infections are caused annually by unsafe medical transmissions. 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). WHO estimates that 5-10% of new HIV infections are caused by unsafe blood transfusions. See 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. 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 healthcare (260,000 through unsafe injections and 250,000 through unsafe blood transfusions) occur every year.

that enable people infected with the virus to take precautions against transmitting the disease to others, and they are the gateway to the interventions that will promote infected people's own health. Every step towards ending discrimination against people living with HIV/AIDS is a crucial step in stopping the spread of the disease. One such step is providing the training and supplies to enable health care providers to adhere to universal precautions, including injection safety.

To assure people's human rights and to help stop the HIV/AIDS pandemic, immediate efforts to increase injection safety, the safety of blood supplies, and adherence to universal precautions are necessary to prevent infections from unsafe injections, transfusions of contaminated blood, and HIV transmission between patient and health care provider.

In the early years of the HIV/AIDS epidemic, the risk of HIV transmission in health care settings received considerable attention. Studies in the mid-1980s suggested its importance to the emerging HIV/AIDS pandemic in Africa, with crude risk measures even associating a higher proportion of HIV infections with medical injections than with measures of sexual exposure.⁶⁴ In 1987, the U.S. Centers for Disease Control and Prevention (CDC) developed universal precautions, measures to protect against the transmission of HIV and other bloodborne pathogens in the medical setting. When the World Health Organization (WHO) concluded in 1988, however, that about 90% of HIV cases in adults in Africa were caused by sexual transmission, the risks of HIV transmission in the medical setting, especially from unsafe injections, largely dropped out of the discussion of AIDS in Africa.⁶⁵ Prevention efforts in Africa came to focus almost exclusively on sexual transmission, along with blood safety.

More than a decade later, in June 2001, the Declaration of Commitment on HIV/AIDS that emerged from the UN General Assembly Special Session on HIV/AIDS acknowledged the risk of HIV transmission in health care settings – and the need to do something about it. The Declaration called for the “implement[ation of] universal precautions in health-care settings to prevent transmission of HIV infection [by 2003].”⁶⁶ It also called on nations to ensure, by 2005, “expanded access to essential commodities, including . . . sterile injecting equipment.”⁶⁷ The United Nations' HIV/AIDS coordinating body, UNAIDS, has been slow to incorporate these elements of the Declaration into its own programming. Not until a year later, in October 2002, did UNAIDS consider these measures to be important enough to include universal precautions and safe medical injection equipment in their estimate of the cost of a global response to the HIV/AIDS pandemic. The estimate also included a third measure that acknowledged the risk of

⁶⁴ See David Gisselquist, John J. Potterat, Stuart Brody & François Vachon, “Let it be sexual: how health care transmission of AIDS in Africa was ignored.” *International Journal of STD & AIDS* (March 2003) 14: 148-161, at 151.

⁶⁵ See *id.* at 148. For example, “[b]y mid-1989, an overview of global HIV epidemiology by leading AIDS experts at the Fifth International Conference on AIDS did not even mention medical injections as a risk for HIV.” *Id.*

⁶⁶ *Declaration of Commitment on HIV/AIDS*, United Nations General Assembly Special Session on HIV/AIDS (UNGASS), adopted June 27, 2001, at para. 51. Available at: <http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html>.

⁶⁷ *Id.*, at para. 52.

the transmission of HIV in the medical setting, post-exposure prophylaxis (PEP) for health care providers.⁶⁸

While steps in the past two years have placed the issue of HIV transmission in health care settings back on the international agenda after an absence of more than a decade, the unhurried pace at which the international community is moving is inconsistent with these risks. As new data emerging out of South Africa and other strands of evidence discussed in this paper strongly suggest, every year many hundreds of thousands, and possibly even a million or more, new HIV infections are caused by HIV transmission in health care settings. Huge numbers of lives could be saved by ensuring the practice of universal precautions, including safe injections and other infection control practices in health care settings, the use of safe blood and blood products, and providing post-exposure prophylaxis for health care providers potentially exposed to HIV through needlestick accidents.

HIV is only one of many bloodborne pathogens spread by unsterile medical care. Every year, about 8-16 million people become infected with hepatitis B and 2.3-4.7 million with hepatitis C because of unsafe medical injections.⁶⁹ A study published in the *Bulletin of the World Health Organization*, which used low-end estimates of the numbers of hepatitis infections caused by unsafe injections, estimated that unsafe medical injections given each year will cause about 1.0 million deaths from hepatitis B and another 200,000 deaths from hepatitis C.⁷⁰ A new model, by

⁶⁸ See UNAIDS press release, *New figures show AIDS fight under-resourced: Existing funds insufficient to keep pace*, Oct. 10, 2002. Available at:

http://www.unaids.org/whatsnew/press/eng/pressarc02/GlobalFund101002_en.html.

⁶⁹ 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. A more recent model, the same one that estimates that every year 260,000 HIV infections are caused by unsafe medical injections, estimates that 20.6 million hepatitis B and 2.0 million hepatitis C infections are caused by unsafe medical injections every year. 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). For a summary of evidence on the link between unsafe injections and transmission of hepatitis B, 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 794-795. Available at:

<http://www.who.int/bulletin/pdf/issue10/simonsen.pdf>. Six of nine studies that this article reviews on the connection between hepatitis B and unsafe injections estimate the proportion of infections attributable to unsafe injections. The proportion ranges from 20% to 80%. See *id.* at 794. Unsafe medical injections have also been linked to outbreaks of malaria (*plasmodium falciparum*), Ebola, and Lassa fever. See *id.* at 793-795. Hepatitis deaths are caused by cirrhosis of the liver and liver cancer. See World Health Organization, *Hepatitis B Fact Sheet*, Oct. 2000. Available at: <http://www.who.int/inf-fs/en/fact204.html>.

⁷⁰ See M.A. Miller & E. Pisani, "The Cost of Unsafe Injections." *Bulletin of the World Health Organization* (1999) 77(10): 808-811, at 808-09. Available at: <http://www.who.int/bulletin/pdf/issue10/miller.pdf>. The same estimate placed the number of unsafe injection-related HIV deaths at about 100,000 per year. See *id.* The SIGN study that estimates 260,000 HIV infections per year from unsafe injections estimates far lower numbers of hepatitis deaths from unsafe injections. It estimates that by the year 2030, unsafe injections given in 2000 will lead to 49,000 deaths from hepatitis B and 24,000 deaths from hepatitis C. 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). As the authors of this study note, these estimates are low compared to the number of infections. One reason is the delay between infection and death, meaning that many deaths might occur outside of the 30 year period included in the study. They also note that as hepatitis B vaccination rates increase, transmission through unsafe injections will decrease. See *id.* WHO estimates that at present, more than 1 million people die every year as a result of hepatitis B infections. See Hepatitis B Foundation,

the WHO-affiliated Safe Injection Global Network (SIGN), put the number of annual, global HIV infections from unsafe injections in the medical setting at 260,000, or about 5% of the total HIV incidence,⁷¹ but ongoing debates, along with recent reports from South Africa, suggest that the number could be significantly higher. Based on the WHO and SIGN estimates of hepatitis and HIV transmission through unsafe injections, and evidence that unsafe injections are a more significant cause for HIV infections than even SIGN has recognized, it appears that unsafe injections given each year will likely be responsible for more than 1.5 million deaths.⁷²

Facts on Hepatitis B, <http://www.hepb.org/info.html>. Accessed March 26, 2003. Unsafe injections are believed to cause 20-80% of hepatitis B infections. 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 794. Available at: <http://www.who.int/bulletin/pdf/issue10/simonsen.pdf>. This would suggest that unsafe injections given each year will transmit hepatitis B infections that will be responsible for 200,000-800,000 deaths. However, factors including the much larger birth cohort today compared to decades ago (on average, about 30 years pass between hepatitis B infection and death from that infection), partially offset by hepatitis B immunizations, lead to the higher estimate of 1.0 million deaths attributable to hepatitis B infections contracted annually from unsafe injections. E-mail from Dr. Mark Miller, Director Division of International Epidemiology and Population Studies, Fogarty International Center, National Institutes of Health, Feb. 24, 2003. Dr. Miller co-authored "The Cost of Unsafe Injections" study.

⁷¹ 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).

⁷² For there to be 1.5 million deaths from unsafe injections, 300,000 (about 10% of annual HIV deaths today) would have to come from HIV infections. For reasons discussed below, the 260,000 estimate from SIGN is probably too low, which means the total number of deaths from HIV probably exceeds 300,000, and the total number of deaths from unsafe injections exceeds 1.5 million. This number of deaths from HIV assumes all HIV infections will lead to death, so this number could fall once anti-retroviral therapy because widely available in poor countries and HIV/AIDS ceases to be a death sentence in those countries. Until then, however, except for a fortunate few, an HIV infection almost always means death in Africa and the developing countries of Asia. Of 6 million people in the developing world in urgent need of anti-retroviral therapy, only 230,000 are receiving it, including not many more than 30,000 in Africa. See World Health Organization, *Scaling Up Antiretroviral Therapy in Resource-Limited Settings, Guidelines for a Public Health Approach, Executive Summary*, April 2002, at 6; UNAIDS press release, *New UNAIDS report warns AIDS epidemic still in early phase and not leveling off in worst affected countries*, July 2, 2002. Available at: <http://www.unaids.org/whatsnew/press/eng/pressarc02/PRreport020702.html>.

UNSAFE INJECTIONS

Background

Medical injections are procedures that pierce the skin and introduce a substance into the patient for curative or preventative medical purposes, including immunizations. In developing countries, substances commonly injected are vitamins, antibiotics, analgesics, and quinine. Symptoms and conditions often treated with injections include fever, upper respiratory infections, colds, ear infections, tonsillitis, pelvic inflammatory disease, pneumonia, skin infections, diarrhea, malaise, and fatigue.⁷³

Injections are common in the developing world. In addition to being unsafe, injections are frequently given unnecessarily because patients view injections as “a symbol of the best that medicine has to offer and the most efficient and rapid way to find relief.”⁷⁴ In one study, more than 70% of injections given to outpatients in developing countries were unnecessary, “antibiotics, vitamins, analgesics, or other drugs inappropriately given for upper respiratory disease, diarrhea, fever, or general fatigue.”⁷⁵ Other studies have found more than 90% of injections given in developing countries to be unnecessary.⁷⁶ Estimates of the number of medical injections given yearly vary significantly, ranging from about 4.3 billion in the developing world to at least 16.7 billion globally.⁷⁷ At least 12 billion syringes are sold each year for medical injections, including about 1 billion for childhood immunizations.⁷⁸ Immunizations are estimated to account for 3-10% of medical injections given each year.⁷⁹ The areas of the

⁷³ 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 791. Available at: <http://www.who.int/bulletin/pdf/issue10/simonsen.pdf>. Analgesics are pain-killers and quinine is a medicine used to treat malaria.

⁷⁴ Anne V. Reeler & Lone Simonsen, *Bill and Melinda Gates Child Vaccine Program Occasional Paper #2, Unsafe Injections, Fatal Infections*, May 2000, at 1. Available at: http://www.childrensvaccine.org/files/CVP_Occ_Paper2.pdf.

⁷⁵ *Id.*

⁷⁶ See Safe Injection Global Network (SIGN), *Annual Meeting Report, 24-26 October 2002*, 2002, at 4. Available at: http://www.who.int/injection_safety/sign/meetings/past/2002MeetingReport.pdf. Along with the dangers of unnecessary injections, they drain government health resources, as 20-40% of national health budgets are spent on drugs, with antibiotics and injections being among the most expensive. See *id.*

⁷⁷ See M.A. Miller & E. Pisani, “The Cost of Unsafe Injections.” *Bulletin of the World Health Organization* (1999) 77(10): 808-811, at 808. Available at: <http://www.who.int/bulletin/pdf/issue10/miller.pdf> (4.3 billion); 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* (in press) (16.7 billion).

⁷⁸ 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 789. Available at: <http://www.who.int/bulletin/pdf/issue10/simonsen.pdf>.

⁷⁹ See World Health Organization, *Safety of Injections Fact Sheet*, April 9, 2002. Available at: <http://www.health.fgov.be/WHI3/krant/krantarch2002/kranttekstapr2/020409m02a-who.htm> (estimating that immunizations account for about 3% of all injections, with injections for curative care accounting for about 95% of injections, with other injections, including of blood, blood products, and contraceptives, accounting for the rest); 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 791. Available at: <http://www.who.int/bulletin/pdf/issue10/simonsen.pdf> (reporting that in five studies in developing countries, immunizations ranged from 2% to 15% medical injections, with a median of 5%); A. Kane et al., “Transmission of Hepatitis B, Hepatitis C and Human Immunodeficiency Viruses through Unsafe Injections in the Developing World:

world with the highest proportion of unsafe injections are South Asia and sub-Saharan Africa.⁸⁰ In sub-Saharan Africa, a literature review carried out by WHO researchers found that in five of seven studies in which the percent of unsafe medical injections was calculated, at least half of the injections were unsafe. Injections are considered unsafe when syringes are re-used without being sterilized.⁸¹

Significant mode of HIV transmission

The WHO-affiliated Safe Injection Global Network (SIGN) recently estimated that globally, about 260,000 – or 5% – of annual HIV infections occur because of unsafe injections in health care settings.⁸² However, various threads of evidence strongly suggest that the 260,000 estimate is, as the researchers who made it concede, “conservative.”⁸³ Indeed, several researchers have estimated that unsafe injections have caused as many as 20-40% of HIV infections in Africa.⁸⁴

- The SIGN model used WHO estimates that about 17-19% of injections administered in Africa were unsafe.⁸⁵ But an earlier WHO study that compiled eleven surveys on the prevalence of unsafe injections in Africa from the late 1980s to the late 1990s found that in five of seven studies in which the percent of unsafe injections was calculated, at least half of the injections were unsafe.⁸⁶
- One source of controversy over the importance of unsafe injections as a method of transmitting HIV revolves around the efficiency with which HIV is transmitted by unsafe injections. The standard assumption is that the transmission efficiency is about 0.3%, which is based on studies of needlestick injuries to health care providers in the United States and Europe. Most of these injuries are superficial.⁸⁷ However, unsafe injections

Model-Based Regional Estimates.” *Bulletin of the World Health Organization* (1999) 77(10): 801-807, at 802. Available at: <http://www.who.int/bulletin/pdf/issue10/kane.pdf> (estimating that the ratio of immunization to curative injections is 1 to 8-12).

⁸⁰ 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. Available at: <http://www.who.int/bulletin/pdf/issue10/kane.pdf> (estimating that half of injections are unsafe in Asia and sub-Saharan Africa, compared to 15% in the former socialist economies of Europe, and 15% in the Middle East crescent).

⁸¹ 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, 795. Available at: <http://www.who.int/bulletin/pdf/issue10/simonsen.pdf>.

⁸² 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).

⁸³ *Id.*

⁸⁴ See David Gisselquist, Richard Rothenberg, John Potterat & Ernest Drucker, “HIV infections in sub-Saharan Africa not explained by sexual or vertical transmission.” *International Journal of STD & AIDS* (2002) 13: 657-666, at 657.

⁸⁵ 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).

⁸⁶ 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>.

⁸⁷ See David Gisselquist, Richard Rothenberg, John Potterat & Ernest Drucker, “HIV infections in sub-Saharan Africa not explained by sexual or vertical transmission.” *International Journal of STD & AIDS* (2002) 13: 657-666,

may be more akin to deep needlestick injuries, which have a transmission efficiency of about 2.3%.⁸⁸ The 260,000 estimate used a transmission efficiency of 1.2%.⁸⁹ If the efficiency is greater, the number of HIV infections caused by unsafe injections is greater as well.

- The first nationally representative study of HIV prevalence in South Africa, which was released in late 2002, found HIV prevalence among children ages 2-14 to be 5.6%.⁹⁰ According to an estimate that uses data on HIV prevalence for children and for women attending antenatal care clinics, and makes several assumptions about the death rate of children infected with HIV from their mothers, 70% of the HIV cases among children 2-14 cannot be explained by mother-to-child transmission.⁹¹ The study on HIV/AIDS in South Africa found very low levels of sexual activity among children, raising the possibility that almost all of the children who did not contract HIV through mother-to-child transmission contracted it while receiving medical care, including unsafe injections.⁹² Further research is underway to confirm or refine these estimates and to determine the source of confirmed infections not linked to maternal HIV.
- The 260,000 estimate is based on data that placed the proportion of HIV infections in Africa caused by unsafe injections at 2.5%, below the global average of 5%. Yet numerous studies suggest a higher association. In the four African studies cited by the

at 662; David P. Gisselquist, "Estimating HIV-1 Transmission Efficiency through Unsafe Medical Injections." *International Journal of STD & AIDS* (2002) 13: 152-159, at 152.

⁸⁸ 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* (in press). See also David Gisselquist, Richard Rothenberg, John Potterat & Ernest Drucker, "HIV infections in sub-Saharan Africa not explained by sexual or vertical transmission." *International Journal of STD & AIDS* (2002) 13: 657-666, at 662 (suggesting transmission efficiency for HIV during unsafe injection could be an order of magnitude greater than 0.3%). See generally David P. Gisselquist, "Estimating HIV-1 Transmission Efficiency through Unsafe Medical Injections." *International Journal of STD & AIDS* (2002) 13: 152-159.

⁸⁹ 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).

⁹⁰ See Centre for AIDS Development, Research and Evaluation (CADRE), *Nelson Mandela/HSRC Study of HIV/AIDS, South African National HIV Prevalence, Behavioral Risks, and Mass Media, Household Survey 2002*, 2002, at 47. Available at: <http://www.cadre.org.za/pdf/HIV%20Report.pdf>. The prevalence was similar for boys and girls. See *id.* The researchers further analyzed the data for children to determine how many could be attributed to mother-to-child transmission. Of the 86 HIV-positive children, 20 could be linked to biological parents whose HIV-status was known. Only 5 were HIV-positive (4 mothers and 1 father); the other 15 were HIV-negative. These results could not be explained by a hypothesis that most of the children became infected through mother-to-child transmission and that their parents had since died. Of the 86 HIV-positive children, only 6.1% had a deceased biological mother, and 7.0% had a deceased biological father. See *id.* at 63. The study involved nearly 10,000 participants, including anonymous HIV tests of 8,840 people. See Centre for AIDS Development, Research and Evaluation (CADRE), *Nelson Mandela/HSRC Study on HIV/AIDS press briefing*, Dec. 5, 2002. Available at: <http://www.cadre.org.za/doc/SABSSM%20press%20briefing%203%20Dec.doc>.

⁹¹ See David Gisselquist, *Estimate of the Proportion of Non-MTCT HIV Infections in South African Children 2-14 Years Old*. (Unpublished) Dec. 13, 2002.

⁹² Another possible source of some of these infections is child rape, which is a significant problem in South Africa, and not likely to be reported. See Charlene Smith, "South Africa: Child Rape Crisis Fueled by 'Virgin Cure' Myth." *African Eye News Service (Nelspruit, South Africa)*, Dec. 18, 2002. Available at: <http://allafrica.com/stories/200212230241.html>. Other possible sources include scarification and other non-medical sources of incisions.

authors of the 260,000 estimate, the “crude” population attributable fraction (PAF) of incident HIV associated with medical injections was 8% to 46%.⁹³ In other words, these studies found that people reporting more injections were significantly more likely to have HIV infections than people reporting fewer injections. The crude PAF is a rough measure of the proportion of HIV cases attributable to unsafe injections. A review of 15 large studies that provide enough data to calculate crude PAFs for HIV associated with injections found PAFs below 22% in only four of the studies, and the unweighted average PAF of all studies was 29%.⁹⁴

The crude PAF may overestimate the actual proportion of cases attributable to unsafe injections. For example, people might get more injections because they have HIV/AIDS. Or people with more injections might have more sexually transmitted diseases (STDs) (and receive injections for STDs) and hence more sexual risks for HIV. In most of these studies, it is not possible to determine what proportion of the association between HIV status and number of injections is the result of injections causing the HIV infections, and what proportion can be attributed to HIV infection leading to more injections. One study in which it was possible statistically to remove reverse causation (HIV infection leading to more injections) found that even controlling for the possibility that having HIV/AIDS might cause people to seek more medical injections, the PAF of HIV associated with medical injections was 21%.⁹⁵

A study design that eliminates the possibility of reverse causation is one that compares the HIV prevalence between people with STDs who did not receive injections for their STDs to people with STDs who did receive injections for their STDs. The possibility of reverse causation is eliminated because the injections are specifically for STDs, not for symptoms of HIV/AIDS. These studies have found that people with STDs who received injections were significantly more likely to become HIV-positive than people with STDs who received no injections. In one study, for example, HIV prevalence in people with STDs and who had received injections for the STDs was 28.9%, compared to 16.9% for people reporting STDs but no injections for it.⁹⁶

- A recent model of sexual transmission in sub-Saharan Africa casts doubt on the conventional wisdom that sexual transmission accounts for at least 90% of adult HIV cases in sub-Saharan Africa. The model estimated the proportion of HIV infections in Africa caused by sexual transmission based on data that included the proportion of men

⁹³ 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).

⁹⁴ See David Gisselquist, Richard Rothenberg, John Potterat & Ernest Drucker, “HIV infections in sub-Saharan Africa not explained by sexual or vertical transmission.” *International Journal of STD & AIDS* (2002) 13: 657-666, at 661.

⁹⁵ See David Gisselquist, John J. Potterat, Stuart Brody & François Vachon, “Let it be sexual: how health care transmission of AIDS in Africa was ignored.” *International Journal of STD & AIDS* (March 2003) 14: 148-161, at 156-157.

⁹⁶ See *id.* at 157 (citing P. Van de Perre et al., “Risk Factors for HIV Seropositivity in Selected Urban-based Rwandese Adults.” *AIDS* (1987) 1(4): 207-211). See also David Gisselquist, Richard Rothenberg, John Potterat & Ernest Drucker, “HIV infections in sub-Saharan Africa not explained by sexual or vertical transmission.” *International Journal of STD & AIDS* (2002) 13: 657-666, at 661.

and women who are married; the rate of HIV incidence in serodiscordant couples (in which one partner is HIV-negative and the other is HIV-positive); the proportion of couples that are serodiscordant; the number of sexual partners for men and women, and; the number of men and women who were not sexually active in the previous year. According to the model, total sexual transmission could only explain about one-third of the epidemic's growth (25-29% of incidence in women and 30-35% of incidence in men).⁹⁷

- Various studies in Africa have reported significant HIV prevalence levels in adults who reported having never had a sexual partner (or who reported not having had one in the past five years) or whose only reported lifetime sexual partner was HIV-negative. For example, a study in eastern Zimbabwe found a 2.1% HIV prevalence among women who reported never having had a sex partner.⁹⁸ A 1990 study of Ugandan adolescents found that 6.9% of women who reported no sex partners in the previous five years were HIV-positive, compared to 23.3% of women who reported having had at least one sex partner.⁹⁹ A 1995 study of Tanzanians 15-24 years old “found HIV prevalence of 5.6% among men and 3.6% among women who did not report any lifetime sexual activity [compared to] 4.8% and 12% for men and women reporting one or more sexual partners.”¹⁰⁰ A study in Rwanda reported that 15 of 25 HIV-positive women with HIV-negative partners reported only one lifetime sexual partner.¹⁰¹ Injections or other modes of transmission in health care settings are likely candidates for the cause of HIV infection in these cases that sexual transmission cannot explain.

Dangers in Asia

While most of the research described above focuses on Africa, unsafe injections also pose an enormous risk in Asia, especially India and China. Several WHO surveys suggest that the levels of unsafe injections are higher in Southeast Asia than sub-Saharan Africa. The same SIGN study that reported WHO estimates that 17-19% of injections in Africa were unsafe reported other studies showing that 30-75% of injections in Southeast Asia involved re-used syringes, including 30% in China and 75% in India.¹⁰² Another WHO survey found that for all four studies that had

⁹⁷ See David Gisselquist & John J. Potterat, “Heterosexual Transmission of HIV in Africa: An Empiric Estimate.” *International Journal of STD & AIDS* (March 2003) 14: 162-173, at 170. The model assumes an annual epidemic growth of 10%. The actual level of growth in sub-Saharan Africa as a whole has been higher, a difference which would tend to cause the model to overestimate the importance of sexual activity.

⁹⁸ See Basia W. Zuba et al., “Adjusting Ante-natal Clinic Data for Improved Estimates of HIV Prevalence among Women in Sub-Saharan Africa.” *AIDS* (2000) 14(17): 2741-2750, at 2744

⁹⁹ See Joseph K. Konde-Lule et al., “Adolescents, Sexual Behavior and HIV-1 in Rural Rakai District, Uganda.” *AIDS* (1997) 11(6): 791-799, at 796.

¹⁰⁰ David Gisselquist, Richard Rothenberg, John Potterat & Ernest Drucker, “HIV infections in sub-Saharan Africa not explained by sexual or vertical transmission.” *International Journal of STD & AIDS* (2002) 13: 657-666, at 659 (citing A. Tengia-Kessy, G.I. Msamanga & C.S. Moshiri, “Assessment of Behavioural Risk Factors Associated with HIV Infection among Youth in Moshi Rural District, Tanzania.” *East African Medical Journal* (1998) 75:528-532).

¹⁰¹ See Susan Allen et al., “Effect of Serotesting with Counselling on Condom Use and Seroconversion among HIV Discordant Couples in Africa.” *BMJ* (1992) 304: 1605-1609, at 1607.

¹⁰² 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).

data on the proportion of unsafe injections in Asia, at least 50% of injections were unsafe, including 90% or more in two studies from the 1990s.¹⁰³

Furthermore, most hepatitis deaths that result from unsafe injections occur in Asia. According to the study that estimates that each year unsafe injections will cause 1.2 million people to die from hepatitis B and hepatitis C infections (and 100,000 from HIV), more than 1 million of those deaths will occur in Asia, including 475,000 in India and 382,000 in China.¹⁰⁴

Programmatic response

Safe injection equipment and injection safety education

The most basic response to unsafe injections is to make safe injection equipment universally available. This should be accompanied by training on proper use of that equipment and community education on the importance of safe injections and on the appropriate use of injections. A WHO study to be published in 2003 estimates the cost of a comprehensive global program that includes safe injection equipment, training, and education at about \$905 million per year.¹⁰⁵ The overall cost should decrease over time as information on the appropriate use of injections becomes more widespread, and injections come to be given less frequently. UNAIDS has estimated a lower cost of a safe injection program, about \$290 million per year, which would cover all medical injections.¹⁰⁶

There are three major differences between the WHO and UNAIDS estimates. The first is the way in which the two organizations calculated the number of injections for which safe injection equipment is needed. The WHO study uses the number of unsafe injections in the formal public health sector, based on regional data. The UNAIDS estimate uses the estimated overall number of medical injections in low- and middle-income countries.¹⁰⁷ The second and most significant difference is how they calculate the cost of syringes. The WHO study includes the full cost of single-use syringes/needle sets, which varies from about 13 to 23 cents in different regions of the world, and is 13 to 15 cents in most regions. The cost of the syringe/needle sets incorporate the

¹⁰³ 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>.

¹⁰⁴ See M.A. Miller & E. Pisani, "The Cost of Unsafe Injections." *Bulletin of the World Health Organization* (1999) 77(10): 808-811, at 809. Available at: <http://www.who.int/bulletin/pdf/issue10/miller.pdf>.

¹⁰⁵ See Gerald Dziekan et al., "The Cost-Effectiveness of Policies for the Safe and Appropriate Use of Injection in Healthcare Settings." *Bulletin of the World Health Organization* (2003) 81(4) (in press).

¹⁰⁶ See UNAIDS, *Financial resources for HIV/AIDS programmes in low-and middle-income countries over the next five years*, Nov. 28, 2002, at 7, 13. Available at: http://www.unaids.org/about/governance/files/PCB13_FinancialResources_en.doc. According to an e-mail from Catherine Hankins, chief scientist at UNAIDS, the annual cost will rise from \$289 million in 2005 to \$296 million in 2007. E-mail from Catherine Hankins, Feb. 19, 2003.

¹⁰⁷ UNAIDS arrived at its number by using 2.1 injections per person (based on the report from the Commission on Macroeconomics and Health, which Jeffrey Sachs chaired) for non-immunization injections, and adding 10 injections per child born times the immunization rate to cover immunizations. E-mail from Catherine Hankins, chief scientific advisor to UNAIDS, April 1, 2003.

international retail price, international and domestic distribution costs, and waste management costs. About \$826 million of the \$905 million is for this safe injection equipment.¹⁰⁸

UNAIDS, by contrast, uses the incremental cost of auto-disable syringes (a type of single-use syringes) over multi-use syringes, which is about 3 cents per syringe.¹⁰⁹ Most or all of UNAIDS' estimated cost of injection safety is based on the cost of safe injection equipment. This is a third important difference between the two estimates. Unlike the UNAIDS cost estimate, the WHO estimate includes the cost of programs on the safe and appropriate use of injections, about \$79 million.¹¹⁰

The WHO approach appears to more accurately reflect the cost of a comprehensive injection safety program.¹¹¹ The major problem with unsafe injections is that syringes are re-used. Assuming health care providers use all of the syringes they purchase, the fact that they re-use syringes implies that they purchase too few syringes.¹¹² More are needed, and the WHO study calculates how much it would cost to provide these additional syringes. By contrast, the UNAIDS study implicitly assumes that there are enough syringes being purchased, just the wrong kind.¹¹³

Thus, WHO's figure of \$905 million is likely the better estimate of the cost of a safe injection program. The cost should fall as fewer injections are given following education and training on the appropriate use of injections. UNAIDS estimates that the number of injections would decrease by 25% by 2007.¹¹⁴ If that estimate were to be incorporated into the WHO study, the cost of a safe injection program would fall to below \$698 million in 2007.¹¹⁵

¹⁰⁸ See Gerald Dziekan et al., "The Cost-Effectiveness of Policies for the Safe and Appropriate Use of Injection in Healthcare Settings." *Bulletin of the World Health Organization* (2003) 81(4) (in press). The waste management costs are the costs of collecting and incinerating medical sharps waste. See *id.*

¹⁰⁹ E-mail from Catherine Hankins, chief scientific advisor to UNAIDS, April 1, 2003.

¹¹⁰ See Gerald Dziekan et al., "The Cost-Effectiveness of Policies for the Safe and Appropriate Use of Injection in Healthcare Settings." *Bulletin of the World Health Organization* (2003) 81(4) (in press).

¹¹¹ Catherine Hankins, chief scientific advisor to UNAIDS, told PHR that UNAIDS' calculations are less detailed than WHO's because the WHO study was focused solely on injection safety, while UNAIDS had to cost 25 interventions. See *id.*

¹¹² There are too few syringes only for the number of injections actually given. If health care providers gave only injections that were necessary, they would probably have a surplus of syringes.

¹¹³ To illustrate why the WHO estimate is probably more accurate, assume a 50% re-use rate, that multi-use syringes cost 10 cents, and that auto-disable syringes cost 13 cents. (These are approximate numbers that incorporate distribution and waste management costs.) Currently, the health care provider is using one multi-use syringe for every two patients, at a cost of 10 cents. Ideally, the health care provider would use an auto-disable syringe for each injection, which would cost 26 cents – an additional 16 cents. The WHO approach would capture the cost of one auto-disable syringe, or 13 cents. Under the UNAIDS approach, the additional funding required would be 3 cents for each of the 2 syringes, or 6 cents. The WHO approach seems more accurate for calculating the additional cost of reaching the ultimate goal of using only auto-disable (or single-use) syringes.

¹¹⁴ E-mail from Dr. Catherine Hankins, Chief Scientific Advisor to UNAIDS, April 1, 2003.

¹¹⁵ The WHO study estimated the cost of the syringe/needle sets at about \$826 million. If this cost is reduced by 25%, or about \$206.5 million, and added to the \$79 million program costs, the total cost would be about \$698.5 million. The WHO study included the cost of domestic distribution as part of the program costs, so those costs would also decrease to some degree by 2007.

Although the WHO study uses the cost of single-use syringes, a variation of single-use syringes, auto-disable syringes, should be promoted over regular single-use syringes where auto-disable syringes are available and have proven effectiveness.¹¹⁶ The difference between single-use and auto-disable syringes is that while both are meant to be used only once, the auto-disable syringe, as the name implies, is automatically disabled after a single use, rendering it impossible to re-use. Though they are not meant to be, single-use syringes can be re-used. Therefore, the auto-disable feature will help ensure that the syringes and needles are used only once. Auto-disable syringes are currently available for vaccines, injectable contraceptives, and for some curative injections.¹¹⁷ While marginally more expensive than single-use syringes, auto-disable syringes are now available at a cost very near that of standard single-use syringes.¹¹⁸

Along with the cost of providing single-use syringes, the \$905 million includes the cost of holding annual national planning workshops, developing information, education, and communication (IEC) material, sponsoring discussions between patients and health care providers, and conducting annual monitoring surveys. The workshops, educational material, and discussions would cover both the safe and the appropriate use of injections.¹¹⁹ The information on the appropriate use of injections will respond to the significant number of unnecessary injections in much of the developing world.¹²⁰ The information on injection safety will focus on

¹¹⁶ See Gerald Dziekan et al., "The Cost-Effectiveness of Policies for the Safe and Appropriate Use of Injection in Healthcare Settings." *Bulletin of the World Health Organization* (2003) 81(4) (in press).

¹¹⁷ See Yvan Hutin, *Towards Curative Auto-Disable Syringes*, presentation at SIGN Meeting, Oct. 24-26, 2002, Phnom Penh, Cambodia, at 4. Available at: http://www.who.int/entity/injection_safety/sign/meetings/past/hutin2.pps; E-mail from Dr. Yvan Hutin, Safe Injection Global Network (SIGN), Jan. 30, 2003; Comment from Paula V. Nersesian, Public Health Specialist, John Snow, Inc., March 21, 2003. The auto-disable concept does not translate perfectly from the preventative to the curative context because curative injections may involve multiple doses and larger volumes. Multiple doses of smaller doses therefore might be possible. See Yvan Hutin, *Towards Curative Auto-Disable Syringes*, presentation at SIGN Meeting, Oct. 24-26, 2002, Phnom Penh, Cambodia, at 5. Available at: http://www.who.int/entity/injection_safety/sign/meetings/past/hutin2.pps.

¹¹⁸ WHO, UNICEF, and UNFPA (United Nations Population Fund) all support the use of auto-disable syringes for immunizations, and call these syringes "widely available at low costs." See World Health Organization, United Nations Children's Fund (UNICEF) & United Nations Population Fund (UNFPA), *WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services* (Dec. 1999), at 1. Available at: http://www.who.int/bct/Main_areas_of_work/SIGN/pdf_documents/policy.pdf. The international retail price for immunization auto-disable syringes was five to seven cents in 2002, while the price for single-use syringes ranged from four to eight cents (for 2 milliliter and 5 milliliter syringes, respectively). See Gerald Dziekan et al., "The Cost-Effectiveness of Policies for the Safe and Appropriate Use of Injection in Healthcare Settings." *Bulletin of the World Health Organization* (2003) 81(4) (in press).

¹¹⁹ See Gerald Dziekan et al., "The Cost-Effectiveness of Policies for the Safe and Appropriate Use of Injection in Healthcare Settings." *Bulletin of the World Health Organization* (2003) 81(4) (in press). Health care providers should also be trained to avoid other unnecessary invasive procedures, such as unnecessary blood transfusions and suturing. See World Health Organization, *Universal Precautions, Including Injection Safety*, <http://www.who.int/hiv/topics/precautions/universal/en/>. Accessed Dec. 14, 2002. See also M. Dicko, "Safety of Immunization Injections in Africa: Not Simply a Problem of Logistics." *Bulletin of the World Health Organization* (2000) 78(2): 163-169, at 167. Available at: <http://www.who.int/bulletin/pdf/2000/issue2/bu0269.pdf> ("Injection providers should be educated on safe injection practices. . . social mobilization teams should provide populations with adequate information . . . so that consumer demand for safe injections can be created . . .").

¹²⁰ Such programs can be very successful. In Indonesia, a study that involved seminars and interactive group discussions caused the proportion of health care visits that resulted in injections to fall from 75% to below 20%. In Laos, management, training, and planning at five hospitals caused the proportion of prescriptions with an injection

the dangers of unsafe injections and what people can do to protect themselves. For example, people should be taught to demand that their health care provider uses a new, sterile needle and a new syringe, and if the health care provider cannot or will not do so, to bring their own new, sterile syringe.¹²¹

Health care providers must receive training on safe and appropriate injection practices. Along with training, behavior change programs will likely be needed to encourage health care providers to follow these practices. Simply knowing the proper skills might be insufficient to motivate them to follow safe injection practices. Some health care providers, for example, might believe that using a new syringe for each patient is wasteful, an attitude that must be changed. Communication strategies must be devised to ensure that health care providers understand the dangers of unsafe injections and the importance of using a new, sterile syringe and needle for each patient, and are motivated to do so.¹²²

Equipment for safely disposing used syringes and other sharp instruments (medical sharps) must accompany an initiative to promote the use of auto-disable syringes. In particular, puncture- and liquid-proof containers for disposing syringes and other sharp instruments should be made available at all health facilities. Along with the equipment itself, the necessary procedures, training, transportation, and supervision must be in place.¹²³ The safe disposal of syringes and other sharp instruments is necessary to protect health care providers from needlestick and other puncture injuries, and is a universal precaution. The importance of this precaution is heightened as more health care providers begin using syringes only once. By using a new syringe for each injection, health care providers will use more syringes in total in the short term, though syringe use can be expected to diminish as health care worker training and public education programs on the proper use of injections get underway.

to fall from 60% to 20%. See Safe Injection Global Network (SIGN), *Annual Meeting Report, 24-26 October 2002*, 2002, at 4. Available at: http://www.who.int/injection_safety/sign/meetings/past/2002MeetingReport.pdf.

¹²¹ The public health system is responsible for using new syringes for each person. However, where the health system fails to do so, the poor should be able to afford syringes. The international retail price for immunization auto-disable syringes was five to seven cents in 2002, while the price for single-use syringes ranged from four to eight cents (for 2 milliliter and 5 milliliter syringes, respectively). See Gerald Dziekan et al., "The Cost-Effectiveness of Policies for the Safe and Appropriate Use of Injection in Healthcare Settings." *Bulletin of the World Health Organization* (2003) 81(4) (in press). Actual costs to the user may be higher. A recent study in Uganda found that the average cost to users for a syringe (the majority of which were single-use) was \$0.18. See Gerardo Priotto, Ana Ruiz & Catherine Kyobutungi, *Injection use in the population of Mbarara District, Uganda, Cross-sectional Population Survey* (Aug. 2001). A 1998 study found that something like this is taking place in Uganda: "As a consequence of the popular concern with the spread of HIV through communally shared needles and syringes in public facilities, people generally prefer personal hypodermics or insist on being injected with disposable single use equipment rather than risk contamination with public things." Harriet Birungi, "Injections and self-help: Risk and trust in Ugandan health care." *Social Science & Medicine* (1998) 47(10): 1455-1462, at 1460.

¹²² E-mail from Dr. Jules Millogo, Immunization Technical Officer, BASICS II Project, March 21, 2003. Health care providers should also be trained to avoid other unnecessary invasive procedures, such as unnecessary blood transfusions and suturing. See World Health Organization, *Universal Precautions, Including Injection Safety*, <http://www.who.int/hiv/topics/precautions/universal/en/>. Accessed Dec. 13, 2002.

¹²³ See A. Battersby, R. Feilden & C. Nelson, "Sterilizable syringes: Excessive risk or cost-effective option?" *Bulletin of the World Health Organization* (1999) 77(10): 812-819, at 814. Available at: <http://www.who.int/bulletin/pdf/issue10/battersby.pdf>. A survey in Ethiopia found that even where safety disposal boxes were available, they were rarely used. See Yemane Berhane & Jules Millogo, *Report of Injection Safety Survey in Ethiopia*, Oct.-Nov. 2000, at 12.

Safe disposal of medical sharps

Once syringes are disposed in a safety disposal box, the injection waste must be destroyed. It should be disposed of as close to the point of use as possible where safe and effective means of disposal exist. In rural settings, on-site disposal may be appropriate if safety standards are followed. On-site disposal might not be possible in densely-populated urban settings. When it is not, one option to prevent the injection waste from entering the general stream of municipal waste is to develop a reverse supply chain that moves the waste from the health facilities to a central disposal site, although this mechanism is not without numerous technical challenges.¹²⁴

In developing countries, medical sharps are often destroyed or discarded by incinerating them and then burying the ash.¹²⁵ Incineration should take place at high temperatures to prevent possibly carcinogenic by-products from being produced.¹²⁶ At present, “practically no environmentally-friendly, low-cost options for safe disposal of infectious wastes” exist,¹²⁷ although some research is underway.¹²⁸ In developing countries, single-chamber incinerators are commonly used because they are relatively inexpensive, though they operate at low temperatures and produce potentially toxic gases. After the waste is burned, the ashes the incineration creates must be buried.¹²⁹

Despite the risk of toxic by-products, incineration is generally preferable to burying medical sharps waste, which creates the risk that where auto-disable syringes are not used, syringes will be “recycled” – that is, repackaged, resold, and reused.¹³⁰ In developing countries, medical waste disposal is often inadequate, and the waste ends up in garbage dumps, which people scavenge for items that they can sell, including injection equipment. This practice puts scavengers at great risk of needlestick injuries. And used, unsterile syringes may end up back in

¹²⁴ Phone conversation with Paula V. Nersesian, Public Health Specialist, John Snow, Inc., March 13, 2003.

¹²⁵ Another method combines incineration and burying. This method, dubbed burn and bury, involves putting the waste in a pit, burning it, and then (sometimes) covering it with soil. Phone conversation with Paula V. Nersesian, Public Health Specialist, John Snow, Inc., March 13, 2003.

¹²⁶ See World Health Organization, *Waste from Health Care Activities: Fact Sheet No. 253*, Oct. 2000. Available at: <http://www.who.int/inf-fs/en/fact253.html>.

¹²⁷ *Id.*

¹²⁸ See A. Prüss, E. Giroult & P. Rushbrook (editors) (World Health Organization), *Safe management of wastes from health-care activities*, 1999, at 80. Available at:

http://www.who.int/water_sanitation_health/Documents/Healthcare_waste/Manual/077to112.pdf (“Low-cost, high-temperature incinerators of simple design are currently being developed, and a system designed specifically for health-care and pharmaceutical waste in low-income countries is currently under test in England, at De Montfort University.”).

¹²⁹ See A. Prüss, E. Giroult & P. Rushbrook (editors) (World Health Organization), *Safe management of wastes from health-care activities*, 1999, at 86-87. Available at:

http://www.who.int/water_sanitation_health/Documents/Healthcare_waste/Manual/077to112.pdf.

¹³⁰ See M. Dicko, “Safety of Immunization Injections in Africa: Not Simply a Problem of Logistics.” *Bulletin of the World Health Organization* (2000) 78(2): 163-169, 166. Available at: http://www.who.int/bct/Main_areas_of_work/SIGN/pdf_documents/dicko.pdf (finding that the recycling of syringes and needles not properly disposed of was one reason for the re-use of syringes and needles without sterilization for immunizations in Senegal).

the health system.¹³¹ This informal “recycling” of syringes and needles is particularly harmful because people might purchase what they believe to be new syringes on the open market when their health care provider cannot or will not provide them a new, sterile syringe. The seemingly new syringes that they purchase might actually be these “recycled” syringes. There are ways to greatly reduce this risk, such as through a process called encapsulation, which involves adding an immobilizing material (such as cement mortar) to containers that hold the medical sharps, thus making it very difficult for scavengers to gain access to the discarded equipment.¹³²

Multi-dose vials

At least eight studies have implicated multi-dose vials in transmitting hepatitis B, hepatitis C, or HIV. In one of these studies, the use of multi-dose vials was suspected of transmitting HIV.¹³³ In another suspected case of HIV transmission through the use of multi-dose vials, four patients in Australia may have become infected with HIV in a private doctor’s consulting room (where the doctor performed minor surgery) because of the use of a multi-dose vial for anesthetics. The surgeon in that case denied using multi-dose vials.¹³⁴ Multi-dose vials contain multiple doses of an injectable substance. The health care provider will therefore insert syringes or needles into the vial multiple times, the number of times depending on how many doses the vial contains. Multi-dose vials can become contaminated with HIV if a syringe or needle that has already been used on an infected patient is inserted into the vial. Once the vial has been contaminated, it has the potential of transmitting the virus during subsequent uses of the vial.¹³⁵

¹³¹ Phone conversation with Paula V. Nersesian, Public Health Specialist, John Snow, Inc., March 13, 2003; World Health Organization, *Waste from Health Care Activities: Fact Sheet No. 253*, Oct. 2000. Available at: <http://www.who.int/inf-fs/en/fact253.html>.

¹³² See A. Prüss, E. Giroult & P. Rushbrook (editors) (World Health Organization), *Safe management of wastes from health-care activities*, 1999, at 109. Available at: http://www.who.int/water_sanitation_health/Documents/Healthcare_waste/Manual/077to112.pdf.

¹³³ See Safe Injection Global Network (SIGN), *Best Infection Control Practices for Skin-Piercing Intradermal, Subcutaneous, and Intramuscular Needle Injections, Background Paper for the WHO Working Group Meeting, 19-20 October 2000, Salle A*, 2000, at 10, 26-28 (seven studies); Marco Massari et al., “Transmission of Hepatitis C Virus in a Gynecological Surgery Setting.” *Journal of Clinical Microbiology* (2001) 39: 2680-2683 (eighth study).

¹³⁴ See K. Chant et al., “Patient-to-patient transmission of HIV in private surgical consulting room,” *Lancet* (Dec. 18/25, 1993) 342: 1548-1549; J.W. Shields, “Patient-to-patient transmission of HIV,” Letter. *Lancet* (1994) 343: 415.

¹³⁵ A hepatitis C outbreak in a Nebraska clinic may have been occurred because “a clinic worker used a syringe to administer medicine to a patient who had hepatitis C, then drew more medicine from the same vial for the patient with the same syringe.” Lara Weber & Jason McKean, “Clinic Blamed for Hepatitis C Outbreak.” *Chicago Tribune*, Nov. 20, 2002, at 8. In another case, hepatitis C may have been transmitted when “the syringe used to administer [an anesthetic] to [a patient with hepatitis C] was also used to draw [the anesthetic] from the multidose vials and administer it to the subsequent patients, blood contamination of the syringe is likely to have resulted and to have determined the spread of HCV [hepatitis C] infection.” Marco Massari et al., “Transmission of Hepatitis C Virus in a Gynecological Surgery Setting.” *Journal of Clinical Microbiology* (2001) 39: 2680-2683. In a third case, also involving hepatitis C and reported by the CDC, a multi-dose vial of saline was the source of infection for three patients. “Investigators suspect that the [multi-dose vial] was contaminated either from reuse of a needle or syringe or improper decontamination of the rubber membrane.” Institute for Safe Medication Practices, *Patient safety movement calls for reexamination of multidose vial use*, June 14, 2000. Available at: <http://www.ismp.org/MSAarticles/Multidose.html>. See also American Society of Anesthesiologists, *Recommendations for Infection Control for the Practice of Anesthesiology*, 2d ed., 1999, at 8. Available at: <http://www.asahq.org/publicationsAndServices/infectioncontrol.pdf> (“With breaks in aseptic technique, microbial contamination of the needle, syringe or rubber septum can be introduced into the vial”).

SIGN considers the risk of infection through multi-dose vials significant enough that it includes as a best practice avoiding multi-dose vials when possible, which it “[s]trongly recommend[s] . . . on the basis of strong theoretical rationale and suggestive, descriptive evidence.”¹³⁶ Attendees at a CDC conference “were strongly encouraged to use prefilled syringes or single dose vials for inexpensive but widely used substances (e.g., saline, bacteriostatic water, heparin, lidocaine) to reduce the risk of contamination.”¹³⁷

Multi-dose vials have received less attention than re-used syringes, and studies linking HIV transmission to multi-dose vials are far fewer than those linking HIV transmission to re-used syringes. However, the risks of multi-dose vials are significantly magnified in sub-Saharan Africa and parts of Asia. The role of multi-dose vials in HIV transmission largely depends on the re-use of syringes and needles, and the higher the prevalence of HIV or hepatitis, the more likely it is that these viruses will contaminate a multi-dose vial. Syringes are frequently re-used in both sub-Saharan Africa and much of Asia, and both regions have high prevalence of HIV, hepatitis, or both.

While definitive evidence is lacking, these factors, along with the evidence that multi-dose vials can transmit viruses, suggest that a significant number of HIV transmissions in Africa and Asia will be prevented if multi-dose vials are no longer used. This paper strongly recommends using only single-use or auto-disable syringes, but so long as the risk remains that syringes will be re-used, only single-dose vials should be used.

Multi-dose vials are used in immunization programs, which are often funded out of national health budgets. While it is desirable that these programs switch to single-dose vials, the cost increases this would entail will likely require international assistance. Until that assistance is forthcoming, it may be necessary to continue using multi-dose vials in these programs.¹³⁸

Responses thus far

An international movement is forming to promote injection safety. Perhaps most importantly, in 1999, a coalition of stakeholders formed the Safe Injection Global Network (SIGN), which has

¹³⁶ See Safe Injection Global Network (SIGN), *Best Infection Control Practices for Skin-Piercing Intradermal, Subcutaneous, and Intramuscular Needle Injections, Background Paper for the WHO Working Group Meeting, 19-20 October 2000, Salle A, 2000*, at 23-24. See also Philip P. Mortimer, “Away with multi-use vials!” Editorial Comment. *AIDS* (1999) 13(13): 1779-1781 (1999) (“The time has surely come to banish all multi-use containers, whether of saline, heparin, local anesthetic, or any other injectable. Reports of their microbial contamination are now legion . . .”).

¹³⁷ Institute for Safe Medication Practices, *Patient safety movement calls for reexamination of multidose vial use*, June 14, 2000. Available at: <http://www.ismp.org/MSAarticles/Multidose.html>.

¹³⁸ Conversation with Dr. Jules Millogo, Immunization Technical Officer, BASICS II Project, March 24, 2003. The cost of the vials relative to the cost of vaccines is high, so switching to single-dose vials could significantly increase the cost of immunization programs. Also, using multi-dose vials would increase the total volume that vaccine vials fill, which would require additional investments in the cold supply chain needed to transport and store the vaccines. See *id.* Multi-dose vials pose additional risks, though, in immunization programs. Live vaccines, such as the measles vaccine, must be used within six hours after the vial is opened, or else there is a risk that the vaccine could be contaminated with dangerous pathogens and transmit communicable diseases. With proper training, such risks can be minimized. See *id.*

its secretariat in the Blood Safety and Clinical Technology department of WHO.¹³⁹ Other organizations, such as UNICEF¹⁴⁰ and the Global Alliance for Vaccines and Immunization (GAVI), have also engaged in injection safety advocacy and programs. The International Council of Nurses has endorsed the use of auto-disable syringes for immunizations,¹⁴¹ and at its 2002 meeting, SIGN reported that the World Medical Association was preparing a policy statement on auto-disable syringes.¹⁴² Also at that meeting, SIGN reported that the International Organization for Standardization (ISO) had completed draft standards for auto-disable syringes for immunizations, and WHO had agreed to support the development of ISO standards for auto-disable syringes used for curative purposes. Until they are developed, WHO would provide procurement specifications for curative auto-disable syringes.¹⁴³ WHO has set the goal of the exclusive use of single-use injection equipment by 2005.¹⁴⁴

The greatest strides in injection safety have been made in immunizations, as demonstrated by the “bundling” policy. Under this policy, donors and lenders who finance vaccines are encouraged to also finance auto-disable syringes and safety boxes for their disposal.¹⁴⁵ Along with ensuring that injections are given with auto-disable syringes, donors can prevent shortages of auto-disable syringes by bundling injectable substances with the matching quantity of auto-disable or single-use syringes, safety disposal boxes, and single-dose vials.¹⁴⁶

Several multilateral and bilateral organizations have begun to adopt bundling policies, the first being WHO and UNICEF which, in 1997, devised the bundling policy for mass immunization campaigns.¹⁴⁷ In a 1999 joint statement, UNICEF, WHO, and the UN Population Fund (UNFPA) recommended a bundling policy for all immunization programs. The statement also

¹³⁹ World Health Organization, *The SIGN Alliance*, http://www.who.int/injection_safety/sign/en/. Accessed Feb. 21, 2003. Associates of the network include international organizations, NGOs, governments, universities, health care providers and student organizations, consultants, and industries. See Safe Injection Global Network (SIGN) brochure, http://www.who.int/bct/Main_areas_of_work/SIGN/pdf_documents/pamphlet.pdf. Accessed Feb. 22, 2003.

¹⁴⁰ UNICEF distributed 410 million auto-disable syringes in 2002. See International Council of Nurses, *Fact Sheet: First Do No Harm: Auto-Disable Syringes for Immunization Safety*, 2003. Available at: http://www.icn.ch/matters_syringes.htm.

¹⁴¹ See *id.*

¹⁴² See Safe Injection Global Network (SIGN), *Annual Meeting Report, 24-26 October 2002*, 2002, at 13. Available at: http://www.who.int/injection_safety/sign/meetings/past/2002MeetingReport.pdf.

¹⁴³ See *id.* at 33.

¹⁴⁴ See Yvan Hutin, *Towards Curative Auto-Disable Syringes*, presentation at SIGN Meeting, Oct. 24-26, 2002, Phnom Penh, Cambodia, at 3. Available at: http://www.who.int/entity/injection_safety/sign/meetings/past/hutin2.pps. WHO announced this goal at the 2002 Barcelona International AIDS Conference. See Safe Injection Global Network (SIGN), *Annual Meeting Report, 24-26 October 2002*, 2002, at 29. Available at: http://www.who.int/injection_safety/sign/meetings/past/2002MeetingReport.pdf.

¹⁴⁵ The auto-disable syringes and safety boxes are not necessarily physically bundled together with the vaccines. The bundling is conceptual, not physical.

¹⁴⁶ See World Bank, *Public Health at a Glance: Injection Safety*, June 2002. Available at: <http://wbln0018.worldbank.org/HDNet/hddocs.nsf/c840b59b6982d2498525670c004def60/ed32ddafbdbfe02d85256bfe00694d2f?OpenDocument>.

¹⁴⁷ See World Health Organization, *Proposed Working Draft for the Injection Equipment Section of Report of the Expert Committee Meeting on the WHO Model Essential Drug List*, April 8, 2002. Available at: http://www.who.int/medicines/organization/par/edl/proposed_workdoc_inj.doc.

called for the exclusive use of auto-disable syringes in all vaccine programs by 2003.¹⁴⁸ In June 2001, the board of the Global Alliance for Vaccines and Immunization endorsed the bundling policy and committed to providing auto-disable syringes and safety disposal boxes with new vaccines funded by GAVI.¹⁴⁹ In 2002, 42% of developing countries used auto-disable syringes for routine vaccinations.¹⁵⁰

The bundling policy is beginning to extend beyond the realm of immunizations. The Global TB Drug Facility has agreed to bundle auto-disable syringes with injectable tuberculosis treatments, such as streptomycin. This is an important first step in implementing a bundling policy for curative injections.¹⁵¹

Funding from the U.S. Agency for International Development (USAID), the principal source of U.S. foreign aid, was used to help develop the first auto-disable syringe, which has been used by UNICEF throughout the world in its immunization initiatives.¹⁵² USAID is also a member of GAVI's injection safety subgroup.¹⁵³ In 2001, USAID endorsed a bundling policy outside of the immunization sphere – though still in the realm of preventative medicine – for an injectable contraceptive as part of its aid to family planning programs.¹⁵⁴ USAID began implementing this policy in the latter part of 2002.¹⁵⁵

¹⁴⁸ See World Health Organization, United Nations Children's Fund (UNICEF) & United Nations Population Fund (UNFPA), *WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services*, Dec. 1999, at 1, 4. Available at: http://www.who.int/bct/Main_areas_of_work/SIGN/pdf_documents/policy.pdf; Safe Injection Global Network (SIGN), *Improving Access to Injection Equipment to Improve Injection Safety: Policy Analysis*, Nov. 27, 2001, at 2. Available at: http://www.who.int/medicines/organization/par/edl/policy_analysis.pdf.

¹⁴⁹ See Safe Injection Global Network (SIGN), *Improving Access to Injection Equipment to Improve Injection Safety: Policy Analysis*, Nov. 27, 2001, at 2. Available at: http://www.who.int/medicines/organization/par/edl/policy_analysis.pdf.

¹⁵⁰ See International Council of Nurses, *Fact Sheet: First Do No Harm: Auto-Disable Syringes for Immunization Safety*, 2003. Available at: http://www.icn.ch/matters_syringes.htm.

¹⁵¹ See Yvan Hutin, *Towards Curative Auto-Disable Syringes*, presentation at SIGN Meeting, Oct. 24-26, 2002, Phnom Penh, Cambodia, at 6. Available at: http://www.who.int/entity/injection_safety/sign/meetings/past/hutin2.pps. SIGN is also exploring the possibility of using auto-disable syringes to treat sexually transmitted diseases through HIV prevention and care programs. See Safe Injection Global Network (SIGN), *Annual Meeting Report, 24-26 October 2002*, 2002, at 29. Available at: http://www.who.int/injection_safety/sign/meetings/past/2002MeetingReport.pdf.

¹⁵² See U.S. Agency for International Development, *Global Health: Child Survival: Health Technologies*, http://www.usaid.gov/pop_health/cs/cshealthtech.htm. Accessed Feb. 22, 2003.

¹⁵³ See Heidi Larson & Rebecca Fields, *Injection Safety Working Group within the GAVI advocacy task force*, presentation at Safe Injection Global Network (SIGN) Meeting, Aug. 29-31, 2001, New Delhi, India, at 10. Available at: <http://www.injectionsafety.org/meetings/2001/files/2>. Other members of the subgroup include the World Bank, the International Federation of Pharmaceutical Manufacturers, the Children's Vaccine Program, and UNICEF. See *id.*

¹⁵⁴ See Safe Injection Global Network (SIGN), *Improving Access to Injection Equipment to Improve Injection Safety: Policy Analysis*, Nov. 27, 2001, at 2. Available at: http://www.who.int/medicines/organization/par/edl/policy_analysis.pdf.

¹⁵⁵ Phone conversation with Paula V. Nersesian, Public Health Specialist, John Snow, Inc., March 11, 2003. Four hundred vials of Depo-Provera are packaged together with 400 auto-disable syringes and four safety disposal boxes. See *id.*

Progress in using auto-disable syringes for curative injections is critical since about 95% of medical injections are curative.¹⁵⁶ Recognizing the importance of injection safety to HIV prevention should spur organizations to follow the lead of the Global TB Drug Facility by urgently pursuing bundling and other policies to make auto-disable and single-use syringes universally available for curative injections.

Unfortunately, USAID has not recognized unsafe injections as a significant mode of HIV transmission. According to USAID's website, only 0.01% of global HIV infections are caused by health care exposure (excluding blood transfusions).¹⁵⁷ USAID might soon re-evaluate its position on HIV and unsafe injections. After a study was published in February 2002 on unsafe injections and HIV/AIDS, the head of the USAID bureau of global health indicated openness to the data on unsafe injections, noting that USAID "plan[s] to take a pretty hard look at this."¹⁵⁸ USAID has begun a process of internal discussions on how to address injection safety across sectors, including HIV/AIDS.¹⁵⁹

Thus far, USAID has not emphasized the importance of injection safety as a form of HIV prevention. A USAID website on HIV/AIDS prevention does not refer to injection safety,¹⁶⁰ nor do USAID's descriptions of its HIV/AIDS programs.¹⁶¹ USAID has, however, funded programs in numerous countries to train health care providers on universal precautions, including injection safety. These programs emphasize never re-using disposable needles and syringes and how to safely dispose injection waste using locally available resources.¹⁶²

USAID is not alone in failing to emphasize the link between HIV/AIDS and unsafe injections in its HIV/AIDS prevention efforts. Although UNAIDS is a member of the SIGN coalition, it has not made addressing unsafe injections a high priority.¹⁶³ UNAIDS has taken an important step upon which it must follow through. In October 2002, UNAIDS for the first time included injection safety as part of its costing estimate. Having found that injection safety will cost about \$290 million (though as noted, there is a significant discrepancy between this and another estimate), UNAIDS must now pressure donors to provide this funding and countries to include injection safety in their national HIV/AIDS plans.

¹⁵⁶ See World Health Organization, *Safety of Injections Fact Sheet*, April 9, 2002. Available at: <http://www.health.fgov.be/WHI3/krant/krantarch2002/kranttekstapr2/020409m02a-who.htm>.

¹⁵⁷ See U.S. Agency for International Development, *Global HIV Infections by Mode of Transmission*, http://www.usaid.gov/pop_health/aids/News/chart_transmission.pdf. Accessed Feb. 21, 2003.

¹⁵⁸ Tom Carter, "USAID Plans Probe of AIDS Research." *Washington Times*, March 5, 2003 (quoting Dr. Anne Peterson).

¹⁵⁹ Phone conversation with Mary Harvey, Technical Advisor for Child Survival, USAID, March 12, 2003.

¹⁶⁰ See U.S. Agency for International Development, *USAID's Efforts: HIV/AIDS Prevention*, http://www.usaid.gov/pop_health/aids/TechAreas/prevention/preventionfactsheet.html. Accessed , Feb. 21, 2003.

¹⁶¹ See U.S. Agency for International Development, *HIV/AIDS Countries*, http://www.usaid.gov/pop_health/aids/Countries/index.html. Accessed Feb. 22, 2003.

¹⁶² E-mail from Dr. Charlene Brown, Office of HIV/AIDS, USAID, March 26, 2003. Countries in which USAID has supported these training programs include Malawi, Ghana, Kenya, Honduras, Guatemala, Nepal, Indonesia, Haiti, Senegal, Uganda, Guinea, Bolivia, Mali, Burkina Faso, the Philippines, and Ukraine. See *id.*

¹⁶³ See Safe Injection Global Network (SIGN), *Links to the Associations of the Safe Injection Global Network*, http://www.injectionsafety.org/html/body_links.html. Accessed March 7, 2003. This website also has information on other coalition partners, and a summary of their activities related to injection safety. Strikingly, the website does not refer to any specific activities that UNAIDS is taking related to injection safety. See *id.*

As another example of the failure to make injection safety an important part of HIV prevention efforts, a much-publicized study in a July 2002 edition of *The Lancet* did not include injection safety among 12 essential prevention interventions that it explained could reduce new adult HIV infections from 4 million to 1.5 million per year.¹⁶⁴

Notwithstanding the tardy response of donors to this issue, several countries have included injection safety as part of their national responses to HIV/AIDS. As early as 1985, injection safety was part of Uganda's HIV/AIDS strategy.¹⁶⁵ Much more recently, in 2002, Senegal developed a draft injection safety policy. Senegal has recognized that reducing transmission through unsafe injections is part of the new strategies needed to obtain better results by 2006.¹⁶⁶

¹⁶⁴ See John Stover et al., "Can we reverse the HIV/AIDS pandemic with an expanded response?" *Lancet* (July 6, 2002) 360: 73-77.

¹⁶⁵ See Harriet Birungi, "Injections and self-help: Risk and trust in Ugandan health care." *Social Science & Medicine* (1998) 47(10): 1455-1462, at 1458-59.

¹⁶⁶ See Ibrahim Ndoye (Executive Secretary, National Council on HIV/AIDS/Senegal), *Senegal Experience on HIV/AIDS Control*, presentation at conference on Fighting HIV/AIDS in Africa: What Works, Jan. 8, 2003, Washington, DC, at 11-12. Available at: <http://www.cgdev.org/events/ndoye.ppt>. The only time injection safety came up in the day-long conference "Fighting HIV/AIDS in Africa: What Works" was in Dr. Ndoye's presentation.

STERILIZATION OF REUSABLE MEDICAL INSTRUMENTS

The current practice of other medical procedures, such as blood tests, vaginal exams, 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.¹⁶⁷ Ensuring that health care providers have and use equipment for sterilization correctly is therefore a priority.

Efforts must be made to ensure that instruments are properly sterilized. Such efforts require at least three steps. First, the staff of health centers must be trained in proper sterilization techniques. This training should include 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.¹⁶⁸ This indicator affirms that an instrument has been properly sterilized by changing color only when sterilization conditions have been met.¹⁶⁹

¹⁶⁷ See A. Battersby, R. Feilden & C. Nelson, “Sterilizable syringes: Excessive risk or cost-effective option?” *Bulletin of the World Health Organization* (1999) 77(10): 812-819, at 814. Available at: <http://www.who.int/bulletin/pdf/issue10/battersby.pdf>.

¹⁶⁸ See M. Dicko, “Safety of Immunization Injections in Africa: Not Simply a Problem of Logistics.” *Bulletin of the World Health Organization* (2000) 78(2): 163-169, 166. Available at: <http://www.who.int/bulletin/pdf/2000/issue2/bu0269.pdf>. See also Philip P. Mortimer, “The lurking epidemic,” commentary. *Lancet* (Feb. 12, 1994) 343: 368-370, at 369.

¹⁶⁹ TST indicators turn color once exposed to a certain temperature for the period of time necessary to ensure that the instrument has been properly sterilized (for syringes and needles, 121 degrees Celsius for more than 20 minutes). See A. Battersby, R. Feilden & C. Nelson, “Sterilizable syringes: Excessive risk or cost-effective option?” *Bulletin of the World Health Organization* (1999) 77(10): 812-819, at 815. Available at: <http://www.who.int/bulletin/pdf/issue10/battersby.pdf>. Boiling water kills HIV, so while other pathogens can survive if an instrument is improperly sterilized, HIV might not survive. E-mail from Dr. Jules Millogo, Immunization Technical Officer, BASICS II Project, March 25, 2003. A survey of health facilities in Ethiopia conducted under the auspices of WHO found them sorely lacking sterilization equipment. Of 43 facilities surveyed where it was possible to determine, “29 (67%) had at least one steam sterilizer without a leak.” Only 2 of 56 facilities (4%) had a TST indicator. “[O]nly 14 (25%) of the 56 facilities visited had spare seals or spare valves for their sterilizers,” “[f]ew” had “a timer to monitor the length of the sterilization process,” and only 38 of 56 health facilities (68%) had sufficient quantities of an energy source for sterilization. Yemane Berhane & Jules Millogo, *Report of Injection Safety Survey in Ethiopia*, Oct.-Nov. 2000, at 10-11.

BLOOD TRANSFUSION SAFETY

HIV transmission in health care settings can occur through blood transfusions. Unlike unsafe injections, WHO and UNAIDS have consistently recognized the danger of HIV transmission through unsafe blood transfusions,¹⁷⁰ though WHO has recently issued conflicting estimates of the significance of this danger. A document published in October 2002 by WHO's Department of Blood Safety and Clinical Technology estimates that unsafe blood transfusions are responsible for 5-10% of new HIV infections worldwide, and that up to 13 million transfusions take place every year with blood that has not been screened.¹⁷¹ But another WHO document from 2002, from the Department of HIV/AIDS, reports, "In general . . . it appears that most blood donations are screened today, so that few new infections should be occurring [in low- and middle-income countries] due to unsafe blood."¹⁷² This latter document appears to be the exception.¹⁷³

Blood transfusions in Africa

About 6 million blood transfusions occur in Africa yearly.¹⁷⁴ The transfusions are used primarily to treat children who have anemia associated with malaria and for pregnant women who have anemia associated with pregnancy or for complications of pregnancy. Transfusions are also used in trauma and surgery.¹⁷⁵

Estimates from WHO on the amount of donated and transfused blood that is screened vary significantly. WHO's Regional Office for Africa reported in 2001 that only about 75% of blood units transfused in sub-Saharan Africa has been screened for HIV, and furthermore, fewer than one-half are tested for hepatitis B, and only 19% are tested for hepatitis C. The same report stated that 5-10% of HIV infections in Africa are transmitted via blood and blood product transfusions.¹⁷⁶ But a 2001 WHO study encompassing 35 African countries found that 94% of

¹⁷⁰ USAID also recognizes this danger. According to the USAID website, 5% of HIV infections are caused by unsafe blood transfusions. See U.S. Agency for International Development, *Global HIV Infections by Mode of Transmission*, http://www.usaid.gov/pop_health/aids/News/chart_transmission.pdf. Accessed Feb. 21, 2003.

¹⁷¹ See 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. See also U.S. Centers for Disease Control and Prevention, *Global AIDS Programs: Strategies: Blood Safety*, http://www.cdc.gov/nchstp/od/gap/strategies/2_3_blood_safety.htm. Last updated May 4, 2002 ("Fifteen years after the development of a screening test for HIV, reducing transmission of HIV and other infectious diseases by blood transfusion remains a serious public health challenge in many developing countries.").

¹⁷² World Health Organization, HIV/AIDS Department, *The Health Sector Response to HIV/AIDS: Coverage of Selected Services in 2001: Preliminary Assessment*, 2002, at 18.

¹⁷³ For example, WHO's website currently states "5-10% of HIV infections are caused by unsafe blood and blood products." World Health Organization, Department of Blood Safety and Clinical Technology, *Blood Screening*, http://www.who.int/bct/Main_areas_of_work/BTS/Blood%20Screening.htm. Accessed March 25, 2003. The site also reports that "the Global Database on Blood Safety indicated that 80% of the world's population does not have access to reliable and safe blood" and "that 43% of the blood collected in developing countries is not tested for transfusion-transmissible infections (HIV, HCV, HBV; Syphilis, Chagas disease)." *Id.*

¹⁷⁴ See Safe Blood for Africa Foundation, *Safe Blood for Africa*, <http://safebloodforafrica.org>. Accessed Jan. 1, 2003.

¹⁷⁵ See U.S. Centers for Disease Control and Prevention, *Global AIDS Programs: Strategies: Blood Safety*, http://www.cdc.gov/nchstp/od/gap/strategies/2_3_blood_safety.htm. Last updated May 4, 2002.

¹⁷⁶ See World Health Organization Regional Committee for Africa press release, *Ensuring blood transfusion safety in Africa*, Aug. 27-Sept. 1, 2001. Available at:

blood donations in Africa were screened for HIV. That study might have overestimated the safety of blood transfusions because emergency donations and shortages of HIV screening kits may prevent normal testing procedures from being followed.¹⁷⁷ Also, many of the donations studied took place in central hospitals, which can be expected to have safer transfusions than health clinics, which might be outside the normal transfusion service.¹⁷⁸

A report cited at a 2000 WHO meeting of directors of national blood transfusion services in Africa stated that only 13 of 46 – fewer than one-third – of countries in the African Region had implemented national blood safety policies.¹⁷⁹ A news article from the same year reported that only nine African countries had legal frameworks for a national blood transfusion service.¹⁸⁰ Other countries are working on developing national blood transfusion policies. The Biennial (2000-2001) Report of the WHO Regional Director for Africa stated that WHO was helping 11 African countries finalize their national blood transfusion policies.¹⁸¹

The experience of the Democratic Republic of Congo (DRC) demonstrates the danger of an unsafe blood supply. A recent study in Bas Congo Province in the DRC found that only 42% of the blood that was transfused in the province was screened for HIV.¹⁸² In this province of about 3.3 million people,¹⁸³ blood transfusions led to approximately 888 HIV infections in the first nine months of 2001.¹⁸⁴

It is well within the capacity of African nations to implement effective blood transfusion policies. Countries including South Africa, Zimbabwe, Namibia, and Uganda have achieved a safe blood supply, although the systems may not be perfect.¹⁸⁵ In Zimbabwe, a questionnaire and interview process eliminates most would-be donors who are infected with HIV. The blood

<http://www.afro.who.int/press/2001/regionalcommittee/rc51004.html>. Other estimates are even lower. The NGO Network for Infection Prevention cites an estimate that only 50-60% of blood in sub-Saharan Africa is tested for HIV before being transfused. See Network for Infection Prevention, *Pathways for HIV Infection in Medical Settings*, <http://www.africa-hiv.org/injections.cfm>. Accessed Jan. 15, 2003.

¹⁷⁷ See World Health Organization, HIV/AIDS Department, *The Health Sector Response to HIV/AIDS: Coverage of Selected Services in 2001: Preliminary Assessment*, 2002, at 18.

¹⁷⁸ E-mail from Neff Walker (UNAIDS), Jan. 17, 2003. Some hospitals might have also inflated their blood screening levels. See *id.*

¹⁷⁹ 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>.

¹⁸⁰ See Marjolein Harvey, "South Africa: WHO on Defensive over 'Bad Blood' Allegations." *WOZA*, Oct. 27, 2000. Available at: <http://allafrica.com/stories/200010270018.html>.

¹⁸¹ See World Health Organization African Region press release, *Health in Africa 2000-2001: A Balance Sheet*, Oct. 8-12, 2002. Available at: <http://www.whoafr.org/press/2002/pr20021008-12rc01.html>.

¹⁸² See International Rescue Committee, Health Unit, 2002 (Unpublished data).

¹⁸³ See Populations.com, *Dem. Republic of the Congo: Bas Congo*, <http://populations.com/Country.asp?ID=41&CityID=1241>. Accessed March 11, 2003.

¹⁸⁴ See International Rescue Committee, Health Unit, 2002 (Unpublished data).

¹⁸⁵ See PANOS Institute, *Safe Blood: an affordable right*, June 10, 1996. Available at: <http://www.aegis.com/news/panos/1996/PS960601.html>. See Marjolein Harvey, "South Africa: WHO on Defensive over 'Bad Blood' Allegations." *WOZA*, Oct. 27, 2000. Available at: <http://allafrica.com/stories/200010270018.html> ("WHO admits that no safety measure in blood transfusion – such as detailed questionnaires and other screening of donors – can yield an absolute zero risk").

of those donors who are infected is discarded.¹⁸⁶ According to WHO, HIV prevalence among the general adult population in Zimbabwe was about 25.8% in 1998-1999, but only 2.3% among first-time blood donors, and 0.7% among regular donors.¹⁸⁷ This selective recruitment of voluntary, unpaid donors using effective donor selection procedures populations is a key part of creating a safe blood supply. Such donors generally have lower rates of HIV and other infectious diseases than paid donors or family/replacement donors.¹⁸⁸

In Uganda, where the European Commission provided assistance to develop a safe blood supply, the recurrent costs of providing a safe blood supply were calculated in 1995 to be about \$30 per unit of safe blood, or a total of \$1.2-1.5 million per year. The cost includes the selective recruitment of voluntary donors and screening the blood for HIV and a marker for hepatitis B. That year, about 32,100 units of blood were collected, and 26,194 used. About \$7-8 was required per unit of safe blood for screening, while the rest of the cost went to collecting, storing, and distributing the blood.¹⁸⁹

In Uganda, the blood safety program was created from scratch – no blood safety facilities were in place as of 1988.¹⁹⁰ Uganda created the Uganda Blood Transfusion Service (UBTS), which supplies blood to more than 90% of Uganda’s hospitals (some in northern Uganda are out of reach due to the security situation, but even those hospitals have local screening arrangements). The UBTS has a central laboratory and blood bank in Uganda’s capital, Kampala, along with four regional blood banks. Each blood bank has one blood donor recruiter, except for the Kampala blood bank, which has six. In all, about 100 people work for the UBTS, which supplies hospitals with about 40,000 units of blood per year.¹⁹¹

As in Zimbabwe, the process of selecting donors is a key part of Uganda’s blood safety program. Indeed, according to WHO “[i]t is imperative for blood donor programmes to consider carefully how such donors are selected.”¹⁹² In Uganda, blood donor recruiters meet with and provide

¹⁸⁶ See Marjolein Harvey, “South Africa: WHO on Defensive over 'Bad Blood' Allegations.” *WOZA*, Oct. 27, 2000. Available at: <http://allafrica.com/stories/200010270018.html>. According to this article, only 0.29% of blood donors were HIV-positive. See *id.*

¹⁸⁷ See World Health Organization, Department of Blood Safety and Clinical Technology, *Global Database on Blood Safety: Summary Report 1998-1999*, 2001, at 5. Available at: http://www.who.int/bct/Main_areas_of_work/Resource_Centre/BTS/SumRep_English.pdf.

¹⁸⁸ See *id.* at 4. A replacement donor is a family member or friend of the person who needs the blood transfusion.

¹⁸⁹ See Lieve Fransen, “Safety of blood and blood products: An additional burden for the health sector facing HIV/AIDS.” In: Martha Ainsworth, Lieve Fransen, & Mead Over (editors), *Confronting AIDS: Evidence from the Developing World*, 1998, 315-322, at 319-320. Available at: http://europa.eu.int/comm/development/aids/limelette/pdfs/confront_aids_chapter_14.pdf.

¹⁹⁰ See *id.* at 319.

¹⁹¹ See Hands On (BBC World program), *Blood safe – Uganda*, <http://www.tve.org/ho/doc.cfm?aid=413>. Accessed Jan. 1, 2003. The program aired Jan. 28-Feb. 5, 1999.

¹⁹² World Health Organization, Department of Blood Safety and Clinical Technology, *Blood Transfusions Safety, Educate, motivate, recruit and retain blood donors from low risk populations*, http://www.who.int/bct/Main_areas_of_work/BTS/Blood%20Donors.htm. Accessed March 25, 2003. According to WHO, the following steps are necessary for “the education, motivation and recruitment of voluntary non-remunerated blood donors from low-risk populations who give blood regularly”: establishing a blood donor unit; “training staff responsible for donor education, motivation, recruitment, selection and retention”; identifying donor populations at low risk for diseases that can be transferred through blood transfusions; establishing “educational and media campaigns in workplaces, communities and educational institutions”; maintaining “a register of voluntary

leaflets to potential donors in an effort to recruit voluntary, unpaid donors. Donors receive confidential counseling and, with their consent, their blood is collected and tested. Donors receive further counseling when they are given the results of the blood tests. The recruitment process is also an opportunity to educate donors on HIV. In Uganda, only 3% of blood taken from donors is infected with HIV.¹⁹³

Uganda's program reveals much of the infrastructure required for safe blood transfusions. Donor recruiters, counselors, blood collectors, laboratory staff, and quality managers must all receive proper training. Health clinic staff who prescribe the transfusions must also be trained on when transfusions should be given. In some countries, transfusions are often given unnecessarily.¹⁹⁴ Blood banks to type, process, and store the blood must be built, and test kits and reagents are necessary for testing the blood for HIV and other infectious diseases, such as hepatitis B and C and malaria. With the advent of rapid testing technology, HIV testing is becoming increasingly fast, easy, and inexpensive. In addition, blood transfusion services require supplies for obtaining blood from the donor as well as administering it to the recipient. These supplies include large gauge venous cannulas, blood tubing, soap, and collection bags.¹⁹⁵ Safe disposal supplies and destruction procedures should be in place for the medical waste resulting from the blood transfusion process.

An effective supply chain is needed to ensure that essential supplies are available and in their proper condition.¹⁹⁶ Some of the supply chain considerations regarding test kits include the challenge of procurement – many different kinds of kits employing different testing technologies are available – the short shelf life of the kits (particularly when improperly stored), and the need to keep their temperature regulated, including during transport.¹⁹⁷

Equipment is also necessary to process the blood and to transport it to hospitals. The blood must be kept cold from the time it is donated until it is transfused, a concept known as the blood cold chain.¹⁹⁸ This requires special refrigerators and other equipment,¹⁹⁹ such as the WHO-developed

non-remunerated blood donors”; implementing “[s]afe blood collection procedures, including donor selection and deferral, donor care and confidentiality”; notifying donors and referring them to counseling, and; “monitoring . . . transfusion-transmissible infections in the blood donor population.” *Id.*

¹⁹³ See Hands On (BBC World program), *Blood safe – Uganda*, <http://www.tve.org/ho/doc.cfm?aid=413>. Accessed Jan. 1, 2003. The program aired Jan. 28-Feb. 5, 1999.

¹⁹⁴ See World Health Organization, Department of Blood Safety and Clinical Technology, *Global Database on Blood Safety: Summary Report 1998-1999*, 2001, at 6-7. Available at: http://www.who.int/bct/Main_areas_of_work/Resource_Centre/BTS/SumRep_English.pdf.

¹⁹⁵ Comment from Paula V. Nersesian, Public Health Specialist, John Snow, Inc., March 21, 2003.

¹⁹⁶ E-mail from Paula V. Nersesian, Public Health Specialist, John Snow, Inc., March 12, 2003.

¹⁹⁷ Comment from Paula V. Nersesian, Public Health Specialist, John Snow, Inc., March 21, 2003. While the temperature at which the test kits should be kept to ensure maximum shelf life varies, it is typically about 2-8 degrees Celsius. Several can be stored at room temperature. See John Snow, Inc., *HIV Test Fact Sheets*, May 2002-Feb. 2003. Available at: http://deliver.jsi.com/2002/archives/hivaids/test_kits/index.cfm.

¹⁹⁸ See World Health Organization, Department of Blood Safety and Clinical Technology, *Blood Safety and Clinical Technology, Strategy 2000-2003*, May 2001, at 22. Available at:

http://www.who.int/bct/Main_areas_of_work/Resource_Centre/General_docs/BCT_Strategy_2000-2003.pdf; World Health Organization, Department of Blood Safety and Clinical Technology, *Global Database on Blood Safety: Summary Report 1998-1999*, 2001, at 5. Available at:

http://www.who.int/bct/Main_areas_of_work/Resource_Centre/BTS/SumRep_English.pdf (recommending blood screening for HIV, hepatitis B, and syphilis, and where appropriate, hepatitis C, malaria, and Chagas disease).

blood time temperature indicator, which monitors the blood's temperature during transportation.²⁰⁰

An administrative system, such as the UBTS, is necessary to oversee the blood transfusion system. And a computerized information management system can facilitate the system in a variety of ways, including by keeping an up-to-date donor database and inventory of available blood and its components, by improving record-keeping and the traceability of the blood and its products, by enhancing communications among participants in the transfusion system, and by making the latest information on blood transfusions widely available.²⁰¹

UNAIDS has estimated that the annual cost of extending a safe blood supply to those not already covered is about \$200 million or less.²⁰² This estimate uses the coverage figures of 94% for Africa and 96% for low- and middle-income countries overall,²⁰³ figures that, based on other estimates of safe blood coverage in Africa, are probably too generous. The additional resources required to extend a safe blood supply to all countries might, therefore, be higher than the UNAIDS estimate.

Blood transfusions in Asia

The AIDS epidemic in rural China that was caused by blood-selling practices provides tragic evidence of the potential efficiency of blood transfusions in causing very large numbers of infections. In the 1990s, with provincial government backing during the first half of the decade,²⁰⁴ many poor Chinese farmers sold their blood. The plasma was collected for medicines, and the red blood cells injected back into the blood donors. This highly unsterile process led to hundreds of thousands of HIV infections in Henan Province, the epicenter of the epidemic in China. Credible estimates place the number of people infected in Henan at more than one million.²⁰⁵

¹⁹⁹ For more information on the necessary equipment, see World Health Organization, Department of Blood Safety and Clinical Technology, *The Blood Cold Chain: Guide to the Selection and Procurement of Equipment and Accessories*, Nov. 2002. Available at:

http://www.who.int/bct/Main_areas_of_work/DCT/documents/Blood%20Cold%20Chain.pdf.

²⁰⁰ See World Health Organization, Department of Blood Safety and Clinical Technology, *Blood Safety Clinical Technology Progress 2000-2001*, 2002, at 13. Available at:

http://www.who.int/bct/Main_areas_of_work/Resource_Centre/General_docs/BCT%20Progress%20Report.pdf.

²⁰¹ See World Health Organization, Department of Blood Safety and Clinical Technology, *Blood Safety and Clinical Technology, Strategy 2000-2003*, May 2001, at 23, 36. Available at:

http://www.who.int/bct/Main_areas_of_work/Resource_Centre/General_docs/BCT_Strategy_2000-2003.pdf.

²⁰² See UNAIDS, *Financial Resources for HIV/AIDS Programmes in Low- and Middle-Income Countries over the Next Five Years*, Nov. 28, 2002. Available at:

http://www.unaids.org/about/governance/files/PCB13_FinancialResources_en.doc. The information is presented graphically, so the figure is an approximation.

²⁰³ See *id.*; World Health Organization, HIV/AIDS Department, *The Health Sector Response to HIV/AIDS: Coverage of Selected Services in 2001: Preliminary Assessment*, 2002, at 18.

²⁰⁴ See Wan Yanhai, *China Health News and the Henan Province Health Scandal Cover-up*, Jan. 20, 2001. Available at: <http://www.usembassy-china.org.cn/english/sandt/ChinaHealthNews-criticism.html>.

²⁰⁵ See UNAIDS (UN Theme Group on HIV/AIDS in China), *HIV/AIDS: China's Titanic Peril*, June 2002, at 28. Available at: <http://www.unaids.org/whatsnew/newadds/AIDSChina2001update.pdf> (citing Gao Yaojie's estimate that more than one million people in Henan are infected with HIV/AIDS).

China is beginning to respond to the problem of blood transfusion safety. Although its 2001 five-year AIDS action plan leaves HIV/AIDS programs underfunded,²⁰⁶ the plan does focus on strengthening China's blood transfusion system. The plan allocates about \$115 million over the five years to build 250 blood collection centers in Western and Central China, adding to the 420 blood collection stations that China already has. Nonetheless, along with more blood collection centers, China will have to increase the proportion of voluntary blood donors, particularly in rural areas. As of 2001, only 58.8% – or significantly less – of transfused blood came from voluntary donors, though the rates exceeded 90% in some major cities. Voluntary blood donors are less likely to be infected with bloodborne diseases than paid or family/replacement donors. The government plans on encouraging voluntary blood donations in rural areas.²⁰⁷ It is also critical that blood donation centers and hospitals comply with China's HIV-screening rules.

India is the other Asian country at risk of an HIV/AIDS epidemic that could infect tens of millions of people. Its government has put in place measures to prevent HIV infection through blood transfusion, which had been a significant source of infection. It has made "HIV screening mandatory at all blood banks, bann[ed] professional blood donations, establish[ed] National and State Blood Transfusion Councils to oversee all aspects of the blood safety program, and launch[ed] a program to modernize and strengthen the management of blood banks."²⁰⁸

It is critical that China, India, and other Asian countries follow through on commitments to improve their blood supplies, and commit to a clean blood supply if any have not already done so. Significant improvements are necessary. In 1995, WHO estimated that "less than 50 percent of blood transfusions in [South and Southeast Asia] were being routinely screened for HIV."²⁰⁹ As of 1997, "virtually no screening for HIV antibodies [was being] performed in the nearly 200,000 units of blood transfused annually" in Bangladesh.²¹⁰ According to researchers from Northwestern University, 95% of blood in India was deemed unsafe as recently as 1996.²¹¹ And

²⁰⁶ Overall, China's five-year plan called for only 100 million yuan (about \$12 million) in annual spending on HIV/AIDS/STD prevention and control, though local and provincial governments were expected to spend about 400 million yuan (nearly \$50 million) per year as well. See UNAIDS (UN Theme Group on HIV/AIDS in China), *HIV/AIDS: China's Titanic Peril*, June 2002, at 35. Available at: <http://www.unaids.org/whatsnew/newadds/AIDSchina2001update.pdf>.

²⁰⁷ See "Hospitals asked to be alert in taking blood." *China Daily*, Aug. 6, 2001. Available at: <http://www.china.org.cn/english/2001/Aug/17039.htm>. An independent source places the proportion of voluntary donations lower than the government estimate. According to researchers at Northwestern University, 60% of China's blood supply comes from paid donors. See Alan Mozes, "Tainted blood supply spreads HIV in poor nations." *Reuters Health*, Feb. 22, 2002. Available at: http://archive.mail-list.com/hbv_research/msg03239.html.

²⁰⁸ World Bank, *India's National AIDS Control Program*, Sept. 1999. Available at: <http://wb1n1018.worldbank.org/SAR/sa.nsf/All/0C8B13C927927CA3852567F4005394FC?OpenDocument>.

²⁰⁹ *Status and trends of HIV/AIDS Epidemics in Asia and the Pacific*, provisional report from the first Monitoring the AIDS Pandemic (MAP) Network symposium, an official satellite symposium of the 4th International Congress on AIDS in Asia and the Pacific, Oct. 21-23, 1997, Manila, Philippines. Available at: <http://www.cdpc.com/2AP.htm>.

²¹⁰ *Id.*

²¹¹ See Alan Mozes, "Tainted blood supply spreads HIV in poor nations." *Reuters Health*, Feb. 22, 2002. Available at: http://archive.mail-list.com/hbv_research/msg03239.html.

a “recent study” reported in a November 2000 newspaper article found that 44.4% of HIV-positive children became infected through contaminated blood.²¹²

²¹² “Avoid taking blood from strangers.” *Ludhiana Tribune* (India), Nov. 9, 2000. Available at: <http://www.tribuneindia.com/2000/20001109/ldh3.htm>.

PROTECTING HEALTH CARE PROVIDERS AND THEIR PATIENTS

Injection safety is only one aspect of universal precautions, which protect both health care providers and their patients from HIV and other pathogens that can be transmitted through exposure to blood and certain other body fluids. The CDC developed universal precautions in the mid-1980s, and health care providers are now legally required to observe them in the United States.²¹³ Yet because of a lack of supplies and necessary training, universal precautions are not consistently implemented in much of the developing world.²¹⁴

WHO has succinctly explained the universal precautions:

- *Use . . . new, single-use disposable injection equipment for all injections is highly recommended. Sterilizable injection should only be considered if single use equipment is not available and if the sterility can be documented with Time, Steam and Temperature indicators.*
- *Discard contaminated sharps immediately and without recapping in puncture and liquid proof containers that are closed, sealed and destroyed before completely full.*
- *Document the quality of the sterilization for all medical equipment used for percutaneous procedures.*
- *Wash hands with soap and water before and after procedures; use of protective barriers such as gloves, gowns aprons, masks, goggles for direct contact with blood and other body fluids.*
- *Disinfect instruments and other contaminated equipment.*
- *[Properly handle] soiled linen. (Soiled linen should be handled as little as possible. Gloves and leakproof bags should be used if necessary. Cleaning should occur outside patient areas, using detergent and hot water.)²¹⁵*

²¹³ See U.S. Department of Labor, Occupational Safety & Health Administration, (*Lack of Universal Precautions*, http://www.osha.gov/SLTC/hospital_etool/hazards/univprec/univ.html. Accessed Dec. 3, 2002. See also Health Care Worker Safety Center, University of Virginia, <http://hsc.virginia.edu/medcntr/centers/epinet/home.html>. Accessed Dec. 3, 2002.

²¹⁴ See, e.g., Charles Sagoe-Moses et al., "Risks to Health Care Workers in Developing Countries." *New England Journal of Medicine* (Aug. 16, 2001) 345(7): 538-541, at 538.

²¹⁵ World Health Organization, *Universal Precautions, Including Injection Safety*, <http://www.who.int/hiv/topics/precautions/universal/en/>. Accessed Dec. 13, 2002. For more information on universal precautions, see U.S. Centers for Disease Control and Prevention, *Recommendations for Prevention of HIV in Health Care Settings, MMWR36(SU02); 01, Precautions to Prevent Transmission of HIV: Universal Precautions*, Aug. 21, 1987. Available at: <http://aepo-xdv-www.epo.cdc.gov/wonder/prevguid/p0000318/p0000318.asp#head006001000000000>. The CDC has since clarified these precautions in several other documents. See U.S. Centers for Disease Control and Prevention, *Issues in Health Care Settings: Universal Precautions for Prevention of Transmission of HIV and other Bloodborne Infections*, <http://www.cdc.gov/ncidod/hip/blood/universa.htm>. Accessed Dec. 3, 2002.

Occupational risks for health care providers in developing countries

The risk to health care providers outside North America and Western Europe has been the subject of relatively little research. Although North America and Western Europe have only about 4% of the world's HIV-infected population, 90% of the cases of documented occupational HIV infection through September 1997 come from these two regions.²¹⁶ The research that has been conducted, though, along with the prevalence of dangerous practices, such as re-using unsterile needles and not wearing gloves, provides an initial picture of the greatest risks and the greatest needs.

The greatest risk of occupational exposure to HIV for health care providers appears to come from needlestick injuries. For example, one study of nurse-midwives in Uganda that examined several possible sources of occupational exposure – needlestick injuries, use of gloves, hand-washing practices, number of deliveries, and length of time in practice – found that only one, having a needlestick injury in the past month, was significantly related to HIV infection.²¹⁷

A review of 19 health care providers in tropical regions who had become infected by HIV from a patient, for whom the source of the infection was known and whose cases had been documented by February 1989, found that needlestick injuries caused 15 of the infections.²¹⁸ One-third of these needlestick injuries occurred during recapping. Training alone could have prevented these injuries. Some institutions and training programs used to promote recapping needles as a safety measure to prevent the needle from stabbing anybody while storing the needle for future use or while disposing the needle, but the dangers associated with recapping have since been recognized,²¹⁹ and universal precautions warn against this practice. The recommendations to prevent infections that the authors of that study offer suggest the importance of proper procedures in preventing needlestick injuries, although they also emphasize the importance of safely disposing, transporting, and storing needles, presumably in puncture-proof containers.²²⁰

The other four documented HIV infections that the study reported occurred through exposure of the health care provider's non-intact skin (an open wound and certain other skin conditions) or mucous membranes (most importantly, eyes) to patient blood. Gloves and other protective

²¹⁶ See Charles Sagoe-Moses et al., "Risks to Health Care Workers in Developing Countries." *New England Journal of Medicine* (Aug. 16, 2001) 345(7): 538-541, at 539.

²¹⁷ See World Health Organization, *1992-1993 Progress Report: Global Programme on AIDS*, 1995, at 86 (also finding no statistically significant association between the five factors and HIV status among nurse-midwives in Zambia).

²¹⁸ See Hans Veeken et al., "Occupational HIV infection and health care workers in the tropics." *Tropical Doctor* (Jan. 1991) 21: 28-31. The study does not specify the countries in which the health personnel were working when they became infected.

²¹⁹ E-mail from Dr. Janine Jagger, Health Care Worker Safety Center, University of Virginia, Jan. 29, 2003.

²²⁰ See Hans Veeken et al., "Occupational HIV infection and health care workers in the tropics." *Tropical Doctor* (Jan. 1991) 21: 28-31, at 28-30. Another study also found that 33% of needlestick injuries occurred during recapping. A different study found 17% of needlestick injuries occurred during recapping, while 15% occurred when used needles were improperly disposed. See R. de Graaf, H. Houweling & G. van Zessen, "Occupational risk of HIV infection among Western health care professionals posted in AIDS endemic areas." *AIDS Care* (1998) 10(4): 441-452, at 442.

equipment are central to preventing these infections.²²¹ Wearing double gloves helps prevent transmission by reducing the amount of blood transmitted. Used gloves tear more easily than new gloves, so provide less protection.²²² Disposable gloves should be used. Goggles or other protective glasses are important too, perhaps especially so for health care providers delivering babies and performing surgery. In a study of Dutch health professionals working in Africa, many potential exposures to HIV occurred when blood splashed in their eyes during surgery. Another study found that in 25% of operations (in a Western setting), blood splashes were found on surgeons' glasses.²²³

The high HIV prevalence in many African countries creates a significant risk of HIV transmission during surgery. A study of the risk for surgeons in Zambia found that because of the high HIV prevalence among patients – 22.3% in the study – surgeons' risk of becoming infected with HIV while performing surgery was 15 times that of their Western colleagues.²²⁴ The study estimated that surgeons practicing for five years in Zambia had a 1.5% risk of contracting HIV from their work.²²⁵

That study documented twelve cases where the surgeon was exposed to the patient's blood through a puncture wound or laceration, or when the surgeon had a skin defect or mucous membrane that was exposed to the patient's blood. Ten of these exposures were injuries caused by non-hollow suture needles, one was caused by a knife wound, and the twelfth occurred when the surgeon was splashed in the eye with the patient's blood.²²⁶ Wearing a thimble on the non-dominant index finger – where the suture needle injuries occurred – would have greatly reduced the risk of HIV exposure while suturing,²²⁷ and goggles could have protected the surgeon from being splashed with the patient's blood.

Using blunt, rather than sharp, suture needles might have also helped prevent the exposure during suturing – which, as the study above indicates, is the most significant source of HIV exposure during surgery (assuming that the surgeons were wearing gloves). Suture needles with a blunt tip are less likely to cause needlestick injuries during certain surgical procedures because they do not penetrate the skin as easily as sharp needles. One study that compared the use of sharp curved needles and blunt needles during gynecologic surgery found that blunt needles did not cause any injuries. By contrast, health care providers experienced 1.9 needlestick injuries per 1,000 conventional sharp curved suture needles used. In a small portion of procedures,

²²¹ See Hans Veeken et al., "Occupational HIV infection and health care workers in the tropics." *Tropical Doctor* (Jan. 1991) 21: 28-31, at 31.

²²² See R. de Graaf, H. Houweling & G. van Zessen, "Occupational risk of HIV infection among Western health care professionals posted in AIDS endemic areas." *AIDS Care* (1998) 10(4): 441-452, at 442, 449. Used gloves might also not be sterile.

²²³ See *id.* at 449-450. See also Janine Jagger, Melanie Bentley & Patricia Tereskerz, "A study of patterns and prevention of blood exposures in OR personnel." *AORN Journal* (May 1998) 67(5): 979-996, at 979 (highlighting the vulnerability of the health care workers' eyes to the patient's blood during surgery).

²²⁴ This increased risk comes despite the fact that most surgeries in poorer countries take less time and are simpler than many performed in wealthier countries, and do not use equipment (such as power tools) or techniques that could increase the risk of exposure. See Esther C.J. Consten et al., "A prospective study on the risk of exposure to HIV during surgery in Zambia." *AIDS* (1995) 9: 585-588, at 587.

²²⁵ See *id.* at 585.

²²⁶ See *id.* at 586.

²²⁷ See *id.* at 587.

surgeons reported problems using blunt suture needles, such as difficulty penetrating the tissue they were suturing, but none of these difficulties were considered clinically important.²²⁸

A study that examined occupational exposure to HIV for a wide range of surgical procedures also indicated the important protective value of blunt suture needles. The study found that the surgical device that caused the most skin penetration injuries were suture needles. Blunt suture needles could have prevented many of these injuries, for “[b]lunt suture needles are designed to penetrate muscle and fascia [connective tissue], but do not penetrate denser cutaneous [skin] tissue easily,”²²⁹ and 59% of the injuries that occurred during suturing involved suturing muscle and fascia. Thus, blunt suture needles could be highly effective in preventing a majority of injuries caused by suture needles.²³⁰

The value of blunt needles is particular to the context of suturing relatively low-density tissue that can be penetrated with blunt needles easily; blunt needles are not recommended in other contexts. The review of 19 documented cases of HIV infections in health care providers recommends using sharp needles because “repeatedly used needles become blunt and therefore considerable force is required to manipulate them through tissue, with subsequent risk of injury.”²³¹

Need for improvements

In much of the developing world, health care providers lack gloves, masks, and other protective barriers. They also lack safe disposal systems for waste. In 1999 in Eastern Cape Province, South Africa, for example, only 38% of clinics used plastic boxes to store waste or medical sharps (and it is not clear that even these were puncture-proof), whereas 48% either used ordinary refuse bags or color-coded bags, which presumably would not be puncture-proof.²³² Globally, not even 10% of syringes are supplied with safety disposal boxes.²³³ Health care providers in developing countries also routinely use “[u]nnecessarily hazardous diagnostic equipment, such as nonretracting finger-stick lancets and glass capillary tubes (both of which

²²⁸ See M. Mendelson et al., “Evaluation of Blunt Suture Needles in Preventing Percutaneous Injuries Among Health-Care Workers During Gynecologic Surgical Procedures — New York City, March 1993–June 1994.” *Morbidity & Mortality Weekly Report* (Jan. 17, 1997) 46(2): 25-29.

²²⁹ Janine Jagger, Melanie Bentley & Patricia Tereskerz, “A study of patterns and prevention of blood exposures in OR personnel.” *AORN Journal* (May 1998) 67(5): 979-996.

²³⁰ See *id.* Blunt suture needles are only one of a number of technical innovations that could reduce the risk of exposure to HIV during surgery. See *id.*

²³¹ Hans Veeken et al., “Occupational HIV infection and health care workers in the tropics.” *Tropical Doctor* (Jan. 1991) 21: 28-31, at 30.

²³² See Xoli Mahlalela et al. (EQUITY Project), *Primary Health Care in the Eastern Cape Province, 1997-2000*, c. 2001, at 43. It is not clear what disposal system the other 14% of clinics used, though they may have disposed of the medical sharps locally (such as by burying them). Improper disposal places not only health care providers at risk, but also, in facilities that have them, cleaning staff as well. See *id.*

²³³ See M.A. Miller & E. Pisani, “The Cost of Unsafe Injections.” *Bulletin of the World Health Organization* (1999) 77(10): 808-811, at 809. Available at: <http://www.who.int/bulletin/pdf/issue10/miller.pdf>.

have been associated with the occupational transmission of HIV).²³⁴ Safer alternatives exist, namely automatically retracting lancets and plastic or plastic-wrapped capillary tubes.²³⁵

Reports of health care providers lacking such basic protective equipment as gloves are common in Africa. Shortages of gloves were reported as problems at some health centers and hospitals in a situational analysis of health centers, clinics, and hospitals at five districts in Namibia.²³⁶ Many nurses who left Zimbabwe in the “brain drain” reported “taking considerable risks by handling Aids patients without gloves, masks and other protective devices.”²³⁷ In 1993, Ghana’s Ministry of Health acknowledged a lack of gloves in the country.²³⁸ The United Kingdom’s Voluntary Service Overseas has reported that in Zambia, “care workers have no special training or equipment to implement universal precautions.”²³⁹ A study of HIV exposure among Ugandan health care providers reporting that of the 65 health care providers interviewed at two hospitals in Kampala, Uganda, who reported that they felt in danger while at work, all cited or implied that lack of gloves was a hazard, and many also mentioned lack of goggles, aprons, disinfectant, and foot protection.²⁴⁰

In some countries in Africa, it is common for health care providers or other people who assist with childbirth not to have gloves. In Tanzania, birth attendants are reported having had to “cover their hands with plastic bags to protect themselves from exposure to HIV during deliveries because there are no gloves available.”²⁴¹ A needs assessment of a district in Zambia found that a “major complaint” among relatives and traditional birth attendants who assisted with home delivery was that they could not use gloves.²⁴² A 1995 study of more than 200 family planning clinics in Kenya found that at most, gloves were not generally available.²⁴³ This is of particular concern because of the large quantities of blood that midwives, traditional birth

²³⁴ Charles Sagoe-Moses et al., “Risks to Health Care Workers in Developing Countries.” *New England Journal of Medicine* (Aug. 16, 2001) 345(7): 538-541, at 538.

²³⁵ See *id.*

²³⁶ See N.T. Hamata, B. Hailemariam & S.N. Ipinge, *Obstetric Care Services in Namibia: A Situation Analysis Report*, Oct. 2001, at 14. Available at: www.un.na/who/SITUATION%20ANALYSIS%20MMR%202001.2.doc.

²³⁷ Rudo Gaidzanwa, *Executive Summary, Harsh Working Conditions Make Medical Professionals Migrate: Zimbabwean Doctors and Nurses in the Era of Structural Adjustment*, <http://www.nai.uu.se/forsk/avslut/sap/summaries/111.html>. Last updated Dec. 3, 2002.

²³⁸ See Kofi Awusabo-Asarea & Constance Marfob, “Attitudes and management of HIV/AIDS among health workers in Ghana: The case of Cape Coast municipality.” *Health Transition Review* (1997) 7 (supp): 271-280, 274-75. Available at: <http://nceph.anu.edu.au/htc/pdfs/Awasabo6.pdf> (also reporting study from Ghana in which 6 of 13 physicians interviewed “felt that they, or some of their nurses, could be at risk due to the inadequate supply of basic items such as disinfectants, gloves and other protective clothing”).

²³⁹ International Development Committee, United Kingdom House of Commons *Appendix 6: Memorandum Submitted by Voluntary Service Overseas (VSO)*, March 20, 2001. Available at: <http://www.parliament.the-stationery-office.co.uk/pa/cm200001/cmselect/cmintdev/354/354ap07.htm>

²⁴⁰ See Flávio Casoy, *Occupational Exposure to HIV among Healthcare Workers: Perceptions of Risks and Rights*, (Unpublished) 2002, at 13.

²⁴¹ Charles Sagoe-Moses et al., “Risks to Health Care Workers in Developing Countries.” *New England Journal of Medicine* (Aug. 16, 2001) 345(7): 538-541, at 538.

²⁴² Prevention of Maternal Mortality (Zambia) Programme, *Summarised Maternal Mortality Needs Assessment Report*, 2002. Available at: <http://www.pmmz.org.zm/report.htm>.

²⁴³ See *Frontiers in Reproductive Health, Executive Summaries of Operation Research Studies and Situation Analysis Studies 1995 Situation Analysis study of Kenya*, <http://www.popcouncil.org/frontiers/orta/sa-kenya.html>. Accessed Dec. 3, 2002.

attendants, and other people who assist delivery come into contact with.²⁴⁴ Along with the problem of inadequate supplies, health care providers might not have proper training on the protective gear that is available.²⁴⁵

Similar problems exist in Asia as well. A recent study of a primary health care facility in Indonesia found inadequate supplies to carry out universal precautions, inadequate glove use, inadequate disposal of medical sharps, and inadequate adherence to decontamination procedures.²⁴⁶ A UNAIDS study in India found that in some hospitals, HIV-positive patients had to pay for gloves and other protections for health care providers or go to a public hospital without the equipment necessary to implement universal precautions. While most private hospitals included in the study could afford the equipment necessary to implement universal precautions, the supply of gloves and other protective gear was poor in most public hospitals.²⁴⁷ A 1997 study of a hospital in Beijing found that “[t]he universal precaution practices of nurses was not good,” with the use of protective barriers the poorest of the practices.²⁴⁸ According to Burma Watch International, one reason for the spread of HIV/AIDS in Burma is the “lack of universal precautions [in] health care settings.”²⁴⁹

²⁴⁴ While the possibility of large quantity of blood coming into contact with non-intact skin or mucous membranes raises extra concern, it is important to emphasize that studies have found even brief contact with a small quantity of blood can transmit HIV. E-mail from Dr. Janine Jagger, Health Care Worker Safety Center, University of Virginia, Jan. 29, 2003. Laboratory technicians, who analyze blood and often draw it as well, are also at high risk of coming into contact with blood.

²⁴⁵ See Kofi Awusabo-Asarea & Constance Marfob, “Attitudes and management of HIV/AIDS among health workers in Ghana: The case of Cape Coast municipality.” *Health Transition Review* (1997) 7 (supp): 271-280, 274-75. Available at: <http://nceph.anu.edu.au/htc/pdfs/Awasabo6.pdf> (citing Kenya study that show even where gloves are available, health care providers might not use them because they believe them to be unnecessary or a waste of time).

²⁴⁶ See Universal Precautions and Training Project. Surabaya, Indonesia, *Universal Precaution Guidelines for Primary Health Care Centers in Indonesia*, July 2000, at 8. Available at: <http://www.initiativesinc.com/Guidelines.PDF>.

²⁴⁷ See UNAIDS, *India: HIV and AIDS-Related Stigma, Discrimination and Denial*, Aug. 2001, at 27-29. Available at: http://www.unaids.org/publications/documents/human/law/HR_India.pdf.

²⁴⁸ Gao Fengli, *Knowledge and Attitudes toward AIDS and Universal Precautions Practices of Nurses at Peking Union Medical College Hospital*, thesis, 1998. Available at: <http://www.chiangmai.ac.th/abstract1998/Abstract/nur/abstract/nur980256.htm>.

²⁴⁹ Burma Watch International, *How Health and Human Rights are Interrelated*, 2002. Available at: <http://www.burmawatch.org/com-khin-1.html>.

HUMAN RIGHTS

Respect for human rights demands that the international community and nations combating the HIV/AIDS pandemic respond to HIV transmission in health care settings. Among the rights at issue are the rights to health, safe working conditions, and to benefit from scientific advances.

Right to health

Preventing HIV transmission in health care settings involves core concerns of the right to the highest attainable standard of health, as set forth in the International Covenant on Economic, Social and Cultural Rights (ICESCR).²⁵⁰ The ICESCR refers specifically to the requirement that in working to achieve this right, states take steps necessary for “[t]he prevention, treatment and control of epidemic, endemic, occupational and other diseases.”²⁵¹ Unsafe injections and unsafe blood transfusions are both important contributors to the HIV/AIDS epidemic. For health care providers, who are at risk of becoming infected with HIV in their workplace, HIV/AIDS is also an occupational disease.

Safe health care

The Committee on Economic, Social and Cultural Rights, charged with monitoring adherence to the ICESCR,²⁵² has made clear that safe health care is a central aspect of the right to health, one that captures the celebrated command to physicians associated with the Hippocratic Oath: first, do no harm. It is this command that unsafe medical injections and unsafe blood transfusions so lethally violate.

In 2000, the Committee released its General Comment 14, which provides its authoritative interpretation of the right to health. General Comment 14 explains that “[t]he right to health in all its forms and at all levels contains [four] interrelated and essential elements.”²⁵³ Among these “interrelated and essential elements” is quality: “health facilities, goods and services must . . . be scientifically and medically appropriate and of good quality.”²⁵⁴ Re-using syringes and transfusing blood that has not been screened for HIV and other bloodborne pathogens are not scientifically or medically appropriate practices. These practices are responsible for at least half a million HIV infections per year, along with millions of hepatitis infections. Because of the tremendous harm caused by unsafe injections and unsafe blood transfusions, these unsound practices are also anathema to another of the “interrelated and essential elements,” acceptability, according to which “[a]ll health facilities, goods and services must be . . . designed to . . .

²⁵⁰ *International Covenant on Economic, Social and Cultural Rights*, G.A. res. 2200A (XXI), 21 U.N.GAOR Supp. (No. 16) at 49, U.N. Doc. A/6316 (1966), 993 U.N.T.S. 3, entered into force Jan. 3, 1976, at art. 12 [hereinafter “ICESCR”].

²⁵¹ ICESCR, art. 12 (c).

²⁵² The Committee on Economic, Social and Cultural Rights is charged with monitoring the adherence of state parties to the ICESCR and is developing a jurisprudence of its own. See Office of the High Commissioner for Human Rights, *Fact Sheet No.16 (Rev.1), The Committee on Economic, Social and Cultural Rights*, July 1991. Available at: <http://193.194.138.190/html/menu6/2/fs16.htm#6>.

²⁵³ *Id.* at para 12.

²⁵⁴ *Id.* at para. 12(d).

improve the health status of those concerned.”²⁵⁵ Safe, practical alternatives endorsed by organizations such as WHO exist to eliminate or virtually eliminate these risks: using single-use and auto-disable syringes for all injections and testing donated blood for HIV and other pathogens to ensure that the blood supply is uncontaminated. Safe injections and a safe blood supply are both medically appropriate and designed to improve people’s health, and are therefore essential elements of the right to health.

General Comment 14 states that “the precise application [of the four interrelated and essential elements] will depend on the conditions prevailing in a particular State.” Safe injection equipment is inexpensive and simple to use, requiring only that health care providers are appropriately trained in the safe and appropriate use of injections and that single-use and auto-disable syringes and safety disposal boxes are made available to health care providers. Every country with a primary health care system trains its health care providers and has a drug distribution system, and therefore can provide the training and equipment required for injection safety. Since every country is able to provide primary health care, the conditions needed for injection safety prevail in every country. The right to health therefore requires that safe injections be made universally available now.²⁵⁶

Conditions also prevail in every country to implement a safe blood transfusion system,²⁵⁷ though in some cases donor assistance may be necessary to help realize the near universal potential for a safe blood supply. Through its pledge to ensure safe blood supplies in all countries by 2005,²⁵⁸ the Declaration of Commitment on HIV/AIDS reveals the sense of the international community that a safe blood supply is not beyond the reach of any country. Experience bears this out. Even some of the world’s poorest countries, such as Uganda, have successfully implemented safe blood transfusion systems. And although the WHO estimate of blood safety coverage of 96% in low- and medium-income countries, including 94% in Africa, is probably not wholly representative (judging from the notably more negative contemporaneous estimates), it does indicate that safe blood supplies are possible – and to some extent already exist – even in poor countries.²⁵⁹ Therefore, because prevailing conditions will so allow, the right to health requires countries to create and implement safe blood transfusion systems.

²⁵⁵ *Id.* at para. 12(c).

²⁵⁶ Every country has a primary health system. There are regions of some countries, however, such as Afghanistan and the Democratic Republic of Congo, where the government might not be in actual control of all of its territory because of civil war or other security reasons. In such regions (but not for the regions of these countries over which the government does have effective control), prevailing conditions might not permit the government to ensure universal injection safety.

²⁵⁷ As is the case for injection safety, conditions might not prevail for governments to ensure blood safety in parts of certain countries where the government does not effectively control parts of its territory. So long as that remains the case, the right to health would not necessarily require governments to implement safe blood transfusion systems in these areas, though they should try. It may be that even in areas that pose security challenges to the government, safe blood supplies can be developed. For example, security problems in northern Uganda prevent the national Uganda Blood Transfusion Service from supplying blood directly to that region, but local blood screening nonetheless takes place in northern Uganda. See Hands On (BBC World program), *Blood safe – Uganda*, <http://www.tve.org/ho/doc.cfm?aid=413>. Accessed Jan. 1, 2003. The program aired Jan. 28-Feb. 5, 1999.

²⁵⁸ See *Declaration of Commitment on HIV/AIDS*, United Nations General Assembly Special Session on HIV/AIDS (UNGASS), adopted June 27, 2001, at para. 52. Available at: <http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html>.

²⁵⁹ See World Health Organization, HIV/AIDS Department, *The Health Sector Response to HIV/AIDS: Coverage of Selected Services in 2001: Preliminary Assessment*, 2002, at 18. The survey includes 35 African countries. See *id.*

Donor assistance might be necessary to enable some poor countries to establish safe blood transfusion systems. Under the international legal obligation to cooperate and provide assistance in helping all states realize their human rights obligations (see “International Obligations” below), states are obliged to provide this assistance. This obligation is particularly strongly for establishing a safe blood transfusion system, as this is an “essential” requirement under the right to health.²⁶⁰

Core obligations

The right to health requires states to take steps towards realizing this and other rights to “the maximum of [their] available resources, with a view to achieving progressively the full realization of the rights.”²⁶¹ Certain obligations are so fundamental that states are under an absolute obligation to meet these obligations immediately. These are known as “core obligations,” which are the “minimum essential levels of each of the rights enunciated in the Covenant, including essential primary health care.”²⁶² “[A] State party cannot, under any circumstances whatsoever, justify its non-compliance with the core obligations . . . which are non-derogable.”²⁶³ Resource constraints therefore cannot be used to justify non-compliance with core obligations.

Enabling health care providers to adhere to universal precautions must be considered a core international legal obligation. Although it is not explicitly included among the core obligations listed by the Committee on Economic, Social and Cultural Rights, it is necessary to meet the first core obligation listed, “ensur[ing] the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups.”²⁶⁴ Furthermore, central aspects of an undertaking to ensure safe health care and universal adherence to the universal precautions are listed as being of “comparable priority” to the core obligations, namely education and access to health information, appropriate training for health personnel, and “measures to prevent, treat and control epidemic . . . diseases.”²⁶⁵

²⁶⁰ With respect to other central elements of the right to health, the core obligations, General Comment 14 states “that it is particularly incumbent on States parties and other actors in a position to assist, to provide ‘international assistance and cooperation, especially economic and technical’ which enable developing countries to fulfil their core and other obligations [of comparable priority].” Committee on Economic, Social and Cultural Rights, *General Comment 14, The right to the highest attainable standard of health*, U.N. Doc. E/C.12/2000/4 (2000), at para. 45.

²⁶¹ ICESCR, art. 2(1). Because the issues covered by this paper are all among the core obligations or required under the “essential element” of the right to scientifically and medically appropriate health care, this paper will not discuss the progressive realization requirement.

²⁶² Committee on Economic, Social and Cultural Rights, *General Comment 14, The right to the highest attainable standard of health*, U.N. Doc. E/C.12/2000/4 (2000), at para. 43,

²⁶³ *Id.* at para. 47.

²⁶⁴ *Id.* at para. 43(a).

²⁶⁵ *Id.* at para. 44.

Injection safety and safe blood supplies

Health information

States have the responsibility to ensure that health care providers are trained to provide safe injections and always have an adequate supply of auto-disable or single-use syringes. Safeguards are required, however, to help guarantee that people do in fact receive safe injections. Public education on safe injections and the proper use of injections are therefore key aspects of a safe injection strategy. This public knowledge will complement the quality health care requirement. It will create the public awareness and pressure to help ensure that health facilities do provide safe injections, enable members of the public to protect themselves when health facilities fail to provide safe injections, and reduce demand for unnecessary injections. It will empower people to know that it is their prerogative to insist that they watch the health care worker take a new syringe out of its packaging.

General Comment 14 includes the right to health information as an “obligation[] of comparable priority” to the core obligations: “To provide education and access to information concerning the main health problems in the community, including methods of preventing and controlling them.”²⁶⁶ This informational aspect of the right to health has special import to organizations such as WHO and UNAIDS, which are committed to human rights principles.²⁶⁷ Their influence in creating national HIV/AIDS strategies and in forming health strategies more generally gives them unique influence in determining whether or not people throughout the developing world learn about the dangers of unsafe injections, and how to ensure that they receive safe injections.

Several reactions to a recent short series of articles²⁶⁸ arguing that HIV transmission in health care settings in Africa is much more prevalent than commonly believed suggest that organizations that have a critical role in emphasizing the danger of HIV transmission in health care settings, including UNAIDS and NGOs, might be reluctant to do so. The chief scientist at UNAIDS worried that this sort of information “might tend to make people drop their guard and not use condoms.”²⁶⁹ A doctor with an AIDS NGO working in Kenya raised the possibility that this information “could lead to a serious change in terms of health behaviour with people being reluctant to enter hospitals.”²⁷⁰ Also, it has been suggested that one reason that health professionals in WHO and elsewhere downplayed the importance of unsafe injections in

²⁶⁶ *Id.* at para. 44(d). Along with this particular obligation, more generally the right to health “includes the right to seek, receive and impart information and ideas concerning health issues.” *Id.* at para. 12(b).

²⁶⁷ *See, e.g.,* UNAIDS, *HIV/AIDS and Human Rights: International Guidelines*, 1998. Available at: <http://www.unaids.org/publications/documents/human/law/hright2e.pdf>; World Health Organization, *Health & Human Rights*, <http://www.who.int/hhr/>. Accessed Jan. 20, 2003. *See also* Committee on Economic, Social and Cultural Rights, *General Comment 14, The right to the highest attainable standard of health*, U.N. Doc. E/C.12/2000/4 (2000), at paras. 63-65.

²⁶⁸ David Gisselquist & John J. Potterat, “Heterosexual Transmission of HIV in Africa: An Empiric Estimate.” *International Journal of STD & AIDS* (March 2003) 14: 162-173; David Gisselquist, John J. Potterat, Stuart Brody & François Vachon, “Let it be sexual: how health care transmission of AIDS in Africa was ignored.” *International Journal of STD & AIDS* (March 2003) 14: 148-161.

²⁶⁹ Nick Adcock, “Dirty Needles ‘Spread Africa AIDS.’” *Accra Mail* (Accra, Ghana), Feb. 21, 2003. Available at: <http://allafrica.com/stories/200302200835.html>.

²⁷⁰ *Id.*

transmitting HIV in the late 1980s and early 1990s was that they feared that people would avoid immunizations if they thought that injections were unsafe.²⁷¹

Information should be tailored to address these concerns. For example, messages on unsafe injections can also highlight the need for people to continue to use condoms and otherwise guard against sexual transmission of HIV. The same messages that inform people about the dangers of unsafe injections should inform people about how to ensure that the injections they receive (when injections are necessary) are safe and can highlight the importance of continuing to receive immunizations. These concerns should not deter organizations from educating people on the risk of unsafe injections, or on the possible scale of this risk. People have a right to this information so that they can make informed decisions about how to protect themselves.

Evidence from Uganda suggests that emphasizing the dangers of HIV transmission through unsafe injection will not have the feared consequences. A household survey in Uganda conducted in June 1989, which covered five health districts and a municipality, might help allay the fear that people will avoid immunizations if they are informed of the risks of unsafe injections. Children of mothers who believed that injections can transmit HIV/AIDS were more likely to have their children fully immunized than children of mothers who did not believe that injections can transmit HIV/AIDS. The children of mothers who expressed a concern about immunizations transmitting HIV/AIDS were immunized at rates similar to children whose mothers did not express this concern. Further, the same educational material and messages that inform people of the risks of re-used syringes can also inform people that they should continue to receive immunizations and that immunizations (where auto-disable syringes are used) are safe.²⁷² The leadership that UNICEF and other organizations that provide and promote immunizations have displayed in advancing injection safety for immunizations indicates a broadly shared belief that the benefits of promoting safe injections outweigh any risks that may exist of parents not getting their children immunized because they fear that the immunizations are unsafe.

Uganda's anti-AIDS campaign "warned people about the dangers of sharing unsterile needles and syringes" in the medical setting,²⁷³ yet Physicians for Human Rights is not aware of any evidence suggesting that this led people to stop seeking necessary health care. There is evidence, however, that people – quite appropriately – came to distrust injection equipment at government health facilities, and often used their own personal injection equipment or insisted on receiving new syringes.²⁷⁴ A study in one of the districts in Uganda most affected by HIV/AIDS found that people were "no longer demanding treatment by injections when they go to hospitals," that they preferred disposable syringes to re-useable ones, and that "[m]any people [did] not trust the sterilization process in the health units."²⁷⁵

²⁷¹ David Gisselquist, John J. Potterat, Stuart Brody & François Vachon, "Let it be sexual: how health care transmission of AIDS in Africa was ignored." *International Journal of STD & AIDS* (March 2003) 14: 148-161, at 158.

²⁷² See Seth Berkley et al., "Immunisation and fear of AIDS," letter. *Lancet* (Jan. 6, 1990) 335: 47-48.

²⁷³ Harriet Birungi, "Injections and self-help: Risk and trust in Ugandan health care." *Social Science & Medicine* (1998) 47(10): 1455-1462, at 1458-1459.

²⁷⁴ See *id.* at 1459-1460.

²⁷⁵ Joseph K. Konde-Lule, M. Musagara & S. Musgrave, "Focus Group Interviews about AIDS in Rakai District of Uganda." *Social Science & Medicine* (1993) 37: 679-684, at 682.

Including messages on the dangers of unsafe injections in Uganda's anti-AIDS campaign did not interfere with the messages on the risk of sexual behavior. In Uganda, sexual activity was lower among women ages 15-19 and men ages 18-19 in 2000 compared to 1988; the proportion of unmarried sexually active women of all ages with multiple partners, and of unmarried sexually active men ages 18-19 with multiple partners, was less in 2000 than in 1995, and; condom use in the unmarried sexually active population rose significantly from 1988 to 2000.²⁷⁶ Indeed, changes in sexual behavior are generally considered the main reason that Uganda has been able to reverse its AIDS epidemic.

Appropriately trained health personnel

The other “obligation[] of comparable priority” to the core obligations that is central to providing safe health care is the obligation “[t]o provide appropriate training for health personnel.”²⁷⁷ In the context of injection safety, appropriate training means that health care providers must understand the dangers of unsafe injections, the importance of using each syringes only once, and how to properly sterilize injection equipment if no new needles and syringes are available. They must also be trained on the appropriate use of injections, so as to reduce the number of unnecessary, irrational injections. For blood transfusions to be safe, training is necessary for donor recruiters, counselors, blood collectors, laboratory staff, and quality managers, as well as the health care providers who prescribe transfusions.

Measures to control epidemic disease

Another “obligation[] of comparable priority” to the core obligations is “[t]o take measures to prevent, treat and control epidemic and endemic diseases.”²⁷⁸ In much of Africa and Asia, HIV/AIDS, hepatitis B, and hepatitis C are all epidemic diseases, with unsafe injections and unsafe blood transfusions being among their major routes of transmission. Measures to improve injection and blood safety are therefore critical to preventing and controlling these diseases, and fall under this obligation.

Universal precautions

Non-discriminatory access to health care

The core obligation “[t]o ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups” requires that health care providers have the training and supplies needed for them to adhere to universal precautions. People living with HIV/AIDS are a vulnerable or marginalized group, as General Comment 14 explicitly acknowledges.²⁷⁹ Many states are not meeting this core obligations with respect to

²⁷⁶ See Susan A. Cohen, “Flexible but Comprehensive: Developing Country HIV Prevention Efforts Show Promise.” *Guttmacher Report on Public Policy* (Oct. 2002) 5(4), at 2. Available at: <http://www.guttmacher.org/pubs/journals/gr050401.pdf>.

²⁷⁷ Committee on Economic, Social and Cultural Rights, *General Comment 14, The right to the highest attainable standard of health*, U.N. Doc. E/C.12/2000/4 (2000), at para. 44(e).

²⁷⁸ *Id.* at para. 44.

²⁷⁹ See *id.* at para. 12(b).

people infected with HIV, as discrimination against HIV-positive people in the health sector remains common.²⁸⁰

This discrimination has roots in health care setting, though societal stigma against people living with HIV/AIDS also contributes to this discrimination.²⁸¹ If health care providers lack the necessary precautions, they have legitimate fears about becoming infected with HIV when caring for HIV-positive patients. According to one Nigerian policymaker, “Most hospitals don’t have protective supplies. There is no incentive for health care providers to risk infection.”²⁸² A Nigerian health care provider told Physicians for Human Rights, “The stigma is still there. . . . Some things we need to do our work, like protective gloves, should be provided.”²⁸³ The fear among health care providers that they might contract the virus from HIV-positive patients sometimes leads health care providers to refuse to care for HIV-positive patients. Or they might discriminate against them in other ways, such as by segregating them from other patients.²⁸⁴ There are few surer ways to ensure the discrimination against HIV-positive patients will continue than to deny the health providers who care for them the means of protecting themselves from infection.

If health care providers have the training and supplies needed to implement universal precautions, they will be at much lower risk of contracting HIV and other bloodborne pathogens from their patients. They can be expected to be less afraid of their HIV-positive patients, and be more willing to treat patients infected with HIV the same as other patients. Universal precautions alone might not end discrimination of HIV-infected patients in health care settings, but they will help reduce that discrimination, thus helping states meet their obligation to ensure access to health care for all on a non-discriminatory basis.

Appropriately trained health personnel

Given the dangers of occupational exposure to HIV, training on universal precautions is required not only as part of the core obligation of non-discriminatory access to health care, but also as part of the obligation “[t]o provide appropriate training for health personnel.” This training must emphasize the importance of adhering to these precautions for all patients. If health care providers follow these precautions only when caring for those they suspect are HIV-positive, these precautions will mark these patients as different, and so likely contribute to the stigma of HIV.²⁸⁵

²⁸⁰ See, e.g., UNAIDS, *India: HIV and AIDS-Related Stigma, Discrimination and Denial*, Aug. 2001, at 18-33. Available at: http://www.unaids.org/publications/documents/human/law/HR_India.pdf; Ivy Ncube, “Stigma, Discrimination Fuel HIV/Aids Epidemic.” *Herald (Harare, Zimbabwe)*, Nov. 28, 2002. Available at: <http://allafrica.com/stories/200211300191.html>; PHR interview, Nov. 2002, Nigeria.

²⁸¹ Other factors contribute to discrimination in the health care setting as well, such as the belief that HIV-positive patients will die soon anyway, so are not entitled to the same level of care as other people. See UNAIDS, *India: HIV and AIDS-Related Stigma, Discrimination and Denial*, Aug. 2001, at 33. Available at: http://www.unaids.org/publications/documents/human/law/HR_India.pdf.

²⁸² PHR interview, Nov. 2002, Nigeria.

²⁸³ PHR interview, Oct./Nov. 2002, Nigeria.

²⁸⁴ See UNAIDS, *India: HIV and AIDS-Related Stigma, Discrimination and Denial*, Aug. 2001, at 30. Available at: http://www.unaids.org/publications/documents/human/law/HR_India.pdf.

²⁸⁵ See *id.* at 27.

State obligations

State parties to the ICESCR are required to respect, protect, and fulfill the right to health. To respect this right, states must refrain from denying, limiting, or otherwise obstructing it. Protecting the right requires states to prevent third parties from interfering with the right to health. And fulfilling the right requires states to take positive steps to provide health care, such as enacting and implementing legislation.²⁸⁶

These three requirements indicate that state obligations extend beyond enacting programs necessary to fulfill the right to health, including access to health care for all on a non-discriminatory basis, such as health care worker training and public education on injection safety, funding auto-disable and single-use syringes, creating a safe blood donation and transfusion system, and providing the training and supplies necessary to enable health care providers to follow universal precautions. States must also ensure that they do not themselves contribute to poor quality health care, such as by providing reusable syringes in public health facilities. And states need to avoid obstructing health care providers and ordinary citizens from accessing single-use or auto-disable syringes, whether by taxing or regulating these items in ways that would reduce people's ability to obtain these types of syringes, or by some other method.

Protecting people's right to health requires states to regulate often large private health care markets to ensure that private health care providers are providing quality care and are not, for example, trying to save money by re-using syringes, or by collecting blood outside of a regulated blood collection system. States must also regulate the type of injection equipment that third parties sell or donate to health care facilities and providers in their territory, ensuring that the equipment is safe, meaning that it consists of single-use or auto-disable syringes.

International obligations

Under international law, countries are obliged to assist one another in promoting human rights. This obligation arises under international law from the United Nations Charter and other treaties, including the ICESCR. The UN Charter obliges members to "take joint and separate action"²⁸⁷ to promote "universal respect for, and observance of, human rights and fundamental freedoms" and to promote "solutions of international . . . health . . . problems. . . ."²⁸⁸ The ICESCR requires parties to the treaty to take "steps, individually and *through international assistance and co-operation*, especially economic and technical to the maximum of its available resources, with a view to achieving progressively the full realization of the rights" in the Covenant,²⁸⁹ including the right to the highest attainable standard of health.²⁹⁰

²⁸⁶ See Committee on Economic, Social and Cultural Rights, *General Comment 14, The right to the highest attainable standard of health*, U.N. Doc. E/C.12/2000/4 (2000), at para. 36.

²⁸⁷ UN Charter, art. 56.

²⁸⁸ *Id.* at art. 55.

²⁸⁹ ICESCR, art. 2 (emphasis added).

²⁹⁰ See *id.* at art. 12.

The Committee on Economic, Social and Cultural Rights highlights the important and obligatory nature of the international community's role in enabling countries to fulfill their core obligations under the right to health (and those of comparable priority): "the Committee wishes to emphasize that it is particularly incumbent on States parties and other actors in a position to assist, to provide 'international assistance and cooperation, especially economic and technical' which enable developing countries to fulfil their core and other obligations [of comparable priority]."²⁹¹ Because safe injections, safe blood transfusions, and universal precautions are all measures necessary to prevent and control a pandemic – and so all related to an obligation of comparable priority to the core obligations – the international obligations are heightened for all of these HIV prevention strategies. The international obligations are especially robust for universal precautions, which are needed to meet the core obligation to ensure access to health care on a non-discriminatory basis, and for those aspects of the injection and blood safety interventions necessary to meet the core obligations to provide appropriate training to health care providers and to ensure access to health education and information. The essential nature of the right to medically appropriate and good quality health care would appear to further heighten the extent of the international obligation with respect to ensuring injection safety and safe blood supplies. In short, the multiple and overlapping core and essential obligations that injection safety, universal precautions, and a safe blood supply encompass create a very strong obligation for donor countries to assist resource-poor countries in implementing comprehensive initiatives on injection safety, safe blood supplies, and universal precautions.

Right to safe working conditions

The ICESCR provides that as part of "the right of everyone to the enjoyment of just and favourable conditions of work," people have a right to "[s]afe and healthy working conditions."²⁹² The Convention concerning Occupational Safety and Health and Working Environment (ILO No. 155), though itself ratified by only five sub-Saharan countries (Cape Verde, Ethiopia, Lesotho, Nigeria, and South Africa) and a handful of Latin American and Asian countries,²⁹³ provides guidance for the "safe and healthy working conditions" requirement of the ICESCR. The central article of the Convention concerning Occupational Safety and Health requires national policies on occupational safety, occupational health, and the working environment to aim "to prevent accidents and injury to health arising out of, linked with or occurring in the course of work, by minimising, so far as is reasonably practicable, the causes of hazards inherent in the working environment."²⁹⁴ In the context of health care providers working in environments where they may be exposed to HIV, this article must require, at the least, that universal precautions be followed to minimize risk of HIV infection. Given the basic nature of these precautions, which require training and simple equipment such as gloves and puncture-proof containers, they easily fit within the category of "reasonably practicable." If even these simple infection control measures were not required as part of the right to "safe and healthy working conditions," this right would have very little meaning at all.

²⁹¹ Committee on Economic, Social and Cultural Rights, *General Comment 14, The right to the highest attainable standard of health*, U.N. Doc. E/C.12/2000/4 (2000), at para. 45.

²⁹² ICESCR, art. 7(b).

²⁹³ See International Labour Organization, *Convention No. 155 was ratified by 39 countries*, <http://ilolex.ilo.ch:1567/cgi-lex/ratifce.pl?C155>. Accessed March 6, 2003.

²⁹⁴ *Convention concerning Occupational Safety and Health Convention and the Working Environment (ILO No. 155)*, 1331 U.N.T.S. 279, entered into force Aug. 11, 1983, at art. 4.

Right to benefit from scientific progress

The ICESCR provides everyone the right “[t]o enjoy the benefits of scientific progress and its applications.”²⁹⁵ Science has created auto-disable and other single use disposal syringes, single-use vials, and methods of training to vastly improve the safety of medical injections. Equipment and practices have been developed to protect health care providers from occupational infections. So have the procedures and the testing supplies and equipment needed for a safe national blood supply. Within the basic parameters of the ICESCR (as well as the UN Charter), including the use of states’ maximum available resources to achieve and progressively realize this right, and the requirement of international assistance and cooperation to help achieve this right, these benefits of science must be made available to everyone.

²⁹⁵ ICESCR, art. 15(b).

ADDITIONAL URGENCY OF ADDRESSING HIV TRANSMISSION IN HEALTH CARE SETTINGS

Health care worker shortage

Health systems in Africa, and in rural and other underserved areas throughout the developing (and even the developed) world, face shortages of health care providers, in some cases quite severe shortages. The shortages have multiple causes, with the “brain drain” and underlying factors to that phenomenon, such as low pay and poor working conditions, being perhaps the most important. Another very important cause is that health care providers are dying of HIV/AIDS. Mostly, they are infected by the same routes as other adults – sexual transmission, unsafe injections, blood transfusions (and in some parts of the world, intravenous drug use), and possibly other forms of transmission in health care settings. But they also become infected through occupational exposure, whether through needlestick injuries or through contact between their own blood or mucous membranes and the blood of HIV-infected patients.

Implementing universal precautions will prevent many of these occupational HIV infections, as well as other diseases that can be transmitted through the same modes. For the many health systems that are understaffed and overburdened, each health worker lost is another blow. Protecting health care providers is critical to strengthening health care systems, and implementing universal precautions is an important part of protecting health care providers.

Possibility of significant impact soon

With sufficient commitment and resources, it should be possible to relatively quickly make significant strides in implementing universal precautions and greatly increasing the proportion of medical injections that are safe. The relative ease of these interventions contrasts sharply with prevention efforts aimed at the other major route of HIV transmission in countries with generalized epidemics, sexual transmission. While interventions related to preventing sexual transmission of HIV are critically important and are registering successes throughout Africa and elsewhere, they are difficult and take time, for they require people to talk about – and change – their most intimate behaviors.

This paper in no way seeks to discount the tremendous importance of such interventions. However, measures to prevent HIV transmission in health care settings promise to prevent (at the least) hundreds of thousands of HIV infections (and millions of hepatitis infections) every year. Injection safety especially will be a new source of infection control in many cases. If the upper-end projections of the significance of unsafe injections in transmitting HIV are correct, measures taken to make medical injections safe and prevent other HIV infections acquired in the medical setting create the possibility that many countries could replicate what thus far only a handful, such as Uganda, Thailand, and Brazil, have accomplished – turning the tide on HIV/AIDS, significantly reducing HIV prevalence and incidence.²⁹⁶

²⁹⁶ One skeptic of the importance of unsafe injections as a route of HIV transmission observes believes that “[t]he needle reuse theory oversimplifies a complex epidemic . . . and offers the allure of an easy answer,” saying “[t]he reality is that it is a lot easier to fix dirty needles than it is to fix people’s behavior.” Sabin Russell, “New AIDS

Snowball effect

A “snowball effect” (positive feedback loop) increases the urgency of addressing unsafe injections in both high and low prevalence countries. The epidemic caused by unsafe injections feeds on itself: the higher the HIV prevalence, the more likely it is that an unsafe injection will transmit HIV-contaminated blood, and so the greater the number of people who will become infected through unsafe injections. This further increases HIV prevalence, creating a positive feedback loop of still more HIV transmitted through unsafe injections, leading to still more injections. This is true too for sexual transmission: the higher the HIV prevalence levels, the more likely that a person’s sexual partner is HIV-positive and will transmit HIV, leading to still higher prevalence levels. These routes of transmission, sexual and unsafe health care, interact, so that people who are infected through an unsafe injection may transmit HIV to their sexual partner, and people who are infected through sexual transmission might be the source of the HIV on a contaminated needle.

This positive feedback effect is even worse for unsafe injections, however. While higher levels of HIV-prevalence levels do not lead people to engage in more risky sexual behavior, higher HIV levels do lead to people to seek more injections. Because of the ill health associated with the later stages of HIV infections, HIV-positive people require more injections than HIV-negative people. WHO reports that “HIV-infected persons tend to receive 10-100 times more injections than healthy people.”²⁹⁷ As a result, not only do injections become increasingly likely to transmit HIV because of higher HIV prevalence, but also because people with HIV are receiving more injections than people without HIV, leading to increased levels of HIV contamination of the needle supply.²⁹⁸

suspect; Researchers say reuse of needles as much to blame as sex behavior.” *San Francisco Chronicle*, Dec. 1, 2002, at A1 (quoting Nancy Padian, a University of California at San Francisco researcher).

²⁹⁷ 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 795. Available at: <http://www.who.int/bulletin/pdf/issue10/simonsen.pdf> (“Because febrile, ill and HIV-infected persons tend to receive 10-100 times more injections than healthy people, the true probability of a syringe being contaminated with blood tainted with a pathogen may actually be considerably higher than the average population prevalence of that pathogen”).

²⁹⁸ Higher prevalence among persons seeking injections increases the proportion of needles that have HIV-contaminated blood and thereby increases HIV transmission. However, as the rate of prevalence among those seeking injections passes 50%, transmission slows as the proportion of persons seeking injections who are susceptible falls.

CONCLUSION

The degree to which medical injections and health care more generally contribute to the astronomical rates of HIV/AIDS in much of sub-Saharan Africa is a matter of considerable controversy. The common understanding is that unsafe injections have played a relatively small role, while some researchers argue that they have played quite a significant role in the pandemic. While the discussion of the number of people who become infected with HIV through unsafe injections and other medical modes is one that should take place, PHR urges WHO, UNAIDS, national HIV/AIDS programs, donor countries, and others who are responding to the pandemic to focus their energies not on debating numbers, but on implementing programs and initiating new, life-saving policies.

Whatever the exact number of people who become infected with HIV because of unsafe injections, the problem is severe and must be addressed urgently. According to figures endorsed by WHO,²⁹⁹ unsafe injections given each year will cause nearly 1.5 million deaths. Putting an end to unsafe injections will save millions of lives.

That health care settings present significant infection risks does not diminish risks caused by sexual behavior, nor does it diminish the importance of HIV/AIDS prevention initiatives that address sexual behavior. But the most effective HIV/AIDS prevention strategy will be one that responds aggressively to all sources of infections. While responses vary by country, and blood transfusions have long been recognized as a significant risk, on the whole a missing element of HIV/AIDS prevention strategies has been interventions to address HIV transmission in health care settings, especially unsafe injections. Physicians for Human Rights has offered recommendations on ways the various actors should respond to these dangers. Meanwhile, initiatives are underway to improve understanding of HIV transmission in health care settings. For example, WHO and UNAIDS convened a meeting of experts in March 2003 to discuss the connections between HIV transmission and unsafe medical injections.

National and international HIV/AIDS prevention strategies should include activities to prevent transmission in the medical setting among the essential prevention interventions. Countries and multilateral organizations should implement and fund these policies and programs with the urgency that the millions of lives that hang in the balance command.

²⁹⁹ A WHO fact sheet states that the “[e]stimated annual deaths due to unsafe injection practices” is 1.3 million. World Health Organization, *Fact Sheet No. 232: Safety of Injections: Facts & Figures*, Oct. 1999. Available at: <http://www.who.int/inf-fs/en/fact232.html>. This fact sheet used an earlier estimate of about 100,000 HIV infections from unsafe injections. See also World Health Organization, *Safety of Injections Fact Sheet*, April 9, 2002. Available at: <http://www.health.fgov.be/WHI3/krant/krantarch2002/kranttekstapr2/020409m02a-who.htm>. Two of the three authors of the article calculating that 260,000 HIV infections are caused annually from unsafe injections work for the WHO Department of Blood Safety and Clinical Technology. (The third works for the CDC.) 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).