

# Microbicide Research

*Hope for the Future, Benefits for Today*



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MICROBICIDES



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## INTRODUCTION

**The world's response to HIV/AIDS has generated tangible benefits, including the first-ever widespread introduction of chronic care in resource-limited settings and an unprecedented scaling up of medical services. The AIDS epidemic has brought renewed attention to global health inequities, resulted in the establishment of innovative financing mechanisms for health programs and prompted new resolve to strengthen fragile health systems in developing countries.**

Yet the HIV/AIDS epidemic continues to expand because not enough progress has been made to slow the rate of new HIV infections. Since the epidemic first appeared 28 years ago, more than 60 million people have become infected with HIV and more than 25 million have died.

In 2008 alone, 2.7 million people worldwide became newly infected with HIV.<sup>1</sup> The rate of the epidemic's expansion continues to outpace the response. For every individual placed on antiretroviral therapy in 2007, more than two individuals became newly infected with the virus.<sup>2</sup> In sub-Saharan Africa — home to two out of three new HIV infections in 2008 — HIV/AIDS has become endemic at extraordinarily high levels.<sup>1</sup> AIDS is now the number one killer of women globally 15 to 44 years of age.<sup>3</sup> In addition, survey data from Swaziland, released in 2009, indicate that HIV prevalence among pregnant women has increased since 2006, reaching a concerning 42 percent.<sup>4</sup>

Studies have validated an array of effective HIV prevention strategies — including behavioural interventions, male and female condoms, voluntary HIV testing and counselling services to prevent mother-to-child transmission, access to sterile injecting materials and adult male circumcision. To date, however, these strategies have not succeeded in lowering new infections to a manageable rate.

Current HIV prevention options — especially for women — are limited, and new self-initiated prevention options are urgently needed. Vaginal microbicides, biomedical products in the form of gels, rings, films and tablets, are under development to reduce the transmission of HIV to women during sex with an HIV-infected male partner. These products would give women a new way to protect themselves from HIV/AIDS, empowering them to safeguard their health.

The International Partnership for Microbicides (IPM) focuses on developing safe and effective microbicides based on the same types of antiretroviral (ARV) drugs already being used successfully to treat HIV/AIDS and to prevent mother-to-child transmission of HIV. Microbicide development is a long and complex process involving many steps to test and introduce a new product. Years of sustained involvement by a large number of researchers, community health workers and clinical trial volunteers are required to turn the hope of this medical research into a reality.

Benefits from microbicide development are already being reaped today, as the research required to develop microbicides generates important immediate and long-term gains. Research efforts both strengthen clinical research capacity in the areas hardest hit by the HIV epidemic and directly benefit the people and communities that host clinical trials.

## REDUCING WOMEN'S RISK OF HIV/AIDS

### *Microbicide research strengthens medical research capacity by:*

- ▶ building capabilities in geographical areas of need.
- ▶ addressing the "10/90" research gap.
- ▶ increasing and developing physical infrastructure and human resources at research centres.
- ▶ enhancing the understanding of epidemic trends through HIV incidence studies.
- ▶ developing the capability to conduct ethical, high-quality clinical trials.
- ▶ building the foundation to get new medical products approved for use.

### *In addition, microbicide research can significantly benefit the people, communities and countries that host clinical trials by:*

- ▶ promoting health and HIV awareness.
- ▶ empowering women through education and counselling.
- ▶ involving men in HIV prevention.
- ▶ encouraging HIV testing.
- ▶ strengthening the access to health services.
- ▶ engaging communities and building community advisory platforms.
- ▶ providing employment and professional development opportunities.

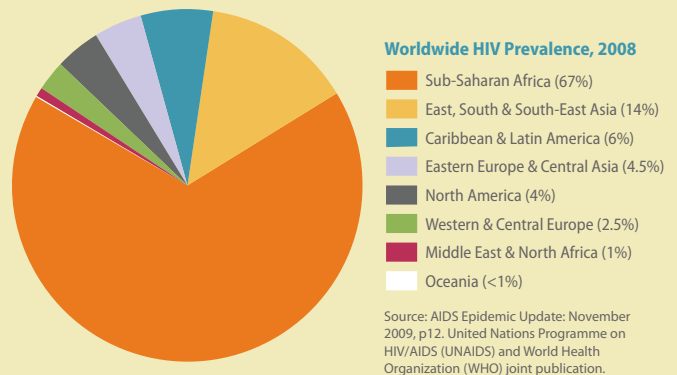
The promise of microbicides to prevent HIV infection continues to provide hope for the future. As microbicide research moves us closer to this goal, it directly advances the global health agenda, including the United Nation's Millennium Development Goals (MDGs), and delivers important benefits to the people, communities and countries of today.

### *A Key Global Development Objective*

The effect of HIV/AIDS on social and economic development can be seen clearly in regions of high prevalence, such as sub-Saharan Africa, where the epidemic is decreasing life expectancy and reducing the number of individuals who participate in various sectors of the economy.

At the end of 2008, more than 14 million children in Africa had lost one or both parents to AIDS. Women and girls continue to experience a heavy burden from HIV, accounting for 60 percent of all people living with HIV in sub-Saharan Africa. In some countries, young women between 15 and 19 years of age are three times more likely to be infected than their male counterparts. In addition, women ages 20 to 24 are more than five times more likely to be living with HIV than men of the same age group.<sup>1</sup>

### Sub-Saharan Africa: Addressing the Greatest Need



Women are biologically more susceptible to HIV transmission than men during heterosexual intercourse. In addition, women experience persistent social, legal and economic disadvantages that increase their vulnerability to HIV. Women and girls frequently lack the means to persuade their male partners to use condoms or remain faithful.

The health and well-being of the world's women and girls — IPM's primary concern — is at the heart of the global development agenda. In addition to calling on the world to halt and, ultimately, to reverse the global HIV epidemic by 2015, the MDGs envision concrete progress towards gender equality and improved maternal health, as well as a reduction in other global health and economic inequities. While working to develop new medical technologies that will reduce women's risk for HIV infection, IPM and its partners also actively focus resources to improve health and build capacity.



## The Role of Microbicides in Advancing the UN Millennium Development Goals

In 2000, global leaders gathered at the United Nations to chart an ambitious development agenda for the new century, agreeing on eight overarching goals to be achieved by 2015. The microbicide field is working to accelerate progress toward these aims. Microbicides would directly contribute to progress on six of the MDGs and yield considerable indirect benefits toward other development goals, including:

**Goal 1: Eradicate extreme poverty and hunger** — HIV/AIDS deepens poverty and exacerbates income inequities. By helping to lower HIV incidence, microbicides would contribute toward the global goal of cutting the poverty rate in half.

**Goal 2: Achieve universal primary education** — By reducing the number of new HIV infections, microbicides would help reduce the number of teachers lost to AIDS and prevent households from withdrawing children from school to cope with HIV-related illnesses in the family.

**Goal 3: Promote gender equality and empower women** — Access to microbicides would empower women to protect their own health. As the UN Millennium Task Force found, “A large body of evidence shows that sexual and reproductive health and rights are central to women’s ability to build upon their capabilities, take advantage of economic and political opportunities and control their destinies.”

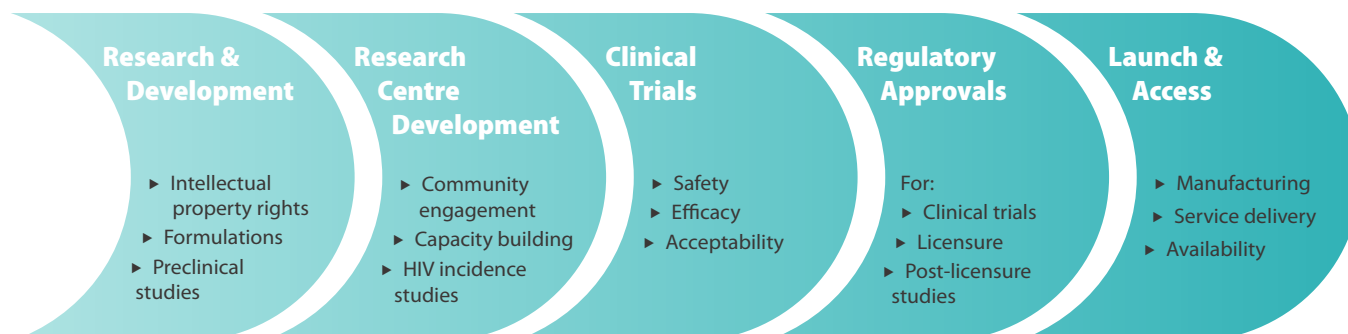
**Goal 4: Reduce child mortality** — By reducing HIV incidence among women, microbicides would play a key role in lowering the number of babies born annually with HIV, thereby reducing childhood illness and death.

**Goal 5: Improve maternal health** — By helping women of reproductive age to remain healthy, microbicides would increase women’s productivity and reduce the number of children being orphaned.

**Goal 6: Combat HIV/AIDS, malaria and other diseases** — Women represent one out of two people living with HIV globally, so microbicides could play a key role in reversing the global epidemic.

# DEVELOPING MICROBICIDES TO SAVE LIVES

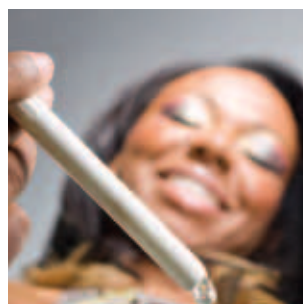
## IPM Microbicide Development Process



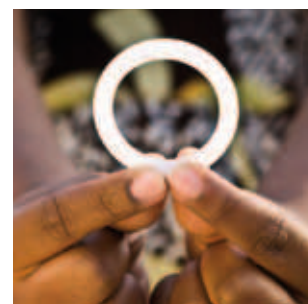
IPM is a nonprofit product development partnership (PDP) established in 2002 to prevent HIV transmission by accelerating the development and availability of microbicides for use by women in developing countries. It coordinates, contributes funding to and directly conducts the different phases of work needed to bring microbicides from initial laboratory testing and subsequent clinical development to final regulatory approval and product distribution.

Microbicide products are being developed based on the same types of ARVs that are being used to treat HIV/AIDS and prevent mother-to-child transmission of HIV. Work is underway to identify the most promising ARV drugs or combinations of drugs that would be suitable for use as microbicides. ARV-based microbicides would work in a variety of ways by either preventing HIV from attaching to or entering a healthy human cell, or by preventing the virus from making copies of itself once it is inside a cell.

Microbicides can be provided in a variety of product formulations, with the goal of giving women greater choice and convenience. Microbicide gels were the most common formulation tested in early generation trials, but those products needed to be applied shortly before sexual intercourse. Newer formulations currently under development include once-daily vaginal gels, films and tablets, as well as vaginal rings that would provide up to one month's protection from HIV. All of these formulations could potentially be used independently of sexual activity, offering more convenience and providing protection during anticipated or unanticipated sex. Over time, microbicide products could be formulated to offer contraception in addition to HIV protection.



ANDREW LOXLEY



ANDREW LOXLEY

A rigorous, step-wise approach is taken to developing new microbicide products by:

- ▶ supporting preclinical research needed to prepare products for clinical trials.
- ▶ developing new formulations or drug delivery approaches.
- ▶ partnering with clinical research centres in both developing and developed countries to conduct the clinical trials needed to evaluate the safety, efficacy and acceptability of candidate microbicides.

From its inception in 2002 through 2009, IPM completed eight clinical trials studying the safety and pharmacokinetics (PK) of microbicide gels and rings. Six additional safety and/or PK trials in Africa, Europe and the United States are ongoing. Eleven epidemiological studies of HIV incidence were completed in Africa, with two more under way. Additionally, two market research studies assessing the acceptability of placebo vaginal gels, films, tablets and soft gel capsules were conducted in five countries in Africa.

In total, as of May 2010, IPM had completed or initiated 29 studies. At least five more clinical trials are planned at various locations. A Phase III programme testing the safety and efficacy of dapivirine, IPM's most advanced microbicide candidate, is scheduled to begin in 2011.

## Partnering to Accelerate Microbicide Development

Product development partnerships (PDPs) such as IPM are nonprofit organisations created to accelerate the development of new tools to fight disease in resource-limited settings. PDPs manage resources and partnerships from across public, private and philanthropic sectors to develop new products that advance global development goals and could potentially save millions of lives.

Since 2004, IPM has obtained several non-exclusive, royalty-free licenses from pharmaceutical companies to develop, manufacture and distribute ARV compounds as microbicides in developing countries.

IPM does not and will not profit from its work to develop microbicides. Pharmaceutical companies have given IPM the right to develop compounds as vaginal microbicides for HIV prevention and to distribute them to women in developing countries at low or no cost.

Such agreements serve as a model of public-private partnership in fostering global health solutions. Sample contract structure and consultations are available to other product developers seeking to negotiate similar agreements with the private sector, on behalf of greater public health goals.

Compound	License	Mechanism*
Dapivirine	Tibotec/Johnson & Johnson	<b>Reverse transcription</b> — Stops virus from copying its genetic material inside human cells
L167, L872, L882	Merck	<b>Cell attachment</b> — Prevents virus from attaching to human cells
BMS793	BMS	<b>Cell attachment</b> — Prevents virus from attaching to human cells
Tenofovir (IPM & CONRAD)	Gilead	<b>Reverse transcription</b> — Stops virus from copying its genetic material inside human cells
Maraviroc	Pfizer	<b>Cell attachment</b> — Prevents virus from attaching to human cells
L'644 peptide	Merck	<b>Cell Fusion</b> — Prevents virus from entering human cells

\* Step blocked in the HIV life cycle

## Ensuring Access

Once developed, microbicides must be made widely available and affordable. Historically, it can take decades for the benefits of scientific innovation to reach emerging or developing countries. IPM and the broader microbicide field are committed to expediting widespread availability and access of all effective products, reaching those most in need first.

Microbicide developers are fundamentally committed to the principle that all participants in microbicide trials should have access to the product studied once it has proven to be safe and effective, and has been approved for use in the country. Ensuring access to microbicides is a responsibility that must be shared by trial sponsors, research teams, donors, multilateral and bilateral agencies, and national governments.



## BUILDING CLINICAL RESEARCH CAPACITY



*“We have staff that came to us with no research skills, and they have been trained by IPM. In terms of career development, they are able to go further with their education through the experience they’ve gained.”*

— Site Manager, Reproductive Health and HIV Research Unit, South Africa

### **Addressing the “10/90” Research Gap**

The communities in Africa where IPM is conducting microbicide research are among those most heavily affected by HIV/AIDS. Continued research holds the promise to help these and other regions combat their national epidemics. Along with this hope, research efforts also generate immediate and long-term benefits by building clinical research capacity in sub-Saharan Africa. Microbicide research builds additional infrastructure and helps job creation in those regions where research is conducted.

In recent years, growing concern has focused on what has come to be called the “10/90” research gap — a short-hand reference to the fact that only about 10 percent of global medical research spending is focused on the health problems in developing countries that carry about 90 percent of the world’s health burden. To help eliminate the “10/90” research gap, it is essential to increase research capacity in countries where these products are most urgently needed. IPM’s core mission to develop microbicides directly addresses this gap. Clinical trials designed to evaluate potential new health products, such as microbicides, must be conducted in the populations where such products would be used.

Investments have already expanded research capacity and understanding of HIV/AIDS in the communities that host clinical trials. IPM is collaborating with more than 15 local research centres in seven countries in Africa (Kenya, Malawi, Rwanda, South Africa, Tanzania, Zambia and Zimbabwe). About half of the research centre partners were newly established with IPM’s support. The remainder were pre-existing clinical research institutions whose infrastructure, equipment and staff training have been enhanced.

For example, a new research centre established through IPM funding in the KwaZulu-Natal province of South Africa is located in a community where more than 40 percent of women between 18 and 35 years are HIV-infected. This new centre is now conducting IPM microbicide clinical trials and collaborating with a local organisation that provides ARV treatment, home-based care, and support for orphans and vulnerable children in the community.

*“We had rented the upper story of an NGO building for the new research centre. We ripped it apart and started from scratch with IPM support all the way through, including infrastructure, all the equipment and the appointment of staff. We’ve recently modified the accommodation to handle colposcopy needs and additional lab needs.”*

— Principal Investigator, Prevention of HIV/AIDS Project (PHIVA), South Africa



## IPM-sponsored research and activities in Africa



### *A Three-Part Process is Used to Build Research Capabilities*

**Building Research Centre Infrastructure:** An important first step is to conduct a comprehensive assessment of each research centre's readiness and to evaluate the quality and accessibility of primary health and social support services in the local area. Funding and support is then provided for building or expanding the research centre's physical infrastructure as well as its human resource capacity. IPM also offers guidance on developing standard operating procedures (SOPs) at the centre, provides training and equipment needed to ensure that trial-related procedures and laboratory tests are performed in accordance with international and national Good Clinical Practice (GCP) standards, and advises on community outreach and education activities.

**Understanding HIV Incidence:** Epidemiological studies of HIV incidence are designed to assess, through regular HIV testing and counselling, the rate of new infections in a community. These studies help identify settings that are suitable for microbicide efficacy trials, but they also help build the case for the pressing need to fight HIV/AIDS among women. By early 2010, IPM had sponsored HIV incidence studies in 10 communities across Africa and had begun planning for similar studies in additional communities. Studies

that detail HIV prevalence and incidence rates among women of reproductive age can aid national and local authorities in devising strategies to address the needs of women who continue to be at extremely high risk of HIV infection.

**Conducting Clinical Trials:** Training and capacity building are continued at research centres to support the staff in conducting high-quality clinical trials in accordance with international and national GCP standards.

### *Partnering With Other PDPs Further Increases Capacity*

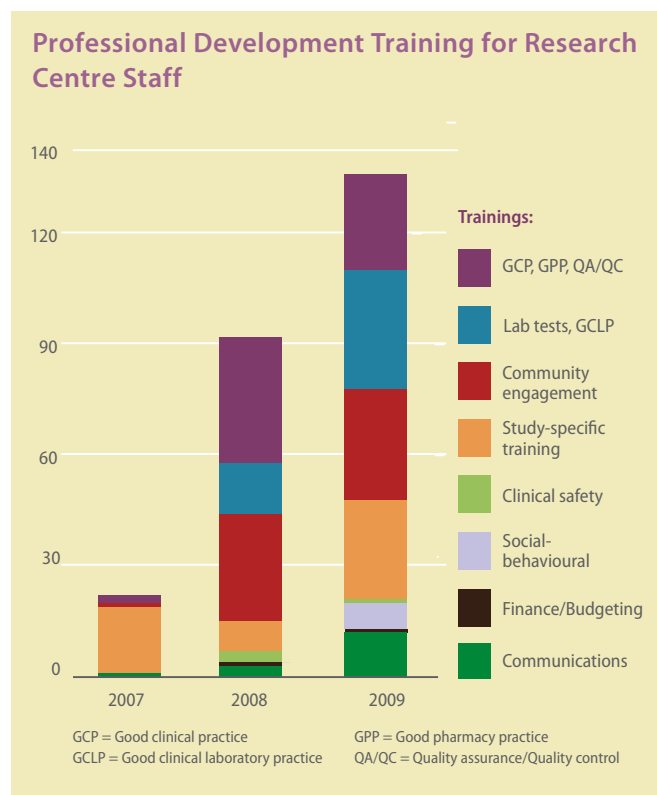
Partnerships have been created with other PDPs working on new HIV prevention technologies to increase the capacities of all involved. For example, collaboration with the International AIDS Vaccine Initiative (IAVI) to use its safety laboratory in Kigali, Rwanda, for analysing samples from IPM trials eliminated the need to build a new laboratory for this purpose. IPM also partners with research centres that were previously involved with HIV vaccine trials, such as the Desmond Tutu HIV Foundation centre in Nyanga, South Africa, the Africa University centre in Mutare, Zimbabwe, the Zambia-Emory HIV Research Project centres (supported by IAVI) in Lusaka and Ndola, Zambia, and the University of North Carolina Project in Lilongwe, Malawi.

*“I had never participated in research, so I learned the science and then became the coordinator of the HIV cohort study. Later I coordinated a vaginal ring study. When I look at where I came from, it’s amazing how much I’m able to do now.”*

— Project Officer, International Centre for Reproductive Health, Kenya

### Employment and Professional Development

Microbicide research augments the number of professional opportunities available to clinical researchers in Africa. Microbicide studies provide professional opportunities for both well-established experts and newly qualified scientists to advance their scientific careers in their home countries.



*“This is also a way for us, the more mid-level researchers, to pass on our knowledge to the next generation. And we’re hoping that some of these students that we’re currently training will go on to become investigators, so that all of these research projects become sustainable.”*

— Study Investigator, Projet Ubusima, Rwanda

Research centres employ a wide range of staff, including key technical staff, namely physicians, nurses, counsellors, pharmacists and lab technicians as well as other professionals such as community liaison staff, management, finance and administrative staff.

In addition to obtaining experience in conducting complex clinical trials, local researchers benefit from ongoing professional development activities. IPM conducted more than 200 training events for research centre staff in Africa between 2007 and 2009. Additional training was conducted in Europe and the United States. Representatives from centres in Africa at which IPM conducts studies also come together for annual clinical affairs meetings, where new developments are discussed, and challenges and successes are shared. In 2009, 77 research centre staff attended the five-day meeting in Nairobi, Kenya.

Non-technical research centre staff also gain experience that supports their professional development. For example, training is provided for financial management, community education and engagement, counselling, social-behavioural science and communications.

### Ethical Conduct of Clinical Trials

IPM is committed to sponsoring clinical trials that meet international and local standards, and receive approval from national regulatory agencies and local ethics committees. Conduct of clinical trials with rigorous standards not only protects the health and rights of clinical trial volunteers, but also helps research centre staff learn how best to conduct high-quality clinical research. As part of the ethical conduct of trials, research centres ensure that each woman who volunteers for a microbicide clinical trial gives her consent freely, based on a clear understanding of the trial, including the potential risks and benefits of trial participation. Informed consent is an ongoing process that requires periodic discussions with participants.

### Getting Approvals for Clinical Trials and New Products

The European Commission, with IPM’s facilitation, sponsors annual consultations of representatives from regulatory agencies and ethics committees across Africa. These sessions help build a common understanding of key issues related to microbicide and other HIV prevention research throughout the African region. The meetings serve as a forum to share best practices on standards of care, safety evaluation and factors affecting product efficacy. They also address approval processes for clinical trial protocols, community outreach, and future access to products. Once the first safe and effective microbicide is developed, IPM and its partners will move rapidly to get the new product approved and distributed first in Africa to meet the needs of women to prevent HIV transmission.

## IMPROVING LIVES AND HEALTH

### **Benefiting Clinical Trial Participants**

Many clinical trial participants live in settings where HIV prevalence is high and where access to basic health services is limited. Women who participate in clinical trials receive care or referrals to medical services that help improve their health.

Participants of both clinical trials and epidemiology studies receive regular HIV tests, risk reduction counselling, and free access to condoms. Participants are also assessed for other common sexually transmitted infections (STIs) and offered or referred for treatment for curable STIs that are identified.

Participants obtain family planning services and receive ongoing contraceptive counselling for the duration of the trial. Participants who nevertheless become pregnant will discontinue use of the investigational product and will be referred to the appropriate clinic for further management of the pregnancy while continuing to be monitored for safety by research centre personnel.

Trial participants who, despite risk reduction counselling, may still be unable to protect themselves and become HIV-positive during the time period of the trial are referred for appropriate HIV-related care and ARV treatment.

Testing volunteers for HIV regularly provides value since it can alert women who otherwise may not have known of their HIV status. Individuals who test positive for HIV during pre-trial screening also receive referrals for support and care.

*“I’m personally convinced that the voluntary counselling and testing, and handing out condoms during a study do have an effect on HIV incidence. If you do the counselling well, it’s definitely possible to lower the incidence.”*

— Study Investigator, Projet Ubusima, Rwanda

### **Empowering Women Through Education and Counselling**

The regular health counselling received by trial participants helps mainstream primary health care and health literacy. According to a physician working at an IPM research centre in Kenya, “Women are coming to the clinic and learning about essential tests and services like Pap smears and complete cervical check-ups. It has enhanced their health-seeking behaviours.”

*“The new doctor who is working with us has never had the opportunity to do microscopy before. He is now thinking he should also do microscopy in his practice. Normally he would send everything to the lab, but in his setting, laboratory tests are not affordable, so he’d be able to pick up those things without needing to send them out.”*

— Principal Investigator, Madibeng Centre for Research, South Africa

There is also evidence that women who participate in clinical trials benefit from the regular HIV prevention counselling they receive, including learning new skills to negotiate safer sex and protect themselves from risky situations. “Women who participated in one IPM study felt more confident to negotiate safer sex because they had the information and the tactics, and they knew they had a right to protect themselves,” one research centre staff member said.

*“Study participants really appreciated a full medical exam — that’s something they never get anywhere else — including tests which can pick up things... like a blood disorder. We’d then be able to refer her to the local university hospital. We’re also picking up asymptomatic STI cases... there are probably many of those cases out there that we don’t even know about.”*

— Principal Investigator, Madibeng Centre for Research, South Africa

### **Improving HIV Awareness**

Through community education and recruitment efforts, research centres raise awareness about the epidemic and its risks. As a principal investigator in South Africa observed, “Our work is sort of opening up people’s minds, because when we are recruiting or mobilizing or raising awareness, we are talking about HIV/AIDS. We broadly open up discussion about HIV in our communities.”

These efforts are producing tangible prevention benefits. “Individuals who are reached by IPM research activities are more aware of how to be healthy, and how they should behave to reduce their risk of infection,” a study coordinator said.

IPM is helping reach girls and young women in Africa, as well as their male partners and the communities in which they live, with HIV education and awareness. In South Africa, for example, research centre staff have built links with schools giving them an opportunity to engage in dialogue with young adults. Research centres host special community events to raise awareness about the disproportionate risk of infection in women and the ways in which men and women, young and old, can protect themselves.

### ***Encouraging HIV Testing and Helping to Reduce Stigma***

Regular HIV testing for participants in HIV incidence studies and microbicide clinical trials helps to encourage HIV testing and promotes knowledge of HIV status. There are also additional broader efforts under way to increase community awareness about the benefits of HIV testing. This represents a concrete contribution to the broader HIV response, as inadequate testing rates continue to impede more effective action on AIDS. In Kenya, for example, authorities estimate that 84 percent of people living with HIV are unaware of their status. As a Kenyan Project Officer reported, "People in the community are more comfortable going for HIV testing because it's not the end of the road for them. I asked a local religious leader, 'What is the one thing that IPM-sponsored studies have done for the women here?' He said, 'It demystified HIV testing. People used to be afraid to go for HIV testing. Now that fear is not as much as it used to be.'"



### ***Engaging Communities and Expanding the Delivery of Health Services***

Research activities are undertaken in close partnership with local communities. All IPM research centre partners design and implement a community engagement program to support partnerships between researchers and the community. These efforts build community support for participants and the research itself and foster strengthened relationships with local authorities and other stakeholders. Community outreach promotes regular contact with local clinics, community leaders, traditional healers, teachers' associations and public health officials.

Microbicide development efforts contribute to improving the capacity within communities to deliver key health care services that are related to the research being done. IPM supports infrastructure improvements and additional capacity needed by its sponsored research centres. Links are also created or strengthened between research centres and public health clinics and hospitals that can serve as referral facilities.

A new IPM-funded research centre, Be Part Yoluntu Centre, opened its doors in 2007 in Western Cape, South Africa. The centre was established with IPM support and was able to obtain additional financing that allowed it to initiate an after-hours voluntary counselling and HIV testing service for men. The centre has completed one IPM HIV incidence study and is currently conducting clinical trials examining the safety of the vaginal microbicide, dapivirine.

An IPM-sponsored research centre near Durban, South Africa, is working towards becoming a centre for delivering family planning services to its community. The site was offering family planning to microbicide trial participants when local government officials recognised the value of the services provided.

*"We're currently a family planning site, in a way. We submit statistics to the municipal district office, and there is a partnership between us and them. We're getting a lot of requests from participants ... they want to come back and continue to get family planning even after the study ends."*

— Principal Investigator, Reproductive Health and HIV Research Unit, South Africa

"I've seen many changes in the community where an IPM study is going to take place," reported a community liaison officer at an IPM-sponsored research centre in Malawi. "With the building in the area, community members see it as 'someone' coming in to do something in their community. The clinic built for the IPM study has staff that build stronger relationships with the government health workers. The IPM community educator assists in HIV prevention talks at the government clinics and in the larger community."

*“We have a community goal, and a very strong one. With the community engagement unit through IPM, we have better structures. They have helped and built our capacity as leaders, and we can now grow and make community engagement and community participation a more visible item.”*

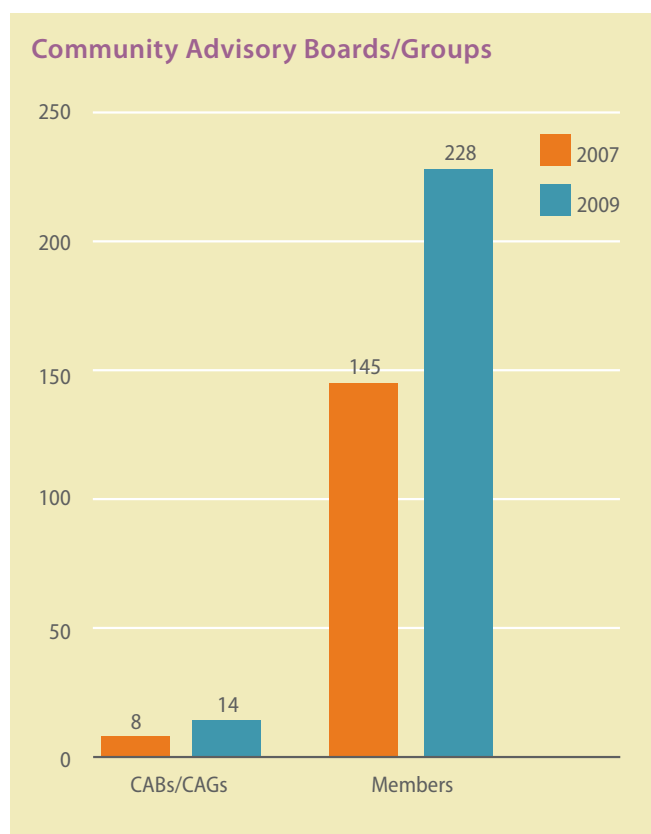
— Project Officer, International Centre for Reproductive Health, Kenya

### Community Advisory Boards and Groups

Each IPM research centre partner is linked to a Community Advisory Board or Group (CAB/CAG). These serve as educational conduits between the research centre and the community, help ensure support for the clinical trials as well as voice suggestions or concerns from the community. They also help increase the number of community members and advocates who are knowledgeable about clinical research. These bodies often include former clinical trial participants, prominent community leaders, opinion leaders, religious leaders and people living with HIV/AIDS.

Another benefit of research is the involvement of men in HIV prevention efforts. Research centres serve as a hub from which information about HIV/AIDS, HIV prevention and HIV treatment can flow to community members, both women and men.

According to the manager of a research centre in South Africa, “There are general community members — many men — who come to the site to get more information about HIV issues. It really helps ordinary members of the community with sexual behaviour. There has definitely been a great change.”



CABs/CAGs meet on a regular basis and provide a liaison between clinical research centres and the communities where clinical trials take place. These groups provide input on important subjects such as informed consent. In some cases, IPM’s support and guidance enabled research centres to assemble a CAB or CAG for the first time. IPM conducted two regional workshops during 2009 — in Rwanda and South Africa — for CAB/CAG members from communities and countries in which IPM clinical trials are ongoing or planned.

Between 2007 and 2009, the number of CABs and CAB members increased markedly. During this time, IPM also sponsored more than 60 training events, meetings and workshops, addressing such topics as product adherence, counselling and outreach for community staff at research centres.

*“We have open days and women’s days. Once we had someone come to talk about Pap smears and cancer, it was quite enlightening for the community. And for women’s day, we had a lot of young people there. We had a panel talking about violence against women, HIV/AIDS and ARVs, etc. There is a lot of impact in the community from this study.”*

— Principal Investigator, Reproductive Health and HIV Research Unit, South Africa

## CONCLUSION

While working to advance its primary mission of developing safe and effective microbicides for HIV prevention, IPM is producing tangible benefits today for the people, communities and countries that host its clinical trials and epidemiological studies. These benefits directly advance the UN Millennium Development Goals endorsed by the international community and bring value to the very communities where HIV/AIDS burden is the highest.

Microbicide development builds medical research capacity, infrastructure and staff expertise. This capacity is being built in the areas of greatest HIV/AIDS burden, thereby helping to address the “10/90” research gap. Capacity building encompasses both physical infrastructure and human resources, helping to create research centres with the equipment, facilities and staff needed to carry out effective and ethical clinical trials. HIV epidemiological studies promote a better understanding of HIV prevalence and incidence rates in the studied areas.

Communities also benefit from hosting clinical trials. Enhancing existing facilities and creating new clinical research centres provides employment and professional development for people of many backgrounds. Clinical trial participants receive medical screening, education and counselling, leading to better HIV awareness. Outreach and engagement programs based at the centres also enhance health and HIV awareness among community members.

Developing tools, such as microbicides, that empower women to protect their health and save lives is of key importance to stem the tide of HIV infection. IPM is dedicated to turning this hope for the future into a reality, and is committed to continuing to generate benefits for the people, communities and countries of today.

*“I have been working in Africa for 15 years in multiple countries, and the one big thing that I see changing is that the mindset of people has become a bit more research oriented.*

*Now, people are finally equipped with the tools. It’s a different way of thinking if you do research; it’s also a different way of thinking from your normal clinical routine. It has really benefitted programmes as well, particularly in the monitoring and evaluation of programmes. ... It’s quite impressive what these networks have done.”*

— Study Investigator, Projet Ubuzima, Rwanda

### Endnotes

- 1 UNAIDS/WHO, “AIDS Epidemic Update”, November 2009
- 2 UNAIDS, “Report on the global AIDS epidemic”, August 2008
- 3 WHO, “The Global Burden of Disease, Update 2004”, Geneva, 2008
- 4 Swaziland Ministry of Health & Welfare, “11th HIV sentinel surveillance report”, February 2009





## *Hope for the Future, Benefits for Today*



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