INTERNATIONAL PARTNERSHIP *for* MICROBICIDES

MICROBICIDES:
An Essential HIV Prevention Strategy For Achieving The Millennium Development Goals

A policy paper prepared by the International Partnership for Microbicides

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Executive summary

Attaining the Millennium Development Goals (MDGs) is critically dependent on the successful reversal of the AIDS pandemic. The International Partnership for Microbicides (IPM), an organisation working to develop a new method of preventing the transmission of HIV to women, argues that unless the world is able to halt and reverse the devastating spread of HIV among the poor, and especially among women and girls, there is a strong probability that many of the MDGs will not be reached. Microbicides — a new prevention technology currently under development — could give women a new option for protecting themselves from HIV. This could indirectly reduce HIV infection in men and children, and therefore substantially reduce the global spread of the virus.

"Microbicides are a development priority. I can think of no other technology that has the potential to dramatically improve the health of women in developing countries. Moreover, I do not see how we can meet the MDGs without safe and effective microbicides".

— Stephen Lewis, UN Special Envoy for HIV/AIDS in Africa

The rapid transmission of HIV, particularly among the young and most productive members of society, has contributed to turning HIV/AIDS into the world's most devastating infectious disease. The statistics — 40 million cases worldwide, 15,000 new infections per day and an increasing incidence among women, especially young women in resource-poor nations — reveal how critical it is that the pandemic be halted. Nearly two-thirds (64 per cent) of all people living with HIV/AIDS are in sub-Saharan Africa. Of these, women account for 57 per cent of adults (aged 15-49) living with HIV/AIDS. For young women, the figures are even worse: 75 per cent of young people infected with HIV are women and girls[1].

New prevention technologies such as microbicides and vaccines are urgently needed to significantly reduce and ultimately halt the spread of new infections. Globally, the vast majority of HIV infections are transmitted through heterosexual sex. If men and women had an equal say in their sexual relations, then abstinence, condoms and mutual monogamy, the so-called 'ABC approach', could make a considerable dent in the incidence of HIV transmission. However, the unequal gender relations that characterise most relationships, particularly in cultures where the epidemic is growing the fastest, result in women and girls having little control over the conditions under which sexual intercourse takes place. This limits the effectiveness of current prevention strategies, as is clearly evidenced by the growing number of new infections each year. A female-initiated HIV prevention strategy is needed — one that does not interfere with sex and is not necessarily contraceptive. Microbicides would be one such HIV prevention strategy.

With the appropriate financial resources and political leadership, a microbicide will likely be available within the decade, by the MDG goalpost year of 2015. Equally important, the ongoing support and innovative participation

of the international community is needed if the promise of microbicides is to become a reality. IPM, working with the Global Campaign for Microbicides and the Alliance for Microbicide Development, has estimated that investment will need to increase dramatically from US$140 million in 2004 to US$280 million per year for the next five to ten years in order to significantly accelerate the research and development of microbicides.

At the planned High-Level Plenary Meeting to discuss the MDGs at the United Nations in September 2005 ('The 2005 World Summit'), as well as at other international gatherings over the next several years, world leaders will consider the progress that has been made towards reaching the goals, and what else needs to be done to ensure the goals are met by 2015. These leaders must acknowledge the extent to which the growing burden of HIV is undermining human development and thwarting progress towards achieving the MDGs. This paper outlines the role that microbicides could play in helping to address the challenge that HIV presents to poverty reduction and the human development agenda, and urges world leaders to accord greater priority to the development and delivery of much-needed public health goods such as microbicides, without which many of the MDGs will not be met.

Introduction

HIV/AIDS has the potential to destroy a generation. Due to its rapid spread and its propensity for affecting the young and most productive members of society, HIV/AIDS ranks among the world's most devastating infectious diseases. The statistics are familiar — 40 million cases worldwide, 15,000 new infections per day and an increasing incidence among women, particularly young women in developing nations.

WHAT ARE MICROBICIDES?

Microbicides are products that could be applied topically to the vagina to reduce the transmission of HIV during sexual intercourse. Microbicides could take the form of a gel, cream, film, suppository, sponge or vaginal ring that releases the active ingredient gradually, or even a new formulation or delivery method yet to be invented.

The rapid feminisation of the AIDS pandemic calls for a re-orientation of poverty reduction strategies and an urgent re-thinking of the global AIDS response. Current efforts to end poverty and to control the pandemic are largely gender-neutral. Gender-specific development and a female-focused response must form the basis of future efforts if we are to break the deadly link between women, HIV/AIDS and poverty. There is a strong rationale for re-prioritising global spending to accord primacy to gender-specific interventions that can reduce the burden of both poverty and disease on women.

The Global Coalition of Women and AIDS, an initiative of UNAIDS, recognises that a comprehensive approach is needed to halt the spread of HIV infections, particularly among women, including the development of vaccines and microbicides. Researchers in the vaccine field acknowledge that the discovery of an effective HIV vaccine will be scientifically

WHAT ARE THE MILLENNIUM DEVELOPMENT GOALS?

The eight Millennium Development Goals (MDGs) were adopted in 2001 by all 189 United Nations (UN) member states to inspire global action towards development and poverty eradication by 2015 through the pursuit of 18 quantifiable development targets. In January 2005, a series of benchmark reports was released by the UN Millennium Development Project, an independent advisory body commissioned by the UN Secretary-General to advise the UN on strategies for achieving the MDGs. The reports chart progress made to date and propose blueprints for further action. The UN General Assembly will convene in September 2005 to consider the content of these reports and recommend further ways in which the world community can meet the goals. The goals are:

Goal 1: Eradicate extreme poverty and hunger
Goal 2: Achieve universal primary education
Goal 3: Promote gender equality and empower women
Goal 4: Reduce child mortality
Goal 5: Improve maternal health
Goal 6: Combat HIV/AIDS, malaria and other diseases
Goal 7: Ensure environmental sustainability
Goal 8: Develop a global partnership for development

challenging and it is unlikely that one will be available before 2015. While aggressive vaccine research must continue to ultimately deliver this critically needed tool, equal priority must also be accorded to microbicides. It is likely that a microbicide could be available within the decade, before the MDG goalpost year of 2015. However, this is dependent on greater financial resources being made available and increased support and innovative participation from the international community.

When world leaders and policy makers gather for the United Nations' High-Level Plenary Meeting to discuss the MDGs in September 2005 ('The 2005 World Summit'), as well as at other international gatherings over the next several years, they must acknowledge the extent to which the increasing spread of HIV is affecting human development and preventing progress towards the goals. These leaders must use this meeting as an opportunity to accord greater priority to much-needed HIV prevention tools such as microbicides, without which many of the MDGs will not be met.

Why are women particularly vulnerable to HIV infection?

Women make up the great majority of the world's poorest people. Since HIV is both a cause and an effect of poverty, it is not surprising that women are highly vulnerable to HIV and its effects. This integral link is highlighted by the disproportionate impact of the HIV/AIDS pandemic on the world's poorest regions and on women, in particular. Nearly two-thirds (64 per cent) of all people living with HIV/AIDS are in sub-Saharan Africa, which holds only one-tenth of the world's population. Of these, women account for more than half the adults (aged 15-49) living with HIV/AIDS (57 per cent). For young women, the figures are even worse: 75 per cent of young people infected with HIV are women and girls[2]. For the past two decades, HIV/AIDS has affected more women worldwide than any other life-threatening infectious disease[3].

Women's increased susceptibility to HIV infection results from a combination of biological, social and cultural factors. Biological determinants include women's exposure to more bodily fluids containing HIV (semen) during intercourse, the vaginal microbial ecology and physiology, a high prevalence of undiagnosed and asymptomatic sexually transmitted disease in the female population, and hormonal changes. Added to this are social and cultural factors such as gender inequalities, poverty, cultural and sexual norms, lack of education and the tolerance of violence against women[4]. All compound female vulnerability to HIV infection.

Young women are recognised as being at even more risk of HIV infection. Their heightened risk for HIV is due to: (a) an immature physiology; (b) profoundly inequitable gender norms which foster a climate that accepts exploitation and violence towards girls and expects passivity from them; and (c) the prevalence of transactional sex, coupled with liaisons and marriages between girls and older, more sexually experienced men. The situation is particularly dire for young African women. In parts of sub-Saharan Africa, young women are more than three times as likely to be infected as young men[5].

How are current HIV prevention methods failing women?

In 2004, nearly five million people became infected with HIV[6]. This is more new cases than in any prior year. There is a growing consensus that more attention needs to be accorded to HIV prevention. If prevention efforts are not strengthened, it will become increasingly difficult to ensure sustainable treatment for those living with HIV.

"The long-overdue drive to expand treatment... now dominates the AIDS agenda at all levels. Every effort must now be made to bring the same sense of urgency and excitement to meeting ambitious prevention goals. Unless prevention remains a fundamental priority of leaders, donors and those who battle the epidemic on the ground, tens of millions more will become infected and the need for treatment will grow inexorably".

— *Combating AIDS in the Developing World*, UN Millennium Project, Task Force on HIV/AIDS, Malaria, TB and Access to Essential Medicines, Working Group on HIV/AIDS, 2005.

Renewed prevention efforts must expand access to existing prevention methods. However, at the same time, it is important to recognise the limitations of these methods. Globally, the vast majority of HIV infections are transmitted through heterosexual sex. The current prevention strategies — condom use and behaviour change, often summed up by the 'ABC' approach of Abstain, Be faithful and use Condoms — do not enable women to protect themselves from HIV infection. In fact, being female, married and poor are often the most significant risk factors for HIV infection, particularly in sub-Saharan Africa.

For married women, or women in long-term relationships, abstinence is clearly not an appropriate solution, particularly if they desire

children. For many women in the world, particularly in resource-poor nations, their ability to bear children determines their status in society and within their marriage. Nor is abstinence an appropriate prevention strategy for the many women who are raped or experience forced sex. In a recent ten-country study sponsored by the World Health Organization on women's health and domestic violence, between six and 59 per cent of women at the different sites reported sexual violence by an intimate partner[7].

A GLIMPSE OF THE IMPACT OF HIV/AIDS ON MARRIED WOMEN

- More than 40 per cent of new infections in Cambodia and Thailand are among women whose only sexual partner was their husband.
- In sub-Saharan Africa, 60 to 80 per cent of HIV-positive women report having had sexual relations only with their husbands.
- A study in India found that 90 per cent of HIV infected women were married, monogamous and had only one sex partner in their lives: their husbands.

** References in annex*

Being faithful is of little help if the main risk factor for HIV infection for women is being married, as is the case in many regions in sub-Saharan African. Studies in Kenya and Zambia looking at HIV infection rates in sexually active young women 15 to 19 years old have reported that HIV infection rates were ten per cent higher in married women than in sexually active unmarried young women[8]. In rural Uganda, among HIV-infected women aged 15 to 19, 88 per cent were married[9]. This is because young women, particularly teenagers, often marry significantly older men, who are more likely to have previously had other partners and been exposed to HIV. For many young women, their main risk for HIV infection is being married and faithful to a husband with previous or other current sex partners.

Male and female condoms, when used correctly, remain the most effective means for preventing sexual transmission of HIV and other infections. Condom promotion efforts have led to their increased use, especially among high-risk populations, and their use and distribution should be encouraged. However, it is also vital to appreciate that, for a variety of reasons, condoms may not always be used.

Within marriages and long-term relationships, condom use remains low and is unlikely to rise. Surveys in 13 African countries confirmed that fewer than seven per cent of women reported condom use in the last sex act with a regular partner[10]. There are many reasons why condom use within couples is low. Condoms block both HIV and conception, and are not a viable option for couples who wish to conceive. In other situations, couples may not be able to use condoms because they indicate a lack of trust. For example, whereas female commercial sex workers may have a high success rate in initiating condom use in their commercial sexual relations, with their personal partners success rates for condom use are often much lower. In their personal relationships, they face the same barriers to condom use as other long-term couples.

In addition to these factors, prevailing gender norms often mean that women lack the power to convince male partners to use condoms. In studies in Papua New Guinea, Jamaica and India women reported that bringing up the issue of condom use, with its inherent implication that one of the partners has been unfaithful, can result in violence[11]. Economic dependence and fear of sexual violence also often compel women and girls to accept unsafe sex. For many women, the consequences of leaving a long-term relationship are perceived as more of a risk than staying in the relationship, even if they know their partner is unfaithful or HIV-positive. There are also cultural and religious oppositions to condom use to consider.

The limits of these current prevention strategies illustrate the need for an expanded range of new prevention options, particularly ones women can initiate or control.

Microbicides: a new hope for HIV prevention

Microbicides are being developed with the intention that there will be different types: those that will allow conception while protecting from HIV infection, and those that would also be contraceptive. It is also possible that some microbicide products may be developed that will help prevent transmission of other sexually transmitted infections in addition to HIV.

Microbicide research has gathered an extraordinary degree of scientific momentum. With the proper resources, political will, development expertise and support, microbicides could become a reality for women in the developing world within five to seven years. This achievement could actually tip the balance to reaching Goal 6 of the MDGs by 2015.

Goal 6 — Combat HIV/AIDS, malaria and other diseases

Microbicides are expected to prevent millions of HIV infections in women, men and children. According to researchers at the London School of Hygiene and Tropical Medicine, even a microbicide that is only 60 per cent effective would prevent at least 2.5 million infections over the course of three years[12]. Microbicides could directly prevent HIV transmission from men to women and would, therefore, prevent onward transmission from women to male partners and unborn children.

In all likelihood the potential public health impact of microbicides will be far greater, as these predictions rest upon conservative assumptions about access to microbicides. Progress towards achieving other MDGs will boost levels of access and use further still, with gains in gender equality, access to health care and universal primary education likely to empower women and enhance their ability to understand and utilise microbicides. By offering a new way to protect women, men and children from HIV, microbicides have the potential of slowing the devastation of HIV on the families, communities and societies in which it is spreading the fastest.

How is combating HIV/AIDS central to achieving many of the MDGs?

Halting and reversing the spread of HIV/AIDS — meeting Goal 6 — is fundamental to the achievement of many of the other goals. Unless the world is able to stop the spread of HIV/AIDS among the poor, and especially among women and girls, there is a strong probability that few of the MDGs will be achieved. Microbicides will offer women and girls a means to protect themselves from HIV infection, which in turn will increase the likelihood that the other MDGs will also be met.

Goal 1 — Eradicate extreme poverty and hunger

The AIDS pandemic is deepening poverty. Since HIV/AIDS incapacitates and kills, it reduces the productivity of the labour force. In sub-Saharan Africa, where 70 per cent of the population is involved in agriculture[13], any reduction in the quantity or quality of labour has a direct impact on food production. In most resource-poor regions of the world, women dominate family agriculture and food production. These tasks suffer as AIDS affects family members and especially as women fall ill or act as primary caregivers to husbands or other relatives ill with AIDS. Enabling women to protect themselves from HIV infection is an important step for protecting food production and preventing hunger and poverty.

Goal 2 — Achieve universal primary education

Beyond causing shortages in teaching staff, HIV is critically undermining girls' access to education. Reducing HIV infection is critical to keeping girls in school and achieving the target of universal primary education. When a family member becomes ill with AIDS, it is often the girls who are withdrawn from school in order to care for them. Girls are also more likely than boys to leave school permanently upon a parent's death in order to take over agricultural and income support roles. By preventing cases of HIV among parents, microbicides would indirectly enhance girls' school attendance, reducing the gender disparity in schooling or protecting gains made in that regard. By preventing cases of HIV infection in adolescent girls, microbicides would also directly enhance girls' school attendance, by keeping them well enough to go to school.

Goal 3 — Promote gender equality and empower women

Improvement in women's status is critical. Gender inequality contributes to women's disproportionately greater poverty, unequal

"Biological differences are amplified by deep-rooted gender inequalities and social norms that require women, and particularly girls, to be passive and ignorant about sex, and submissive to the will of men in determining the terms of sexual relationships. Add to this the high level of coerced or forced sex in the sub-region and you have a recipe for disaster".

— *Facing the Future Together: Report of the Secretary-General's Task Force on Women, Girls and HIV/AIDS in Southern Africa,* Global Coalition on Women and AIDS, Joint United Nations Programme on HIV/AIDS (UNAIDS), 2004.

access to resources and schooling, and their lack of political, legal and economic power. In the realm of sexuality, prevailing gender norms hinder women from seeking information about sexual health, including HIV prevention. Microbicide research and social marketing must be pursued to empower women with a new option for HIV prevention that they can actively initiate to protect themselves and others.

Goal 4 — Reduce child mortality

Lowering HIV infection rates in women will reduce the number of children born with HIV, an important contributor to child mortality. HIV-related illnesses in the mother also contribute to child mortality independent of the child's own HIV status. HIV compromises her ability to breastfeed, and thwarts a mother's ability to care for her children. Keeping women free from HIV infection will mean that they have healthier babies. Keeping mothers alive and healthy is of paramount importance to a child's health and general well-being. In the hardest-hit countries of Africa, AIDS is now the greatest cause of parental death. In sub-Saharan Africa, 12 million children have lost one or both parents to AIDS, and that number is expected to rise to 18 million by 2010[14]. Preventing HIV infection in parents, especially in women, will help to preserve families and reduce the number of orphaned children.

Goal 8 — Develop a global partnership for development

Goal 8 promotes making new technologies globally available for development. This comprises both developing new technologies and making them globally accessible for those who need them.

THE TOP TEN LIST

Microbicides are one of ten top technologies named by a Goal 8-related task force report, *Genomics and Global Health*, as being "well-positioned to have a positive impact on the health needs of developing countries over the next five to ten years".

** Reference in annex*

To achieve the goal of developing a new technology such as microbicides, many partners have a role to play. The public and private sectors of the North need to provide increased funding for microbicide research and development; pharmaceutical companies need to help widen the pipeline of candidate microbicides by making compounds available for screening; and national governments need to work together to build increased clinical trial site capacity, as well as facilitate the regulatory pathway for microbicide development and licensure. The people for whom microbicides are ultimately destined, initially women in resource-poor settings, must also be involved in the process of microbicide development to ensure that their needs are being met and that microbicides will be acceptable and, subsequently, used. Such collaboration between scientists in the North and South, and the future 'consumers' in the South, is critical to assure the appropriateness of microbicides.

Microbicide research and development is severely under-funded compared to other research and development efforts. IPM, working with the Global Campaign for Microbicides and the Alliance for Microbicide Development, has estimated that investment

will need to dramatically increase from US$140 million in 2004 to US$280 million per year for the next five to ten years in order to significantly accelerate the research and development of microbicides.

Only with true global partnership for development will microbicides become a reality for women, thereby reducing the spread of HIV and helping to achieve the MDGs.

Conclusion

Achieving the MDGs is essential if the world is to have any hope of eradicating poverty and fostering development in resource-poor countries. The spread of HIV and the AIDS pandemic is thwarting progress towards all the MDGs, since they are by nature interconnected and mutually reinforcing. A women-focused effort to prevent HIV infection could enhance the chances of achieving all the goals, including those that are, at first glance, seemingly unrelated to HIV. Leaders must see microbicides as a development tool, one that is integral to the improvement of women's health, a tool that will help to reduce the burden of death and disease for both women and men, and one that can contribute significantly to eradicating poverty and attaining the MDGs by 2015.

Annex

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IPM MISSION:

The mission of IPM is to prevent HIV transmission by accelerating the development and availability of safe and effective microbicides for use by women in developing countries.

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