Re-Building Distribution Networks to Assure Future Microbicide Access

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ABSTRACT

The first candidate topical microbicides — products designed to reduce women's risk of HIV infection — are now in the final stages of efficacy testing, and, if successful, could start to be available by the end of the decade. Advocates in public health and international development are already discussing how to expedite access to this new technology in countries where it could have the largest public health impact.

The World Health Organization (WHO), World Bank, and the European Union support the integration of family planning and HIV programs. Such integration is impeded by U.S. policy, funding restrictions, and reluctance to integrate family planning and HIV/AIDS funding.

This article describes how these policies weaken, rather than strengthen, the capacity of distribution networks to play an urgently needed role in microbicide roll-out when the time comes.

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This article was published in March 2007.

THE FEMINIZATION OF HIV/AIDS

The HIV/AIDS pandemic has undergone a dramatic demographic shift in the last two decades, with women and girls becoming the majority of newly infected individuals. This impact is most pronounced in sub-Saharan Africa.[1] Although home to only one-tenth of the world's population, the region supports roughly two-thirds of all people living with HIV/AIDS.[2] In 2005, women made up 57 percent of those living with HIV/AIDS in the region,[3] and girls comprised 76 percent of all HIV-positive young people (15 to 24 years old) there.[4]

Socio-economic, cultural, and physiological factors place women and girls at greater risk for contracting HIV than men. This vulnerability heightens the urgency of the need for woman-initiated HIV-prevention methods.

Topical microbicides are being developed to meet this need. Designed for insertion into the vagina prior to intercourse as a suppository, gel, or foam, microbicides are being developed in contraceptive and noncontraceptive forms. Unlike a male or female condom, a microbicide can be used by a woman without her partner's active cooperation at each act of intercourse. Analysts estimate that the

first generation of microbicides may only be 50 to 60 percent effective, although effectiveness is expected to increase as the second and third generations of products are refined and improved.[5] While far from optimal, a product that is 50 percent effective could give millions of women who are unable to insist on condoms an opportunity to reduce their risk of infection by half. Research done among women and men on the potential acceptability of this product reveals a range of reactions to the possibility of microbicides, but the fact that such a product could offer a risk-reduction option that does not interfere with sexual pleasure and spontaneity is generally regarded very positively.[6]

All too often, new medical technologies take years, even decades, to "trickle down" to developing countries. The first candidate microbicides are now in the final stages of efficacy testing and advocates in public health and international development — determined to prevent this delay — are already discussing how to expedite access to this new technology in countries where it may have the largest public health impact. Mathematical modeling indicates that an estimated 2.5 million new HIV infections could be averted over three years in 73 developing countries if a 60 percent efficacious microbicide were to reach 20 percent of the population with access to healthcare — even if it were used in only half of sexual acts not involving a condom.[7] Averting 2.5 million infections would also yield $2.7 billion in direct savings to the healthcare system, not including savings on the costs of antiretroviral therapy (ART) and losses in economic productivity.[8]

Collaborative work is beginning to address the access and distribution problems expected to impede the rapid introduction of a safe and effective microbicide. The subsidized price of a first generation microbicide in the developing world is expected to be about $0.35 per dose when purchased in a 20-dose multipack.[9] As noted, subsequent generations of microbicides are expected to increase in effectiveness and the subsidized cost is expected to decrease to about $0.28 per dose.[10] Because of this partial efficacy, introduction of the use of microbicides will necessarily be framed by risk-reduction messages explaining that condoms are more protective than microbicides, but that, when condom use is impossible, a microbicide used alone will reduce risk better than using no protection at all.[11]

When comparing the effectiveness of condoms and microbicides, it is vital to factor in the realities of condom use. Even in communities that have undergone condom promotion programs (including free condom access), the percentage of long-term couples using condoms consistently rarely exceeds 20 to 30 percent, except when both partners know that they differ in HIV sero-status.[12] A 2004 report issued by the United Nations Population Fund (UNFPA), the Joint United Nations Programme on HIV/AIDS (UNAIDS), and the United Nations Development Fund for Women

Acronyms Used in this Article

ABC model	Abstinence, Be faithful, or use Condoms
ART	antiretroviral therapy
CSIS	Center for Strategic and International Studies
GAO	General Accounting Office
GRHR	Harvard University Global Reproductive Health Forum
IPPF	International Planned Parenthood Federation
MTCT	maternal-to-child transmission
NGO	non-governmental organization
OGAC	Office of the Global AIDS Coordinator
PAI	Population Action International
PEPFAR	President's Emergency Plan for AIDS Relief
RH-FP	reproductive health/family planning
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNIFEM	United Nations Development Fund for Women
USAID	United States Agency for International Development
WHO	World Health Organization

(UNIFEM) noted that, in sub-Saharan Africa, "60 to 80 per cent of HIV-positive women report having had sexual relations only with their husbands." Among married women in India, the report adds, "condom use was extremely rare."[13] In the context of this level of risk, even a partially effective microbicide could make a crucial difference.

INTEGRATING FAMILY PLANNING AND HIV/AIDS PROGRAMMING

The World Health Organization (WHO), World Bank, and the European Union all support the integration of family planning and HIV programs,[14] on the grounds that these programs offer optimal entry points for HIV-prevention services and information to women who are at high risk of infection. Jodi L. Jacobson observes, "For women who are already or suspect they may be infected, integrated services provide confidential outlets for voluntary counseling and testing, drugs to prevent maternal-to-child transmission (MTCT), and accurate information on sensitive issues, such as whether HIV-positive mothers can safely breastfeed infants. They provide a source of care free from the stigma often associated with stand-alone HIV prevention programs."[15]

The WHO further observes, "Integrating HIV/AIDS services and programmes into the existing mainstream health system frequently results in effective, cost-efficient outcomes."[16] Integration of services also allows people to access services through providers they already know and trust. Describing their experience in Zambia, researchers at the Policy Project, which is funded by the U.S. Agency for International Development (USAID), note that both the clients seeking family planning/antenatal care and HIV- positive women coming for HIV care "said they trusted the service providers to maintain confidentiality."[17]

Several international agencies have been urging the global donor community to increase funding for condoms and HIV-related supplies to providers of family planning services, thus taking advantage of well-established systems, where they exist, and strengthening those that are underperforming.[18]

After recognizing the utility of integrating services, envisioning the potential value of integration in facilitating distribution of the first successful microbicides is a logical next step. Unfortunately, the ability to take this step is impeded by United States policies, specifically the Mexico City Policy, funding restrictions imposed in the President's Emergency Plan for AIDS Relief (PEPFAR), and the Bush administration's apparent reluctance to integrate family planning and HIV/AIDS funding. These factors are steadily eroding the public's access to careproviders who are experienced in women's health and in family planning — the very entities who are the most logical conduits for distributing microbicides in the future.

This article describes how these policies weaken, rather than strengthen, the capacity of distribution networks to play an urgently needed role in microbicide roll-out when the time comes.

THE MEXICO CITY POLICY

Announced in 1984 at the United Nations International Conference on Population held in Mexico City, the Mexico City Policy (also known by its opponents as the Global Gag Rule) prohibits provision of U.S. federal funding to foreign non-governmental organizations (NGOs) that perform or "actively promote abortion as a method of family planning."[19] President Clinton rescinded this policy in 1993, but President Bush reinstated it in 2001.[20] The Harvard University Global Reproductive Health Forum (GRHF) notes that, under the policy, "abortion related activities include information provision, counseling, advocacy and lobbying, as well as clinical services."[21] The GRHF adds, "Lobbying and advocacy work is restricted under the Mexico City Policy and yet this would be unconstitutional if imposed on U.S. soil under the First Amendment of the U.S. Constitution, which protects the freedom of speech."[22]

Population Action International (PAI) concurs with this interpretation. According to PAI, no U.S. family planning assistance dollars can be provided to foreign NGOs that use funding from any source whatsoever to do any of the following:

- Perform abortions in cases other than a threat to the life of the woman, rape, or incest;
- Provide counseling and referral for abortion; or
- Lobby to make abortion legal or more available in their country.[23]

The Mexico City Policy forbids foreign NGOs that receive U.S. federal funding to undertake these activities, regardless of the sources through which those activities, themselves, are funded. The direct and indirect impact of the Mexico City Policy is difficult to quantify overall, but some data exist. In 2000, the International Planned Parenthood Federation (IPPF) provided family planning services to 24 million clients in 180 countries through 50,000 outlets.[24] Unwilling to jeopardize its clients' health by withholding full medical advice, IPPF chose to decline U.S. funding rather than comply with the Mexico City Policy when it was reinstated. As a result of this decision, an estimated 1.6 million clients lost IPPF services in Ethiopia, Ghana, and Kenya due to immediate clinic closures.[25]

By 2002, the Mexico City Policy restrictions had stopped the flow of USAID funding to leading family planning associations in 14 developing countries (sometimes due to denial of funding to noncompliant grantees and sometimes due to grantees' decision to refuse funding rather than comply), and stopped the flow of U.S.-funded contraceptive supplies to 16 more;[26] 11 clinics in three countries closed, and the closure of three more in Tanzania[27] was expected as a direct result of the policy. Other national governments and multilateral agencies have taken action to help compensate for the withdrawal of U.S. funding, but critical gaps in service and supply remain.

On 29 August 2003, President Bush issued a memo to the U.S. Secretary of State clarifying that the Mexico City Policy restrictions apply to all family planning assistance provided by the U.S. to foreign NGOs — whether supplied by USAID or by the U.S. State Department.[28] The memo went on to note, however, that the Mexico City Policy did not apply to assistance provided by "multilateral organizations that are associations of governments," and further specified, "This policy shall not apply to foreign assistance furnished pursuant to the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Public Law 108-25)."[29]

The decision not to attach the Mexico City Policy to funding for PEPFAR means that condoms and other family planning supplies can be purchased and counseling provided by PEPFAR-funded programs without application of the Mexico City Policy restrictions. But, although this has been politically popular, the decision to exempt PEPFAR programs from the ban has further complicated the challenge of integrating family planning and HIV programs. Any project funded with a mix of family planning and PEPFAR funds is automatically subject to the restrictions of the Mexico City Policy. This compromises the provision of care at a number of levels; for example, programs are not able to provide comprehensive counseling to HIV-positive women regarding their options should a contraceptive fail, or to young people who seek advice should a condom break or slip, even in countries where abortion is legal.

The Mexico City Policy has not only caused the loss of vital clinic services; it also has impeded the integration of reproductive health and HIV-prevention services. A 2006 report published by the Center for Strategic and International Studies (CSIS) notes, "it often precludes organizations with years of experience in reproductive health from bringing their expertise into an integrated program approach. While such groups could work the HIV side of a project, they cannot work on the RH-FP [reproductive health/family planning] piece. Given the important overlap between

the two fields, there are serious concerns that this policy is contributing to a weakening of reproductive health systems in HIV-affected countries, which are vital avenues to reaching women and girls."[30]

PEPFAR

PEPFAR has significantly increased U.S. capacity to combat the global HIV/AIDS pandemic. Passed as the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Public Law 108-25), PEPFAR is a five-year, $15 billion plan to provide HIV treatment, prevention, care, and support in 15 heavily impacted countries.[31]

Thus far, the initiative has trained 536,000 local staff in the 15 focus countries and supported 14,960 program sites. Prevention funding for abstinence and fidelity programs stood at $63.3 million in 2004 and $75.6 million in 2005. Funding for condoms and related prevention was $45.2 million in 2004 and $65.7 million in 2005. By the end of fiscal year 2005, PEPFAR's prevention outreach programs reached 42 million people with efforts to prevent the sexual transmission of HIV.[32]

PEPFAR's stated intention to avert 7 million new infections in five years is laudable. However, women and girls are falling through the cracks because PEPFAR embraces a behavior change approach to HIV prevention based on an "ABC" model (Abstinence, Be faithful, or use Condoms, in that priority order).[33] While PEPFAR funding is not subject to the Mexico City Policy, its ABC approach is hierarchical — emphasizing abstinence and monogamy as the "best" approaches to HIV prevention, with the use of condoms recommended as a last resort.[34] The funding restrictions in Public Law 108-25 reinforce this philosophical orientation by requiring that 20 percent of PEPFAR funding be allocated to HIV- prevention programming, and that one-third of these prevention funds be used for abstinence-until-marriage programs.[35]

Abstinence programs cannot address the needs of married and partnered women — a serious deficit given that, according to the United National Population Fund, more than 80 percent of new HIV infections among women occur through sex with a husband or long-term partner.[36] In early 2006, the U.S. General Accounting Office (GAO) released a report documenting the negative impact of "abstinence-only" prevention funding restrictions and called for less stringent requirements.[37]

PEPFAR's current approach to prevention substantially reduces its ability either to take full advantage of the healthcare infrastructure created with USAID funding under previous administrations or to work toward fully integrating HIV-prevention programs and family planning programs. In the 2006 CSIS report, analysts note, "During a CSIS mission to Zambia in 2005, one US embassy official described a 'firewall' between HIV and reproductive health, inhibiting important synergies between the two."[38]

PLANNING FOR MICROBICIDE DISTRIBUTION

Microbicides are being developed to save lives by averting new HIV infections, particularly among women and girls. If any of the three candidate microbicides now in the final stages of testing proves effective, the first microbicides could become available in a handful of countries (probably those hardest hit by the HIV pandemic) by 2010. The question, then, becomes how to maximize distribution of these new products, given the extent to which the Mexico City Policy has diminished natural distribution networks by causing clinic closures and PEPFAR's failure to optimize access to existing services by integrating the provision of reproductive health services and HIV/AIDS services.

The potential reach of U.S.-funded healthcare providers in heavily impacted countries is vast. In fiscal year 2005 alone, PEPFAR allocated $479 million to expanding HIV treatment. These resources have created substantial new healthcare infrastructures in target countries — infrastructures sufficient to pro-

vide or contribute to the provision of ART to approximately 400,000 people in the target countries, as well as HIV-related care and support to nearly 3 million people. A reported 42 million people have been reached by PEPFAR HIV-prevention outreach activities thus far.[39]

Lifting the policy-imposed "firewall" between HIV and reproductive health services and actively promoting integration of the two would enable the U.S. to build on the distribution capacity created first with family planning funding and more recently with PEPFAR dollars. PEPFAR is up for re-authorization in 2008. Even without lifting the Mexico City Policy (which may be politically impossible at present), a reallocation of $15 million (less than 1 percent of overall PEPFAR funding proposed by the President in fiscal year 2007) could build reproductive health services within PEPFAR programs and link them to existing reproductive health services, thus facilitating the distribution of microbicides to PEPFAR service recipients as soon as such products become available.

This could potentially provide access to microbicides for approximately 8 million HIV-negative women in the 12 PEPFAR focus countries in sub-Saharan Africa (see table 1), thus potentially averting as many as 862,500 new HIV infections among women annually (see table 2).

CONCLUSION

Since the 1960s, USAID has played a significant role in procuring and distributing supplies and providing services and/or technical assistance to reproductive health programs in the developing world. As HIV/AIDS began to heavily impact developing countries, USAID responded by generating a substantial U.S.-funded HIV/AIDS prevention effort.

USAID-funded sites would be natural outlets for microbicide access since the agency works in nearly 100 countries through HIV-prevention and family planning clinics.[40] Within the imposed restrictions, USAID decides how to allocate funding based on demand and resources available.

In the wake of the GAO report, advocates are calling on PEPFAR to better meet the prevention needs of women and girls, stipulating that programs should "Ensure universal access to all existing sexual and reproductive health technologies, including HIV prevention technologies, such as male and female condoms; contraceptives; and microbicides when these become available."[41]

Microbicides are being developed in both contraceptive and noncontraceptive forms, and no overt opposition to them has yet emerged among the political constituencies opposed to condom distribution. There is unlikely to be political opposition to the allocation of either USAID or PEPFAR funds to distribute microbicides if the effectiveness of these products against HIV is well documented and if such distribution is occurring in response to demand for them expressed by the governments, communities, and the in-country providers receiving USAID donated supplies.

An optimal scenario for the rapid development of microbicide distribution networks would be as follows:

- The U.S. repeals the Mexico City Policy altogether, and
- The U.S. loosens restrictions on PEPFAR to allow local NGOs to allocate resources to the prevention strategies that have been shown to be the most effective in reducing incidence of HIV in their own communities.

Since these two goals may not be achievable in the current political environment, the next best strategy is the one capable of saving the most lives under current constraints. This may be to advocate for the full integration of reproductive health and HIV-prevention programs both in USAID-funded family planning programs and in PEPFAR-funded treatment, care, and prevention services, where appropriate.

The CSIS reports that Deputy U.S. Global AIDS Coordinator Mark Dybul wrote the following in a letter to IPPF in 2006: "The Emergency Plan has communicated to countries and partners the importance of voluntary family planning as a 'wraparound' intervention. We have made our staff aware that voluntary family planning clinics and programs are important HIV/AIDS care-delivery points."[42]

Ambassador Dybul's explicit recognition of the role that family planning clinics and programs can play as venues for HIV/AIDS care is encouraging. For the countries and partners he is addressing to implement his advice, however, they need more explicit guidance on what is meant by a "wraparound intervention" and how comprehensive care can be expanded in these natural venues. Does this guidance, in fact, mean that organizations such as IPPF, which have chosen to refuse U.S. State Department family planning funding rather than comply with the Mexico City Policy, are still eligible to receive HIV/AIDS funding supplied by PEPFAR and/or USAID?

It is time for the U.S. Office of the Global AIDS Coordinator (OGAC) to take the following steps:

1. Clarify for all grantees the differences (if any) between "wraparound" services and integrated services,

TABLE 1 The Number of HIV-Negative Women Who Might Gain Access to Microbicides Should They Be Distributed through Existing PEPFAR Programs, Once Microbicides Are Available

Due to the overlap of prevention, counseling, and testing programs, it seems reasonable to assume that a portion of the women who receive counseling and testing services are also those who are reached by programs that promote fidelity. Given this, we estimate that as many as 8 million HIV-negative women could have potential access to microbicides through these two PEPFAR programs, if PEPFAR programs provided them. This figure is based on the following data and assumptions:

- Approximately 7.3 million HIV-negative women have accessed PEPFAR programs that promote fidelity. This figure was estimated as follows. A total of 17 million people were reached through these fidelity programs in the 12 African PEPFAR countries.[1] If one-half of those who use the programs are women, as many as 8.5 million women may be reached by the programs. The weighted average of HIV prevalence rates in the PEPFAR countries in Africa is 13.6 percent.[2] This indicates that approximately 86.4 percent, or 7,344,000, of the 8.5 million women reached by the PEPFAR programs were presumably HIV negative.
- Approximately 3 million HIV-negative women were reached by PEPFAR-funded counseling and testing programs other than the programs for the prevention of MTCT. This number is estimated from reports that 69 percent of the people reached by the counseling and testing programs were women, as stated in the Annual Report for PEPFAR by the U.S. Office of the Global AIDS Coordinator (OGAC) in 2005.[3] (The same weighted average of 13.6 percent was used as above.)

NOTES

We realize that microbicides may also help prevent re-infection among HIV-positive women and transmission from HIV-positive women to their HIV-negative partners. The potential efficacy of such secondary prevention, however, is very unclear at this point. We have, therefore, to limit these calculations estimating the seroconversions that may be averted among HIV-negative women who access PEPFAR services.

1. The 12 countries are Botswana, Côte d'Ivoire, Ethiopia, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia. U.S. Office of the Global AIDS Coordinator, "Annual Report to the Congress on the President's Emergency Plan for AIDS Relief," 8 February 2006, *http://www. state.gov/s/gac/rl/c16742.htm.*

2. United Nations Population Fund (UNFPA), "State of World Population 2005," 2006, *http://www.unfpa.org/swp/2005/english/ch1/index.htm*, "Indicators."

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2. Identify the policy barriers (if any) to the integration of reproductive health and HIV/AIDS services, and
3. Provide leadership to overcome these barriers.

Acting now to re-build and expand networks that are capable of assuring the rapid and targeted distribution of microbicides and other HIV prevention tools has the potential to save women's lives. If we delay such rebuilding, the cost will be paid in the same currency.

NOTES

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TABLE 2 The Number of HIV Infections that May Be Averted Should 8 Million HIV-Negative Women Have Access to Microbicides

- Although microbicides do not technically require the cooperation of a male partner, many women indicate that they would most likely discuss the use of a microbicide with their male partner.[1] If a woman's use of a microbicide depends on the cooperation of her partner, this may limit the use of microbicides. Based on available research, we assume that 86 percent of these women may agree to use a microbicide.[2] Thus, 86 percent of 8 million women who may be reached through PEPFAR programs — 6.9 million women — may see the use of a microbicide as a viable option.
- Of those 6.9 million women, we estimate that half may want to use a microbicide on an ongoing basis, and may use the product in half of the sex acts in which they do not use a condom. Thus, 3.45 million may use a microbicide on an ongoing basis.
- We reduced the 3.45 million by half — 1.73 million — to allow for the risk incurred by inconsistent use of a microbicide, and halved that number again, because the first-generation microbicides are expected to be 50 percent effective.[3]
- Given these assumptions, as many as 862,500 women might avoid infection by the use of first-generation microbicides.

NOTES

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10. Ibid.

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